

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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INTAS PHARMACEUTICALS LTD.,  
Petitioner

v.

ATOSSA THERAPEUTICS, INC.,  
Patent Owner

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Case PGR2025-00043  
Patent 12,071,391

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**PATENT OWNER'S RESPONSE**

**LIST OF EXHIBITS**

<b>Exhibit</b>	<b>Description</b>
EX2001	ATOSSA THERAPEUTICS, INC. QUARTERLY REPORT FORM 10-Q (March 31, 2025)
EX2002	Atossa Therapeutics Proposes Potentially Groundbreaking Study Aimed at Reducing Interval Breast Cancer in High-Risk Women at AACR 2025 (April 29, 2025)
EX2003	Atossa Therapeutics Announces Plans to Pursue Metastatic Breast Cancer Indication for (Z)-Endoxifen and Continued Engagement with FDA on Additional Indications (March 11, 2025)
EX2004	Financials – Intas Pharmaceuticals Ltd., <a href="http://www.intaspharma.com/financials/">http://www.intaspharma.com/financials/</a>
EX2005	Atossa Therapeutics Announces Issuance of Key U.S. Patent Covering Endoxifen (March 08, 2022)
EX2006	Efficacy and Safety of Endoxifen in Bipolar I Disorder Patients, NCT06608641 (Last Updated March 17, 2025), <a href="https://clinicaltrials.gov/study/NCT06608641">https://clinicaltrials.gov/study/NCT06608641</a>
EX2007	Declaration of Sayem Osman
EX2008	Atossa Covenant Not to Sue
EX2009	Atossa Therapeutics Announces Full Results from Phase 2 KARISMA-Endoxifen Study Demonstrating Statistically Significant Reductions in Mammographic Breast Density (Dec. 11, 2024)
EX2010	Atossa Therapeutics Announces First Quarter 2025 Financial Results and Provides a Corporate Update (May 13, 2025)
EX2011	INTENTIONALLY OMITTED
EX2012	Breast Center Year in Review, An Unmet Need in HR-Positive Endocrine-Resistant Breast Cancer, <i>available at</i> <a href="https://jons-online.com/special-issues-and-supplements/2021/2021-year-in-review-breast-cancer/an-unmet-need-in-hr-positive-endocrine-resistant-breast-cancer">https://jons-online.com/special-issues-and-supplements/2021/2021-year-in-review-breast-cancer/an-unmet-need-in-hr-positive-endocrine-resistant-breast-cancer</a>
EX2013	ATOSSA THERAPEUTICS, INC. ANNUAL REPORT FORM 10-K for the Fiscal Year Ended December 31, 2024
EX2014	U.S. Patent No. 11,572,334
EX2015	Intas Requirements For Resolving Disputes With Atossa (FILED UNDER SEAL)

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EX2016	Default Protective Order
EX2017	<i>Intas Pharmaceuticals, Limited v. Atossa Therapeutics, Inc.</i> , IPR2025-00799, Pap.1 (Apr. 3, 2025)
EX2018	<i>Intas Pharmaceuticals, Limited v. Atossa Therapeutics, Inc.</i> , PGR2023-00043, Pap.1 (Aug. 18, 2023)
EX2019	Rishab Gupta & Swarndeeep Singh, <i>Endoxifen Approval for Bipolar in India, A Premature or a Pragmatic Decision?</i> , 43(1) J. CLINICAL PSYCHOPHARMACOLOGY 3 (2023)
EX2020	Zonalta, Why Zonalta?, <a href="https://zonalta.in/">https://zonalta.in/</a>
EX2021	Atossa Therapeutics Granted Additional Patent Protection for Endoxifen (August 28, 2024)
EX2022	Declaration of Megan Raymond
EX2023	Corrected Covenant Not to Sue
EX2024	December 6, 2025, Collection of Email Communications with Intas’s Counsel
EX2025	Declaration of Sayem Osman
EX2026	U.S. Patent No. 12,245,997
EX2027	Declaration of Jacob M. Berman
EX2028	Declaration of Han Xu
EX2029	Declaration of Hayley R. LeBlanc
EX2030	Declaration of Stephen Graham Davies, DPhil
EX2031	The Merriam-Webster Dictionary (2004)
EX2032	Transcript of January 16, 2026 Deposition of Jason McConville, Ph.D.
EX2033	Transcript of January 20, 2026 Deposition of Ron Bihovsky, Ph.D.
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EX2042	INTENTIONALLY OMITTED
EX2043	INTENTIONALLY OMITTED
EX2044	INTENTIONALLY OMITTED
EX2045	INTENTIONALLY OMITTED

<b>Exhibit</b>	<b>Description</b>
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## I. Introduction

Atossa Therapeutics Inc. (“PO”/“Atossa”) submits this §42.220<sup>1</sup> Response to the above-captioned Petition (“Petition”/“Pet.”). U.S. Patent 12,071,391 (“’391 Patent”/“’391”, EX1001) claims a materially distinct pharmaceutical composition from the earlier U.S. Patent No. 11,572,334 (“’334 Patent”, EX2014). Rather than claiming endoxifen simply placed inside a capsule that has enteric-coating, the ’391 claims are directed to compositions in which endoxifen is *combined with* an enteric material in the composition itself, enabling broader formulation flexibility, including fluid suspensions, and improving delivery to the patient.

At institution, the Board recognized that the parties’ dispute turns on what the claims require when they recite “a composition comprising an endoxifen and an enteric material,” and it preliminarily referenced claim differentiation based on claims 6 (“capsule”). However, the issue is not whether claim 1 can “encompass” a capsule, but whether the endoxifen and enteric material of the composition must be mixed together (rather than merely having a separate enteric coating on the outside of a capsule). The well-established Federal Circuit precedent and intrinsic evidence answer that question in the affirmative.

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<sup>1</sup> Unless stated, statutory and regulatory citations are to 35 U.S.C. or 37 C.F.R., as context indicates, internal citations omitted, and emphases/annotations are added.

Once the claims are properly construed, Petitioner's grounds collapse. The primary art, Ahmad, discloses only capsules with an optional exterior enteric coating, not compositions in which endoxifen and enteric material are mixed together. Ground 2 fails to identify any missing element, specific modification, or articulated reason to combine, let alone a reasonable expectation of success.

And regardless of the construction of "composition," the grounds challenging various dependent claims also fail. The suspension claims (claims 9-15, 30-31) require suspensions containing enteric material that Ahmad does not disclose. The endoxifen quantity claims (claims 26-29, 33-35) rely on a generic dosage range in Ahmad that does not disclose or suggest a composition comprising the claimed amounts of endoxifen. The stability claim (claim 16) relies on testing that does not involve the claimed enteric material. And the steady-state claims (claims 36-37) are based on inherency theories that fall far short of the legal standard. Ground 8's written description and enablement arguments are equally perfunctory and unsupported by expert testimony.

For these reasons, detailed below, the Petition fails to prove, by a preponderance of the evidence, that any challenged claim is unpatentable.

## **II. The '391 Patent**

The '391 Patent addresses persistent shortcomings in tamoxifen-based hormone breast cancer therapy by enabling delivery of (Z)-endoxifen, the primary

active metabolite of tamoxifen, using a novel pharmaceutical composition that improves stability, purity, and therapeutic reliability. *See* EX1001, 2:41-43. The patented composition includes (Z)-endoxifen and an *enteric material*, which, when formulated together (without the need for, *e.g.*, an external enteric coating), such as in an uncoated enteric tablet, enable intestinal absorption of endoxifen while protecting it from degradation in the acidic environment of the stomach. *See id.*, cl.1; 39:22-28; EX2030, ¶34.

The '391 Patent is the third in a family of patents focused on endoxifen-based compositions, but materially differs from its predecessor '334 Patent. While the '334 Patent claimed endoxifen compositions “encapsulated in an enteric capsule” (EX2014, cl.1), the '391 claims take a different approach: they require the enteric material be part of the composition itself (*e.g.*, mixed or suspended with the endoxifen, such as in an uncoated enteric tablet), not merely as a capsule shell or shell coating. *See e.g.*, EX1001, cls.1, 30 (“*suspending* the endoxifen and the enteric material in a fluid”); 39:1-4, 39:22-51, 40:1-6. In this way, the '391 Patent claims are not simply refinements of the '334 claims but claim a materially different pharmaceutical strategy.

### **III. Claim Construction: “A Composition Comprising an Endoxifen and an Enteric Material”**

Claim terms are construed here in accordance with their ordinary and customary meaning as understood by a POSITA in view of the intrinsic record.

*Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-1317 (Fed. Cir. 2005) (*en banc*).

Although Petitioner acknowledged that “all terms should be given their plain and ordinary meaning” (Pet.8), the Board noted that the parties dispute the scope of “[a] composition comprising an endoxifen and an enteric material” recited in the independent claims of the ’391 Patent. ID, 11. Properly construed, and consistent with the plain language of the claims, this limitation requires that the composition includes a *mixture* of endoxifen and enteric material. The composition limitation is not satisfied by merely including endoxifen (without an enteric material) inside, *e.g.*, a capsule shell that has an exterior enteric coating (where the only enteric material is this coating on the capsule).

**A. The Claim Language Requires the Composition Itself Include a Mixture of Endoxifen and Enteric Material**

The meaning of this claim language is plain. Both independent claims of the ’391 Patent recite “[a] composition comprising an endoxifen and an enteric material.” EX1001, cl.1, cl.32. “*The term ‘composition’ in chemistry is well-established. It generally refers to mixtures of substances.*” *PIN/NIP, Inc. v. Platte Chemical Co.*, 304 F.3d 1235, 1244 (Fed. Cir. 2002). The Federal Circuit has consistently “*equated a composition with a mixture*” and “construed the term ‘composition’ to refer to the claimed ingredients *after* they were joined together.” *Mars, Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1373-74 (Fed. Cir. 2004) (non-bolded italics emphasis original) (citing *PIN/NIP*, 304 F.3d at 1244). In *PIN/NIP*, the

Federal Circuit construed “a composition comprising CIPC and a substituted naphthalene” to mean “a physical *mixture* of CIPC and a substituted naphthalene existing together at approximately the same time.” 304 F.3d at 1246. The court explained:

[A] chemical composition exists at the moment the ingredients are *mixed together*. Before creation of the *mixture*, the ingredients exist independently... Consequently, as properly interpreted, [patentee’s] claims are to a composition that contains the specified ingredients at any time from the moment at which the ingredients are *mixed together*.

