

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPE MEDICAL ENTERPRISES, INC.,
Petitioner,

v.

FENNEC PHARMACEUTICALS, INC.,
Patent Owner.

IPR2022-00125
Patent 10,792,363 B2

Before CHRISTOPHER L. CRUMBLEY, KRISTINA M. KALAN, and
JULIA HEANEY, *Administrative Patent Judges*.

HEANEY, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Granting Patent Owner's Revised Noncontingent Motion to Amend
35 U.S.C. § 318(a)

I. INTRODUCTION

Hope Medical Enterprises, Inc. (“Petitioner”) filed a Petition (Paper 2, “Pet.”) requesting an *inter partes* review of claims 1–27 of U.S. Patent No. 10,792,363 B2 (Ex. 1001, “the ’363 patent”). Fennec Pharmaceuticals, Inc. (“Patent Owner”) waived a preliminary response to the Petition. Paper 9. We determined the information presented in the Petition established that there was a reasonable likelihood that Petitioner would prevail as to at least one of the challenged claims of the ’363 patent, and we instituted this *inter partes* review as to all challenged claims. Paper 10.

After institution, Patent Owner filed a Noncontingent Motion to Amend (Paper 14 (“MTA”)), and did not file a Patent Owner Response. Patent Owner submitted a statutory disclaimer of claims 1–17, 19, and 21–27 of the ’363 patent (Ex. 2008) concurrently with its Motion to Amend; Patent Owner also requested to cancel claims 18 and 20 and proposed revised substitute claims 28 and 29. MTA 2, 4–5. Petitioner filed an Opposition to the MTA. Paper 15. We issued Preliminary Guidance on the MTA (Paper 16, “Prelim. Guid.”), after which Patent Owner filed a Revised Noncontingent Motion to Amend (Paper 18, “RMTA”), again requesting cancellation of claims 18 and 20 and seeking to substitute revised claims 28 and 29 for the claims presented in its MTA. Petitioner filed an Opposition to the RMTA (Paper 21, “Opp. RMTA”); Patent Owner filed a Reply (Paper 24, “Reply RMTA”); and Petitioner filed a Sur-reply (Paper 28, “Sur-reply RMTA”).

Petitioner filed the Declaration of Robin D. Rogers, Ph.D. (Ex. 1008) in support of the Petition. Patent Owner filed a transcript of Dr. Rogers’s deposition (Ex. 2005).

An oral hearing was held on March 21, 2023, and a transcript of the hearing is included in the record. Paper 34 (“Tr.”). The Chief Administrative Patent Judge determined good cause exists to extend the one-year period for issuing a Final Written Decision under 35 U.S.C. § 316(a)(11); this panel subsequently extended the time to administer this proceeding to September 15, 2023. Paper 35; Paper 37.

We have jurisdiction under 35 U.S.C. § 6. This decision is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of proposed revised substitute claims 28 and 29 of the ’363 patent. For the reasons discussed below, we hold Patent Owner has met the requirements for grant of a motion to amend and that Petitioner has not demonstrated by a preponderance of the evidence that proposed revised substitute claims 28 and 29 are unpatentable, and we grant Patent Owner’s RMTA, cancel claims 18 and 20, and enter proposed substitute claims 28 and 29.

A. Real Parties-in-Interest

Petitioner states that “Hope Medical Enterprises, Inc. is the real party-in-interest.” Pet. 72. Patent Owner identifies Fennec Pharmaceuticals, Inc. as the real party-in-interest. Paper 4, 1 (Patent Owner’s Mandatory Notices).

B. Related Proceedings

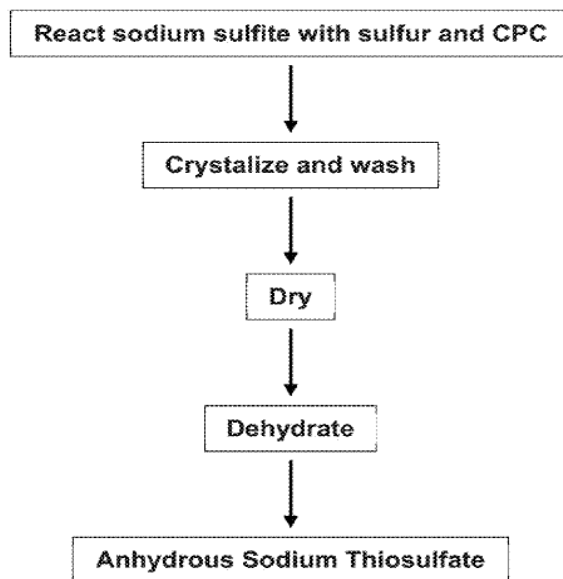
Petitioner states that “[t]he ’363 Patent is not currently the subject of litigation.” Pet. 72; *see also* Paper 4, 1. Patent Owner identifies U.S. Patent Application Nos. 17/585,335, 17/584,257, and 17/005,997—each claiming benefit to the ’363 patent or the provisional applications leading to the ’363 patent—as related matters. Paper 8, 1 (Patent Owner’s Supplemental Mandatory Notices).

C. The '363 Patent

The '363 patent, titled “Anhydrous Sodium Thiosulfate and Formulations Thereof,” issued on October 6, 2020. Ex. 1001, codes (45), (54). The '363 patent describes methods for synthesizing anhydrous sodium thiosulfate (“STS”) and pharmaceutical compositions of anhydrous sodium thiosulfate. *Id.* at 1:18–20. According to the '363 patent, “[p]latinum based therapeutics are highly important components of treatment regimens used in a variety of pediatric malignancies” but “[a]t commonly used doses and schedules, platinum based therapeutics such as cisplatin and carboplatin, frequently cause hearing loss that is progressive, bilateral, irreversible, and often accompanied by tinnitus.” *Id.* at 1:26–34. As described in the '363 patent, “the administration of sodium thiosulfate was found to not adversely affect the efficacy of the platinum based chemotherapeutic and decreased the incidence and severity of ototoxicity in pediatric patients.” *Id.* at 6:49–53.

