

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ENCUBE ETHICALS PVT. LTD.,
Petitioner

v.

DERMAVANT SCIENCES GMBH,
Patent Owner.

IPR2024-00834
Patent 11,590,088 B2

Before ROBERT A. POLLOCK, TAWEN CHANG, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

CHANG, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Petitioner Encube Ethicals Pvt. Ltd. (“Petitioner”) filed a Petition for *inter partes* review of claims 1–4, 6–10, 16, 18, 21, and 22 of U.S. Patent No. 11,590,088 B2 (Ex. 1001, “the ’088 patent”). Paper 1 (“Pet.”). Patent Owner, Dermavant Sciences GmbH (“Patent Owner”), timely filed a Preliminary Response. Paper 6 (“Prelim. Resp.”). The parties further submitted an authorized Reply and Sur-Reply to the Preliminary Response. Paper 7 (“Reply”); Paper 8 (“Sur-Reply”); Ex. 3001.

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has demonstrated a reasonable likelihood that at least one claim of the ’088 patent is unpatentable and because we determine there is no reason to exercise our discretion to deny institution, we institute an *inter partes* review of all challenged claims on each of the Grounds raised in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require “a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition”); *see also* Guidance on the Impact of SAS on AIA Trial Proceedings (April 26, 2018).¹

¹ Available at <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial>.

A. Real Parties-in-Interest

Petitioner identifies itself as the real party-in-interest. Pet. 73. Patent Owner identifies itself and Dermavant Sciences, Inc. as the real parties-in-interest. Paper 5, 1.

B. Related Proceedings

Petitioner states that, “[a]s of the filing date of this Petition and to the best knowledge of Petitioner, the ’088 patent has not been involved in any other judicial or administrative matters.” Pet. 73.

Patent Owner states that the ’088 patent “claims the benefit of U.S. Patent Application No. 16/682,485, filed November 13, 2019 (now U.S. Patent No. 11,497,718); and U.S. Patent Application No. 16/682,476, filed November 13, 2019 (now abandoned).” Paper 5, 1. Patent Owner further states that “U.S. Patent Application No. 18/459,788, filed September 1, 2023 (now U.S. Patent No. 11,938,099); and pending U.S. Patent Application No. 18/163,631, filed February 2, 2023, claim the benefit of the ’088 patent.” *Id.*

C. The ’088 Patent and Relevant Background

1. Psoriasis

Psoriasis is a “common, chronic relapsing inflammatory skin disease with recurrent episodes of prominently erythematous and scaly patches (plaques).” Ex. 1001, 5:66–6:1.

The ’088 patent states that “[a]pproximately 2 to 3% of the global population is affected by psoriasis,” and, of those, “[u]p to 80% . . . have mild to moderate plaque-type psoriasis, which is generally managed with

topical treatments,” including “[t]opically-applied corticosteroids and Vitamin D analogs, alone or in combination.” Ex. 1001, 6:1–2, 11–15. The ’088 patent states, however, that vitamin D analogs are only “moderately efficacious as monotherapy,” and “application of topical corticosteroids—particularly the very potent ones—is restricted in terms of body areas that can be treated and the duration of use due to the well-known application site and systemic adverse drug reactions.” *Id.* at 6:15–20.

According to the ’088 patent, “[a]lthough numerous topical treatment options are available, there still remains a need for a topical treatment [for psoriasis] that combines a high level of efficacy with an acceptable safety profile that permits application to a large body surface area (BSA) without restrictions on duration of treatment.” Ex. 1001, 6:21–25.

2. Psoriasis Assessment

The ’088 patent describes assessments by which one or more symptoms of chronic psoriasis may be measured, including “Physician Global Assessment (PGA) score, Psoriasis Area and Severity Index (PASI), target lesion grading, Itch/Pruritus numeric rating scale (NRS), percent body surface area (BSA) affected, Psoriasis Symptom Diary (PSD), Dermatology Quality of Life Index (DLQI), and SF-36 questionnaire.” Ex. 1001, 22:14–21.

More particularly, the ’088 patent states that PGA is “a static 5-point morphological assessment of overall disease severity, as determined by the investigator, using the clinical characteristics of erythema, plaque thickness,

and scaling as guidelines.” Ex. 1001, 22:24–27. Regarding the scoring system for PGA, the ’088 patent explains:

Score of 0 represents clear skin with no signs of psoriasis, postinflammatory hyperpigmentation may be present; Score of 1 represents almost clear skin with no thickening, normal to pink coloration, no to minimal focal scaling; Score of 2 represents mild psoriasis with just detectable to mild thickening, pink to light red coloration, predominantly fine scaling; Score of 3 represents moderate psoriasis with clearly distinguishable to moderate thickening, dull to bright red, clearly distinguishable erythema, moderate scaling; and Score of 4 represents severe psoriasis with severe thickening with hard edges, bright to deep dark red coloration, severe/coarse scaling covering almost all or all lesions.

Id. at 22:30–42.

The ’088 patent states that “[t]he assessment of the % BSA affected is an estimate of the percentage of total involved skin with psoriasis,” which is evaluated from 0 to 100%, and that “[t]he extent of BSA affected by psoriasis is a general indicator of disease severity.” Ex. 1001, 23:24–27, 37–38.

The ’088 patent states that PASI utilizes the % BSA assessment and further “takes into account the overall severity of erythema (redness), thickness (induration), and scale (desquamation).” Ex. 1001, 23:36, 23:64–24:2. The ’088 patent states that

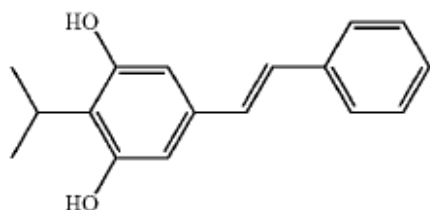
[t]he 3 clinical signs are each graded on a 5[-]point scale (0 to 4) and the % BSA affected is scored on a 7-point scale (0 to 6) for each of the 4 specified body regions (head, upper extremities, trunk, and lower extremities).

The individual scores are multiplied by a weighted factor for each body region; the sum of these scores give the overall PASI score.

Id. at 24:2–8.

3. Tapinarof Compositions

The '088 patent describes tapinarof as “a fully synthetic hydroxylated stilbene . . . for the topical treatment of . . . plaque psoriasis” and having the following structure:



Ex. 1001, 6:26–28, 7:4–21.

The '088 patent teaches that tapinarof may also be referred to as 3,5-Dihydroxy-4-isopropyl-trans-stilbene or (E)-2-isopropyl-5-syrylbenzene-1,3 diol. Ex. 1001, 7:7–10. The '088 patent states that “[i]t was surprisingly and unexpectedly found that the 1% tapinarof cream formulation applied topically once daily was just as effective as the 1% twice daily.” Ex. 1001, 6:52–54. The '088 patent states that

[t]his is surprising because both the 0.5% and 1% concentrations demonstrated an acceptable safety profile when applied once or twice daily but the 1% concentration was shown to be more effective than the 0.5% concentration[;] accordingly, one would have expected that a twice daily application would have been even more effective than a once daily application. . . . A once daily

application regimen may reduce systemic exposure . . . , thereby providing a better efficacy and safety profile for a drug intended for long-term use to treat a chronic condition. In addition, once daily application may improve treatment adherence compared to more frequent dosing administrations.

Id. at 6:54–7:2.

D. Overview of Challenged Claims

Petitioner challenges claims 1–4, 6–10, 16, 18, 21, and 22 of the '088 patent. Claim 1, reproduced below, is the sole independent claim:

1. A method for treating mild to severe plaque psoriasis in a subject comprising topically administering a topical composition containing about 1.0% tapinarof to affected areas of the subject once a day, wherein after topically administering the topical composition a Physician Global Assessment (PGA) score is improved by 2 grades or has improved to a score of 0 or 1.

Ex. 1001, 101:42–48 (claim 1).

Claims 2–4, 6–10, 16, 18, 21, and 22 depend directly or indirectly from independent claim 1 and recite additional features of the method or characteristics of the composition used in the method.

E. Relevant Prosecution History

The '088 patent was filed as U.S. Patent Application No. 17/871,663 (the '663 application) on July 22, 2022. Ex. 1001, codes (21), (22). The '663 application is a continuation of U.S. Patent Application No. 16,682,485 (the '485 application, now Patent No. 11,497,718), which was filed on November 13, 2019 and claims the benefit of U.S. Provisional Application

No. 62/760,704, filed on November 13, 2018 and U.S. Provisional Application No. 62/833,276, filed on April 12, 2019. *Id.* at codes (63), (60), 1:7–11. The '485 application is a continuation-in-part of U.S. Patent Application No. 16,682,476 (abandoned), filed on November 13, 2019, which claims the benefit of U.S. Provisional Application No. 62/760,692, filed on November 13, 2018 and U.S. Provisional Application No. 62/833,269, filed on April 12, 2019. *Id.* at codes (63), (60), 1:11–17.

1. October 17, 2022 Non-Final Office Action

In an Office Action dated October 17, 2022, the Examiner rejected the pending claims as anticipated by each of Chen '429,² Chen '041,³ and Chen '245.⁴ Ex. 1002, 236–237. The Examiner found that each of the above Chen references “discloses methods for treating psoriasis comprising [applying] a composition contain[ing] tapinarof to affected areas,” which “read on the instant claim[s].” *Id.*

2. October 28, 2022 Response to Non-Final Office Action

In response, Applicant noted that psoriasis “can include guttate psoriasis, pustular psoriasis, inverse psoriasis, erythrodermic psoriasis, and plaque psoriasis.” Ex. 1002, 284–286. Applicant argued that none of the

² Chen et al., US 2003/0171429 A1, published Sept. 11, 2003 (Ex. 1027, “Chen '429”).

³ Chen et al., US 2010/0094041 A1, published Apr. 15, 2010 (Ex. 1028, “Chen '041”).

⁴ Chen et al., US 2008/0255245 A1, published Oct. 16, 2008 (Ex. 1029, “Chen '245”).

Chen references cited by the Examiner “mention treating plaque psoriasis specifically with the compounds described therein.” *Id.*

Applicant further argued that, even if the cited Chen references disclosed treatment of plaque psoriasis specifically, none of the references discloses “(i) how to demonstrate that effective treatment of said plaque psoriasis can be done via numerous measurements, or (ii) what is a measure of effective treatment of said plaque psoriasis.” Ex. 1002, 284–286.

Applicant argued that, in contrast, the pending claims are directed to determining whether a treatment is effective using specified assessments (e.g., Physician Global Assessment (PGA) score), and are further directed to improving a subject’s assessment results by a specified degree (e.g., improving a subject’s PGA score by 2 grades or to a score of 0 or 1). *Id.*

Applicant contends that, “[a]ccordingly, a generic disclosure to simply treat plaque psoriasis but which does not teach how to do so cannot destroy the novelty of a claim.” *Id.*

3. November 17, 2022 Non-Final Office Action, November 22, 2022 Response, and January 20, 2023 Notice of Allowance

The Examiner subsequently issued a new ground of rejection finding the claims to be anticipated by Gold.⁵ The Examiner noted that Applicant’s

⁵ Linda Stein Gold et al., *Secondary Efficacy Outcomes from a Phase 2b, Randomized Dose-Finding Study of Tapinarof Cream for the Treatment of Plaque Psoriasis*, 81 J AM. ACAD. DERMATOLOGY AB121 (2019). We note that both the Examiner and Applicant refer to this article as “Rubenstein”

prior arguments regarding the cited Chen references “have been considered but are moot because the new ground of rejection does not rely on any reference applied in the prior rejection of record for any teaching or matter specifically challenged in the argument.” Ex. 1002, 292.

Applicant argued in response that Gold “is not available as prior art to the present application under 35 U.S.C. §[]102(a)(1),” either because the claims have effective filing date(s) that pre-date Gold or because Gold “falls under the exception of 35 U.S.C. §[]102(b)(1),” relating to disclosures made 1 year or less before the effective date by the inventor, joint inventor, or another who obtained the disclosed subject matter from them. Ex. 1002, 302–303.

The Examiner subsequently allowed the claims to issue, stating in the Reasons for Allowance that the claimed methods “were not found to be obvious or anticipated by the prior art of record” and that “[t]he prior art does not teach or suggest the methods encompassing compounds substituted in the manner claimed by the Applicant.” Ex. 1002, 312.

during prosecution. However, we follow the convention of referring to an article by the first author’s last name, i.e., “Gold.”

F. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 3):

Ground	Claims Challenged	35 U.S.C § ⁶	Reference(s)/Basis
1	1–4, 6, 8, 9, 16, 18, 22	102	Sonti ⁷
2	1–4, 6–10, 16, 18, 21, 22	103	Sonti
3A	7, 9, 10, 21	103	Sonti (Ground 1), Bissonnette ⁸
3B	7, 9, 10, 21	103	Sonti (Ground 2), Bissonnette
3C	7, 9, 10, 21	103	Sonti (Grounds 1 & 2), Bissonnette
4A	1–4, 6–10, 16, 18, 21, 22	103	Bissonnette, Sonti
4B	1–4, 6–10, 16, 18, 21, 22	103	Bissonnette, Chen ⁹
4C	1–4, 6–10, 16, 18, 21, 22	103	Bissonnette, Sonti, Chen

⁶ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102 and 103, effective March 16, 2013. Because the ’088 patent has an effective filing date after March 16, 2013, the AIA version of §§ 102 and 103 applies. Our decision, however, would be the same under either version.

⁷ Sonti et al., US 2016/0338973 A1, published Nov. 24, 2016 (Ex. 1005, “Sonti”).

⁸ R. Bissonnette et al., *Efficacy and Safety of Topical WBI-1001 in Patients with Mild to Moderate Psoriasis: Results from a Randomized Double-Blind Placebo-Controlled, Phase II Trial*, 26 J. EUR. ACAD. DERMATOLOGY AND VENEREOLOGY 1516 (2012) (Ex. 1008, “Bissonnette”).

⁹ Chen et al., US 7,868,047 B2, issued Jan. 11, 2011 (Ex. 1013, “Chen”).

By way of clarification, because Petitioner uses the phrase “and/or” in connection with Grounds 3 and 4, Pet. 3, 46, we divide each of Ground 3 and Ground 4 into three sub-grounds (Grounds 3A–3C and Grounds 4A–4C, respectively). With respect to Grounds 3A–3C, claims 7, 9, and 21 depend from claim 1 and claim 10 depends from claim 9. Petitioner asserts that Sonti anticipates claims 1 and 9 (Ground 1) and renders obvious claims 7, 9, 10, and 21 (Ground 2), among other claims. Pet. 3. Petitioner asserts that, alternatively, claims 7, 9, 10, and 21 are obvious “for the reasons explained in Ground 1 and/or Ground 2, further in view of Bissonnette.” *Id.* at 46 (emphasis omitted). Thus, although each of grounds 3A–3C relies on the same set of prior art references (Sonti and Bissonnette), we understand Petitioner relies on the reasoning of Ground 1, further in view of Bissonnette, for asserting obviousness under Ground 3A; the reasoning of Ground 2, further in view of Bissonnette, for asserting obviousness under Ground 3B; and the reasoning in both Grounds 1 and 2, further in view of Bissonnette, for asserting obviousness under Ground 3C. We address in Section II.F.1.b, below, Patent Owner’s contention that Petitioner’s asserted grounds lack particularity because of the use of “and/or” in the grounds.

Petitioner further relies, *inter alia*, on the declarations of Dr. Wieke Liem, M.D., F.A.A.D. (Ex. 1003, “Liem Declaration”) and Mr. Paul Sudhakar, M.S., M.B.A. (Ex. 1032, “Sudhakar Declaration”).

G. Overview of Asserted References

1. Overview of Sonti (Exhibit 1005)

Sonti teaches “topical pharmaceutical emulsion compositions comprising a therapeutically effective amount of 3,5-Dihydroxy-4-isopropyl-trans-stilbene [(i.e., tapinarof)] or a pharmaceutically acceptable salt thereof” and “methods of treating a dermatological condition or disorder in a patient by administering the . . . compositions to the skin of the patient.” Ex. 1005, Abstract; Ex. 1001, 7:4–21.

Sonti teaches embodiments wherein 3,5-Dihydroxy-4-isopropyl-trans-stilbene or a pharmaceutically acceptable salt thereof is present in the emulsion composition in an amount (1) from about 0.01% to about 5% by weight, such as from about 0.05% to about 2% by weight, (2) from about 0.1% to about 1% by weight, (3) of about 0.25%, 0.30%, 0.40%, 0.50%, 0.75%, 1% or 2% by weight, or (4) from about 0.25% to about 0.50% by weight. Ex. 1005 ¶ 55; *see also id.* ¶ 196.

Sonti teaches that “[a]pplication of a composition of the present invention may be applied to the affected areas twice daily, once daily, once every other day; twice weekly; three times weekly, or once weekly, with the dose represented by any of the embodiments herein.” Ex. 1005 ¶ 387. Sonti teaches that, “[i]n another embodiment, the treatment may be administered in two phases, an initial dosage frequency such as once or twice daily, followed by a maintenance phase, such as every other day; twice weekly; three times weekly, or once weekly.” *Id.*

Sonti teaches that there are “many psoriasis assessment tools currently available,” and that, of these, “the Psoriasis Area and Severity Index (PAS[I]) and Physician Global Assessment (PGA) tools are most used.” Ex. 1005 ¶ 285.

2. Overview of Bissonnette (Exhibit 1008)

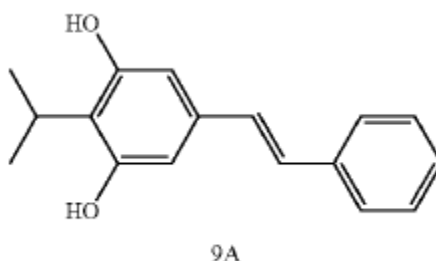
Bissonnette describes a study in which “[a] total of 61 patients with 1–10% body surface area (BSA) covered with plaque psoriasis and a physician’s global assessment score (PGA) of 2–4 . . . receive[d] either 1% WBI-1001 in a cream formulation or placebo, applied twice daily for 12 weeks.” Ex. 1008, Abstract; *see also id.* at 1517, left col. WBI-100 has the chemical name of 2-isopropyl-5-[(E)-2-phenylethenyl]benzene-1,3-diol. Ex. 1008, 1516, right col. It is not currently disputed that WBI-1001 is tapinarof. Ex. 1003 ¶ 89.

Bissonnette states its study “demonstrated that topical WBI-1001 at 1% is effective for the treatment of mild to moderate plaque psoriasis.” Ex. 1008, 1519, right col. In particular, Bissonnette teaches that “the proportion of patients that achieved a PGA of 0 (clear) or 1 (almost clear) at Day 84 was 67.5% for patients randomized to WBI-1001 when compared with 4.8% for patients randomized to placebo.” *Id.* Bissonnette further teaches that the body surface area affected by psoriasis “decreased by 79.1% at week 12 for patients randomized to WBI-1001 when compared with an increase in 9.4% for patients randomized to placebo.” *Id.*

3. Overview of Chen (Exhibit 1013)

Chen teaches methods of treating diseases, including psoriasis, using hydroxystilbenes and novel stilbene derivatives. Ex. 1013, Abstract; *see also id.* at 3:3–4 (explaining that “[t]he compounds of the invention possess specific activity against psoriasis”).

Chen teaches that “[a] particularly preferred compound is 3, 5-dihydroxy-4-isopropylstilbene (9A).” Ex. 1013, 8:53–54. The chemical structure of Compound 9A is reproduced below:



Id. at 16:40–45. Chen states that “[t]he compounds of this invention and the inventive compositions encompass both the trans and cis stereochemical forms of the compounds, and mixtures of the trans and cis forms.” *Id.* at 9:47–51.

Chen teaches compositions comprising the compounds of its invention in a therapeutic effective amount together with a suitable pharmaceutical carrier “are envisioned to contain the active ingredient in a 0.01–10% by weight amount.” Ex. 1013, 14:4–6, 23–25. Chen teaches that “[t]he required daily dosages may be administered in single or divided doses.” *Id.* at 14:28–29.

Chen discloses an example (Example 4) in which a 1% cream of 3, 5-dihydroxy-4-isopropylstilbene was applied once a day to the affected area on the body of three volunteers “each with a long psoriasis history” and who had, respectively, “scalp psoriasis,” “plaques on her back,” and “an unspecific type of eczema.” Ex. 1013, 32:25–43. Chen states that “the inventive compound showed great efficacy on the volunteers treated in comparison with the untreated areas and before and after treatment.” *Id.* at 32:51–53.

II. ANALYSIS

A. Principles of Law

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (2012) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review). The Board may authorize an *inter partes* review if we determine that the information presented in the Petition and Patent Owner’s Preliminary Response shows a reasonable likelihood that Petitioner will prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314(a).

Petitioner contends that claims 1–4, 6, 8, 9, 16, 18, and 22 are anticipated by Sonti. Pet. 3. To show anticipation under 35 U.S.C. § 102, each and every claim element, arranged as in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008). The prior art need not, however, use the same words as the claims to find anticipation. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). In evaluating anticipation, it is permissible to take into account not only the literal teachings of the prior art reference, but also the inferences the skilled artisan would draw from it. *Eli Lilly and Co. v. Los Angeles Biomedical Res. Inst. At Harbor-UCLA Med. Ctr.*, 849 F.3d 1073, 1074–75 (Fed. Cir. 2017) (holding that the “dispositive question regarding anticipation is whether one skilled in the art would reasonably understand or infer from a prior art reference that every claim element is disclosed in that reference”). As such, “a reference can anticipate a claim even if it does not expressly spell out all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would at once envisage the claimed arrangement or combination.” *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (internal quotation and alteration marks omitted).

Petitioner also contends that claims 1–4, 6–10, 16, 18, 21, and 22 would have been obvious under § 103 in view of (1) Sonti, (2) Sonti and Bissonnette, and (3) Bissonnette combined with Sonti and/or Chen. Pet. 3. A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the claimed invention as a

whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. *See 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) objective evidence of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art “to combine . . . known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (internal quotations omitted).

We address Petitioner’s challenges with these standards in mind, and in view of the definition of the skilled artisan and the claim constructions discussed below.

B. Person of Ordinary Skill in the Art

Factual indicators of the level of ordinary skill in the art include “the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field.” *Jacobson Bros., Inc. v. U.S.*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros.*).

Petitioner asserts that a person of ordinary skill in the art (“POSA”) for purposes of the ’088 patent “would have been a medical doctor with an M.D. degree and a specialization in dermatology (such as a dermatologist), with at least two years’ experience as a clinician diagnosing and treating patients afflicted with skin conditions that include plaque psoriasis.” Pet. 6 (citing Ex. 1003 ¶¶ 23–24). Petitioner further asserts

[a] POSA would have had access to and would have consulted with a collaborative team of ordinarily skilled artisans, including drug formulators having a bachelor of pharmacy (B.Pharm) with at least 5 years of experience, or a masters in pharmacy (M.Pharm) with at least two years of experience, in the pharmaceutical sciences that included developing topical compositions for treating skin conditions.

Id.

Patent Owner states that, for the purposes of its Preliminary Response, Patent Owner applies Petitioner’s definition of a person of ordinary skill in the art. Prelim. Resp. 5. However, Patent Owner “reserves the right to submit its own definition should the Board decide to institute trial.” *Id.*

On the current record, for purposes of this Decision, we apply Petitioner’s proposed definition, as it appears consistent with the level of skill in the art reflected in the prior art of record and the disclosure of the ’088 Patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (“the prior art itself [may] reflect[] an appropriate level” as evidence of the ordinary level of skill in the art) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)). We note, however, that the open-ended language “at least” expands the range of experience indefinitely with no upper bound. Therefore, we do not apply this aspect of Petitioner’s formulation.

C. Claim Construction

We construe claims “using 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 (2024). Therefore, we construe the challenged claims under the framework set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc). Under this framework, claim terms are given their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art, at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id.*

The parties do not propose express constructions for any claim term. More particularly, Petitioner states that the “Petition applies the ordinary and customary meaning” of claim terms and states that, “[a]t this time, Petitioner does not believe it necessary for the Board to expressly construe any term for the purpose of this IPR proceeding.” Pet. 7. Patent Owner does not address claim construction in the Preliminary Response.

Petitioner bears the burden of stating “[h]ow the challenged claim is to be construed.” 37 C.F.R. § 42.104(b)(3). However, only those terms that are in controversy need be construed, and 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); *see also 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 AIA trial proceeding). Based on the preliminary record, we find it unnecessary to construe any claim term to decide whether Petitioner satisfies the “reasonable likelihood” standard for instituting trial.

Any final written decision entered in this case may include express claim constructions, or may include discussion of claim scope that differs from that provided in our analysis below. Any final claim constructions will be based on the full trial record.