*Id.* at 1244 (emphasis original) (citing *Exxon Chemical Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553 (Fed. Cir. 1995)); *see also Ex Parte Xu*, No. 2010-003415 (PTAB Feb. 2010) (citing *Exxon* and explaining that “a composition exists from the moment the ingredients are *mixed together*”).

Consistent with that “well-established” meaning, the natural reading of this phrase in the ’391 patent is a mixture of endoxifen and enteric material (*i.e.*, the endoxifen and enteric material are mixed together). *See PIN/NIP*, 304 F.3d at 1244; *Exxon Chemical Patents*, 64 F.3d at 1557–58; *Mars*, 377 F.3d at 1373-74; EX2031, 3 (“**composition**...: a product of mixing various elements or ingredients”). Nothing in the claim language suggests that the “enteric material” can be satisfied by merely placing the endoxifen inside a capsule that itself has an enteric coating. *See id.*

Moreover, this is also a way the claims distinguish the '391 claims from the related '334 claims, which were drafted differently to require an “*endoxifen composition*” encapsulated in an *enteric capsule*.” EX2014, cl.1. In the '334 claims, the “enteric” feature is not mixed together with the endoxifen; instead, it is supplied by a separate capsule shell or shell coating, and the claim language, logically, does not include the enteric shell or shell coating as part of the composition itself (since the two could not be mixed). By contrast, the Challenged Claims here require that the composition itself include the enteric material and endoxifen mixed together, not merely that endoxifen be encapsulated inside a container that has an exterior enteric-coating. If (contrary to its plain meaning) a “composition” were interpreted *not* to require mixing its components together, this would also improperly negate the difference in structure between the two patents’ claims, where the '391 includes the enteric material in the composition (“composition comprising an endoxifen and an enteric material”) but the '334 does not (“formulation comprising an endoxifen composition *encapsulated in* an enteric capsule”). Indeed, unlike the '391, the '334 claims recognize that the enteric capsule is separate and distinct from the composition it surrounds. This distinction is shown below in Petitioner’s own comparison (excerpted here from the Petition, with red lines added):

391 Patent	334 Patent (Unpatentable)
<p>1. A <b>composition comprising an endoxifen and an enteric material</b>, wherein: the endoxifen comprises a compound of Formula (III):</p> <div data-bbox="342 506 712 695" style="border: 1px solid black; padding: 5px; text-align: center;"><p>Chemical structure of endoxifen (Formula III) showing a central carbon atom double-bonded to a phenyl ring and single-bonded to a 4-hydroxyphenyl ring and a 4-(2-methylaminoethoxy)phenyl ring.</p></div> <p>or a pharmaceutically acceptable salt thereof, and <b>at least 90% by weight of the compound of Formula (III) is (Z)-endoxifen.</b></p>	<p>1. An oral formulation <b>comprising an endoxifen composition encapsulated in an enteric capsule</b>, wherein <b>the endoxifen composition comprises a compound of Formula (III):</b></p> <div data-bbox="951 506 1321 695" style="border: 1px solid black; padding: 5px; text-align: center;"><p>Chemical structure of endoxifen (Formula III) showing a central carbon atom double-bonded to a phenyl ring and single-bonded to a 4-hydroxyphenyl ring and a 4-(2-methylaminoethoxy)phenyl ring.</p></div> <p>wherein <b>at least 90% by weight of the compound of Formula (III) is (Z)-endoxifen.</b></p>

Pet.20.

Indeed, the different claim language and structures used in the related '334 and '391 patents further confirm PO's interpretation. The Federal Circuit "has made clear that when a patent claim 'does not contain a certain limitation and another claim does, *that limitation cannot be read into the former claim in determining either validity or infringement.*'" *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1326 (Fed. Cir. 2003) (applying claim differentiation to independent claims). Here, the related '334 independent claims expressly required "an endoxifen *composition encapsulated in* an enteric capsule," whereas the '391 independent claims omit any "encapsulated in...capsule" requirement or a composition that requires only endoxifen, and instead recite a "*composition comprising* an endoxifen

and an enteric material.” Petitioner’s construction ignores these distinct formulations by treating “composition” and “encapsulated” (in ’334) as doing no real work—precisely the type of claim language rewrite *Amgen* warns against.

Indeed, if a “composition” does not require that the components of the composition be mixed together, and instead allows for the components to remain separate and layered (as Petitioner asserts), then it makes no sense that the ’334 patent claims do not **include** the enteric capsule itself in the composition. Instead, the ’334 claims explicitly recite that the endoxifen composition is itself “**encapsulated in** an enteric capsule” (*i.e.*, the capsule is distinct from and not part of the endoxifen composition). That same structural logic confirms the proper understanding of “composition” in the ’391 claims, which expressly include the enteric component **as part of** the claimed composition itself (the composition includes endoxifen **and** enteric material). Petitioner’s interpretation essentially reads out “composition” (particularly in the context of it requiring both endoxifen “**and**” enteric material) from the ’391 patent, violating the settled principle that claims must be construed to give effect to all their terms. *See, e.g., Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006).

The specification plainly contemplates a mixture of endoxifen and enteric material. For example, the specification expressly teaches **uncoated** enteric tablets. EX1001, 40:1-2 (“the enteric tablets ...**may be uncoated.**”); 54:37-42; *see* EX1001,

4:31-40; 4:58-64, 5:66-6:5; 9:36-39; 10:63-67. In an uncoated enteric tablet, the enteric material would be understood to be part of the composition itself and mixed with the endoxifen since there would be no outer enteric coating on the tablet to provide the enteric property. EX2030, ¶35. Indeed, the specification teaches different embodiments, including compositions containing endoxifen and enteric material claimed here (such as the compositions found in an uncoated enteric tablet) and compositions of endoxifen (without enteric material) formulated as a tablet with an enteric coating (EX1001, 38:56-67; 84:61-62 (“*capsules are coated* with an enteric coating”); 39:55-57).

The dependent claims also reflect the concept of a mixture of endoxifen and enteric material. Claim 9 recites that “the composition” is “formulated as a suspension,” and claim 30, a method of making claim 9, is expressly directed to making that suspension embodiment, and requires “suspending the endoxifen and the enteric material in a fluid.” EX1001, cl.9, cl.30. Notably, Petitioner’s own admission underscores this point. For claim 30, Petitioner concedes that Ahmad, which discloses a composition of endoxifen encapsulated in an enteric coating, “*does not explicitly disclose the use of an enteric material in a suspension...*” Pet.60; EX1032, ¶143. This reflects that Petitioner itself understands the claims to require a suspension that includes both enteric material and endoxifen. Pet.74. Yet in its anticipation analysis, Petitioner’s discussion of claim 9 effectively ignores that same

requirement that the suspension must include enteric material in addition to endoxifen. *See* Pet.28. Claim construction should not turn on such shifting, prior-art-driven framing. Under *Phillips*, it turns on the claim language confirmed by the intrinsic record, and claims 9 and 30 make explicit what claim 1’s plain language already conveys: the enteric material is mixed together with endoxifen in the claimed composition.

Nor does Petitioner’s “species”-“genus” framing supply a construction supported by the intrinsic record. Petitioner asserts only that “enteric material” is broader than an “enteric capsule.” Pet.19. But the issue is not whether, in the abstract, “enteric material” can encompass multiple enteric technologies. Instead, the issue is whether the claims require the enteric material to be mixed with the endoxifen to form the composition, as the claim language states. Construing the claimed composition as satisfied whenever an endoxifen-only composition is merely placed into a separate container that has an exterior enteric coating would read the “enteric material” out of what the claims affirmatively require the “composition” to “compris[e].”

**B. Claim Differentiation Does Not Justify Expanding the Claimed Composition Beyond Its Plain Language**

At institution, the Board reasoned that under the doctrine of claim differentiation, the recitation of “[a] composition comprising endoxifen and enteric material” “must be broad enough to encompass a capsule,” because dependent claim

6 further recites the composition is a capsule. ID, 13. PO respectfully submits that the Board's preliminary reliance on claim differentiation, and particularly on claim 6, does not resolve the actual dispute presented here, and it cannot override what the claim language and intrinsic record make clear.

First, claim 6 does not speak to the interpretive issue that matters, namely what it means for claim 1's *composition* to comprise endoxifen and enteric material. Claim 6 merely specifies how the composition is formulated for delivery, an issue separate and distinct from any coating, and nothing in the claim suggests that requirement of the "composition" including "an enteric material" can be satisfied merely by a coating on the exterior of the delivery vehicle. In particular, the specification treats the "composition" as prepared in, or "formulated as," a tablet (claim 5) or capsule (claim 6), not that the *composition* includes an exterior *coating* on the capsule/tablet itself. *See, e.g.*, EX1001, 36:9-13 ("*Compositions* intended for oral use may be prepared in solid or fluid unit dosage forms."); 13:36-45 ("[A] *composition disclosed herein* (for example, *in the same capsule, tablet*, ointment, etc.)..."); 5:66-6:2. Stated differently, the coating of a capsule (or tablet, as in claim 5) is not a *part or component of* a composition; rather, it is an exterior coating on a delivery vehicle (capsule or tablet) that the composition is "prepared in" or "formulated as." EX1001, 36:9-13; 5:66-6:2. Claim 6 does not indicate that the enteric material *of the composition* is supplied by the coating on the exterior of a

capsule. PO's proposed construction thus not only respects the plain meaning of this term consistent with the specification, but is also wholly compatible with the claim 1 mixture of endoxifen and enteric material being in the form of a capsule, as claim 6 requires. That claim 1 must be "broad enough to encompass a capsule," as the Board observed, does not require, and thus cannot justify, reading claim 1's claimed composition as satisfied whenever an endoxifen-only composition formulated as a capsule is merely coated with an additional enteric layer.