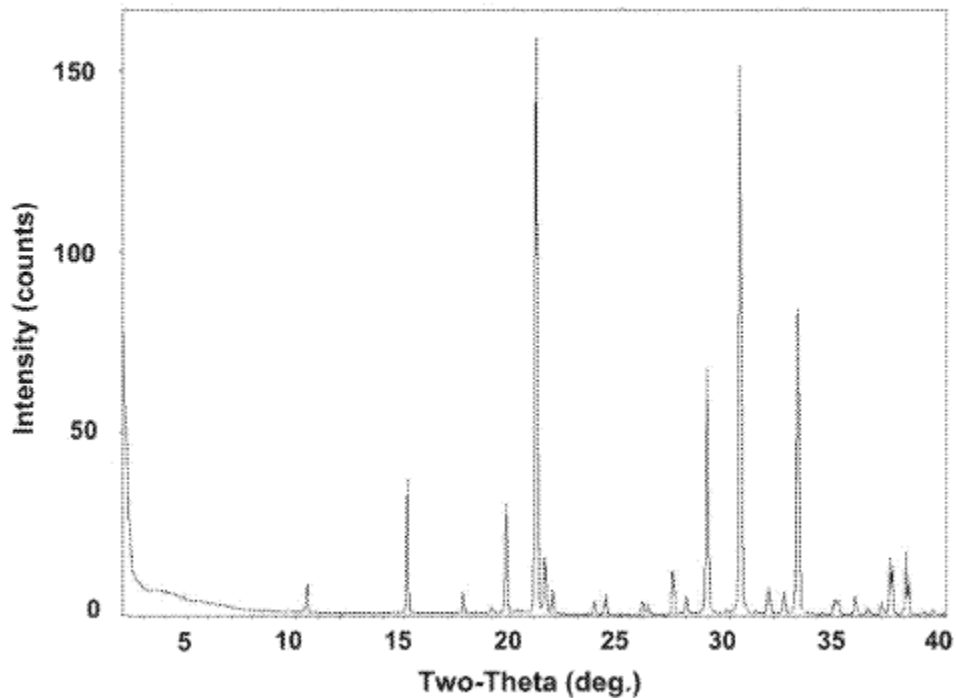
According to the '363 patent, anhydrous sodium thiosulfate may be synthesized according to Example 1, which is also depicted in Figure 1 reproduced below.

FIG. 1



Id. at 42:30–43:15; Fig. 1. Figure 1 depicts “a scheme for synthesizing anhydrous sodium thiosulfate.” *Id.* at 11:41–42. Figure 1 is a flow diagram illustrating the steps of reacting aqueous sodium sulfite with sulfur and cetylpyridinium chloride (“CPC”), crystalizing and washing the reaction product, drying the reaction product, and dehydrating the “wet sodium thiosulfate” to produce anhydrous sodium thiosulfate. *Id.* at 42:30–43:15; Fig. 1. Samples of anhydrous sodium thiosulfate were analyzed using X-ray powder diffraction (“XRPD”). The results of the XRPD are shown below in Figure 2A.

FIG. 2A



Id. at Fig. 2A. Figure 2A “shows X-ray powder diffraction pattern for anhydrous sodium thiosulfate synthesized as described herein.” *Id.* at 11:43–45.

The anhydrous sodium thiosulfate of the '363 patent is also characterized by low amounts of impurities. For example, one embodiment describes

no greater than 0.1 $\mu\text{g/g}$ of cadmium; no greater than 0.25 $\mu\text{g/g}$ lead; no greater than 0.75 $\mu\text{g/g}$ arsenic; no greater than 0.15 $\mu\text{g/g}$ mercury; no greater than 0.25 $\mu\text{g/g}$ cobalt; no greater than 0.5 $\mu\text{g/g}$ vanadium; no greater than 1.0 $\mu\text{g/g}$ nickel; no greater than 12.5 $\mu\text{g/g}$ lithium; no greater than 4.5 $\mu\text{g/g}$ antimony; no greater than 15.0 $\mu\text{g/g}$ copper; no greater than 1500 ppm methanol; no greater than 3% (w/w) water; and no greater than 1.5% (w/w) of total impurities.

Id. at 2:6–16, 17:18–27, claim 4.

The '363 patent also describes a method for determining the binding capacity of anhydrous sodium thiosulfate for cisplatin, a platinum-containing chemotherapeutic. *Id.* at 3:4–17, claim 22. Specifically, the '363 patent states that the binding capacity can be measured by “(a) mixing one or more ratios of sodium thiosulfate with a predetermined quantity of cisplatin; (b) incubating the mixture for a period of time; and (c) analyzing the apparent concentration of cisplatin.” *Id.* at 3:6–9. The “analyzing comprises HPLC and UV detection.” *Id.* at 3:16–17; *see also id.* at 45:51–59 (describing use of high performance liquid chromatography ultra-violet spectroscopy).

II. MOTION TO AMEND

A. Cancelled and Disclaimed Claims

Our rules provide for cancellation of challenged claims. *See* 37 C.F.R. § 42.121(a)(3) (“A motion to amend may cancel a challenged claim”).¹ Patent Owner requests cancellation of claims 18 and 20, and has disclaimed challenged claims 1–17, 19, and 21–27 under 37 C.F.R. § 1.321(a) MTA 2, 4–5; Ex. 2008 (“Disclaimer”). Specifically, Patent Owner states that it considers the Disclaimer “its ethical duty when it has been convinced that a claim has been established to be invalid.” MTA 2.

Petitioner responds that as a result of Patent Owner’s statement, Patent Owner “agreed” that limitations from the disclaimed original claims, which appear in proposed substitute claims 28 and 29, are known amounts of

¹ In a non-contingent motion to amend, “the Board provides a final decision on the patentability of substitute claims in place of determining the patentability of corresponding original claims.” Notice Regarding a New Pilot Program Concerning Motion To Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board, 84 Fed. Reg. 9497, 9505 (Mar. 15, 2019).

impurities or methods of making anhydrous STS. Opp. RMTA 4–6. Specifically, Petitioner argues Patent Owner’s Disclaimer effectively admits the amounts of impurities disclosed in Table 4 of the ’363 patent “were not new in pharmaceutical compositions” and that “each of the steps in the method of making anhydrous STS [recited in disclaimed claims 9–15] were ‘established to be invalid.’” *Id.* At oral hearing, Petitioner’s counsel clarified Petitioner is not arguing that Patent Owner “is precluded necessarily or somehow foreclosed from making the argument that they are in this proceeding” as a result of its MTA statements (Tr. 10:22–24), and that “Patent Owner’s comments are not dispositive necessarily” (Tr. 11:6–7) as to the determination of obviousness. We consider these arguments in our discussion of Petitioner’s obviousness challenges to the proposed substitute claims. *See* III.F.1 *infra*.