D. Merits Analysis

We next turn to the information presented in the Petition and Patent Owner’s Preliminary Response to determine whether, based on the present record, there is a reasonable likelihood that Petitioner will prevail with

respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314(a). We emphasize our determination in this Decision is not a final determination on the construction of any claim term or the patentability of any challenged claim and, thus, leaves undecided any factual issues necessary to determine whether sufficient evidence supports Petitioner's contentions by a preponderance of the evidence in the final written decision. *See TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting that “there is a significant difference between a petitioner's burden to establish a ‘reasonable likelihood of success’ at institution, and actually proving invalidity by a preponderance of the evidence at trial”) (quoting 35 U.S.C. § 314(a) and comparing § 316(e)).

1. Ground 1: Asserted Anticipation by Sonti

Petitioner provides a mapping of each element of claims 1–4, 6, 8, 9, 16, 18, and 22 to the disclosures in Sonti. Pet. 13–28. We focus our analysis on claim 1.

a. Claim 1

Relying on the testimony of Dr. Liem, Petitioner asserts that an ordinarily skilled artisan would understand Sonti's disclosure of “‘using a topical emulsion composition as described herein’ includes topically administering the composition containing about 1% tapinarof once a day.” Pet. 17 (citing, e.g., Ex. 1003 ¶ 141). Petitioner asserts, therefore, that even if Sonti did not *expressly* provide a single embodiment having all of the limitations of claim 1, an ordinarily skilled artisan would understand that is

what Sonti discloses when it teaches—in the contexts of treating plaque psoriasis or achieving a particular PGA score improvement—using “a topical emulsion composition as described herein.” Pet. 15, 17.

Petitioner further asserts that, even if Sonti did not expressly spell out the combination, “Sonti focuses specifically on treating a limited number of diseases (atopic dermatitis and plaque psoriasis . . .), tapinarof strengths (including ‘1%’), and application frequencies (including ‘once daily’),” to achieve “a limited number of metrics for plaque psoriasis treatment response—the recited ‘PASI’ and ‘PGA’ scales.” Pet. 16, 18. Petitioner asserts that, accordingly, “a POSA would at once envisage the option of treating plaque psoriasis with a 1% tapinarof composition administered once a day” that “results in the claimed PGA score improvement” based on Sonti’s disclosures. Pet. 16, 18.

Patent Owner contends that “Sonti . . . discloses nearly *one million* different treatment options” and that Petitioner improperly “cherry-picks different claim elements out of multiple lists and different embodiments.” Prelim. Resp. 32–33. Patent Owner contends that “[t]he Petition thus fails to meet the ‘at once envisage’ standard” set forth in *In re Petering*, 301 F.2d 676, 681 (CCPA 1962).¹⁰ Prelim. Resp. 37.

¹⁰ In support of its calculations, Patent Owner contends that Sonti “describe[s] at least *67 different dermatological conditions*” and “a range of tapinarof amounts [from about 0.01% to about 5% by weight] in 0.01% increments—i.e., *500 different amounts of tapinarof*.” Prelim. Resp. 34

Based on the record currently before us, Petitioner has demonstrated a reasonable likelihood that claim 1 of the '088 patent is anticipated by Sonti. Although the predecessor to our reviewing court has cautioned against “picking, choosing, and combining various disclosures *not directly related to each other by the teachings of the cited reference*” in the context of an anticipation rejection, *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972) (emphasis added), we find Petitioner has sufficiently established, for purposes of institution, that Sonti’s teachings directly relate the relevant disclosures regarding treating plaque psoriasis with a 1% tapinarof composition, administered once a day, to achieve the claimed PGA score improvement.

Patent Owner alleges that Sonti discloses 938,000 total treatment options, including treatment of “67 disease indications.” Prelim. Resp. 36 n.6. However, Petitioner’s declarant Dr. Liem explains that, although “Sonti does mention treating other similar skin conditions, . . . it focuses specifically on atopic dermatitis and plaque psoriasis.” Ex. 1003 ¶ 124.¹¹

(citing Sonti ¶¶ 55, 298–299). Patent Owner further asserts that Sonti “describes at least *14 application frequencies*,” including six options for single-phase dosing and eight options for two-phase dosing (e.g., where an initial dosage frequency is followed by a maintenance phase). *Id.* at 35 (citing Sonti ¶ 387). Patent Owner asserts that “67 different disease indications x 500 different tapinarof amounts x 14 different application frequencies x two different clinical criteria (PASI score or PGA score) = 938,000 total options.” *Id.* at 36 n.6.

¹¹ We note, for instance, that claim 23 of Sonti specifically limits the disease treated to psoriasis, atopic dermatitis, or acne. Ex. 1005, claim 23.

Likewise, although Sonti more broadly discloses tapinarof amounts in ranges of 0.01% to 5% by weight, 0.05% to about 2% by weight, 0.1% to about 1.0% by weight, 0.25% to about 2% by weight, and 0.25% to about 0.50% by weight, Ex. 1005 ¶¶ 55, 196, Sonti describes example formulations (Formulations 1–9, 11–42)¹² comprising only a limited number of different tapinarof amounts, i.e., 0.10%, 0.50%, 1.00%, 2.00%, 3.00%, and 4.00%. *See, e.g.*, Pet. 14 (relying on example formulations comprising 1% tapinarof), 15 (stating that “Sonti focuses on . . . a limited number of potential amounts of tapinarof,” including 1%); Ex. 1003 ¶¶ 120–121, 124. In view of the entirety of Sonti’s disclosure—including its particular focus on the treatment of certain diseases and compositions comprising specific amounts of active ingredients—and the presently unrebutted testimony of Dr. Liem, we find Petitioner has sufficiently established, for purposes of institution, that an ordinarily skilled artisan would “at once envisage” the claimed method based on Sonti’s disclosures.

b. Claim 3

Claim 2, from which claim 3 depends, recites “[t]he method of claim 1, wherein the topical composition is an oil-in-water emulsion.” Pet. 76 (App. A: Claims Listing). Petitioner has established a reasonable likelihood of showing, and Patent Owner does not currently dispute, that Sonti discloses the additional limitation in claim 2. Pet. 18–19; Ex. 1003 ¶¶ 147–

¹² Formulation 10, containing no tapinarof, was used as the placebo. Ex. 1005 ¶¶ 327 (Table 4), 348.

148; Ex. 1032, ¶¶ 92–94. Claim 3 further requires the topical composition to have an oil phase comprising nine enumerated ingredients. Pet. 76 (App. A: Claims Listing).

Patent Owner contends that “the Petition selects individual ingredients from at last *13 different formulations* embodied in Sonti, some of which Sonti characterizes as ‘non-uniform.’” Prelim. Resp. 40. Patent Owner contends that Petitioner’s argument relies on impermissible picking and choosing from disparate disclosures. *Id.* at 41.

Although Petitioner’s declarant Mr. Sudhakar cites to additional formulations to support his opinion that Sonti discloses all of the additional elements of dependent claim 3, Mr. Sudhakar cites to formulations 21 and 30–33—which all contain 1% tapinarof as recited in independent claim 1 and differ from each other only in the amounts of white petrolatum in the formulation—as disclosing almost all of these ingredients. Ex. 1032 ¶¶ 97, 98, 100–105; Ex. 1005 ¶¶ 355 (Table 8), 370 (Table 9). Based on the present record and for purposes of institution, therefore, we do not find that Petitioner engaged in impermissible picking and choosing with respect to claim 3.

Patent Owner contends the Petition also cites to Formulations 1a and 13, and that its reliance on these formulations is problematic because “‘chemical degradation of the active ingredient [was] observed’ in Formulation 1a” and “Formulations 2–14 [were] ‘non-uniform’ emulsions with solubility and stability issues.” Prelim. Resp. 40. However, the evidence of record at present suggests that the particular ingredients for

which Petitioner cites to these formulations (non-ionic emulsifying wax, polyoxyl stearyl ether-2, and polyoxyl stearyl ether-20) were not the cause of the instability, because they are included, together with the other ingredients recited in claim 3, in formulations 21 and 30–33, which Patent Owner acknowledges are described by Sonti as physically stable. Ex. 1005 ¶¶ 355 (Table 8), 370 (Table 9); Prelim. Resp. 40.

In light of the testimony of Petitioner’s declarant and Sonti’s example formulations comprising all of the oil phase ingredients recited in claim 3, and further in light of our analysis regarding claim 1 and the discussion in the Petition and the Liem and Sudhakar Declarations regarding claim 2, we find Petitioner has sufficiently established a reasonable likelihood that Sonti anticipates the method of dependent claim 3.

c. Claims 3 and 4

Patent Owner contends that “neither of [Petitioner’s] experts provides a complete opinion or analysis for claim 3 and 4, and the Petition’s arguments lack the required support under 37 C.F.R. § 42.65(a).” Prelim. Resp. 42. Patent Owner asserts “Dr. Liem relies exclusively on Mr. Sudhakar’s testimony to support her opinion that claims 3 and 4 are anticipated and obvious,” but Mr. Sudhakar opined that claims 3 and 4 are anticipated and obvious without analyzing or considering the patentability of claim 1, from which claim 3 depends. *Id.*

We are not persuaded by this argument. Based on a review of the Petition and the Liem and Sudhakar Declarations, we find it is sufficiently clear that the Petition relies on, among other things, (1) the Liem Declaration

to support its arguments with respect to independent claim 1; (2) the Sudhakar Declaration to support its arguments with respect to the additional limitations with respect to dependent claims 3 and 4; and (3) the combination of the Liem and Sudhakar Declarations for its arguments with respect to claims 3 and 4 in their entirety. Reply 5.

d. Conclusion as to Ground 1

For the reasons discussed above, Petitioner establishes sufficiently, for purposes of institution, that Sonti directly relates its disclosures regarding treating plaque psoriasis with a topical 1% tapinarof composition, administered once a day, to achieve the PGA score improvement recited in claim 1. Having considered the evidence of record, we likewise determine that Petitioner has established sufficiently, for purposes of institution, that Sonti discloses a method comprising the additional limitations in claims 2–4, 6, 8, 9, 16, 18, and 22. Accordingly, we find Petitioner has demonstrated a reasonable likelihood that Sonti anticipates claims 1–4, 6, 8, 9, 16, 18, and 22 and institute review on that ground.

2. Ground 2: Asserted Obviousness over Sonti

Petitioner asserts that all of the challenged claims also would have been obvious in view of Sonti's teachings. Pet. 28. Petitioner provides a mapping of each element of claims 1–4, 6–10, 16, 18, 21, and 22 to the disclosures in Sonti. Pet. 29–46. Petitioner further explains why an ordinarily skilled artisan would have had reason to apply Sonti's teachings,

with a reasonable expectation of success, to arrive at the claimed invention.

Id.

Patent Owner asserts that, for each of the obviousness grounds (Ground 2–4), “[t]he Petition (i) does not demonstrate a reasonable expectation of success, (ii) overlooks that the purported ‘need’ in its obvious-to-try analysis was already met; and (iii) fails to address [known] objective indicia of non-obviousness.” Prelim. Resp. 42. With respect to Ground 2 in particular, Patent Owner also asserts that the Petition resorted to an improper inherency argument in addressing the preamble of the claims and that the Petition failed to provide a reason to combine the disclosures in Sonti to arrive at compositions comprising the particular ingredients recited in claims 3 and 4. *Id.* at 53–55.

We focus our analysis on claim 1.

a. Alleged Improper Inherency

The preamble of claim 1 recites “[a] method for treating mild to severe plaque psoriasis in a subject.” Pet. 76 (App. A: Claims Listing). Patent Owner contends that “Ground 2 incorporates Ground 1’s failed inherency showing that purports that disclosure of a treatment for ‘moderate to severe’ plaque psoriasis is necessarily disclosure of a treatment for ‘mild’ plaque psoriasis.” Prelim. Resp. 53. Patent Owner asserts that evidence of record show that “treatment of moderate to severe plaque psoriasis is not *necessarily* the same as treatment of mild psoriasis.” *Id.* at 53–54.

Petitioner relies on Dr. Liem’s testimony, based among other things on her “experience in 30+ years of practice as a dermatologist[] having

treated well over 1,000 patients with mild to severe plaque psoriasis,” that “if a topical treatment is effective for moderate to severe plaque psoriasis (the more severe end of the spectrum), it necessarily follows, as a matter of experience and common sense, that it will also be effective to topically treat mild plaque psoriasis.” Pet 14; Ex. 1003 ¶ 116. We find that, at this stage of the proceeding, and based on the current record, Petitioner has established a reasonable likelihood that Sonti’s disclosed treatment of moderate to severe psoriasis necessarily treats mild psoriasis.