Second, the Federal Circuit has explained that "as [the independent claim] is limited...by its own plain meaning, it would be inappropriate to use the doctrine of claim differentiation to broaden [the independent claim] to include a limitation imported from a dependent claim." *Enzo Biochem, Inc. v. Applera Corp.*, 780 F.3d 1149, 1156-1157 (Fed. Cir. 2015). Nor should claim differentiation need to be invoked since the claims have a difference in scope regardless. *See Google LLC v. Ecofactor, Inc.*, 92 F.4th 1049, 1059 (Fed. Cir. 2024).

The same approach is warranted here. Claim differentiation should not be used to expand claim 1's affirmative requirement for a mixture of endoxifen and an enteric material to include a materially different arrangement in which the endoxifen is merely placed inside a separate capsule with an enteric shell or shell coating.

Third, dependent claim 8, which recites "wherein the composition comprises an enteric coating," likewise does not support Petitioner's position or contradict

PO's construction. The phrase "enteric coating," without further context, only indicates the presence of enteric material that coats. The context in which it appears indicates *what* the "enteric coating" actually coats. Thus, an enteric coating in some contexts may refer to the enteric coating that surrounds (coats) an entire tablet or capsule. In other contexts, such as in claim 8, the recited "enteric coating" is a component of the *composition* that coats another component of the composition, not an exterior enteric coating on a capsule or tablet. Thus, in claim 8, the "enteric coating" is mixed with the endoxifen of the composition and surrounds (coats) the other component(s) of the composition (*e.g.*, the endoxifen). That usage is also distinct from the specification's separate discussion of applying enteric coating "agents" to the *outside* of, *e.g.*, capsules or tablets. *See, e.g.*, EX1001, 39:55-57 ("enteric coating agents, for enteric coating of capsules, caplets, and tablets"); 84:61-62 ("The capsules are coated with an enteric coating"). Consistent with this distinction confirmed by the intrinsic record, claim 8 is best understood as requiring the composition itself to include an enteric coating that coats that with which it is mixed. That this is the correct reading for claim 8 is confirmed by the fact that it is also consistent with claim 7, which requires that *the composition itself* is uncoated ("the composition is uncoated") and thus requires the exterior of the *composition* itself be "uncoated." Claim 8 requires that the composition "*comprises* an enteric coating" as a component within the composition, not something separate that coats

the exterior of a container like a capsule or tablet. Claim 8 does not say that the composition itself is coated, but rather the composition includes a coating. Petitioner's reading would improperly collapse (i) enteric coatings as excipient components in the "compositions" and (ii) enteric coatings applied to the outside of capsules/tablets.

For at least these reasons, PO respectfully submits that "[a] composition comprising an endoxifen and an enteric material" should be construed according to its plain meaning in view of the intrinsic record, namely as a mixture of an endoxifen and an enteric material, not merely that an endoxifen-only composition can be placed inside a separate enteric delivery container. *See PIN/NIP*, 304 F.3d at 1244; *Exxon Chemical Patents*, 64 F.3d 1557–58; *Mars*, 377 F.3d at 1373-74.

#### **IV. Collateral Estoppel Does Not Apply Because the '391 Claims Are Materially Different**

Petitioner incorrectly argues that the Board's Final Written Decision in the '334 PGR ("the '334 FWD"), which reviewed the different claims of the grandparent '334 Patent, should have a collateral estoppel effect for a subset of the Challenged Claims here. Pet.14. But Petitioner did not consider the impact on claim construction in making this assertion. And Petitioner cannot meet its burden to prove collateral estoppel at least when accounting for the correct construction of "composition." *Apple Inc. v. VirnetX Inc.*, IPR2016-00332, Pap.29, 11 (June 22,

2017), *aff'd*, 909 F.3d 1375 (Fed. Cir. 2018) (“Petitioner does not meet its burden of showing collateral estoppel applies here”).

The Federal Circuit has clarified that “it is the identity of the issues that were litigated that determines whether collateral estoppel should apply.” *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013). “For patent claims, collateral estoppel applies where the ‘issues of patentability’ are *identical*, *i.e.*, where ‘the differences between the unadjudicated patent claims and adjudicated patent claims *do not materially alter the question of invalidity.*” *Finjan LLC v. SonicWall, Inc.*, 84 F.4th 963, 969 (Fed. Cir. 2023) (citing *Google LLC v. Hammond Dev. Int'l, Inc.*, 54 F.4th 1377, 1381 (Fed. Cir. 2022) (quoting *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013))); *VirnetX Inc. v. Apple, Inc.*, 909 F.3d 1375, 1377 (Fed. Cir. 2018) (requiring “a prior action present[ing] an identical issue” and that “the prior action actually [was] litigated” for collateral estoppel to apply). Additionally, the Federal Circuit has emphasized that “a court cannot impose collateral estoppel to bar a claim construction dispute solely because the patents are related.” *e.Digital Corp. v. Futurewei Techs., Inc.*, 772 F.3d 723, 727 (Fed. Cir. 2014). “A continuation-in-part, for instance, may disclose new matter that could materially impact the interpretation of a claim, and therefore require a new claim construction inquiry.” *Id.* The Federal Circuit has also instructed “[r]egarding the determination of whether an issue is actually litigated,... ‘[a] judgement is not

conclusive in a subsequent action as to issues which might have been but were not litigated and determined in the prior action.” *Purdue Pharma L.P. v. Iancu*, 767 Fed.App’x 918, 922 (Fed. Cir. 2019) (nonprecedential) (citing *Voter Verified, Inc. v. Election Sys. & Software LLC*, 887 F.3d 1376, 1383 (Fed. Cir. 2018)).

The ’391 claims differ in both language and substance from the previously adjudicated ’334 claims. As explained below, those differences preclude collateral estoppel.

**A. Collateral Estoppel Does Not Apply Because, Under the Proper Construction, the Claims Have Different Scope**

Petitioner argues collateral estoppel applies to claims 1, 4, 7-8, 17-19, 21-26, 32, and 38-44. *See* Pet.23-24, 26, 34-35, 47, 49, 53, 61-62, 67-68. But a central issue for every Challenged Claim in this PGR is *neither “identical” nor “actually litigated”* in the ’334 PGR, and collateral estoppel therefore does not apply to any of the claims.

Unlike the ’334, the ’391 claims recite “[a] composition comprising endoxifen and an enteric material,” and thus require a composition in which the enteric material is mixed together with the endoxifen as part of the claimed composition. When properly construed, the claims here do not cover a compound where the endoxifen is not mixed with the enteric material, and therefore are materially different than the endoxifen claimed in the ’334, which is encapsulated within an enteric capsule (coating) not mixed together with enteric material. The Board itself summarized

PO's point: unlike the '334 claims, the '391 Patent "claims are directed to 'the underlying composition itself, where the enteric material is an ingredient **combined with** the endoxifen.'" ID, 12. These differences are dispositive, and "materially alter the question of invalidity." *Ohio Willow Wood*, 735 F.3d at 1342; *Google*, 54 F.4th at 1381. Further, the Board did not previously decide whether the prior art teaches the claimed endoxifen-enteric mixture. *See* PGR2023-00043, Pap.37, 5.

Consistent with the Board's institution decision, collateral estoppel does not apply to claims where the claim includes a **limitation** in the later proceeding that materially alters the question of invalidity, even if aspects of related claims overlap. *See, e.g., Comcast Cable Commc'n, LLC v. Veveo, Inc.*, IPR2019-00239, Pap.50, 19-21 (June 30, 2020) (finding collateral estoppel did not apply where patent did "not claim, discuss or describe the claimed '**highlighting**' **limitation** 1[e], which [was] the central subject of the arguments presented by Patent Owner in this proceeding."); *Grünenthal GmbH v. Antecip Bioventures II LLC*, PGR2019-00003, Pap.22, 50 (May 5, 2020) (finding collateral estoppel did not apply where "[t]he obviousness analysis in PGR2017-00022 does not address treatment of a patient population having the pain intensity recited in claims 15–30 because the claims of the '862 patent **do not contain such a limitation**."). The Federal Circuit has clarified that their precedent looks to the issue of collateral estoppel based on a "claim-by-claim analysis" rather than by a limitation based analysis. *Apple Inc. v. Smart Mobile*

*Techs. LLC*, No. 24-1352, D.I. 38, 8-9 (Fed. Cir. Jan. 21, 2026) (“We applied issue preclusion in *Ohio Willow* to invalidate a claim... Our analysis did not turn on any single limitation or prior art reference, but on the broader ***claim-by-claim analysis*** to an already-invalidated claim.”).

Moreover, collateral estoppel cannot be imposed by assuming, without standard claim construction analysis, that the scope of later claims is materially the same as prior claims. *ParkerVision, Inc. v. Qualcomm Inc.*, 116 F.4th 1345, 1360 (Fed. Cir. 2024). Nor may Petitioner use collateral estoppel to bar a claim construction dispute simply because the patents are related, where differences in claim language and disclosure can materially affect scope. *e.Digital*, 772 F.3d at 727. Because the ’334 PGR did not adjudicate whether the asserted art discloses a composition in which enteric material is an ingredient mixed with endoxifen, Petitioner cannot show that the “identical issue” was “actually litigated” or that its resolution was “essential” to the ’334 judgment. *Ohio Willow Wood*, 735 F.3d at 1342; *Google*, 54 F.4th at 1381. Accordingly, collateral estoppel does not apply to any of these claims. *See Palo Alto Networks, Inc. v. Centripetal Networks, Inc.*, IPR2021-01153, Pap.10, 18 (Jan. 24, 2022) (“Collateral estoppel does not apply because there are differences between the claim limitation at issue here and the adjudicated claim limitations at issue in the prior IPRs.”); *Dr. Reddy’s Lab’ys., Ltd. v. Monosol RX, LLC*, IPR2016-01111, Pap.14, 17 (Dec. 5, 2016) (finding collateral

estoppel inapplicable where prior decision did not resolve the issue of whether the same prior art disclosed a different limitation in the challenged patents).