Having considered the parties’ positions, we grant Patent Owner’s request to cancel challenged claims 18 and 20. Further, we find that the Disclaimer complies with the requirements of 37 C.F.R. § 1.321(a), and that Patent Owner properly recorded the Disclaimer in the Office. Thus, Patent Owner properly disclaimed challenged claims 1–17, 19, and 21–27 of the ’363 patent, and they are no longer part of this proceeding. Accordingly, the only claims remaining in this proceeding are proposed substitute claims 28 and 29.

B. Proposed Substitute Claims 28 and 29

Proposed substitute claims 28 and 29 are both independent claims. Claim 28 is proposed as a substitute for cancelled claim 18 and is reproduced below, showing added language underlined and deleted language struck out in comparison to cancelled claim 18.

28. (Revised substitute for original claim 18) A method for synthesizing anhydrous sodium thiosulfate for a pharmaceutical composition comprising:

(a) reacting 1.0 mole equivalent of aqueous sodium sulfite with 1.1 mole equivalents of sulfur in the presence of 0.00013 mole equivalents of cetylpyridinium chloride at about 90° C. to about 100° C.; and

(b) crystallizing sodium thiosulfate at <2° C. with acetone and washing with acetone;

(c) dehydrating the washed sodium thiosulfate with methanol; and

(d) drying the dehydrated sodium thiosulfate at about 25° C. to about 60°;

wherein the resulting anhydrous sodium thiosulfate contains less than or equal to 0.05 micrograms per gram (µg/g) cadmium, contains less than or equal to 0.125 µg/g lead, contains less than or equal to 0.375 µg/g arsenic, contains less than or equal to 0.075 µg/g mercury, contains less than or equal to 0.125 µg/g cobalt, contains less than or equal to 0.25 µg/g vanadium, contains less than or equal to 0.50 µg/g nickel, and contains less than or equal to 7.5 µg/g copper;

wherein the resulting anhydrous sodium thiosulfate contains no more than 0.5% (w/w) residual sulfite and contains no more than 1.5% (w/w) residual sulfate; and,

wherein the resulting anhydrous sodium thiosulfate contains less than or equal to 1.5% (w/w) of total impurities.

RM TA, App. A 1–2. Claim 29 is proposed as a substitute for cancelled claim 20 and is reproduced below, showing added language underlined and deleted language struck out in comparison to cancelled claim 20.

29. (Revised substitute for original claim 20) Means for synthesizing anhydrous sodium thiosulfate for a pharmaceutical composition comprising reacting sodium sulfite with sulfur in the presence of cetylpyridinium chloride, crystallizing the

sodium thiosulfate product with acetone, and dehydrating sodium thiosulfate product;

wherein the resulting anhydrous sodium thiosulfate contains less than or equal to 0.05 micrograms per gram ($\mu\text{g/g}$) cadmium, contains less than or equal to 0.125 $\mu\text{g/g}$ lead, contains less than or equal to 0.375 $\mu\text{g/g}$ arsenic, contains less than or equal to 0.075 $\mu\text{g/g}$ mercury, contains less than or equal to 0.125 $\mu\text{g/g}$ cobalt, contains less than or equal to 0.25 $\mu\text{g/g}$ vanadium, contains less than or equal to 0.50 $\mu\text{g/g}$ nickel, and contains less than or equal to 7.5 $\mu\text{g/g}$ copper;

wherein the resulting anhydrous sodium thiosulfate contains no more than 0.5% (w/w) residual sulfite and contains no more than 1.5% (w/w) residual sulfate; and,

wherein the resulting anhydrous sodium thiosulfate contains less than or equal to 1.5% (w/w) of total impurities.

Id. at 2. The final three “wherein” clauses added in claims 28 and 29 recite the same limitations.

C. Asserted Grounds of Unpatentability of Proposed Substitute Claims

Petitioner challenges the patentability of the proposed substitute claims on the following grounds:

Challenged Claims	35 U.S.C.	References
28, 29	§ 103(a)	Levenson ² , Sherman ³ , Edwards ⁴ , USP ⁵
28, 29	§ 103(a)	Levenson, Sherman, Edwards, USP, FDA Guidance ⁶

III. ANALYSIS

A. *Level of Ordinary Skill in the Art*

Factors pertinent to a determination of the level of ordinary skill in the art include: “(1) educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of workers active in the field.” *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696–697 (Fed. Cir. 1983) (citing *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381–82 (Fed. Cir. 1983)). Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case. *Id.*

² G. I. P. Levenson, U.S. 2,763,531, issued September 18, 1956 (Ex. 1004, “Levenson”).

³ Sherman et al., US 8,496,973 B2, issued July 30, 2013 (Ex. 1006, “Sherman”). Sherman on its face identifies Petitioner as assignee. *Id.*, code (73).

⁴ D. A. Edwards & A. A. Woolf, *Hydrates of Sodium Thiosulphate*, 4 POLYHEDRON 513 (1985) (Ex. 1005, “Edwards”).

⁵ U.S. Pharmacopeial Convention, *Pharmacopeial Forum PF 43(1)* 784–799, Jan. 2017 (Ex. 1020, “USP”).

⁶ U.S. Department of Health and Human Services Food and Drug Administration, *Q3D Elemental Impurities: Guidance for Industry*, Sept. 2015 (Ex. 1019, “FDA Guidance”).

Petitioner, relying on the testimony of Dr. Rogers, contends that a person of ordinary skill in the art

would have [had] a bachelor's degree or equivalent in any of the pharmaceutical sciences with at least 5 years of experience in solid state chemistry; a master's degree in any of the pharmaceutical sciences with at least 3 years of experience in solid state chemistry; or a Ph.D. in any of the pharmaceutical sciences with 1 year of experience in solid state chemistry.

Pet. 8 (citing Ex. 1008 ¶¶ 24–28). Petitioner further states that such “[a] person could also have qualified as a [person of ordinary skill in the art] with some combination of (1) more formal education and less technical or professional experience or (2) less formal education and more technical or professional experience.” *Id.*

Patent Owner does not dispute Petitioner's proposed definition of a person of ordinary skill. *See generally* MTA, RMTA.

Having considered the parties' arguments and evidence, we adopt the level of ordinary skill in the art proposed by Petitioner, because it is consistent with the disclosures of the '363 patent and the prior art of record. We note, however, that neither party contends that the outcome of this case would differ based on our adoption of any particular definition of a person of ordinary skill in the art.

B. Claim Construction

We apply the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 42.100(b). Under that standard, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). “In determining the meaning of

the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17).