Patent Owner cites to Table 1 of Raychaudhuri¹³ and Table 2 of Dogra.¹⁴ Prelim. Resp. 53–54. These do not, without more, suggest a contrary result. Table 1 of Raychaudhuri merely classifies psoriasis, based on the percentage of body surface area (BSA) affected, into mild, moderate, and severe forms. Ex. 1015, 492 (Table 1).

Similarly, Table 2 of Dogra classifies psoriasis into mild, moderate, and/or severe forms based on % BSA (or another assessment criteria such as PASI or Dermatology Life Quality Index (DLQI)) and effect on patient’s quality of life. Ex. 1006, 473 (Table 2). It also states that treatments for mild psoriasis “have no known serious risks,” that therapies used for moderate psoriasis have minimal risks, and that, for severe psoriasis, a

¹³ Smriti K. Raychaudhuri et al., *Diagnosis and Classification of Psoriasis*, 13 AUTOIMMUNITY REV. 490 (2014) (Ex. 1015, “Raychaudhuri”).

¹⁴ Sunil Dogra & Rahul Mahajan, *Psoriasis: Epidemiology, Clinical Features, Co-Morbidities, and Clinical Scoring*, 7 INDIAN DERMATOLOGY ONLINE J. 471 (2016) (Ex. 1006, “Dogra”).

patient “does not have satisfactory response to treatments that have minimal risk, and the patients are willing to accept life-altering side[]effects to achieve less disease or no disease.” *Id.* To the extent this disclosure suggests that treatments sufficient for mild psoriasis are not necessarily effective in treating severe psoriasis, it does not, without more, suggest the opposite.

Furthermore, Petitioner’s arguments regarding the preamble of claim 1 are not limited to inherency. First, Petitioner asserts that Sonti discloses the claimed “method for treating mild to severe plaque psoriasis in a subject” because “moderate to severe plaque psoriasis” overlaps or falls within the range of “mild to severe plaque psoriasis.” Pet. 13. With respect to Ground 2, Petitioner further argues Sonti’s disclosures render this limitation obvious because “[a] POSA would have expected a treatment taught as effective for moderate to severe plaque psoriasis to also be effective for lower-grade manifestations, e.g., mild psoriasis” and that, “[t]herefore, a POSA would have been motivated, with a reasonable expectation of success, to apply to mild psoriasis a method of treatment that Sonti expressly teaches is effective for moderate to severe psoriasis.” Pet. 29 (citing Ex. 1003 ¶¶ 182–183).

Citing to Dogra, Patent Owner argues that “Ground 2 fails to explain why a POSA would have allegedly been motivated to use a treatment with potential life-altering side effects (i.e., a treatment for severe psoriasis) to treat a mild form of disease, when . . . other treatments with *no known serious risks* (i.e., treatment for mild psoriasis) were available.” Prelim.

Resp. 54. However, Petitioner’s declarant Dr. Liem notes that “the literature taught that the adverse effects for tapinarof used to treat plaque psoriasis were mostly mild, even when applied twice a day” and that an ordinarily skilled artisan would therefore have been “comfortable using the method to treat mild psoriasis.” Ex. 1003 ¶ 183.

Accordingly, even if Petitioner has not shown a reasonable likelihood that methods of treating moderate to severe plaque psoriasis are necessarily methods of treating mild plaque psoriasis, Petitioner nevertheless has shown a reasonable likelihood of success that Sonti suggests a method of treating mild to severe plaque psoriasis as recited in the claims.

b. Reasonable Expectation of Success

Petitioner asserts that an ordinarily skilled artisan would have been motivated, with a reasonable expectation of success, to topically administer 1% tapinarof composition once a day to treat mild to severe plaque psoriasis in view of Sonti’s teaching to apply its compositions (including 1% tapinarof compositions) in various application frequencies (including once daily) to treat moderate to severe plaque psoriasis. Pet. 29–30 (citing, *e.g.*, Ex. 1003 ¶¶ 182–184, 187–188; Ex. 1005 Abstract, ¶¶ 55, 196, 288, 387).

Patent Owner asserts that Petitioner’s arguments based on Sonti rely on vague cross-referencing. Prelim. Resp. 46. Patent Owner asserts that nowhere in the Petition section cited (i.e., Section VIII.A) does Petitioner argue “it was ‘known’ that ‘1% tapinarof, administered topically once daily, effectively treated plaque psoriasis.’” *Id.* at 47. Patent Owner asserts that, “to the extent the Petition is referring to its argument . . . that ‘[a] POSA

would have known that Sonti’s disclosure of treating moderate to severe psoriasis is inherently also a method of treating mild psoriasis,” Petitioner has not sufficiently established such inherency. *Id.* (citing Prelim. Resp. Section V.A.1).

As an initial matter, and as explained in our discussion of Petitioner’s arguments above, we do not agree that “the Petition offers no further explanation beyond pointing to ‘§VIII.A’” with respect to reasonable expectation of success. Prelim. Resp. 46. Rather, Petitioner cites to specific sections of Sonti and the Liem Declaration in support of its arguments.

We acknowledge the Petition states, as part of “other known reasons for using a method of treatment recited by claim 1, with a reasonable expectation of success,” that Sonti teaches “it was known that 1% tapinarof, administered topically once daily, effectively treated plaque psoriasis.” Pet. 31 (citing Pet. §VIII.A). However, we do not find that the citation to Section VIII.A of the Petition, which provides support for Petitioner’s assertion that Sonti anticipates claim 1 of the ’088 patent, to be vague in context. Claim 1 of the ’088 patent recites “a method for treating . . . plaque psoriasis” comprising “topically administering a topical composition containing about 1.0% tapinarof . . . once a day” and further recites that after topical administration, the PGA score is improved. Thus, we understand Petitioner to be pointing to the entirety of the section as support for its statement regarding what is known from Sonti, i.e., that “1% tapinarof, administered topically once daily, effectively treated plaque psoriasis.” Pet. 31.

Patent Owner asserts Petitioner’s reasonable expectation of success argument also fails because it “presumes—incorrectly—that Chen discloses applying tapinarof to its Volunteers.” Prelim. Resp. 43.

We acknowledge Petitioner asserts “Sonti *also* cites two Chen references as showing that tapinarof was ‘suitable for the treatment of . . . psoriasis.’”¹⁵ Pet. 31 (citing Ex. 1005 ¶ 10). However, Petitioner’s reasonable expectation of success argument is not premised solely on the disclosures of the Chen references cited in Sonti, and, for the reasons discussed above, we find Petitioner has met the requirements, for purposes of institution, of showing reasonable expectation of success based on the other cited disclosures in Sonti.

Nevertheless, we address Patent Owner’s arguments regarding the Chen references (Exs. 1012 & 1013) for the sake of completeness. We note the two Chen references contain similar disclosures with respect to the issue in dispute between the parties, which is further discussed below, except that Chen (Ex. 1013) discloses the application of 1% 3,5-dihydroxy-4-isopropylstilbene to an additional volunteer, “Volunteer 3, Male, 35 years old,” who “had an unspecific type of eczema with 3,000 cm² affected area on the trunk and extremities.” *Compare* Ex. 1012, 19:20–21:25 (Example 3) *with* Ex. 1013, 32:7–33:3 (Example 4).

¹⁵ The two Chen references cited in Sonti are (1) the Chen reference asserted in the Petition (i.e., Ex. 1013, “Chen”) and (2) Chen, WO 2001/042231, published June 14, 2001 (Ex. 1012).

Petitioner asserts the cited Chen references “specifically taught that a topical cream of ‘1% 3,5-dihydroxy-4-isopropylstilbene,’” which Petitioner asserts is tapinarof, “applied ‘once per day’ ‘showed great efficacy’ in treating plaque psoriasis.” Pet. 31 (citing, *e.g.*, Ex. 1003, ¶¶ 99–104, 190–193; Ex. 1013, 2:56–3:4, 32:10–63; Ex. 1032, ¶¶ 68–70).

Patent Owner asserts that “[t]apinarof is 3,5-dihydroxy-4-isopropyl-*trans*-stilbene,” whereas the cited Chen references “disclose[] applying ‘3,5-dihydroxy-4-isopropylstilbene’ (i.e., a mixture of *cis* and *trans* forms)[] to its Volunteers.” Prelim. Resp. 43–44 (discussing Chen (Ex. 1013) and stating that “WO 2001/042231 [(Ex. 1012)] does the same”). Patent Owner asserts that neither Petitioner nor its declarants “explains how a compound that is not tapinarof is informative about efficacy of tapinarof.” *Id.* at 44.

We find that, based on the present record, the Chen references cited in Sonti support Petitioner’s reasonable expectation of success arguments for purposes of institution. As an initial matter, the Petition cites to the testimony of Petitioner’s declarant, Mr. Sudhakar, that “‘3,5-dihydroxy-4-isopropylstilbene is tapinarof.’” Pet. 31 (citing Ex. 1032 ¶¶ 68–70). Moreover, even assuming that tapinarof is limited to the *trans* form of 3,5-dihydroxy-4-isopropylstilbene, the cited Chen references still teach applying tapinarof once a day to treat psoriasis, albeit at a concentration of less than 1% because, under Patent Owner’s interpretation of these references, the 1% 3,5-dihydroxy-4-isopropylstilbene used in Example 3 of WO 2001/042231 (Ex. 1012) and Example 4 of Chen (Ex. 1013) is a mixture of *cis*- (i.e., non-tapinarof) and *trans*- (i.e., tapinarof) forms. Under this scenario, and based

on the present record, the disclosures of the Chen references likewise support a reasonable expectation of success of using a greater amount of tapinarof (i.e., 1%), applied once a day, to treat plaque psoriasis. In this regard, we emphasize that expectation of success need only be reasonable, not absolute. *Soft Gel Technologies, Inc. v. Jarrow Formulas, Inc.*, 864 F.3d 1334, 1342 (Fed. Cir. 2017) (explaining that the legal standard for obviousness requires only a reasonable expectation, not absolute predictability, of success).

Finally, Patent Owner disputes Petitioner's assertion that an ordinarily skilled artisan "would have been motivated to use the '1%' strength and 'once daily' application frequency disclosed by Sonti and known to be effective," because "there were known reasons to use a lower strength and/or lower application frequency of topical pharmaceutical, such as: (i) reducing risk of side effects by minimizing the body's systemic exposure to the active ingredient, (ii) improving patient compliance with treatment recommendations, and (iii) reducing treatment cost." Pet. 31–32 (citing Ex. 1003 ¶¶ 194–199; Ex. 1032 ¶¶ 81–87).

Patent Owner asserts that the above arguments are "unexplained and unsupported" and "simply incorporate[] by reference [Petitioner's] two expert declarations" without "providing . . . explanation or underlying evidence to support its conclusory statements." Prelim. Resp. 48. Patent Owner further asserts that these arguments "fail[] to consider or explain the disclosures in Bissonnette . . . , which directly contradict the Petition's proffered motivations." *Id.*

Having reviewed the Petition and the declarations, we find the above arguments in the Petition to be sufficiently clear, with the cited paragraphs of the Liem and Sudhakar Declarations providing appropriate supporting technical details and/or testimony as to the understanding of a person of ordinary skill in the art. We address Patent Owner's arguments regarding Bissonnette below in our discussion of Ground 4 (asserted obviousness over Bissonnette and Sonti and/or Chen).

c. "Obvious to try"

The Supreme Court has explained that a rationale based on "obvious to try" can support a conclusion of obviousness. *KSR*, 550 U.S. at 402. Indeed, the Court explained, "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art 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." *Id.* at 402–403.

Petitioner asserts that "[t]here was a recognized need" for, e.g., "development of novel non-steroidal topical drugs for the treatment of psoriasis"; that "a finite number of known potential strengths and application frequencies to use when topically treating plaque psoriasis"; and that "a POSA would have had a reasonable expectation of success in pursuing the options, in view of Sonti and Chen's teachings that the options worked." Pet. 32.

Patent Owner argues that Petitioner has not met the obvious-to-try standard because (1) “the ‘recognized’ need stated in the Petition was already satisfied by Bissonnette, which discloses a twice-daily non-steroidal treatment for psoriasis; (2) “Sonti discloses nearly one million options—far more than the required ‘finite number of identified, predictable, solutions’”; (3) “the Petition’s reliance on Chen is misplaced because Chen does not disclose treating plaque psoriasis *with tapinarof*”; and (4) Petitioner “relies on Bissonnette as an example of ‘successful’ treatment while ignoring that Bissonnette administered tapinarof twice daily, not once daily.” Prelim. Resp. 51.