**B. There Is No Dispute that Collateral Estoppel Does Not Apply to at Least Dependent Claims 9-16, 27-31, 33-37**

Petitioner has the burden to establish that collateral estoppel applies. *See Google*, 54 F.4th at 1381 (instructing that “[t]he party seeking to invoke collateral estoppel must show” the four factors of collateral estoppel); *VirnetX, Inc.*, IPR2016-00332, Pap.29, 11. But Petitioner does not assert (and could not show) that collateral estoppel applies to dependent claims **9-15, 30-31** (“suspension” claims), **16** (“stability” claim), **27-29, 33-35** (“1 mg to 20 mg”, “1 mg to 4 mg”, and “8 mg” endoxifen quantity claims), and **36-37** (“plasma endoxifen...steady state” claims). *See* Pet.28-30 (no assertion for claims 9, 11-15, 30-31), 55-61 (no assertion for claims 10, 12-15, 30-31), 42-46 (no assertion for claim 16), 47 (asserting only for claim 26 in Ground 3 and not 27-29, 33-35), 49 (only claims 40-41, and not 36-37).<sup>2</sup> Petitioner also does not assert collateral estoppel with respect to claims **2-3, 5-6, and 20** (and, with respect to Ground 1, claim 26).

Indeed, the ’334 does not contain any of the suspension, stability, dosage, and steady state claims or limitations like the ones at issue here. These materially different limitations were not “actually litigated” in the prior proceeding. *See*

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<sup>2</sup> Petitioner also does not assert in Ground 1 collateral estoppel for claim 26. Pet.31.

*Google*, 54 F.4th at 1381; *VirnetX*, 909 F.3d at 1377; *see also Intas Pharms. Ltd. v. Atossa Therapeutics, Inc.*, PGR2023-00043, Pap.37, 5 (Jan. 29, 2025). Petitioner’s challenges for these claims proceed on new theories or combinations. For example, the alleged prior art combinations for the suspension claims (Ahmad in view of de Villiers (EX1007) and Ghandi (EX1022)) differ from any prior art combination asserted in the ’334 PGR. Pet.55-61. Similarly, for stability claim 16, Petitioner relies on *new* reference Elkins and stability testing performed by Dr. Bihovsky. Pet.42-46.

Where the Petition does not even allege or attempt to show that these claim limitations were previously litigated and necessarily decided, collateral estoppel cannot apply. *See, e.g., Grünenthal*, PGR2019-00003, Pap.22, 50 (declining to apply collateral estoppel where “[t]he obviousness analysis in PGR2017-00022 does not address treatment of a patient population having the pain intensity recited in claims 15–30 because the claims of the ’862 patent do not contain such a limitation.”); *Comcast*, IPR2019-00239, Pap.50, 19-21.

**V. Ahmad Fails to Anticipate or Render Obvious the “Composition” of Independent Claims 1 and 32 (Grounds 1 and 2) and Their Dependents (Grounds 1-7) Under the Correct Claim Construction**

Petitioner’s Grounds 1 and 2 assert anticipation and obviousness, respectively, based on Ahmad. But, as discussed below, Ahmad fails to disclose or render obvious a key limitation required by every independent claim: a mixture of endoxifen and an

enteric material, and Petitioner cannot salvage Ahmad's failure by invoking collateral estoppel, which, as discussed in §IV.A above, does not apply to these materially different '391 claims or the limitation now in dispute.<sup>3</sup>

**A. Ahmad's Teachings of Enteric Coated Capsules Fail to Disclose the Claimed Endoxifen-Enteric Composition as Properly Construed (Ground 1)**

In order to anticipate under §102, a reference "must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.'" *Net MoneyIN Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (further noting that "'arranged as in the claim' is readily understood in relation to claims drawn to things such as ingredients mixed in some claimed order"). Here, both independent claim 1 and 32 of the '391 Patent recites "[a] composition comprising an endoxifen and an enteric material." See EX1001, cl.1, cl.32. As discussed above (*see supra*, §III), the plain language of the claim requires that the composition comprises a mixture of endoxifen and enteric material. But Petitioner argues only that Ahmad discloses a *composition of*

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<sup>3</sup> The Petition does not cite to numerous paragraphs of Petitioner's expert's declarations. *E.g.*, EX1033, ¶¶16-18, 22, 24, 27-29, 31-38, 40-48, 130, 137, 140, 142, 146; EX1034, ¶¶11-13, 18, 20, 23-41, 73, 86. Petitioner, therefore, cannot rely on these uncited paragraphs.

*endoxifen* that can subsequently be placed in a capsule that has an exterior enteric coating. *See, e.g.*, Pet.9, 20, 27. Petitioner never attempts to show (nor could it) that Ahmad teaches the *claimed* composition, which must include a mixture of endoxifen and enteric material. *See* EX2030, ¶¶37-39.

Petitioner’s argument relying on Ahmad’s disclosure is (based on Petitioner’s own assertions) confined to *a composition that includes only endoxifen (and not also an enteric material)*, and that is subsequently encapsulated in an enteric *coated capsule*. *See* Pet.20. As reproduced below, the *entirety* of Petition’s anticipation argument for the claimed composition in Claim 1 (and Claim 32) is limited to these disclosures:

***A composition comprising an endoxifen and an enteric material,***

Ahmad is titled “Endoxifen compositions and methods” and “provides compositions containing endoxifen.” Ex. 1003, Title, Abstract. Ahmad teaches that “[w]hen desired, [the] composition containing endoxifen or endoxifen-lipid complex can be encapsulated in enteric-coated capsules to protect it from acids in the stomach.” *Id.*, 18:19-21. Ahmad explains that the “enteric coatings prevent release of medication before it reaches the small intestine.” *Id.*, 18:22-24. It further teaches that “[e]nteric coating of capsules filled with compositions containing endoxifen can be done as methods known in the art.” *Id.*, 18:27-29. Thus, Ahmad teaches compositions comprising endoxifen and an enteric material. McConville, ¶54.

Pet.20 (bold italic original, underline added); *see also* Pet.24-25 (“Claim 32 recites a ‘method comprising administering to a subject’ a composition that is identical to the composition of claim 1.”).

Likewise, Petitioner’s own expert, Dr. McConville, repeatedly characterizes Ahmad’s disclosure in these same terms. *See, e.g.*, EX1033, ¶¶29, 54. For example, Dr. McConville explains that “Ahmad is titled ‘Endoxifen compositions and methods’ and ‘provides *compositions containing endoxifen.*’” *Id.* at ¶54 (citing EX.1003, Title, Abstract). He explains that this composition can *then* (“[w]hen desired”) be “*encapsulated in enteric-coated capsules.*” *Id.* at ¶54 (“Ahmad further teaches that ‘*[w]hen desired, [the] composition containing endoxifen* or endoxifen-lipid complex *can be encapsulated in enteric-coated* capsules to protect it from acids in the stomach.’”) (citing EX1003, 18:19-21). Indeed, throughout his declaration, Dr. McConville repeatedly describes Ahmad as disclosing an “*enteric coated capsule*” distinct from the composition itself. *See, e.g., id.* at ¶66 (“Ahmad discloses an enteric *coated* capsule. Ahmad explains that the described enteric capsule is designed to prevent release of the drug throughout its time in the stomach until it reaches the intestine.”); ¶67 (“Ahmad discloses an *enteric coated capsule* such that the capsule does not release drug throughout its time in the stomach. Thus, Ahmad to [sic] teaches the use of an *enteric coating.*”).

Thus, the portion of Ahmad relied upon by Petitioner describes a “composition containing endoxifen” that can then be placed in a capsule that has an “enteric coating.” See EX.1003, 18:19-21 (“When desired, [the] *composition containing endoxifen...can be encapsulated in enteric-coated capsules* to protect it from acids in the stomach”). Critically, these disclosures *fail to disclose an enteric material that is mixed with the endoxifen*. EX2030, ¶¶37-40. At most, these disclosures purport to describe (1) a pharmaceutical composition of endoxifen (2) encapsulating the finished composition in a separate capsule that has an external enteric coating. See EX1003, 18:27-29 (“Enteric coating of capsules filled with composition containing endoxifen...can be done as methods known in the art.”); EX2030, ¶39.

Critically, Ahmad’s “enteric-coated capsule” refers to a capsule in which the enteric material is applied as a coating layer on the outside of the capsule shell. See EX1003, 18:27-29 (“*Enteric coating of capsules filled with compositions containing endoxifen...*”); EX2030, ¶39. The capsule shell and the external coating layer thus remain physically separate from, and are not mixed together with, the endoxifen composition contained inside the capsule. EX2030, ¶39. Accordingly, a POSITA would not understand Ahmad’s disclosure of an “enteric-coated capsule” containing an “endoxifen composition” to mean a mixture of endoxifen and enteric

material (*i.e.*, that the enteric coating on the capsule is mixed together with the endoxifen in the composition itself). *Id.*

Thus, Ground 1 fails as to all claims because Ahmad does not disclose a mixture of endoxifen and enteric material as claimed. EX2030, ¶¶37-40.<sup>4</sup>

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<sup>4</sup> Petitioner’s summary table in “Identification of Grounds” purports to include claims 3 and 30 in its anticipation ground (Ground 1) (Pet.3), but Petitioner provides ***no argument or evidence*** mapping the limitations of claim 3 or 30 to the Ahmad reference under its anticipation theory (Pet.19-34). The substantive heading and sections for Ground 1 in the body of the Petition also omit claim 3 entirely. *See* Pet.19 (“Ground 1: Claims **1, 2, 4-6**, 8, 9, 11-15, 20, 23, 26-37, and 40-44 Are Anticipated by Ahmad”). And while the sub-heading for Section X.F of the Petition includes claim 30 (Pet.28-30), the subsequent textual analysis completely ignores it. By failing to offer ***any*** analysis or evidence, and as the Board found at institution with respect to claim 3, Petitioner has failed to meet its burden for any anticipation challenge to claims 3 and 30. *See* ID, 14 n.10 (declining to consider claim 3 under Ground 1 where Ground 1 analysis did not discuss it). And in fact, Petitioner itself seems to recognize that Ahmad does ***not*** teach claim 3 in view of its obviousness arguments in Ground 2. *See* Pet.40-42.