In our Preliminary Guidance, we construed “for a pharmaceutical composition” to mean “in combination with pharmaceutically acceptable excipients,” based on the ’363 patent’s definition providing that “[t]he terms ‘formulation’ or ‘pharmaceutical composition’ as used herein refers to the drug in combination with pharmaceutically acceptable excipients.” Prelim. Guid. 5–6 (citing Ex. 1001, 12:26–28; Ex. 2010, 17:11–12; Ex. 2011, 26:26–27). We also encouraged the parties to address whether “for a pharmaceutical composition,” which appears in the preamble of substitute claims 28 and 29, is limiting, as opposed to a statement of intended use or purpose. *Id.* at 6.

Following our Preliminary Guidance, the parties submitted further arguments concerning the term “for a pharmaceutical composition.” Patent Owner argues the term requires that the claimed process provide STS that is sufficiently pure for use in a pediatric patient (*see* RMTA 8–11) and that the word “drug” in the ’363 patent’s definition of “pharmaceutical composition” requires that the anhydrous STS is of sufficient purity for pharmaceutical use. Reply RMTA 3. Petitioner argues that the construction set forth in our Preliminary Guidance was correct. *See* Sur-reply RMTA 2–3.

Having considered the arguments and evidence, we do not further construe the term “for a pharmaceutical composition” in this Decision because, as discussed in our analysis of obviousness below, it is not

necessary to construe the term in order to determine whether Petitioner has met its burden of demonstrating by a preponderance of the evidence that proposed substitute claims 28 and 29 are unpatentable. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“we 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. Applicable Law

1. Motion to Amend

“Before considering the patentability of any substitute claims, . . . the Board first must determine whether the motion to amend meets the statutory and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121.” *See Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 4 (PTAB Feb. 25, 2019) (precedential). Patent Owner bears the burden of persuasion to show, by a preponderance of the evidence, that the RMTA meets those requirements. 37 C.F.R. § 42.121(d)(1).

A motion to amend “may not enlarge the scope of the claims of the patent or introduce new matter.” 35 U.S.C. § 316(d)(3). New subject matter is any addition to the claims that lacks sufficient support in the subject patent’s original disclosure. *See TurboCare Div. of Demag Delaval Turbomach. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) (“When [an] applicant adds a claim . . . , the new claim[] must . . . find support in the original specification.”). Corresponding Rule 42.121 requires a motion to amend to “set forth: (1) The support in the original disclosure of the patent for each claim that is added or amended; and (2) The support in an earlier-filed disclosure for each claim for which benefit of the filing date of the

earlier filed disclosure is sought.” 37 C.F.R. § 42.121(b). “A motion to amend may be denied where . . . [t]he amendment seeks to . . . introduce new subject matter.” 37 C.F.R. § 42.121(a)(2)(ii).

Sufficiency of a specification’s written description is a fact question, and “the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharm., Inc. v. Mass. Inst. of Tech.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). “And while the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement.” *Id.* at 1352 (internal citations omitted).

When an explicit limitation in a claim “is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description *requires* that limitation.” *Hyatt v. Boone*, 146 F.3d 1348, 1353 (Fed. Cir. 1998) (emphasis added). In other words, where the written description fails to disclose an element *explicitly*, “the applicant must show that *any absent text* is *necessarily* comprehended in the description provided and would have been so understood at the time the patent application was filed.” *Id.* at 1354–55 (emphases added).

2. Obviousness

A claim is unpatentable under 35 U.S.C. § 103 if “the differences between the subject matter sought to be patented 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 said subject matter pertains. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when available, objective evidence indicating obviousness or non-obviousness, such as commercial success, long felt but unsolved needs, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *see KSR*, 550 U.S. at 407 (“While the sequence of these questions might be reordered in any particular case, the [Graham] factors continue to define the inquiry that controls.”).

The Supreme Court made clear that we apply “an expansive and flexible approach” to the question of obviousness. *KSR*, 550 U.S. at 415. Whether a patent claiming the combination of prior art elements would have been obvious is determined by whether the improvement is more than the predictable use of prior art elements according to their established functions. *Id.* at 417. Reaching this conclusion, however, requires more than merely showing that the prior art includes separate references covering each separate limitation in a challenged claim. *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011). Rather, obviousness additionally requires that a person of ordinary skill at the time of the invention “would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention.” *Id.*

D. Motion to Amend— Statutory and Regulatory Requirements

1. Reasonable Number of Substitute Claims

A motion to amend must “propose a reasonable number of substitute claims.” 35 U.S.C. § 316(d)(1)(B); *see* 37 C.F.R. § 42.121(a)(3) (“A motion to amend may cancel a challenged claim or propose a reasonable number of substitute claims.”). Patent Owner proposes the same number of substitute claims as the original challenged claims that are cancelled, i.e., a one-to-one substitution for a total of two substitute claims. MTA 2; RMTA. “There is a rebuttable presumption that a reasonable number of substitute claims per challenged claim is one (1) substitute claim.” *Lectrosonics*, Paper 15 at 4; *see* 37 C.F.R. § 42.121(a)(3). Petitioner does not argue otherwise. *See generally* Opp. RMTA. Therefore, we determine that Patent Owner proposes a reasonable number of substitute claims.

2. Support in the Original Disclosure

Patent Owner has identified written description support in the originally filed disclosure of the ’363 patent for the new limitations added for the proposed substitute claims. *See* RMTA 5–8. We have reviewed Patent Owner’s assertions of support in the original disclosure for the proposed revised substitute claims and determine that sufficient support exists. Petitioner does not argue otherwise. *See generally* Opp. RMTA. Therefore, we determine that Patent Owner has met this requirement.

3. Respond to a Ground of Unpatentability

“A motion to amend may be denied where . . . [t]he amendment does not respond to a ground of unpatentability involved in the trial.” 37 C.F.R. § 42.121(a)(2)(i). Patent Owner asserts that the proposed revised substitute claims are patentable over the combination of references that forms the basis

of the obviousness ground on which we instituted trial. RMTA 12–13. Petitioner does not argue otherwise. *See generally* Opp. RMTA. Therefore, we determine that Patent Owner has met this requirement.

4. *Scope of the Claims*

Patent Owner asserts that the proposed revised substitute claims do not enlarge the scope of original claims 18 and 20. RMTA 5. We have reviewed Patent Owner’s assertion that the purity amendments of proposed revised substitute claims 28 and 29 narrow the claims’ scope. *Id.* Petitioner does not argue otherwise. *See generally* Opp. RMTA. Therefore, we determine that Patent Owner has met this requirement.

E. Ground 1: Alleged Obviousness over Levenson, Sherman, Edwards, and USP

Petitioner contends proposed substitute claims 28 and 29 are unpatentable as obvious over Levenson, Sherman, Edwards, and USP. Opp. RMTA 9–20.