For purposes of institution, and based on the current record, we find Petitioner has sufficiently shown that the method of claim 1 would have been obvious under the obvious-to-try rationale.

As we discussed in our analysis of Ground 1 (*see supra* Section II.D.1.a), we do not find based on the current record that an ordinarily skilled artisan would understand Sonti as disclosing “nearly one million” options. Likewise, as discussed in the section immediately above with respect to reasonable expectation of success, we find that Petitioner has sufficiently established that Chen discloses treating plaque psoriasis with tapinarof for purposes of institution.

As to Patent Owner’s argument that the “need” recognized by the prior art has already been satisfied by Bissonnette, we do not agree that a recognized need is negated merely because one of the finite number of identified, predictable solutions has been found effective. For instance,

although Bissonnette described a study that “demonstrated that topical [tapinarof] at 1% is effective for the treatment of mild to moderate psoriasis” when applied twice daily, Bissonnette nevertheless states that “[f]urther studies are required to better assess the long-term safety and efficacy of [tapinarof] for the treatment of mild to moderate psoriasis.” Ex. 1008, 1520, left col. Indeed, our reviewing court has explained that, “where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *E.I. Dupont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006 (Fed. Cir. 2018) (quoting *In re Aller*, 220 F.2d 454, 456 (CCPA 1955)).

Finally, we disagree that Petitioner’s obvious-to-try rationale fails because Petitioner “relies on Bissonnette as an example of ‘successful’ treatment while ignoring that Bissonnette administered tapinarof twice daily, not once daily,” as Patent Owner alleges. Prelim. Resp. 51. Petitioner explicitly acknowledges Bissonnette as disclosing “1% tapinarof, administered twice daily,” but relies on other references for disclosure of the claimed once-daily application frequency. Pet. 32 (citing to Bissonnette (Ex. 1008) for teaching “1% tapinarof, administered twice daily” and to Sonti (Ex. 1005) and Chen (Ex. 1013) for teaching other application frequencies including once daily). *Cf. Soft Gel*, 864 F.3d at 1341 (explaining that patent owner’s focused attack on one reference “does not undermine the Board’s decision, which is based on a combination of references”).

d. Objective Indicia of Non-obviousness

Patent Owner asserts that, although the “Petition notes the patent’s ‘surprising[] and unexpected[]’ finding that once daily application of 1% tapinarof cream was just effective as twice daily application, . . . the Petition does not analyze, as the law requires, this surprising, unexpected finding in its obviousness arguments.” Prelim. Resp. 52.

We are not persuaded by this argument. Immediately after the Petition’s acknowledgement that “[t]he specification [of the ’088 patent] contends that it was ‘surprisingly’ found that once daily application was just as effective as twice daily,” the Petition notes that, “[h]owever, during prosecution the examiner cited a set of prior art by Chen et al. disclosing treating plaque psoriasis by topically applying a composition containing 1% tapinarof once a day.” Pet. 1 (footnote omitted).

Indeed, Patent Owner acknowledges that Petitioner counters “Applicant’s surprising and unexpected findings” by referring to the Chen references cited during prosecution, but asserts that “Chen . . . does not undermine Applicant’s surprising and unexpected findings” because “Chen discloses applying a composition containing 1% mixture of *cis* and *trans* 3,5-dihydroxy-4-isopropylstilbene, and not one containing 1% tapinarof (3,5-dihydroxy-4-isopropyl-*trans*-stilbene).” Prelim. Resp. 52–53.¹⁶ As

¹⁶ Patent Owner refers to its earlier discussion on this issue. Prelim. Resp. 53 (“As already discussed . . .”). That earlier discussion is with respect to the Chen references cited in Sonti (i.e., Exs. 1012 & 1013), not the Chen

discussed above with respect to reasonable expectation of success and the Chen references cited in Sonti, however, the implication of Patent Owner's assertion is that the Chen references cited during prosecution disclose effectively treating psoriasis by applying <1% tapinarof once a day. We find that, for the purpose of institution, and based on the limited record before us, Petitioner has sufficiently addressed Patent Owner's unexpected results arguments by pointing to the disclosures of the Chen references cited during the prosecution.

e. Claims 3 and 4

Patent Owner asserts that Petitioner “picks and chooses the ingredients recited in claim 3 from at least 13 different formulations in Sonti, combining elements from Sonti’s ‘physically stable’ emulsion embodiments with other embodiments that Sonti negatively characterizes as causing ‘chemical degradation of the active ingredient’ and as ‘non-uniform emulsions.’” Prelim. Resp. 54. Patent Owner asserts “the Petition’s Ground 2 and 4 arguments for dependent claims 3 and 4 fail to reconcile the differences between Sonti’s ‘physically stable’ emulsion formulations and those that cause chemical degradation or are ‘non-uniform.’” *Id.*

references cited during prosecution. However, the Chen references cited during prosecution (Exs. 1027–1029) contain disclosures similar to Example 4 of Chen (Ex. 1013) and/or Example 3 of WO 2001/042231 (Ex. 1012), relating to treating volunteers with “1% 3,5-dihydroxy-4-isopropylstilbene.” *See, e.g.*, Ex. 1027 ¶¶ 91–102 (Example 3), Ex. 1028 ¶¶ 169–176 (Example 4), Ex. 1029 ¶¶ 188–195 (Example 4).

With respect to claim 3, we do not find this argument persuasive for the reasons discussed above in our analysis of the claim in Ground 1. *See supra* Section II.D.1.b.

Patent Owner’s argument with respect to claim 4 is unavailing for similar reasons. Claim 4 depends indirectly from claim 1 and further recites that the water phase of the topical composition is comprised of sodium citrate, edetate disodium, citric acid monohydrate, and water. Pet. 76 (App. A: Claims Listing). Petitioner explains in Ground 1 that “Sonti discloses a water phase comprising sodium citrate, edetate disodium, citric acid monohydrate, and water, including in formulations that have 1% tapinarof.” Pet. 22. Petitioner points to Formulation 13 as well as citing to the formulations in Example 8 (Formulations 17–29) and Example 9 (Formulations 30–40). *Id.* at 22–23. The water phase of each of these formulations, including those described by Sonti as physically stable (e.g., Formulations 17–40), comprises the ingredients recited in claim 4. Ex. 1005 ¶¶ 13, 355, 370. Petitioner’s argument as to the obviousness of claim 4 thus does not require combining ingredients from disparate embodiments.

f. Claims 7, 10, and 21

Claims 7 and 21 depend from claim 1 and further recite “wherein the subject has been diagnosed with” either “mild to severe” (claim 7) or “mild to moderate” (claim 21) plaque psoriasis “having a percent body surface area (BSA) affected of about 3% to about 20%.” Pet. 77 (App. A: Claims Listing). Claim 10 depends indirectly from claim 1 and further recites “wherein the percent body surface area (BSA) affected is decreased to less

than 20% after topically administering the topical composition.” *Id.* Patent Owner separately asserts that Petitioner fails to establish a reasonable likelihood of success as to claims 7, 10, and 21 for Grounds 2 and 3. Prelim. Resp. 48–51.

Patent Owner first argues that, with respect to claims 7 and 21,¹⁷ the Petition relies on a “flawed inherency logic” that “[a] subject diagnosed with *moderate to severe* plaque psoriasis *is also one* with a diagnosis falling within the ‘*mild to severe*’ . . . and ‘*mild to moderate*’” ranges. Prelim. Resp. 48–49 (citing Pet. 38).

Based on the present record, we do not read Petitioner as making a “flawed inherency argument.” Rather, we understand Petitioner as pointing out that the range of “moderate to severe” plaque psoriasis disclosed in Sonti falls within the claimed range of “mild to severe” plaque psoriasis (claim 7) and overlaps the claimed range of “mild to moderate” plaque psoriasis (claim 21).¹⁸ *Synvina*, 904 F.3d at 1008 (stating that, “‘where there is a range disclosed in the prior art, and the claimed invention falls within that range, the burden of production falls upon the patentee to come forward with evidence’ of . . . pertinent objective indicia indicating that the overlapping

¹⁷ Patent Owner referred to claims 7 and 10 in the Preliminary Response, Prelim. Resp. 48, but we understand the argument to be directed to claims 7 and 21.

¹⁸ We do not agree that Petitioner’s argument should be rejected because it is an improper incorporation by reference, as Patent Owner alleges. Prelim. Resp. 49. Rather, this particular argument appears to be based on the plain and ordinary meaning of the claim limitations.

range would not have been obvious in light of that prior art”) (quoting *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013)).

Moreover, Petitioner does not rely solely on the alleged “inherency” argument with respect to claims 7 and 21. Instead, Petitioner also asserts that, “given Sonti’s teaching of treating a subject diagnosed with moderate to severe plaque psoriasis, it also would have been obvious to treat a subject diagnosed with *mild* plaque psoriasis, for the same reasons explained with respect to [1.pre].” Pet. 38 (citing Ex. 1003 ¶ 232).

Accordingly, we find Petitioner’s arguments, and the evidence cited in support, sufficient to meet the requirements of institution with respect to these limitations in claims 7 and 21.

Patent Owner asserts that, “[f]or claims 7 and 21, the Petition argues that Sonti ‘teaches treating a subject having BSA affected with *atopic dermatitis* that is in the claimed range.’” Prelim. Resp. 49 (quoting Pet. 42). For claim 10, Patent Owner asserts Petitioner admits Sonti does not teach the claimed decrease in affected BSA with respect to plaque psoriasis but “argues that a POSA would have a reasonable expectation of success because ‘anti-inflammatory topical treatments for *atopic dermatitis* were commonly used with and expected to work for *plaque psoriasis*.’” *Id.* (quoting Pet. 44).

Patent Owner argues that Petitioner has not adequately explained why or how an ordinarily skilled artisan would have “reasonably expected a topical treatment that is effective for *atopic dermatitis* to be effective as a topical treatment for *plaque psoriasis*.” Prelim. Resp. 49–50. Patent Owner

asserts “Sonti demonstrate[s] that atopic dermatitis is a completely different indication than psoriasis, with different diagnostic criteria and ‘at least 28 different scales’ for classification,”” and Chen also characterizes these indications very differently. *Id.* at 50–51.

As to claims 7 and 21, Petitioner provides several reasons why an ordinarily skilled artisan would have combined the disclosures in Sonti to arrive at a method of treating patients “having a percent body surface area (BSA) affected of about 3% to about 20%,” in addition to the specific Sonti disclosure of treating “a subject having a BSA affected with atopic dermatitis that is in the claimed range.” Pet. 40–43. These include, e.g., that Sonti teaches applying its compositions to a skin surface area within the claimed range; that BSA is a well-known clinical measure for assessing plaque psoriasis, which does not have known biomarkers; that treating patients having the claimed percent BSA affected was known and common; and that an ordinarily skilled artisan “already knew that the method of claim 1 was effective to treat plaque psoriasis” based on, e.g., Sonti and Chen. Pet. 41–42 (citing, e.g., Ex. 1005 ¶¶ 267–268, Ex. 1003 ¶¶ 250–256).

We find Petitioner has sufficiently established, for purposes of institution, a reasonable expectation of success with respect to claims 7 and 21 based on these additional reasons. Moreover, as discussed below with respect to claim 10, we find that Petitioner has established, for purposes of institution, a reasonable expectation of success as to a method of treating plaque psoriasis based on Sonti’s disclosure regarding atopic dermatitis and testimony from Dr. Liem.

In particular, Dr. Liem testifies that “[i]t was known that anti-inflammatory treatments for atopic dermatitis were often used with and could be expected to work for plaque psoriasis,” because both are known to be inflammatory skin diseases. Ex. 1003 ¶¶ 258–259. Furthermore, Dr. Liem acknowledges the differences between plaque psoriasis and atopic dermatitis—such as the fact “[p]soriasis presents with hyperproliferation and inflammation whereas atopic dermatitis is eczematous and inflamed”—but notes that “topical therapies that reduce inflammation (like tapinarof) would have been expected to treat both conditions well (while topical therapies that address the hyperproliferation component would be more likely to be effective in psoriasis rather than atopic dermatitis).” *Id.* ¶ 262. As to Patent Owner’s assertion that “atopic dermatitis is a completely different indication than psoriasis, with different diagnostic criteria and ‘at least 28 different scales’ for classification” (Prelim. Resp. 50), we note Sonti teaches various methods of assessing atopic dermatitis and then states that, “[i]n a similar manner, psoriasis can be assessed.” Ex. 1005 ¶¶ 273–285.

g. Conclusion as to Ground 2

For the reasons discussed above, Petitioner establishes sufficiently, for purposes of institution, that (1) Petitioner does not rely on an improper inherency argument to show that Sonti suggests “[a] method for treating mild to severe plaque psoriasis,” as recited in the claims; and (2) a skilled artisan would have had reason to combine the disclosures of Sonti to arrive at the methods of claims 1, 3, 4, 7, 10, and 21, including on the basis of an obvious-to-try rationale, with a reasonable expectation of success. We

further determine that the Petition has sufficiently addressed the alleged unexpected results based on the current record.