**B. Ground 2’s Throwing Obviousness Argument Does Not Cure (Or Even Address) Ahmad’s Failure Under The Correct Construction And Does Not Render Obvious Any Dependent Claim Under Any Construction**

It is “of the utmost importance” that the petition include “a detailed explanation of the significance of the evidence,” including “where each element of the claim is found in the prior art.” §§42.22(a)(2), 42.204(b)(4); *see also Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016). In particular, “expert testimony, common sense, and other evidence that is not ‘prior art consisting of patents or printed publications’ (collectively, ‘general knowledge’) *may not be used to supply a missing claim limitation.*” July 31, 2025 Director Memo re: *Enforcement and Non-Waiver of 37 C.F.R. §42.104(b)(4) And Permissible Uses of General Knowledge in Inter Partes Reviews*. Petitioner’s obviousness analysis for nearly all claims in Ground 2 (claims 1, 2, 4-6, 8, 9, 11-15, 20, 23, 26-37, and 40-44), on the other hand, rest on a single throwaway paragraph.<sup>5</sup> *See*

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<sup>5</sup> Instead of relying on Ahmad for each limitation, Petitioner asserts “each of the elements of these claims were also separately known and obvious in view of the knowledge of a POSA.” Pet.38. And while Petitioner identifies certain *other* references that it vaguely argues disclose discrete limitations of the claim, those references are not part of the Ground. Instead, Petitioner relies on extensive

Pet.38-39. In this paragraph, Petitioner fails to even identify the specific claim element(s) it contends may be missing from Ahmad but that are nevertheless obvious, and thus necessarily fails to provide the required obviousness analysis, including an explanation and support for how and why a POSITA would have been motivated to modify Ahmad to include any such missing element. *See In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016) (“To satisfy its burden of proving obviousness, a petitioner cannot employ mere conclusory statements. The petitioner must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.”); *In re Lee*, 277 F.3d 1338, 1345 (Fed. Cir. 2002) (“The board cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the

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conclusory assertions from its experts to suggest that those non-asserted prior art disclosures represent the “view of the knowledge of a POSA.” *Id.* For example, Dr. McConville’s “opinions” are largely verbatim or near-verbatim assertions merely parroted from the Petition without any independent analysis or supporting evidence. *Compare* Ex. 1033 ¶¶53-145 with Pet.19-72. Such conclusory testimony that merely echoes the Petition should be accorded little to no weight. *See cxLoyalty, Inc. v. Maritz Holdings Inc.*, 986 F.3d 1367, 1378 (Fed. Cir. 2021); *see also* §42.65(a).

rationale on which it relies.”). Accordingly, every dependent claim challenged in Ground 2 fails for this independent reason.

Other than Ground 1, Ground 2 is the only Ground that challenges the independent claims. However, as discussed above, Petitioner’s Ground 2 arguments for the independent claims do not fix (or even try to fix) Ground 1’s failing regarding the requirement for a mixture of endoxifen and enteric material and asserts only single-reference obviousness based on Ahmad. Pet.38-46. Because Petitioner *does not offer even an allegation* (let alone particularized arguments, or citation to a relevant disclosure) that a POSITA would have included the enteric material within the endoxifen composition itself, as claimed, this perfunctory paragraph cannot cure Ahmad’s fatal omission. Thus, just as Ahmad fails to anticipate the Challenged Claims, it fails to render them obvious.

**C. Petitioner’s Arguments Regarding Dependent Claims Also Fail Because Petitioner Failed to Establish the “Composition” In the Independent Claims Is Anticipated or Obvious (Grounds 3-7)**

Petitioner relies on its analysis for the independent claims in Grounds 1 and 2 for all of its Grounds 3-7 challenges, which are directed only to dependent claims. However, as established in detail above, Grounds 1 and 2 (the only grounds to address the independent claims) fail for both independent claims because Ahmad does not teach (and Petitioner has not argued that Ahmad alone renders obvious) the “composition comprising an endoxifen and an enteric material.” Thus, Petitioner’s

arguments for how a POSITA would modify Ahmad to render obvious added limitations in the *dependent claims* are legally deficient, and Grounds 3-7 also fail. One cannot render a dependent claim obvious by adding requirements to a base reference that fails to teach or obviate the independent claim in the first place. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) (“[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious.”). Further, Grounds 3-7 fail to specify whether they rely on the independent claim analysis from Ground 1, Ground 2, or both.

**VI. Dependent Claims 9-15, 30-31 (Suspension Claims) Are Not Anticipated or Obvious (Grounds 1-2, 5) Regardless of the Construction of “Composition”**

Dependent claims 9-15 and 30-31 explicitly require that the endoxifen and the enteric material be suspended/in a suspension, regardless of the construction of “composition.” Claim 9, and further dependent claims 10 through 15, require that “the composition of claim 1” (which claim 1 explicitly indicates includes both endoxifen and enteric material) is “formulated as a suspension.” Claim 30 (and dependent claim 31) require “suspending the endoxifen *and the enteric material* in a fluid,” and claim 31 adds further fluid limitations.

Petitioner’s challenges fail on the merits, regardless of the interpretation of “composition.” As shown below, Ahmad never discloses a suspension that includes *both* endoxifen and an enteric material, even if, *arguendo*, the “enteric material”

limitation in the independent claims could be satisfied by an exterior coating of a capsule, and Petitioner identifies no teaching, rationale, or reasonable expectation of success to modify Ahmad to arrive at such a suspension. These defects are independently fatal to Petitioner's challenges to the suspension claims. And as discussed in §IV.A above, collateral estoppel does not apply, and Petitioner concedes as much by never invoking it for these claims.

Notably, while Petitioner ignores the enteric material requirements of these claims in these prior art grounds (*e.g.*, Pet.28-30), in Ground 8, where Petitioner argues certain claims lack written description or are not enabled, Petitioner represents "the composition" in claim 9 includes both the enteric material and the endoxifen and that *both* must be part of the suspension. Pet.74 (arguing the claim requires the "enteric material is suspended *in a fluid with the endoxifen*"). Petitioner cannot have it both ways.

**A. Ground 1: Claims 9-15, 30-31 Are Not Anticipated Because Ahmad Does Not Disclose A Suspension That Includes Both Endoxifen And Enteric Material<sup>6</sup>**

Dependent claim 9 requires “the composition is formulated as a suspension” and claims 10-15 and 30-31 depend, directly or indirectly, from claim 9. Regardless of the claim construction of “composition,” the plain language of claim 9 requires that the whole composition be suspended. The “composition” based on the language of the independent claims, includes both endoxifen *and* enteric material. EX1001, cl.1 (“the composition comprising an endoxifen and an enteric material”). Petitioner’s own expert Dr. McConville acknowledges that claim 9 “encompass[es] the independent claim 1... which includes endoxifen *and the enteric material.*” EX2032, 67:3-10. And, Petitioner and Dr. McConville expressly admit that “*Ahmad does not explicitly disclose the use of an enteric material in a suspension.*” Pet.60; EX1033, ¶143. Indeed, Petitioner addresses only the suspension of the endoxifen, not the enteric material in the Petition. *See, e.g.*, Pet.28 (for claim 9, arguing only that Ahmad teaches “[p]harmaceutical preparations...include...suspensions”; for claim 11, arguing “Ahmad teaches that (Z)-endoxifen can be administered as a

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<sup>6</sup> Petitioner did not sufficiently address claim 30 in Ground 1, and therefore cannot meet its burden. *See supra* n.4. Claim 31 in Ground 1 also necessarily fails because it depends from claim 30.

suspension” and saying nothing about the enteric material), Pet.29 (for claims 12 and 14, arguing “Ahmad teaches that its composition of (Z)-endoxifen can include an alcoholic vehicle... Ahmad would have been used as a fluid with Ahmad’s suspension containing (Z)-endoxifen”), 29-30 (for claims 13, 15, and 31, arguing “Ahmad teaches that its composition of (Z)-endoxifen can include an alcoholic vehicle such as ethanol... POSA would have understood that the ‘alcoholic vehicle’ of ethanol described by Ahmad would have been used as a fluid”); *see also* EX1033, ¶¶70-75. Petitioner’s admission that Ahmad does not disclose the required “enteric material in a suspension” and its related decision not to address the enteric material requirements of claim 9 are independent reasons Petitioner’s anticipation arguments for these claims of Ground 1 fail.

**B. Ground 2 Does Not Address (Let Alone Cure) Ahmad’s Failure to Disclose the Claimed Suspension in Claims 9, 11-15, 30-31**

Petitioner purports to challenge the ’391 claims as obvious “over Ahmad in view of the knowledge of a POSA,” but, as discussed in §V.B above, Ground 2 never provides an obviousness analysis for any of the suspension claims. Pet.38-39. Instead, Petitioner sweeps the majority of claims into a single, generic paragraph asserting that the “use of enteric materials, suspensions, oral delivery, and excipients/additives was also well-known in the art.” Pet.39. Where, as here, the Petition does not even address the suspension limitations, does not identify any supposedly missing limitation, does not articulate why a POSITA would have been

motivated to select and modify any Ahmad embodiment to arrive at the claimed suspension limitations, and does not explain why a POSITA would have reasonably expected success, Petitioner's blanket invocation of "general knowledge" cannot satisfy its burden. *See* §V.B.