Petitioner’s challenge to proposed substitute claims 28 and 29 is based on the following contentions: (1) the proposed substitute claims are “an amalgamation of limitations” from disclaimed claims 4 and 9–15 (Opp. RMTA 9–12); (2) the proposed substitute claims are obvious over the combination of Levenson, Sherman, and Edwards for the reasons stated in the Petition with regard to cancelled claims 18 and 20 (*id.* at 13–14 (citing Pet. 54–61; Ex. 1008 ¶¶ 225–237)); and (3) the new limitations recited in the three “wherein” clauses at the end of the proposed substitute claims (hereinafter “the purity clauses”) “reflect merely the proximate results of using prior-art ‘invalid’ specification thresholds to obtain anhydrous STS, and are unpatentable as obvious over Levenson, Sherman, Edwards, and the

USP and Patent Owner’s admission of invalidity.” *Id.* at 14; *see also id.* at 15–19. We begin our discussion of Petitioner’s contentions with the combination of references applied to cancelled claims 18 and 20 presented in the Petition, followed by Petitioner’s contentions as to the purity clauses in the proposed substitute claims, and the limitations amalgamated into proposed substitute claims 28 and 29 from the disclaimed claims. As discussed below, we determine that Petitioner has not met its burden of demonstrating unpatentability on any of these bases.

1. Prior Art

a) Levenson (Ex. 1004)

Levenson discloses that manufacture of sodium thiosulfate on a large scale was well known, by heating sodium sulfite in the presence of cationic surface-active agents such as dodecyl and cetyl pyridinium halides. Ex. 1004, 1:16–20, 1:40–48. According to Levenson, use of cationic surface-active agents greatly accelerates the reaction, “often to such a great extent that very appreciable amounts of the thiosulphate can be obtained in conditions of time and temperature etc. under which in the ordinary way, i.e. without the cationic surface-active agent the amount of thiosulphate obtained is so small as to be negligible.” *Id.* at 1:29–36. Levenson describes preparing sodium thiosulfate in the presence of a surface-active agent in Example 1:

3 grams of sodium sulphite^[7] (anhydrous) and 0.5 gram of finely divided sulphur are boiled together in 20 ml. of water containing 0.002 g. of dodecyl pyridinium bromide of “Fixanol C” (commercial cetyl pyridinium bromide). After only about five

⁷ We reproduce text from Levenson as written. In our discussion, we use American spellings, e.g. sulfite.

minutes boiling the sulphur becomes dissolved and thereafter the solution of sodium thiosulphate which has formed is filtered and concentrated. The sodium thiosulphate may be crystallized out if desired. Without the addition of accelerator the dissolution takes 20 minutes.

Id. at 3:24–35.

b) Sherman (Ex. 1006)

Sherman is a U.S. Patent titled “Sodium Thiosulfate-containing Pharmaceutical Compositions” and assigned to Petitioner. Ex. 1006, codes (54), (73). Sherman discloses preparing sodium thiosulfate comprising the steps of contacting sodium sulfite with sulfur in a solvent to form a reaction mixture and crystallizing the sodium thiosulfate pentahydrate from the solution. *Id.* at 11:52–59. Sherman also discloses crystallizing sodium thiosulfate pentahydrate by the addition of an anti-solvent. *Id.* at 13:16–20.

c) Edwards (Ex. 1005)

Edwards discloses obtaining anhydrous sodium thiosulfate by dehydrating sodium thiosulfate pentahydrate. Ex. 1005, 515. Edwards describes acetone as a suitable solvent because acetone re-precipitates sodium pentahydrate out of solution. *Id.*

d) USP (Ex. 1020)

USP is a monograph published by the U.S. Pharmacopeial Convention in January 2017, relating to assays for identification of sodium thiosulfate and related impurities. It discloses acceptable limits of impurities such as chloride, sulfate, and sulfite. Ex. 1020, 792.

2. Levenson in view of Sherman and Edwards

a) Petitioner’s Contentions

In the Petition, Petitioner asserted “Levenson discloses that it was ‘well known’ that STS pentahydrate was ‘commercially manufactured on a

large scale by heating a solution of sodium sulfite containing a suspension of sulfur.” Pet. 36 (citing Ex. 1004, 1:16–19).⁸ Petitioner asserts Levenson discloses “the presence of cationic surface-active agents, including dodecyl and cetylpyridinium halides, accelerates the reaction of sulfur and sodium sulfite to synthesize [sodium thiosulfate].” *Id.* (citing Ex. 1004, 1:29–36, 1:46–48).

Petitioner asserts “Sherman similarly discloses a preparation of STS pentahydrate including at least (1) contacting sodium sulfite with sulfur in a solvent to form a reaction mixture, (2) filtering the mixture to yield a solution, and (3) crystallizing STS from the solution.” Pet. 36 (citing Ex. 1006, 12:52–59). Based on the similarities between Sherman and Levenson, including that “[b]oth references disclose synthesis of sodium thiosulfate pentahydrate” (Ex. 1008 ¶ 151), Petitioner argues a person of ordinary skill in the art would have had reason to modify the preparation of Sherman to include a surface-active agent such as those disclosed in Levenson in order to accelerate the reaction speed. Pet. 36–37 (citing Ex. 1008 ¶¶ 149–151).

Petitioner relies on Edwards as disclosing preparation of anhydrous STS by dehydration of either solid sodium thiosulfate pentahydrate or aqueous thiosulfate solutions. Pet. 37 (citing Ex. 1005, 513). Petitioner argues it would have been obvious to a person of ordinary skill in the art to synthesize STS pentahydrate using the teachings of Levenson and Sherman

⁸ As discussed below, at oral hearing Petitioner’s counsel stated that the Petitioner’s reference to the pentahydrate form was incorrect, and inconsistent with Petitioner’s statements in the prosecution history of Sherman, which refer to Levenson as teaching the heptahydrate form. Tr. 21:23–22:5; *see also* Petitioner’s Notice of Correction (Paper 32).

and then add Edward's dehydration step to obtain the anhydrous form, because anhydrous forms and methods for dehydrating a compound to achieve the anhydrous form were well-known. *Id.* (citing Ex. 1008 ¶¶ 153–154).

b) Patent Owner's Contentions

In the Revised Motion to Amend, Patent Owner argues a person of ordinary skill in the art would not have looked to Levenson to manufacture STS pentahydrate that meets the purity clause requirements of proposed substitute claims 28 and 29, including the limitation “contains no more than 0.5% (w/w) residual sulfite,” because Levenson is directed to “chemical processes where a small amount of sodium sulphite is unimportant.” RMTA 2–3, 12–14 (citing Ex. 1004, 3:64–65). Patent Owner relies on Petitioner's arguments during prosecution of Sherman about the presence of sulfite in Levenson, including the following:

Small amounts of sulphite (also spelled “sulfite”) can be extremely important in clinical settings. Sulfite is a toxic material, such that exposure to sulfite can cause allergic reactions including anaphylactic shock and death.