Having considered the evidence of record, we likewise determine that Petitioner has established sufficiently that Sonti suggests a method comprising the additional limitations in claims 2 (from which claim 3 depends) and claims 6, 8, 9, 16, 18, and 22. Accordingly, and solely for the purpose of institution, Petitioner has demonstrated a reasonable likelihood that Sonti renders obvious claims 1–4, 6–10, 16, 18, 21, and 22.

3. Ground 3: Asserted Obviousness over Sonti and Bissonnette

Ground 3 applies to claims 7, 9, 10, and 21. We have discussed claims 7, 10, and 21 in Ground 2 above. Claim 9 depends from claim 1, further comprising an improvement of a symptom of the plaque psoriasis after topical administration of the tapinarof composition, as measured according to an assessment selected from a group consisting of, among others, Physician Global Assessment (PGA) score and percent body surface area (BSA) affected. Pet. 77 (App. A: Claims Listing).

As noted above, Patent Owner asserts that, for each of the obviousness grounds including Ground 3, “[t]he Petition (i) does not demonstrate a reasonable expectation of success, (ii) overlooks that the purported ‘need’ in its obvious-to-try analysis was already met; and (iii) fails to address [known] objective indicia of non-obviousness.” Prelim. Resp. 42. We have already discussed these arguments in our analysis of Ground 2. *See supra* Sections II.D.2.b–II.D.2.d.

Patent Owner argues that Grounds 3 and 4 are additionally deficient because Petitioner has not established that a skilled artisan would have had reason to combine the teachings of the cited prior art to arrive at the claimed methods. Prelim. Resp. 55–57.¹⁹

a. Claims 7 and 21

Patent Owner asserts that “Bissonnette is directed to a *twice daily* application of 1% tapinarof” and Petitioner fails to explain why a POSA would have modified that twice-daily application to once-daily application, as recited in the challenged claims. Prelim. Resp. 56. Patent Owner asserts that Petitioner has not explained “how modifying Bissonnette’s twice-daily method in view of Sonti’s teachings would have been ‘predictable,’” or “which of Sonti’s *14 different application frequencies* or *500 different amounts of tapinarof* a POSA would have combined with Bissonnette’s twice-daily application.” *Id.* at 56–57.

We disagree with Patent Owner’s arguments because they do not take into account the *combined* teachings of Sonti and Bissonnette. Although Bissonnette teaches a method of treating psoriasis by applying tapinarof twice a day, Petitioner has established a reasonable likelihood of showing, for purposes of institution, that Sonti teaches a method of treating psoriasis

¹⁹ Patent Owner asserts Bissonnette “belies the purported motivation to combine.” Prelim. Resp. 57–62 (emphasis omitted). This argument appears directed to the motivations discussed in Ground 4 of the Petition, and we discuss the argument *infra* with respect to that asserted ground.

by applying tapinarof once a day that is also effective. *See supra* Sections II.D.1.a and II.D.2. Petitioner has sufficiently established, for purposes of institution, that an ordinarily skilled artisan would have had reason to use Sonti's method, known or suggested to be effective for treating plaque psoriasis as assessed using one scale (PGA), to treat Bissonnette's patients, who are diagnosed with the same disease but assessed using a different scale (BSA), with a reasonable expectation of success, particularly where Bissonnette suggests that the same drug, albeit applied at a different frequency, decreased both plaque severity *and* reduced BSA affected by psoriasis. Pet. 47–49; Ex. 1008, 1519, right col.

b. Claims 9 and 10

Patent Owner asserts that Petitioner “never squares [the] fact [that Bissonnette teaches twice-daily application] with the Petition’s assertion that the skilled artisan would have reasonably expected the BSA reduction reported in Bissonnette to also happen when only half of the amount of tapinarof (1%, once-daily) is applied.” Prelim. Resp. 57. Patent Owner asserts that Petitioner “again misplaces reliance on Chen to assert obviousness” despite the fact that “Chen discloses applying a compound other than tapinarof to its Volunteers.” *Id.*

Patent Owner’s arguments here is unavailing for the same reasons discussed above with respect to claims 7 and 21. Moreover, as discussed above in Section II.D.2.b, we do not find, based on the present record and for purposes of institution, that Petitioner’s reliance on Chen to assert

obviousness is misplaced. As noted previously, the expectation of success need only be reasonable, not absolute. *Soft Gel*, 864 F.3d at 1342.

c. Conclusion as to Ground 3

For the reasons discussed above, and based on our review of the preliminary record, Petitioner establishes sufficiently, for purposes of institution, that claims 7, 9, 10, and 21 would have been obvious over Sonti and Bissonnette.

4. Ground 4: Asserted Obviousness over Bissonnette and Sonti and/or Chen

Petitioner asserts that Bissonnette “discloses nearly every element of the Challenged Claims,” except that it discloses twice daily, instead of once daily, administration. Pet. 52. Petitioner asserts that “Sonti and Chen each disclose once-daily administration of a topical composition containing 1% tapinarof to treat plaque psoriasis.” *Id.* Petitioner asserts that “[a] POSA would have been motivated to combine Bissonnette with the teachings of Sonti and/or Chen, with a reasonable expectation of success, as each taught . . . topical application of the *same* active ingredient (tapinarof) at the *same* strength (1%) to treat the *same* condition (plaque psoriasis),” and “Sonti and Chen also taught that the once-daily administration was highly effective.” *Id.* at 52–53. Petitioner asserts that “there was strong motivation and market pressure to decrease the frequency of application from twice daily to once daily” in order to reduce risk of side effects and cost of treatment and to increase patient compliance. *Id.* at 53.

Patent Owner makes several arguments with respect to Ground 4, which we have addressed above in the context of the other grounds. Patent Owner argues in addition that Bissonnette belies Petitioner's assertion that "a POSA 'would have been motivated to use the once-daily application frequency rather than twice-daily to minimize risk of side effects,'" because Bissonnette reported no meaningful adverse events and also "suggested reducing *the concentration of tapinarof*" instead of suggesting "reducing the frequency from twice-daily to once-daily application to minimize risk" of adverse events. Prelim. Resp. 59 (quoting Pet. 56).

Based on the current record, and even assuming Bissonnette "reported no meaningful adverse events," we find Petitioner has sufficiently established, for purpose of institution, a reason to apply tapinarof once daily rather than twice daily. Petitioner's declarant, Dr. Liem, for instance, testifies that, "[w]hile most of the adverse events within the cohort treated with the 1% tapinarof cream were 'mild' in severity (and two were 'moderate'), a POSA still would have been motivated to minimize the risk of these side effects." Ex. 1003 ¶ 195. Bissonnette itself also suggests that long-term safety continues to be of concern. Ex. 1008, 1520, left col. (stating that "[f]urther studies are required to better assess the long-term safety and efficacy of [tapinarof] for treatment of mild to moderate psoriasis").

Likewise, that Bissonnette states that a lower concentration (0.5%) of tapinarof may decrease incidents of adverse drug reactions does not teach away from other alternatives that may also minimize such adverse events.

Ex. 1003 ¶¶ 194–195 (explaining that “if a treatment containing a lower amount of active ingredient and/or administered less frequently was still effective, there were good reasons to use that lower amount and/or . . . frequency” in order to “predictably reduce risk of side effects”).

Patent Owner asserts that Bissonnette “contradicts [Petitioner’s] assertion that a ‘POSA would have been motivated to use once-daily application rather than twice daily to improve patient compliance with the treatment regimen,’” because Bissonnette reported no compliance concerns with twice-daily application. Prelim. Resp. 60 (quoting Pet. 57).

Even if Bissonnette, which is a single study of 61 patients, reported no compliance concerns, we find Petitioner has established, for purposes of institution, a reason to reduce application frequency, e.g., from twice a day to once a day, based on the totality of the evidence of record at present. Dr. Liem, for example, testifies that, in her experience and the experience of her colleagues, “patients are generally more likely to be compliant with treatment recommendations when the application frequency is once a day, rather than more frequent applications.” Ex. 1003 ¶ 197.

Patent Owner asserts that Petitioner’s argument that lower treatment cost would have motivated an ordinarily skilled artisan to use once-daily tapinarof “relies on incorporation by reference to its expert declaration, providing no actual explanations or underlying evidence to support its conclusory statement.” Prelim. Resp. 61 (citing Ex. 1003 ¶ 338, Ex. 1032 ¶ 86).

We find Petitioner sufficiently explains the asserted motivation, for the purpose of institution, by stating that “[l]ess frequent application uses less volume of the topical composition, resulting in lower overall treatment cost.” Pet. 57. The cited paragraphs of the Liem and Sudhakar Declarations also provide appropriate and presently un rebutted supporting testimony as to the understanding and experience of persons of ordinary skill in the art.

Finally, Patent Owner asserts that “the Petition has failed to show that a POSA would have expected once-daily application of tapinarof would ‘still maintain[] treatment safety and efficacy’ or be a ‘feasible’ treatment given its flawed reliance on Chen to show as such.” Prelim. Resp. 61–62. We are not persuaded by this argument for the reasons discussed above in Ground 2, with respect to reasonable expectation of success.

Accordingly, having considered the evidence of record, we determine that, solely for the purpose of institution, Petitioner has demonstrated a reasonable likelihood that claims 1–4, 6–10, 16, 18, 21, and 22 would have been obvious over the combinations of Bissonnette and Sonti (Ground 4A), Bissonnette and Chen (Ground 4B), and Bissonnette, Sonti, and Chen (Ground 4C).

E. Discretionary Denial under 35 U.S.C. § 325(d)

The parties dispute whether the Board should exercise its discretion to deny the Petition under 35 U.S.C. § 325(d). *See generally* Pet. 71–73; Prelim. Resp. 6–19; Reply 1–4; Sur-Reply 1–4.

1. Legal Standards

Institution of *inter partes* review is discretionary. *Harmonic*, 815 F.3d at 1367 (explaining that “the PTO is permitted, but never compelled, to institute an IPR proceeding”). The Patent Office may, for example, deny institution under 35 U.S.C. § 325(d), which provides, in pertinent part, that “[i]n determining whether to institute or order a proceeding under this chapter, . . . the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.”

In evaluating whether the same or substantially the same prior art or arguments were previously presented to the Office, the Board has identified several non-exclusive factors that may be considered. *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) (“*Becton, Dickinson*”). Those factors are as follows:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;

(e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and

(f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of prior art or arguments.

Id.; see also Patent Trial and Appeal Board Consolidated Trial Practice Guide (“Trial Practice Guide” or “CTPG”) (Nov. 2019), 62–63 (citing the *Becton, Dickinson* factors).²⁰

As more recently explained in *Advanced Bionics, LLC v. MED-EL Electromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8–10 (Feb. 13, 2020) (precedential) (“*Advanced Bionics*”), the Board addresses § 325(d) applying a “two-part framework.” In the first part of the framework, we ask whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office. *Advanced Bionics*, 8. Factors (a), (b), and (d) of *Becton, Dickinson* come into play under this first part of the framework. *Id.* at 8–10. If *either* condition of the framework’s first part is met, we move to part two of the framework, asking “whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of [the] challenged claims.” *Id.* at 8. Factors (c), (e), and (f) of *Becton, Dickinson* fall within part two of the framework. *Id.* at 10 (“[F]actors (c), (e), and (f) relate to whether the petitioner has demonstrated material error by the Office.”).

²⁰ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

Only if the same or substantially the same art or arguments were previously presented to the Office do we then consider whether petitioner has demonstrated error. *Advanced Bionics*, 8–10. “If the petitioner fails to show that the Office erred, the Director may exercise his discretion not to institute *inter partes* review.” *Id.* at 8–9. “At bottom, this [§ 325(d)] framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.* at 9 (“If reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.”).