**C. Ground 5 Does Not Render Claims 10, 12-15, 30-31 Obvious**

Ground 5 purports to combine Ahmad with de Villiers (claims 10, 12-15, and 31) and with Gandhi (claim 30).<sup>7</sup> Even accepting *arguendo* that de Villiers and

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<sup>7</sup> Petitioner's Ground 5 analysis relies on Gandhi for claim 30 and de Villiers (but not Ghandi) separately for claim 31. Claim 31 *depends from claim 30*, yet Petitioner nowhere asserts, much less supports with any articulated motivation, a combination of Ahmad with *both de Villiers and Gandhi* to satisfy claim 31's full scope. Because Petitioner has not actually advanced an obviousness challenge for claim 31 that accounts for all incorporated limitations, ***Ground 5 fails as to claim 31 on that basis alone***. *See* §42.204(b)(4); *Intelligent Bio-Systems*, 821 F.3d at 1369; *In re Magnum Oil Tools Int'l*, 829 at 1380; *see also* ID, 14 n.10 (declining to consider claim 3 under Ground 1 where Ground 1 analysis did not discuss it).<sup>8</sup> Petitioner does not assert inherency of this limitation in the petition arguments (*see* Pet.42-46), and should not be allowed to argue it on Reply. Further, Petitioner cannot change its theory in Reply or offer additional modifications to remedy its deficient arguments here. *See Pfizer*,

Gandhi discuss various vehicles or suspension technologies, Petitioner’s Ground 5 still fails for the same fundamental reasons as Grounds 1 and 2 fail for these claims: Petitioner treats the suspension limitations as if they apply only to endoxifen and does not even address the requirement that the enteric-material be in the suspension.

**D. Claims 10, 12-15, And 31: De Villiers Does Not Cure Ahmad’s Failure to Disclose or Render Obvious a Suspension of the Claimed Endoxifen-Enteric Composition**

Claims 10, 12-15 and 31 all depend from claim 9 (and, in turn, claim 1) and thus incorporate the requirements of the “composition comprising an endoxifen and an enteric material” “formulated as a suspension.” Petitioner’s Ground 5 never addresses that fundamental requirement that the enteric material be in the suspension and incorrectly treats limitations directed to certain requirements of “the

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*Inc. v. Chugai Pharm. Co.*, IPR2017-01358, Pap.56, 21-22 (Nov. 28, 2018), *appeal dismissed*, 812 Fed. App’x (Fed. Cir. 2020) (concluding petitioner’s inherency argument on reply was “an impermissible shift of its anticipation theory” which was absent from the petition); *In re NuVasive, Inc.*, 841 F.3d 966, 972- 73 (Fed. Cir. 2016) (vacating final written decision when Board relied on factual assertion by petitioner made only after patent owner’s response); *Intelligent Bio-Sys, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369-70 (Fed. Cir. 2016); *Apple Inc. v. Smart Mobile Tech. LLC*, IPR2022-00981, Pap.34, 35-36 (Nov. 7, 2023).

composition” as directed only to the claimed endoxifen portion of the composition. *See, e.g.*, Pet.56 (arguing, with respect to claim 10 (Ground 5), “[t]herefore, it would have been routine and within the skill of a POSA to have formulated ***a suspension of highly-pure (Z)-endoxifen*** as taught by Ahmad with a syrup or elixir vehicle as taught by de Villiers” and never addressing the requirement that the enteric material be part of the suspension), 59-60 (conceding that “Ahmad ***does not explicitly disclose the use of an enteric material in a suspension***” and arguing, with respect to claims 12-15 and 31 (Ground 5), “[i]t would have been routine and within the skill of a POSA to have formulated ***a suspension of highly-pure (Z)-endoxifen*** as taught by Ahmad with an alcohol, ethanol, of sorbitol, mineral oil, plant oils, and/or vegetable oils, as taught by de Villiers” but not addressing the enteric requirement). Petitioner concedes that “Ahmad does not explicitly disclose the use of an enteric material in a suspension,” and “does not explicitly disclose that its suspension can comprise a syrup or elixir.” Pet.55-56, 60; EX1033, ¶143. And Petitioner also does not rely on de Villiers for suspending the enteric material. Ground 5 therefore fails as to claims 10, 12-15 and 31.

**E. Claim 30: The Ahmad-Gandhi Combination Fails Because It Does Not Teach or Render Obvious “Suspending the Endoxifen and the Enteric Material in a Fluid”**

Claim 30 depends from claim 9 and requires “suspending the endoxifen and the enteric material in a fluid.” The Petition relies on Gandhi for the disclosure of

an enteric material in a suspension. Pet.60-61. But Petitioner’s theory lacks any supported motivation to combine or reasonable expectation of success, and claim 30 fails for this independent reason. EX2030, ¶¶41-45.

Petitioner does not identify any problem in Ahmad that would have driven a POSITA to adopt Gandhi’s method. EX2030, ¶43. Ahmad already provides its own oral dosage form options for endoxifen, including “suspensions,” and separately discloses an “enteric” solution in the form of enteric coated capsules “filled with composition containing endoxifen” to protect from stomach acid. EX1003, 18:4-8, 18:20-31. Thus, to the extent a POSITA starting from Ahmad sought an enteric approach, Ahmad points the POSITA to enteric coating of a solid dosage form, not to a fundamentally different sustained release pellet system described in Ghandi. EX1003, 18:20-31; EX2030, ¶43. Indeed, the only motivation Petitioner articulates is to “ensure that the endoxifen was released in the small intestine where it would be absorbed into the body and have pharmaceutical effect.” Pet.61. But that asserted goal is already expressly addressed by Ahmad itself through its enteric coated capsules. *See* EX1003, 18:20-31; *see also Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881 (Fed. Cir. 1998) (“Defining the problem in terms of its solution reveals improper hindsight....”); *In re Schweickert*, 676 F. App’x 988, 995-96 (Fed. Cir. 2017) (nonprecedential); EX2030, ¶43.

Under *Schweickert*, where the primary reference “already” provides the solution to the asserted objective, there is no reasoned motivation to further modify it in a manner that merely adds “unwanted cost and complexity.” 676 F. App’x at 995. That is exactly what Petitioner’s proposed Ahmad-Gandhi combination would do. EX2030, ¶¶42-43. Rather than using Ahmad’s straightforward enteric-coated capsule approach, Petitioner’s theory would require a POSITA to shift to Gandhi’s materially different pellet-based architecture, including creating “inert pellets” from “sugar spheres,” forming the active ingredient into a “drug layer” surrounding the pellets, applying another “coating layer” of a “rate controlling polymer” surrounding the “drug layer,” and then suspending those multi-layered pellets in a “suspending medium.” EX1022, 5:8-16, 21:1-22; EX2030, ¶43. This change would also add manufacturing and formulation complexities and costs to Ahmad. EX2030, ¶43. Therefore, Petitioner has not shown that a POSITA would have been motivated to abandon Ahmad’s optional (“when desired”) straightforward enteric-coated capsule approach and instead turn to Gandhi’s far more complex sustained-release pellet suspension system. *See* EX2030, ¶43; *In re Schweickert*, 676 F. App’x at 995.

Moreover, even assuming a POSITA sought to draw from Gandhi, Petitioner failed to establish reasonable expectation of success. EX2030, ¶44. Petitioner asserts only that there is a reasonable expectation of success because “this is taught in Gandhi.” Pet.60-61; EX1033, ¶¶143-145. That circular assertion ignores the

substantial technical mismatch between Ahmad's disclosed endoxifen suspension embodiments and Gandhi's pellet-based platform. EX2030, ¶44. Ahmad teaches preparing "endoxifen lipid complex" by "solubilizing or suspending endoxifen and lipid(s) together in an aqueous solution," and then "filtering" the resulting "complexes" "to control the size distribution," for example "filtering through a 5 micron filter to obtain complexes, each particle having a diameter of about 5 micron or less." EX1003, 16:60-63, 17:45-54. Ahmad further teaches that the "average diameter" of these "complexes" may be "in the micron or submicron range," including as low as "0.1  $\mu\text{m}$  or less." EX1003, 18:31-37, 17:55-66. Gandhi, by contrast, is built around manufacturing and handling "pellets" on "spheres," including "sugar pellets sifted...through the 60/80 mesh" and then "coated on spheres" to form "drug pellets" that are later mixed into a "suspending medium." EX1022, 21:1-4, 21:18-22, 5:8-16. A POSITA would understand Gandhi's "60/80 mesh" terminology as standard sieve sizing, meaning particles roughly in the No. 60-No. 80 range (about ~250 microns to ~180 micron openings). EX2030, ¶44. Therefore, Gandhi's pellets are on the order of *up to hundreds to thousands times larger* than Ahmad's complexes. EX2030, ¶44. This is not a simple modification. It reflects two different physical formats and manufacturing routes: Ahmad teaches suspending and filtering very small "complexes," while Gandhi teaches building significantly larger coated "pellets" on an "inert core" and then suspending those

pellets. EX1003, 17:45-54; EX1022, 5:8-16, 21:1-4; EX2030, ¶44. Yet the Petition does not even attempt to explain how a POSITA would convert Ahmad's "micron or submicron" "complexes" into Gandhi's significantly larger "pellets" or otherwise adapt Gandhi's "inert core" and coating process to Ahmad's formulations. Pet.60-61. Indeed, given such substantial issues posed by the significant size and format mismatch, Petitioner's mere assertion of "this is taught in Gandhi" fails to demonstrate a reasonable expectation of success in redesigning Ahmad, in view of Gandhi, to achieve the claimed method step of "suspending the endoxifen and the enteric material in a fluid." EX2030, ¶44.

Without a motivation to combine, and without any showing that Gandhi's pellet coating platform would or could be modified to yield the co-suspension method step of claim 30 with a reasonable expectation of success, Ground 5 fails as to claim 30. EX2030, ¶¶41-45.