Since the absence of sulfite is extremely important in clinical situations, the material produced by the teaching of Levenson is clearly not suitable for use as a pharmaceutical ingredient.

Levenson does not provide any guidance with respect to the purity of any sodium thiosulfate product, and certainly does not teach or suggest pharmaceutical grade sodium thiosulfate pentahydrate.

RMTA 13–15 (quoting Ex. 2013, 97); *see also* MTA 10–11. Patent Owner argues there would have been no reasonable expectation of success in using Levenson because its process leads to unacceptable impurities in the product, including residual sulfite impurities. RMTA 15.

Patent Owner also argues a person of ordinary skill in the art would not have looked to Levenson to manufacture an STS pentahydrate that meets the purity clause requirements of proposed substitute claims 28 and 29 because Levenson's process uses cetyl pyridinium bromide as a surface-active agent. RMTA 14–18; *see also* MTA 10–11. Patent Owner again relies on Petitioner's statements during prosecution of Sherman, including the following:

Levenson teaches the addition of cetyl pyridinium bromide (Fixanol C), which is not an acceptable component of a pharmaceutical composition. Specifically, the material safety data sheet for cetyl pyridinium bromide . . . states that there are numerous potential acute and chronic health effects associated with cetyl pyridinium bromide and that this compound can be fatal if inhaled.

RMTA 14 (quoting Ex. 2013, 97).

Patent Owner also argues a person of ordinary skill in the art would not have looked to Levenson to manufacture STS pentahydrate because Levenson is directed to STS heptahydrate, not pentahydrate. MTA 12–13. Patent Owner again relies on Petitioner's statements during prosecution of Sherman, including the following:

Levenson does not provide any teaching with respect to sodium thiosulfate pentahydrate . . . , but instead is directed to sodium thiosulfate heptahydrate This is evidenced at least by FIGS. 3–5 and Example 3 of Levenson. While sodium thiosulfate pentahydrate is known to have medicinal applications, sodium thiosulfate heptahydrate is not listed in the USP and, therefore, is not officially recognized as a pharmaceutical ingredient in the United States.

Ex. 2013, 97 (emphasis in original). Patent Owner also argues Dr. Rogers acknowledged that STS heptahydrate is not a stable hydrate; additionally, at his deposition, he incorrectly testified that Levenson teaches

STS pentahydrate. Tr. 34:21–35:9; Patent Owner’s Response to Petitioner’s Notice of Correction (Paper 33) (citing Ex. 2005, 35, 39 (testifying that “the stable hydrates [of STS] are the pentahydrate, the dihydrate, and a monohydrate”)).

c) Analysis

Having considered the parties’ positions and evidence of record, we determine the evidence relied on by Petitioner does not support Petitioner’s position that a person of ordinary skill in the art would have been motivated to combine Levenson, Sherman, Edwards, and USP. Petitioner’s contention that it would have been obvious to a person of ordinary skill in the art to combine the teachings of Levenson with Sherman is based on Dr. Rogers’s testimony that “[b]oth references disclose synthesis of sodium thiosulfate pentahydrate.” Ex. 1008 ¶ 151; *see* Pet. 36, 38. Dr. Rogers further testified it would have been obvious to add Edwards’s dehydrating step to the preparation of STS pentahydrate “which is obtained following the teachings of Levenson and Sherman” because “Edwards itself discloses dehydrating [STS] pentahydrate.” *Id.* ¶ 154.

The Petition included these arguments even though they were inconsistent with Petitioner’s previous statement, during the Sherman prosecution, that Levenson taught STS heptahydrate, and therefore “does not provide any teaching with respect to [STS] pentahydrate.” Ex. 2013, 97. This prior inconsistent statement undercuts Petitioner’s rationale for combining Levenson, Sherman, and Edwards in this proceeding. Moreover, Petitioner’s rationale for combining the references in this proceeding is inconsistent with its statements about Levenson during the Sherman prosecution. Recognizing this inconsistency, Petitioner now takes the

position that the Petition and Dr. Rogers's testimony were incorrect. Paper 32; *see* Tr. 21:14–22:7, 59:1–2 (reemphasizing that “Petitioner maintains the statements that it made in the Sherman prosecution regarding Levenson”).

Petitioner attempts to rationalize the inconsistency between its statements in the Sherman prosecution (including that “Levenson does not provide any teaching with respect to [STS] pentahydrate”) and its position in this proceeding by arguing that Dr. Rogers relies on Levenson as teaching surface activation “regardless of any particular hydrates Levenson discloses.” Tr. 22:8–9. That argument is not persuasive, because Dr. Rogers's declaration clearly states the primary reason for his opinion that it would have been obvious to a person of ordinary skill in the art to combine the teachings of Levenson with Sherman: “[b]oth references disclose synthesis of sodium thiosulfate pentahydrate.” Ex. 1008 ¶ 151. Contrary to Petitioner's argument, Dr. Roger's reliance on the surface activation teachings of Levenson is *because* he believes that both references pertain to STS pentahydrate; the surface activation teachings are not stated as an independent reason to combine the references. *Id.*

Petitioner provides no further explanation of how a person of ordinary skill in the art would have been motivated to combine Levenson's teachings regarding manufacture of STS heptahydrate with Sherman's and Edwards's teachings regarding STS pentahydrate, or how a person of ordinary skill would have regarded the difference between STS hydrates. Dr. Rogers's acknowledgement of stability differences among STS hydrates highlights the insufficiency of Petitioner's showing in this regard. *See* Ex. 2005, 35, 39. Having changed its position at the close of trial and having effectively withdrawn Dr. Rogers's testimony as to similarities between Levenson and

Sherman, Petitioner is left with insufficient evidence to support its proposed obviousness combination. Thus, Petitioner fails to demonstrate by a preponderance of the evidence that a person of ordinary skill would have been motivated to combine Levenson with the other relied-upon references, with a reasonable expectation of success in achieving a method of synthesizing STS as set forth in claims 28 and 29.