2. Analysis

a) § 325(d) Framework: Part One

Petitioner’s unpatentability challenges rely on three different prior art references: Sonti, Bissonnette, and Chen. Pet. 3.

Petitioner acknowledges Sonti is cited in the ’088 patent and further acknowledges that the patent that issued from Sonti (US 10,195,160) is cited on the face of the ’088 patent. Pet. 72 (citing Ex. 1001 8:60–63) & n.10. As Patent Owner points out, this patent was also cited in an Information Disclosure Statement (“IDS”) submitted during prosecution of the application resulting in the ’088 patent and acknowledged by the Examiner. Prelim. Resp. 8 (citing Ex. 1002, 175, 245).

Bissonnette and Chen likewise were listed on an IDS filed during prosecution and acknowledged by the Examiner. Prelim. Resp. 7, 9 (citing

Ex. 1002, 174, 177, 244, 247). They are also listed on the face of the '088 patent. Prelim. Resp. 7, 9; Ex. 1001, 1–2.

Based on the above, we find that the same or substantially the same art previously was presented to the Office. *See Advanced Bionics*, 7–8 (explaining that “[p]reviously presented art includes art made of record by the Examiner, and art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent”). Accordingly, the first part of the *Advanced Bionics* framework has been met, and we move to the second part of the framework. *Id.* at 8 (moving to part two of the framework if *either* substantially the same art *or* arguments were previously presented to the Office).

b) § 325(d) Framework: Part Two

In part two of the framework, we consider “whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of [the] challenged claims,” taking into consideration *Becton, Dickinson* factors (c), (e), and (f). *Advanced Bionics*, 8.

As to *Becton, Dickinson* factor (e), “whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art,” Petitioner asserts that the Examiner erred during the prosecution of the '663 application by overlooking (1) Sonti’s teachings regarding “*methods of treating*” plaque psoriasis using its tapinarof formulations and (2) Chen’s specific disclosure of treating “‘*plaque*’ psoriasis” and its disclosures of “improvements that a POSA would have understood to be the PGA score improvements claimed.” Pet. 72–73. Petitioner asserts that the Examiner

“materially erred . . . by overlooking disclosures in Sonti, Bissonnette, and Chen of the very claim elements the Applicant argued were missing.” Reply 1–2. As further discussed below, we find Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art for purposes of factor (e).²¹

Relevant to *Becton, Dickinson* factor (c), “the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection,” Petitioner argues that “[t]he Examiner never discussed either [Sonti or Bissonnette] or any obviousness combination.” Reply 1. Patent Owner contends, on the other hand, that Petitioner’s “assertion that ‘the examiner materially erred by overlooking [Sonti’s teachings]’ is conclusory speculation” and that “mere absence of a rejection based on certain references does not evidence material error.” Prelim. Resp. 12 (alteration by Patent Owner; quoting Pet. 72).

²¹ Patent Owner contends that Petitioner “has waived any step-two arguments for Bissonnette” because Petitioner did not include such arguments in the Petition itself. Prelim. Resp. 11; *see also* Sur-Reply 3 n.3. Even assuming such a waiver, we find that Petitioner has demonstrated that the Office erred in a manner material to the patentability of the claims at least with respect to consideration of Sonti and Chen. Given that Sonti is the primary asserted reference in three of the four asserted grounds, and Sonti and Chen are implicated as secondary references in Ground 4, we do not find the circumstances of this case warrant the exercise of our discretion to deny institution based on § 325(d) even if we do not consider arguments that the Examiner materially erred with respect to Bissonnette.

Although we agree that mere absence of a rejection does not evidence material error, “[a]n example of a material error may include misapprehending or overlooking specific teachings of the relevant art where those teachings impact patentability of the challenged claims.” *Advanced Bionics*, 8–9 & n.9. Under this standard, we are persuaded that the Examiner materially erred with respect to Sonti. For example, the Examiner states in the Reasons for Allowance that “[t]he prior art does not teach or suggest the methods encompassing compounds substituted in the manner claimed by the Applicant.” Ex. 1002, 312. As noted above in our discussion on the merits, however, Sonti explicitly teaches the claimed compounds (i.e., “compounds substituted in the manner claimed by the Applicant”) and methods of using these compounds to treat plaque psoriasis.

With respect to Chen, Patent Owner argues that it is “cumulative to the EX1027, EX1028, and EX1029 Chen references that each formed the basis of a rejection during prosecution.” Prelim. Resp. 10. However, relevant to *Becton, Dickinson* factor (f), relating to “the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments,” Petitioner asserts that “the Petition provides two new expert declarations,” including one “explaining Chen in view of PGA limitation.” Reply 1.

We agree Petitioner has provided additional evidence and facts, in the form of its declarations, that warrant reconsideration of at least Chen and arguments relating thereto. As noted above, Applicant distinguished the Chen references cited by the Examiner during prosecution by arguing that

they do not “mention treating plaque psoriasis specifically with the compounds described therein,” noting that “[p]laque psoriasis is a particular type of psoriasis, which can include guttate psoriasis, pustular psoriasis, inverse psoriasis, erythrodermic psoriasis, and plaque psoriasis.” Ex. 1002, 284.

Applicant further distinguished the Chen references by arguing that, “even if [the Chen references] disclosed treatment of plaque psoriasis, [they do] not disclose (i) how to demonstrate that effective treatment of said plaque psoriasis can be done via numerous measurements, or (ii) what is a measure of effective treatment of said plaque psoriasis.” Ex. 1002, 284. Although the Examiner did not explicitly accept Applicant’s arguments, the Examiner issued a new ground of rejection that did not rely on any of the Chen references, and subsequently allowed the claims to issue without further specific discussion of the Chen references. *Id.* at 292.

The Liem Declaration, which was not in front of the Examiner, addresses both arguments made by Applicant regarding the Chen references during prosecution of the ’663 application. Dr. Liem explains that, although the phrase “plaque psoriasis” is not explicitly used in Chen, “a POSA would understand that Volunteers 1 and 2 described in Chen had *plaque* psoriasis,” Ex. 1003 ¶ 331, because (1) Volunteer 1 was described as having scalp psoriasis, which is “nearly always plaque-type psoriasis,” and (2) “Volunteer 2 was described as having psoriasis with ‘plaques’ on her back,” *id.* ¶¶ 100–

101.²² Similarly, the Liem Declaration explains that, although PGA was not explicitly discussed in Chen, a skilled artisan would have understood Chen as disclosing the claimed PGA score improvement. *Id.* ¶¶ 354–357.

Patent Owner asserts because the Examiner in the anticipation rejections stated that each of the cited prior art Chen references “[taught] the *exact* methods” in the claims, the Examiner must be presumed to be “aware of the full disclosures of [the cited Chen prior art references], including any teachings related to plaque psoriasis.” Prelim. Resp. 14.

However, the Examiner did not maintain the anticipation rejection with respect to the Chen references in the face of Applicant’s arguments. Furthermore, Dr. Liem did not merely parrot the disclosure of Chen but, rather, explained how a person of ordinary skill in the art would have interpreted such disclosure. Thus, the Liem Declaration provides additional information not before the Examiner that warrants reconsideration of Chen, particularly in view of arguments made by Applicant during prosecution.

Patent Owner argues that “Applicant repeatedly discussed plaque psoriasis in the context of the Chen references and, rather than simply deny the existence of plaque psoriasis in Chen—as Petitioner wrongly posits—

²² The discussion in the Liem Declaration is of the asserted reference Chen (Ex. 1013), rather than the Chen references cited by the Examiner (Exs. 1027–1029). However, as noted above, Patent Owner has taken the position that the asserted Chen reference is “cumulative to the EX1027, EX1028, and EX1029 Chen references that each formed the basis of a rejection during prosecution.” Prelim. Resp. 10.

Applicant actually demonstrated to the Examiner's apparent satisfaction that [the three Chen references cited in the rejections], each 'does not teach each and every element of the pending claims.'" Prelim. Resp. 15 (footnote omitted); *see also* Sur-Reply 2 (emphasizing what Applicant argued during prosecution was that "Chen does not disclose 'treating plaque psoriasis specifically with the compounds described therein'").

To the extent Patent Owner argues that Applicant's argument during prosecution related to whether Chen disclosed tapinarof rather than whether Chen disclosed treatment of "plaque psoriasis," we are not persuaded. Immediately following its statement that "Chen . . . does not mention treating plaque psoriasis specifically with the compounds described therein," Applicant explained that "[p]laque psoriasis is a particular type of psoriasis, which can include guttate psoriasis, pustular psoriasis, inverse psoriasis, erythrodermic psoriasis, and plaque psoriasis." Ex. 1002, 284. Applicant also prefaced its alternative arguments by stating, "*Even if* Chen disclosed treatment of plaque psoriasis . . ." *Id.* (emphasis added). Finally, as noted above, the Liem Declaration also provides material additional evidence, not before the Examiner, regarding Applicant's alternative argument that Chen "makes no mention of what is a measure of effective treatment of . . . plaque psoriasis, whereas the . . . pending claims are directed to improving a subject's PGA score by 2 grades or to a score of 0 or 1." Ex. 1002, 284.

Patent Owner asserts that Petitioner failed to "fully consider the Examiner's reasons for allowance," which "demonstrate[d] that the Examiner understood that the compound disclosed in Chen's Examples cited

in the rejection (and relied upon here in this Petition) was *not* tapinarof.” Prelim. Resp. 17; *see also* Sur-Reply 2. Patent Owner asserts this failure is a “fatal omission” in Petitioner’s § 325(d) analysis. Prelim. Resp. 17. Patent Owner asserts “[t]he Reply’s argument that Chen is used to establish obviousness rather than anticipation does not save the Petition,” because “the Petition failed to explain how application of a compound that is not tapinarof in Chen could possibly provide an expectation of success for tapinarof, an integral part of an obviousness analysis.” Sur-Reply 3.

Even if we assume the Examiner allowed the claims because the Examiner believed the compound disclosed in Chen is not tapinarof, that reason for allowance would constitute material error because, as discussed above in our merits analysis, Chen discloses tapinarof even under Patent Owner’s reading of the reference. *See supra* Section II.D.2.b. Furthermore, as discussed above with respect to Sonti, it cannot reasonably be disputed, based on the current record, that the prior art disclosed the use of tapinarof to treat psoriasis.

Accordingly, considering *Becton, Dickinson* factors (c), (e), and (f) together, we conclude that Petitioner has made a sufficient showing of error in the Office’s prior consideration of at least Sonti and Chen. We conclude that the circumstances presented here do not warrant us exercising our discretion to deny institution based on § 325(d).

F. Discretionary Denial Under 35 U.S.C. § 314

1. Alleged Lack of Particularity

A petition may be considered only if it “identifies, in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim.” 35 U.S.C. § 312(a)(3); *see also* 35 C.F.R. §§ 42.22(a)(2), 42.104(b).

Patent Owner argues that “the Petition suffers from numerous flaws that coalesce in a failure to present arguments with particularity,” specifically with respect to (1) Petitioner’s argument that “disclosure of treating moderate to severe psoriasis is *inherently* also a method of treating mild psoriasis”; (2) the use of “and/or” in the grounds of invalidity presented; and (3) the lack of adequate expert testimony support for the arguments for claims 3 and 4. Prelim. Resp. 19–26. Patent Owner argues that Petitioner’s “omission of particularity . . . infects all four of its Grounds and justifies denial of the entire Petition.” *Id.* at 26.

For the reasons discussed below, we are not persuaded that any of these alleged flaws justifies discretionary denial under 35 U.S.C. § 314.

a. Alleged Undeveloped Inherency Theory

Patent Owner contends that the Petition fails to demonstrate, “with particularity or otherwise,” why “Sonti’s disclosure of treating moderate to severe psoriasis is *inherently* also a method of treating mild psoriasis.” Prelim. Resp. 20–21 (quoting Pet. 14). Patent Owner contends mild and moderate plaque psoriasis have different phenotypes and diagnosis criteria,

and “a specific treatment for one phenotype (e.g., moderate to severe plaque psoriasis) may not be suitable for treating another phenotype (e.g., mild plaque psoriasis).” *Id.* at 21.

For the reasons discussed above in Section II.D.2.a, we are not persuaded that Petitioner’s arguments with respect to the preamble lack particularity.

b. Use of “and/or” in the Petition

Patent Owner asserts that “[t]he Petition . . . fails to explain its arguments with particularity because it relies on multiple references and Grounds ‘connected by the conjunction ‘and/or,’ which ‘results in a multiplicity of grounds, none of which is presented with sufficient particularity.’” Prelim. Resp. 22 (citing *Adaptics Ltd. v. Perfect Co.*, IPR2018-01596, Paper 20 (PTAB Mar. 6, 2019) (informative) (“*Adaptics*”)).