## **VII. Claim 16 (Stability Claim) Is Not Obvious (Ground 2)**

Claim 16 depends from claim 1 and therefore requires, among other things, "a composition" that "compris[es] (Z)-endoxifen and an enteric material," with the additional limitation that "the compound of Formula (III) is stable in the composition for at least 10 days at about 25° C." Petitioner challenges this claim under Ground 2, but fails to carry its burden to prove that limitation is obvious in view of Ahmad, regardless of the construction of "composition." And as discussed in §IV.A above,

collateral estoppel does not apply, and Petitioner concedes as much by never invoking it for this claim.

Petitioner fails to identify “with particularity” its challenge to claim 16. 35 U.S.C. §322(a)(3). Petitioner concedes that Ahmad does not teach that the compound of Formula (III) is stable in the claimed enteric-material composition “for at least 10 days at about 25° C.” Instead, Petitioner points to Elkins and to Dr. Bihovsky’s Liu-based stability testing. Pet.43-46; EX1034, ¶¶76, 79, 81. That showing is legally and factually insufficient for at least three independent reasons.<sup>8</sup>

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<sup>8</sup> Petitioner does not assert inherency of this limitation in the petition arguments (*see* Pet.42-46), and should not be allowed to argue it on Reply. Further, Petitioner cannot change its theory in Reply or offer additional modifications to remedy its deficient arguments here. *See Pfizer, Inc. v. Chugai Pharm. Co.*, IPR2017-01358, Pap.56, 21-22 (Nov. 28, 2018), *appeal dismissed*, 812 Fed. App’x (Fed. Cir. 2020) (concluding petitioner’s inherency argument on reply was “an impermissible shift of its anticipation theory” which was absent from the petition); *In re NuVasive, Inc.*, 841 F.3d 966, 972- 73 (Fed. Cir. 2016) (vacating final written decision when Board relied on factual assertion by petitioner made only after patent owner’s response); *Intelligent Bio-Sys, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369-70 (Fed.

First, Petitioner asserts “stability is based on the composition” (Pet.42) but Petitioner’s “stability” evidence is not tied to the claimed composition, which includes enteric material. Claim 16 does not ask whether isolated (Z)-endoxifen can be stable<sup>9</sup> in the abstract. It requires that the compound of Formula (III) “is stable in the composition,” and the relevant “composition” is the claim 1 composition that comprises both (Z)-endoxifen *and enteric material*. Petitioner itself expressly acknowledges that “[s]tability...depends on the composition.” Pet.42 (citing EX1034 ¶80). Both of Petitioner’s experts acknowledge that claim 16, which depends from claim 1, requires the endoxifen to be stable “in the composition” that includes “the endoxifen *plus the enteric material.*” EX2032, 68:12-17; EX2033, 283:5-9 (“[The composition] would include at least an enteric material”). Yet Petitioner completely ignores the fact that claim 16’s stability requirement must be satisfied in the claimed enteric-material composition, not in an isolated sample or in

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Cir. 2016); *Apple Inc. v. Smart Mobile Tech. LLC*, IPR2022-00981, Pap.34, 35-36 (Nov. 7, 2023).

<sup>9</sup> Petitioner expressly recognizes that “[a] POSA would understand ‘stable’ as used in claim 16 to mean ‘the continued presence of at least 90% (Z)-endoxifen in a composition...measurable by (Z)-endoxifen conversion to (E)-endoxifen starting from the date of synthesis.’” Pet.42 (citing Ex. 1001, 81:14-18).

some other unclaimed composition. Pet.42-46. Indeed, Dr. McConville admits that whether the inclusion of “enteric material” would impact stability is something that requires “stability testing” and he could not rule out differences without such testing, yet none of the prior art or “testing” Petitioner relies on are directed to a composition containing enteric material. EX2032, 68:18-69:2; 70:18-73:20.

Elkins does not describe, much less test, the stability of “the compound of Formula (III)...*in the composition*.” At most, Elkins is cited for the unremarkable proposition that some endoxifen samples can be stored for long periods without significant isomerization. Pet.43-44. Whatever Elkins may show about a particular stored sample in Elkins’ context, Petitioner has not shown it addresses the claimed stability “in the composition” limitation for the claimed enteric-material composition.

Likewise, Dr. Bihovsky’s “stability testing” does not test “the compound of Formula (III)...*in the composition*” and does not replicate the conditions relevant to the claimed limitation. Dr. Bihovsky admits that he did *not* test the stability of (Z)-endoxifen in the claimed composition that includes enteric material. EX2033, 284:2-20. Instead, Dr. Bihovsky states that he “sealed samples of (Z)-endoxifen in vials under nitrogen inside ziplock plastic bags,” stored one sample at 25° C and 60% relative humidity for ten days and another at 40° C and 75% relative humidity for ten days, and observed no isomerization. EX1034 ¶76. That testimony confirms

the point: the test is performed on sealed, inerted samples of (Z)-endoxifen, not on a composition comprising (Z)-endoxifen and an enteric material. Moreover, by sealing the material “in vials under nitrogen” and placing those vials in ziplock bags, Dr. Bihovsky created an artificially isolated environment that does not correspond to the stability of the claimed composition in any ordinary storage, and Petitioner does not provide any data demonstrating the “continued presence of at least 90% (Z)-endoxifen” in the claimed composition over time. EX1034, ¶¶76. Dr. Bihovsky’s testing therefore cannot establish that the compound of Formula (III) in the claimed enteric-endoxifen composition is stable, which is what claim 16 requires.

Second, Petitioner’s reliance on Dr. Bihovsky’s Liu-based testing cannot supply a reasonable expectation of success. EX2030, ¶¶46, 48-50. The Petition expressly uses Dr. Bihovsky’s results as a proxy for an expectation of success that a POSITA, starting from *Ahmad*, could achieve the claimed stability. Pet.43-46. But Dr. Bihovsky did not test Ahmad’s endoxifen at all; he tested only the material he synthesized in attempting to recreate Liu. See EX2033, 284:2-5 (“Q And your stability testing was of the same (Z)-endoxifen material that you synthesized based on your recreation of Liu, right? A That's correct.”). Indeed, Ahmad does not identify a specific crystal structure or polymorph for its endoxifen. Dr. Bihovsky himself admits that “stability of a composition is dependent on...its crystal structure, and its purity.” EX1034, ¶¶74. Thus, Petitioner never establishes that the Liu-

recreated endoxifen Dr. Bihovsky synthesized and tested has similar crystal structure and purity—*i.e.*, the very factors Dr. Bihovsky admits stability depends on—as the endoxifen of Ahmad. EX2030, ¶48. Accordingly, Petitioner’s testing cannot be treated as a proxy for what a POSITA starting from Ahmad would reasonably expect to achieve in stability. *Id.*

Dr. Bihovsky’s recreation of Liu further demonstrates a lack of reasonable expectation of success. EX2030, ¶¶49-50. Indeed, Dr. Bihovsky’s declaration shows that his Liu work is not a straightforward, predictable implementation of Liu at all. He *materially departed* from Liu in numerous ways. EX1034, ¶¶45-61; EX2030, ¶49. For example, in his attempts to recreate Liu, Dr. Bihovsky (1) changed the ratios of his starting materials to be different than what Liu disclosed (thus failing to properly scale down his experiments), (2) changed the temperature of multiple reactions (EX1034, ¶48, pp.69, 72; EX2033, 144:1-146:15) (3) added additional stirring (EX1034, ¶¶58, 68), (4) scratched the flask during his final recrystallization procedure despite Liu not disclosing this (EX1034, ¶58), (5) added multiple additional purification steps (including a column chromatography step that he admitted was superior to Liu’s washing step and an additional purification step to Liu Example 7) (EX1034, ¶¶49 n.4, 59; EX2033, 62:9-63:15, 67:9-12, 67:16-68:9, 293:11-294:21), (6) created a solution when Liu expressly disclosed a suspension (EX1034, ¶64; EX2033, 271:22-272:20), and (7) added a drying step not

disclosed by Liu (EX1034, ¶48 n.1). Importantly, Dr. Bihovsky admitted that but for many of these changes it would have been impossible or at least very difficult to proceed with the following steps of his experiments. *E.g.*, EX2033, 69:1-71:5, 111:11-112:9, 116:12-117:5, 118:2-11, 165:18-166:11, 296:10-297:2. He also admitted that changes to the ratio of starting ingredients would be result in a “different experiment.” *E.g.*, EX2033, 100:7-17, 101:7-102:8.

Taken together, Petitioner’s Liu-recreated synthesis and stability testing underscore the *opposite* of a reasonable expectation of success. EX2030, ¶¶48-50. They show that achieving the specific crystalline form and purity necessary for the claimed stability was not a plug-and-play consequence of simply “following Liu,” and therefore cannot be used to infer any expectations of success or inherent properties *for an entirely different reference* like Ahmad. *Id.* Petitioner’s obviousness argument for Claim 16 is thus built on a foundation of irrelevant and unreliable experimental data, rather than on actual prior art disclosures, and should be rejected.

Third, Petitioner’s fallback to vague “formulation strategies” and “packaging solutions” does not supply the missing limitation or a reasonable expectation of success. EX2030, ¶51. The Petition merely gestures at a grab-bag of potential countermeasures, including stabilizers, coatings, pH optimization, polymorph selection, desiccants, and inert gas packaging. Pet.46; EX1033, ¶120. Critically,

however, Petitioner concedes that these alleged strategies are not one-size-fits-all. The Petition acknowledges that formulation approaches are “specific to the type of degradation mechanism and API,” and that “[p]ackaging solutions are dependent on the type of dosage form.” Pet.46 (citing EX1033, ¶120). Those concessions are fatal because Petitioner fails to identify *any* particular formulation or packaging choices for the specific enteric-endoxifen composition with a reasonable expectation of satisfying claim 16’s stability requirement. Pet.42-47; EX2030, ¶51. Instead, Petitioner offers only a laundry list of potential options, untied to any disclosure in Ahmad, the claimed enteric-material composition, or to any showing that the claimed stability threshold would be met in that composition. Pet.46; EX1033, ¶120; EX2030, ¶51. That kind of hindsight-driven menu of possibilities cannot substitute for an obviousness theory or supply a reasonable expectation of success. *See, e.g., Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1356-57 (Fed. Cir. 2013) (holding claims directed to stability of the claimed formulation were not obvious where prior art offered broad, undirected lists with no indication which options were most promising or would work, and where hindsight “metaphorical darts” experimentation could not substitute for a reasoned obviousness showing); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1365 (Fed. Cir. 2007) (“[T]o have a reasonable expectation of success, one must be motivated to do more than merely vary all parameters or try each of numerous possible choices until one possibly arrived at a

successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.”); *In re Magnum Oil Tools*, 829 F.3d at 1380; *Intelligent Bio-Sys.*, 821 F.3d at 1367-69.