Further, to the extent Petitioner relies on Levenson's teaching of a surface-active agent "regardless of any particular hydrates," Petitioner's obviousness challenge falls short because Petitioner fails to explain how a person of ordinary skill in the art would have been motivated to use cetylpyridinium chloride, as claims 28 and 29 require, in view of Levenson's general teaching of cetylpyridinium halides as surface-active agents, and Levenson's specific teaching of cetylpyridinium bromide. Ex. 1004, 1:46–48, 3:27–28, 3:40, 3:48–49. Although Dr. Rogers testifies that "a person of ordinary skill in the art would have been motivated to use a cationic surface-active agent as disclosed in Levenson in the Sherman preparation to help solubilize the sulfur and speed up the reaction" (Ex. 1008 ¶ 151), he does not address Levenson's specific teaching of cetylpyridinium bromide. Petitioner and Dr. Rogers do not address evidence from the Sherman prosecution (Ex. 2013, 97) that a person of ordinary skill in the art would have understood cetylpyridinium bromide to be an unacceptable surface-active agent for synthesis of a pharmaceutical composition, based on its material safety data sheet. *See generally* Opp. RMTA, Sur-reply RMTA. Although Petitioner criticizes Patent Owner for not having submitted testimony from its own expert (e.g., Tr. 59:19–20), Petitioner bears the burden of showing why a person of ordinary skill in the art would have combined Levenson

with Sherman, and in light of Petitioner's failure to address the concerns about Levenson's cetylpyridinium bromide that Petitioner raised in the Sherman prosecution, we determine Petitioner has not made that showing.

Similarly, Petitioner does not explain how a person of ordinary skill in the art would have reasonably expected to achieve an anhydrous STS meeting the 0.5% residual sulfite limitation of claims 28 and 29, in view of evidence that Levenson teaches manufacture of STS for photographic processes "where a small amount of sulfite is unimportant." Ex. 1004, 3:64–67. Petitioner and Dr. Rogers do not address evidence from the Sherman prosecution (Ex. 2013, 97) that a person of ordinary skill in the art would have understood Levenson's process to be unsuitable for manufacture of a pharmaceutical ingredient. Petitioner submitted only one declaration from Dr. Rogers in this proceeding, with the Petition, and did not submit any declaration following Patent Owner's addition of the residual sulfite limitations in proposed substitute claims 28 and 29. Petitioner's argument concerning reasonable expectation of success does not address the residual sulfite limitations of claims 28 and 29, and moreover, relies only on Dr. Rogers's declaration (Ex. 1008) that was submitted before the residual sulfite limitations of proposed substitute claims were in this proceeding. *See* Opp. RMTA 18–20; Sur-reply RMTA 8–10. In light of Petitioner's failure to address the concerns about Levenson's sulfite amount raised in the Sherman prosecution, and its unsupported contention as to reasonable expectation of success in achieving the residual sulfite limitation in claims 28 and 29, we determine Petitioner has not met its burden to show obviousness of proposed substitute claims 28 and 29.

3. *The Purity Clauses in Proposed Substitute Claims 28 and 29*

Petitioner contends the purity clauses in proposed substitute claims 28 and 29 do not render the claims patentable over the prior art because they “reflect merely the proximate result of using prior-art ‘invalid’ specification thresholds to obtain anhydrous STS.” Opp. RMTA 14; *see also* Sur-reply RMTA 8.

As to the purity clause reciting cadmium, lead, arsenic, mercury, cobalt, vanadium, nickel, and copper, Petitioner argues the amounts of each of those impurities recited in claims 28 and 29 is the same as the data from the “Result” column of Table 4 of the ’363 patent. Opp. RMTA 15. Petitioner argues those results were obtained by following the “specification limits” in Table 4 (which were the amounts recited in disclaimed claim 4), and are not patentably distinct from those specification limits because they “naturally flow” from the methods described in the ’363 patent. *Id.* at 15–16 (citing *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005)). Petitioner further argues that because the “Result” data in Table 4 (and recited in claims 28 and 29) is a proximate result from applying the specification limits, in addition to the USP’s publication of limits for the elemental impurities recited in this purity clause, a person of ordinary skill in the art would have had a reasonable expectation of success in achieving these impurity limits recited in claims 28 and 29. Tr. 26:25–28:5 (citing Ex. 1008 ¶ 145).

As to the purity clauses reciting limits of residual sulfite and sulfate in proposed substitute claims 28 and 29, Petitioner argues those amounts were well-known by the time of the ’363 patent. Opp. RMTA 16. Petitioner

relies on the USP's March 2017 publication of limits for sulfite and sulfate in STS. *Id.* (citing Ex. 1020, 792).

Patent Owner argues that the purity limitations in the proposed substitute claims 28 and 29 are not like those recited in disclaimed claim 4, because the proposed substitute claims are directed to methods of preparing high purity STS, whereas claim 4 was a composition claim. Reply RMTA 5. Patent Owner further argues the residual sulfite limitation was not present in any of the disclaimed claims. *Id.* Patent Owner also argues that the purity specifications in the USP are aspirational, but developing processes to satisfy those specifications is a significant task which can require substantial effort, and none of the asserted prior art references, individually or in combination, teach a manufacturing process to achieve the claimed purity. *Id.* at 9–12.

Having considered the parties' positions and evidence of record, we determine Petitioner has not sufficiently shown that a person of ordinary skill in the art would have known how to combine the teachings of Levenson, Sherman, and Edwards regarding manufacture of anhydrous STS, with the impurity specifications of those references, USP, and disclaimed claim 4, to achieve those specifications with a reasonable expectation of success. Petitioner does not adequately explain how the limits in the purity clauses of claims 28 and 29 are the proximate result of following the specification limits of Table 4. Petitioner apparently relies on *Perricone* and other caselaw in lieu of providing such an explanation, but Petitioner's reliance is misplaced. *Perricone* involved an anticipation analysis based on inherency and recognized that the patent owner's claims reciting particular skin benefits and methods of achieving those benefits were anticipated by

prior art disclosing the same methods, because the benefits naturally flowed from the methods. *Perricone*, 432 F.3d at 1379. Here, claims 28 and 29 are directed to methods of chemical synthesis and recite limitations on impurities in the product resulting from that synthesis, which is not analogous to the method of treatment claims in *Perricone*. For example, the synthesis method of claims 28 and 29 includes numerous variables, such as reactants, reaction temperatures, and post-reaction steps, and the resulting product is highly dependent on those variables; in contrast, the method of treatment claims the court found anticipated in *Perricone* are simply directed to treating skin by topically applying a particular compound. 432 F.3d at 1373, 1379. Petitioner has not shown that the methods of claims 28 and 29 were the same as a prior art synthesis, whereas the court in *Perricone* found that prior art disclosing topical application of the same compound inherently anticipated. *Id.* Further, Petitioner's challenge is based on a combination of references, not on anticipation. We have reviewed the other caselaw on which Petitioner relies (*see* Opp. RMTA 15) and determine it is of no more assistance to Petitioner's arguments.