We do not find the use of “and/or” in the asserted grounds in the Petition results in the “voluminous and excessive grounds” that led to the denial of institution in *Adaptics*. *Adaptics*, 18. Unlike in *Adaptics* where “Petitioner’s use of ‘and/or’ . . . yield[s] hundreds of possible combinations” among ten references, the Petition encompasses at most eight grounds relying on three references.²³

²³ As noted above in Section 1.F., these eight ground are: (1) anticipation by Sonti (Ground 1); (2) obviousness in view of Sonti (Ground 2); (3) obviousness in view of Ground 1, further in view of Bissonnette (Ground 3A); (4) obviousness in view of Ground 2, further in view of Bissonnette

Patent Owner contends that the Petition’s discussion of Ground 3A, relying on Ground 1 in further view of Bissonnette, lacks particularity, because Ground 3 discusses claims 7 and 21, which are not challenged in Ground 1. Prelim. Resp. 23. We do not find this point to be indicative of a lack of particularity. As the Petition explains, claims 7 and 21 depend from independent claim 1, and Ground 1 explains how Sonti anticipates claim 1. Pet. 46; *see also* Reply 5. As the Petition further explains, Ground 3A also relies on the discussions of the claim 1 preamble and claims 8 and 22 in Ground 1, in addition to the disclosures in Bissonnette, for suggesting the limitation in claims 7 and 21 regarding the subject having been diagnosed with “mild to severe” or “mild to moderate” plaque psoriasis. Pet. 46–47. In contrast, the Petition relies on Bissonnette in Ground 3A primarily for suggesting the additional limitation in claims 7 and 21 regarding treating a subject having a “body surface area (BSA) affected [by plaque psoriasis] of about 3% to about 20%” using topical 1% tapinarof. *Id.*

(Ground 3B); (5) obviousness in view of Ground 1 and Ground 2, further in view of Bissonnette (Ground 3C); (6) obviousness in view of Bissonnette, further in view of Sonti (Ground 4A), (7) obviousness in view of Bissonnette, further in view of Chen (Ground 4B), and (8) obviousness in view of Bissonnette, further in view of Sonti and Chen (Ground 4C). Patent Owner argues that Petitioner’s “‘and/or’ approach . . . further highlights the Petition’s violation of the rule on word limits.” Prelim. Resp. 24. We address Patent Owner’s argument regarding word limits below in Section II.F.2.

We also do not find, as Patent Owner alleges, that the Petition’s use of “and/or” in Ground 4, asserting obviousness in view of Bissonnette further in view of Sonti and/or Chen, “leav[es] Patent Owner and the Board to guess at which reference combination is in play for any particular argument.” Prelim. Resp. 23.

With respect to claim 1, for example, the Petition explains that Bissonnette discloses each element of claim 1, except for claim element [1.c], relating to “once a day” administration frequency. Pet. 53–63. The Petition then explains that “each of Sonti and Chen teaches topically administering 1% tapinarof *once a day* as claimed.” *Id.* at 54. Finally, the Petition asserts that, in addition to Bissonnette, each of Sonti and Chen would also have suggested “the claimed PGA score improvement” (i.e., element [1.d]). *Id.* at 59–61.

We thus understand that, with respect to claim 1, each of the combinations of Bissonnette and Sonti (Ground 4A), Bissonnette and Chen (Ground 4B), and Bissonnette, Sonti, and Chen (Ground 4C) are in play. *See also* Reply 4. Patent Owner has not pointed to any specific arguments for which it alleges there is confusion regarding the combination of references in play.

c. Support for Claims 3 and 4

Patent Owner argues that “[t]he Petition . . . fails to explain with particularity its arguments about dependent claims 3 and 4,” because for those claims Petitioner’s declarant Dr. Liem relied “exclusively” on the testimony of Petitioner’s other declarant, Mr. Sudhakar, but Mr. Sudhakar

never discussed claim 1, from which claims 3 and 4 depend. Prelim. Resp. 24–25. Patent Owner argues that “Mr. Sudhakar’s opinions at least on claims 3 and 4 should be given no weight because he fails to disclose the underlying facts or data on which his opinions are based,” and Dr. Liem’s testimony on claims 3 and 4 likewise “deserves no weight because she relies on the unsupported and incomplete analysis of Mr. Sudhakar for these claims.” Prelim. Resp. 25–26.

For the reasons discussed in Section II.D.1.c., we do not find Petitioner’s arguments with respect to claims 3 and 4 to lack particularity as Patent Owner alleges.

2. Asserted Violation of Word Limits under 37 C.F.R.
§ 42.24(a)(1)(i)

Patent Owner asserts that it “counts at least 14,066 words in the Petition when converting it to MS Word format and excluding portions provided in 37 C.F.R. § 42.24(a)(1),” which exceeds the 14,000-word limit set for a petition. Prelim. Resp. 26–27. Patent Owner further asserts that, because “[t]he Petition repeatedly includes *images of text* from exhibits throughout, and relies on the *text in the images* (including highlights and emphasis) for its arguments,” the word count of the Petition is “actually approximately 14,832 words.” Prelim. Resp. 27. Patent Owner provides the

following chart summarizing the additional words that are alleged to appear in various images included in the Petition.

Petition page	Image of text in petition	Approximate number of words in image <i>not counted</i> by word-processing system
10	EX1005, ¶¶[0287]-[0288]	187 words
23	EX1005, Table 4	140 words
55	EX1013, 32:41-50	95 words
58	EX1013, 32:41-62	212 words
59	EX1008, Table 2	66 words
69	EX1008, Table 2	66 words

Id. The image above is a chart that cites the applicable pages of the Petition where the images appear, the source of the images' text, and the approximate number of words included in the respective images. *Id.*

The Trial Practice Guide states:

[W]hen certifying word count, a party need not go beyond the routine word count supplied by their word processing program. Parties should not abuse the process. Excessive words in figures, drawings, or images . . . in order to circumvent the rules on word count, may lead to a party's brief not being considered. *See, e.g., Pi-Net Int'l, Inc. v. JPMorgan Chase & Co.*, 600 F. App'x 774 (Fed. Cir. 2015). . . . If a party feels that it would suffer undue prejudice from an opposing party's alleged word count limit violation or abuse, that party should raise the issue with the Board promptly after discovering the issue. The Board expects the parties to take reasonable steps to remedy any such issues before approaching the Board. If an opposing party raises a word count limit violation or abuse, the Board will consider such a violation or abuse on a case-by-case basis.

CTPG 40.

On this record, it is unclear what caused the 70-word discrepancy between the word count in Petitioner's Certificate of Compliance and that determined by Patent Owner. It also does appear, as Petitioner explains, that the images in the Petition are of already-pin-cited evidence, and the Petition provides an explanation of the significance of the images in the text immediately surrounding the image. Reply 5. Furthermore, Patent Owner neither alleges that it has suffered any undue prejudice from the extra words, nor indicates that it promptly raised the issue to allow Petitioner to take reasonable steps to remedy the issue. CTPG 40; *see also* Reply 5 (stating that Patent Owner declined to state whether Petitioner's offer to remove highlighting in the images of quoted text would alleviate Patent Owner's concerns).

Under the circumstances of this case as described above, we are not persuaded the Petitioner abused the word limits in a manner that would warrant the Petition not being considered. Nevertheless, we caution the parties that all future papers must comply with applicable word-count limits. We note that it is often helpful to the Board for parties to annotate figures with explanatory text, and we do not intend to discourage such helpful annotations. However, adding annotations to figures should not be used as a means to circumvent the word limits in the parties' papers. *See* 37 C.F.R. § 42.24. To the extent a party incorporates substantive arguments into a figure by adding such explanatory text, therefore, the arguments should not appear solely in the figure but also should be located within the text portions of a brief so they are included in word counts. Similarly, the parties should

avoid images of block quotations, so that the words of the quotation are included in the word count.

3. Alleged Improper Incorporation by Reference

Patent Owner asserts that the Petition “improperly incorporates arguments by reference by citing to paragraphs from its expert declaration to supplement its conclusory statements.” Prelim. Resp. 29.

“It is improper to incorporate by reference arguments from one document into another document.” *Cisco Sys., Inc. v. C-Cation Tech., LLC*, IPR2014-00454, Paper 12, 10 (PTAB Aug. 29, 2014) (informative) (citing 37 C.F.R. § 42.6(a)(3)). However, not every statement made by a declarant needs to be repeated in a brief to avoid incorporation by reference. *See, e.g., Sumitomo Elec. Indus., Ltd. v. United Techs. Corp.*, IPR2017-00966, Paper 7, 11 (PTAB Sept. 13, 2017). For the reasons discussed below, we do not find the Petition contains improper incorporation by reference.

Patent Owner points in particular to the following as examples of conclusory statements improperly incorporating paragraphs from the Liem Declaration: (1) “‘POSA would have been motivated, with a reasonable expectation of success, to administer a topical composition containing 1% tapinarof (as taught by Sonti) once a day (as also taught by Sonti).’ Pet. 30 (citing EX1003, ¶¶187–188)”; (2) “‘[a] POSA would have been motivated, with a reasonable expectation of success, to use the method of treatment of claim 1 on body part(s) that are commonly affected by plaque psoriasis.’ Pet. 37 (citing EX1003, ¶¶227–228).” Prelim. Resp. 29–30.

As to Patent Owner's first example, the relevant paragraph from the Petition states in full:

Sonti teaches using the disclosed tapinarof amounts (including claimed 1%) and disclosed application frequencies (including the claimed once daily) with each of its compositions. Sonti teaches that "in all of the compositions described herein, the amount of [tapinarof] which may be present... may be... 1%". Ex-1005, [0196]; *see also id.* [0055]. Sonti also teaches that "a composition of the present invention may be applied to affected areas... once daily... with the dose represented by any of the embodiments herein." Ex-1005, [0387]. In view of Sonti's interoperability teachings, a *POSA* would have been motivated, with a reasonable expectation of success, to administer a topical composition containing 1% tapinarof (as taught by Sonti) once a day (as also taught by Sonti). Ex-1003, ¶¶187-188.

Pet. 30 (emphasis added). As evidenced by the excerpt, the conclusion cited by Patent Owner (italicized above) is supported by the statements immediately prior, which summarize the points also made in paragraphs 187 and 188 of the Liem Declaration and cite to the same portions of Sonti.

Similarly, the relevant paragraph with respect to Patent Owner's second example states:

Sonti discloses claim 6, for the reasons explained in Ground 1. Further, claim 6 would have been both obvious and obvious to try. Ex-1003, ¶¶225-228. Claim 6 just lists body parts, including the body itself, that are commonly affected by plaque psoriasis. Ex-1003, ¶227; Ex-1015, 3; Ex-1006, 2. A *POSA* would have been motivated, with a reasonable expectation of success, to use the method of

treatment of claim 1 on body part(s) that are commonly affected by plaque psoriasis. Ex-1003, ¶¶227-228.

Pet. 37 (emphasis added).

Again, the statements immediately before the conclusion pointed to by Patent Owner (italicized above) explain the reasoning for the conclusion and summarize the points made by paragraphs 227 and 228 of the Liem Declaration. *See, e.g.,* Ex. 1003 ¶ 227 (“From my 30+ years as a practicing dermatologist . . . I know the body, arms, legs, back, chest, buttocks, neck, scalp, fingernails, toenails are all areas of the body commonly afflicted with plaque psoriasis. . . . Claim 6 simply lists these commonly-afflicted body parts. A POSA also would have known this.”).

In both of the examples cited by Patent Owner, therefore, the paragraphs of the Liem Declaration cited in the Petition provide appropriate supporting technical details and/or testimony as to the understanding of a person of ordinary skill in the art. They do not offer wholly new arguments not found in the Petition. This is likewise the case with the additional examples in the Petition cited by the Patent Owner as allegedly evidencing improper incorporation by evidence. Prelim. Resp. 30–31. Accordingly, we do not find the circumstances here to amount to improper incorporation by reference or an attempt to circumvent our word count limits.

III. CONCLUSION

For the reasons provided above, we decline to exercise our discretion under § 325(d) or 35 U.S.C. § 314, and we institute *inter partes* review based on all the Grounds presented in the Petition.

IV. ORDER

In consideration of the foregoing, it is ORDERED that the Petition is granted, and trial is instituted.

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