Petitioner's argument that "[t]he '363 patent specification provides no disclosure suggesting that these resulting purity clauses are inventive or unexpected" (Opp. RMTA 15) is not persuasive, because Petitioner has the burden of showing reasonable expectation of success in support of its obviousness challenge. Petitioner's argument improperly shifts that burden to Patent Owner by suggesting that a person of ordinary skill in the art would have had a reasonable expectation of success because the '363 patent specification does not suggest otherwise. It was incumbent on Petitioner to explain how synthesis of anhydrous STS based on Petitioner's proposed

combination of references would have achieved the limitations recited in the purity clauses with a reasonable expectation of success, and attorney argument cannot cure Petitioner's lack of affirmative evidence.

Fundamentally, Petitioner's obviousness argument fails because it lacks supporting evidence. As discussed above, Petitioner did not submit any expert declaration following Patent Owner's addition of the purity clauses to proposed substitute claims 28 and 29. Although Petitioner argues that paragraph 145 of Dr. Rogers's declaration submitted with the Petition supports its assertion of a reasonable expectation of success, that paragraph merely summarizes the USP limits of impurities for anhydrous STS and concludes that a person of ordinary skill in the art would have been motivated to reduce any impurities to below the levels claimed in claim 4. Ex. 1008 ¶ 145. While this testimony may provide evidence of a motivation to achieve the impurity levels of disclaimed claim 4, it says nothing to support a reasonable expectation of success in achieving the limits in the purity clauses of claims 28 and 29. Accordingly, we determine Petitioner has not shown a reasonable expectation of success by a preponderance of the evidence.

4. Petitioner's Disclaimer Argument

As discussed above (*see* II.A), Petitioner argues that by stating its belief that challenged claims 1–17, 19, and 21–27 were “established to be invalid” in connection with Patent Owner's Disclaimer (MTA 2), Patent Owner has admitted that the amounts of impurities in Table 4 of the '363 patent “were not new in pharmaceutical compositions” and that “each of the steps in the method of making anhydrous STS [recited in disclaimed claims 9–15] were ‘established to be invalid.’” Opp. RMTA 4–6. Petitioner further

argues “Patent Owner agreed claims 5–17 and 19 were unpatentable over the combination of Levenson, Sherman, and Edwards” and “Patent Owner cannot be heard to argue there is no motivation to combine when it has canceled other claims based on and in view of the same combination.” Sur-reply RMTA 10.

Patent Owner responds that its statement in connection with the Disclaimer did not render proposed substitute claims 28 and 29 invalid, because of differences between claims 28 and 29, and the disclaimed claims. Tr. 39:15–40:5. Patent Owner argues that none of the disclaimed claims include a sulfite purity limitation, as claims 28 and 29 include, or the other purity clauses recited in the proposed substitute claims. *Id.* Patent Owner further argues that because none of the disclaimed method claims 5–17 and 19 have purity limitations, its statement as to invalidity (*see* MTA 2) is not relevant to Petitioner’s challenge to proposed substitute claims 28 and 29, which relies on Levenson, because a person of ordinary skill in the art would not have used Levenson’s teachings in a method having the purity clauses of claims 28 and 29. Tr. 43–44. Patent Owner further argues that its statement in connection with the Disclaimer was not an admission as to invalidity of claims 28 and 29 over Levenson, because the Petition’s challenge to disclaimed claim 4, which was a composition claim that included the impurity limitations from the specification column of Table 4 Petitioner now relies on, was based on Benda. Tr. 40:24–41:11.

We are persuaded that Patent Owner’s statement of invalidity in connection with the Disclaimer does not constitute an admission in the context of Petitioner’s challenge to proposed substitute claims 28 and 29. Petitioner’s challenge in the Petition to disclaimed claim 4 relied on Benda,

and therefore, to the extent Patent Owner's statement of invalidity in connection with the Disclaimer related to the impurities limitations of claim 4, it only related to invalidity over Benda. Petitioner's obviousness challenge to proposed substitute claims 28 and 29 relies on Levenson in combination with other references, and as discussed above, we have determined that Petitioner fails to show a person of ordinary skill would have used Levenson's teachings in combination with those references, with a reasonable expectation of success in achieving the limitations of the purity clauses in claims 28 and 29.

5. Conclusion

Based upon consideration of the entire record and for the reasons discussed above, we determine Petitioner has not proven that proposed substitute claims 28 and 29 would have been obvious over the combination of Levenson, Sherman, Edwards, and USP.

F. Ground 2: Alleged Obviousness over Levenson, Sherman, Edwards, USP, and FDA Guidance

Petitioner contends proposed substitute claims 28 and 29 are unpatentable as obvious over Levenson, Sherman, Edwards, USP, and FDA Guidance. Opp. RMTA 21–24. Petitioner's arguments with respect to Ground 2 do not cure the deficiencies discussed above with respect to Ground 1, and Petitioner does not provide further evidence of a reasonable expectation of success in support of Ground 2. *See* Opp. RMTA 25 (arguing reasonable expectation of success based on the combination of Levenson, Sherman, Edwards, USP, and FDA Guidance “to achieve the claimed purity limitations, as these limitations are simply the proximate results of a POSITA following prior-art specification limits.”). Accordingly, for the

reasons discussed above for Ground 1, Petitioner has not demonstrated obviousness of proposed substitute claims 28 and 29 by a preponderance of the evidence.

IV. CONCLUSION

For the foregoing reasons, we grant Patent Owner's Revised Motion to Amend the '363 patent to cancel claims 18 and 20 and add proposed substitute claims 28 and 29, as summarized below:

Motion to Amend Outcome	Claims
Original claims disclaimed or cancelled by amendment	1–27
Substitute claims proposed in the amendment	28, 29
Substitute claims: motion to amend granted	28, 29
Substitute claims: motion to amend denied	
Substitute claims: not reached	

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Patent Owner's Revised Noncontingent Motion to Amend is *granted*;

FURTHER ORDERED that claims 18 and 20 are canceled;

FURTHER ORDERED that revised proposed substitute claims 28 and 29 have not been proven unpatentable and shall be added to the '363 patent; and

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

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