For all of these reasons, claim 16 is not obvious over Ahmad under Ground 2. EX2030, ¶¶46, 48-52.

### **VIII. Claims 26-29, 33-35 (Endoxifen Quantity Claims) Are Not Anticipated or Obvious (Grounds 1-3)**

The endoxifen quantity claims 26-29 and 33-35 depend from claims 1 and 32, respectively, and require that the composition of claims 1 and 32 further comprises a specified amount of (Z)-endoxifen. As detailed below, Petitioner’s challenges to these claims under Grounds 1-2 (Ahmad), and Ground 3 (Ahmad and Ahmad 2010/2012) fail regardless of the construction of “composition.” And as discussed in §IV.A above, collateral estoppel does not apply; indeed, Petitioner concedes as much by never invoking it for these claims. *See* n.10, *infra*.

#### **A. Ahmad’s Generalized “1-10 mg/day” Statement Does Not Anticipate the Claimed Composition Amounts or the Claimed Narrower Range/Point Dosages (Ground 1)**

Petitioner concedes that “Ahmad *does not disclose the exact claimed ranges* of claim 26,<sup>10</sup> 27, and 33.” Pet.31. Instead, Petitioner’s anticipation challenge to

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<sup>10</sup> Petitioner does not assert collateral estoppel for Ground 1 claim 26. Pet.31.

the dosage-dependent claims rests on a single, generalized statement in Ahmad that “endoxifen” may be administered “orally” at “1 to 10 mg/day” to prevent bicalutamide-induced gynecomastia. Pet.31-33 (citing EX1003, 29:20-31). That theory fails for at least two independent reasons.

First, claims 26-29 are *composition* claims. Each requires that “the composition comprises” a specified amount of (Z)-endoxifen. Ahmad’s cited disclosure, by contrast, is an amount administered daily (“mg/day”), *not* the amount of active ingredient actually contained in a claimed *composition* (e.g., a particular formulated dosage). Pet.31-33. Similarly, claims 33-35 are methods to administer a composition. Ahmad’s statement that a compound may be “administered” at some “mg/day” amount does not, without more, disclose a composition that, as formulated, itself *contains* that amount, because a daily *administered* amount can be achieved by innumerable different formulated compositions and dosing schedules (e.g., multiple dosage units per day, different strengths, split dosing, etc.). EX2030, ¶¶53-55. Indeed, *Petitioner’s own expert acknowledges* that e.g., claims 27-29 *require the “composition itself” to include the recited amount* (in a single dosage form), and *admits* that a specific amount of a drug in a composition is *not satisfied by taking, e.g., two separate tablets a day that together add up to that specific amount*. EX2032, 75:22-76:3, 76:14-77:11. Yet, Petitioner argues anticipation without providing *any* analysis tying Ahmad’s “mg/day” statement to the claim

language requiring that “the composition comprises” the recited amount. That deficiency is particularly fatal here, where the cited Ahmad passage is directed to a *different indication and context* (bicalutamide-induced gynecomastia prevention, not hormone-dependent breast cancer treatment), and is expressed as a *generalized daily regimen concept* with *no disclosure of any specific formulated composition* containing the claimed amounts. See EX1004, 29:20-31; EX2030, ¶55.

Second, Petitioner fails to show Ahmad discloses the narrower claimed “1 mg to 4 mg” range of claims 28 and 34 or the specific “8 mg” amount of claims 29 and 35 with the specificity required for anticipation. The Petition argues Ahmad anticipates these claims because Ahmad discloses a range of “1 mg-10 mg/day,” which “overlap[s]” with the claimed amounts. Pet.32-33; EX1033, ¶¶78-79. But the Federal Circuit has repeatedly *rejected* the notion that mere numerical overlap, standing alone, establishes anticipation of a narrower claimed range or a specific claimed value.

In *Atofina v. Great Lakes Chemical Corp.*, the Federal Circuit held that a disclosed range does not necessarily anticipate a narrower claimed subrange merely because the subrange falls within the broader range. 441 F.3d 991, 999-1000 (Fed. Cir. 2006). Indeed, disclosing a range “does not [even] constitute a specific disclosure of the endpoints of that range.” See *Ineos USA LLC v. Berry Plastics Corp.*, 783 F.3d 865, 869 (Fed. Cir. 2015) (“This portion of the specification clearly

discloses ranges, not particular individual values. As we stated in *Atofina*, ‘the disclosure of a range... does not constitute a specific disclosure of the endpoints of that range.’”) (quoting *Atofina*, 441 F.3d at 1000). Likewise, in *UCB, Inc. v. Actavis Laboratories UT, Inc.* cited by Petitioner, the Federal Circuit emphasized that overlapping ranges anticipate only where the prior art ***describes the claimed range with sufficient specificity***, and reversed where the factfinder “improperly” treated a prior-art range as disclosing a particular point. 65 F.4th 679, 688-89 (Fed. Cir. 2023). Relatedly, *OSRAM Sylvania, Inc. v. American Induction Technologies, Inc.* explains that whether a disclosure of a genus/range anticipates a claimed species/point turns on whether the disclosure “provides sufficient specificity” such that the claimed species is ***effectively singled out***, not whether it can be found somewhere within a broader disclosure. 701 F.3d 698, 706 (Fed. Cir. 2012).

Petitioner has not presented evidence to satisfy that standard here. Ahmad’s “1 to 10 mg/day” statement is a generalized range that does not ***single out*** or even describe the entirely different “1 mg to 4 mg” range for a single dose in claims 28 and 34, much less disclose a specific **8 mg** amount of endoxifen required in the claimed composition by claims 29 and 35. Claim 29, in particular, recites a ***single, discrete point*** (“8 mg”), and Petitioner cannot transform a prior-art “mg/day” range into a disclosure of that ***specific (non-range) amount*** in a ***formulated composition*** without impermissible hindsight. *See Nidec Motor Corp. v. Zhongshan Broad*

*Ocean Motor Co.*, 851 F.3d 1270, 1274 (Fed. Cir. 2017) (rejecting “at once envisage” argument as substitute for a missing limitation); *In re Petering*, 301 F.2d 676, 681 (C.C.P.A. 1962); *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375-76 (Fed. Cir. 2006).

Petitioner thus asks the Board to do what the Federal Circuit forbids: misconstrue a generalized broader range as if it were a disclosure of the specific claimed range (claims 26-28) or point (claims 29, 35). *See UCB*, 65 F.4th at 688-89. Petitioner’s only “support” is conclusory testimony simply asserting “there is no reasonable difference in how the invention works” across the allegedly overlapping “ranges.” Pet.32-33 (citing EX1033, ¶79, and mistakenly ignoring, *inter alia*, that claims 29 and 35 do not involve “claimed ranges”). But the disclosure Petitioner cites to support its assertion, again, is not directed to the amount of endoxifen within a single dosage form (*e.g.*, within the individual tablets administered in Petitioner’s references). EX2030, ¶¶56-57. Even setting aside Petitioner’s expert’s unsupported characterization of “no reasonable difference,” conclusory expert assertions cannot supply the missing disclosure or convert a broader range statement into the required disclosure of a specific range or amount, particularly where the cited Ahmad passage is itself directed to a different prophylactic context and is a generalized assertion about daily amounts that says nothing about a formulated composition (as claimed here). *See, e.g., UCB*, 65 F.4th

at 688-89; *Nidec Motor Corp.*, 851 F.3d at 1274; *OSRAM Sylvania, Inc.*, 701 F.3d at 706.

Accordingly, Ahmad does not anticipate claims 26-29 and 33-35, and Ground 1 for those claims fails. EX2030, ¶¶53-58.

**B. Ground 2 Does Not Cure (Or Even Address) Ahmad’s Failure to Disclose the Claimed Endoxifen Amounts in Claims 26-29, 33-35**

As discussed in §V.B above, Ground 2 provides no independent, claim-specific challenge to the dosage-dependent claims. Although Petitioner nominally includes claims 26-29 and 33-35 within a broad laundry list of claims alleged to be “obvious over Ahmad in view of the knowledge of a POSA,” Ground 2 (1) does not actually discuss these dosage limitations at all, (2) does not cite Ahmad’s “1 to 10 mg/day” passage, and (3) does not attempt to explain, with any supporting evidence, why the particular claimed amounts or ranges required in claims 27-29 and 33-35 would be obvious—or, indeed, even *assert* obviousness with respect to dosing. Pet.38-39. Instead, Ground 2 simply repackages Ground 1 as an obviousness allegation and offers sweeping, conclusory statements that “each of the elements of these claims” was known in the art, untied to the specific numerical dosage limitations at issue here. Pet.38-39. That sort of throwaway, undeveloped attorney argument cannot satisfy Petitioner’s burden to prove unpatentability or its obligation to plead its grounds and supporting evidence with particularity (and, of course,

deprives PO of due process and any meaningful opportunity to respond). *See* §322(a); §V.B, *supra*.

### **C. Ground 3’s “Obvious to Try” Challenge Fails**

Under Ground 3, Petitioner contends that it would have been “obvious...to try dosages” in the claimed amounts. Pet.48-49. Petitioner relies primarily on Ahmad’s generalized “1-10 mg/day” statement (which, as discussed above in §VIII.A, is not a disclosure of an 8mg formulation (*e.g.*, 8mg tablet or capsule)) together with Ahmad 2010 and Ahmad 2012. Pet.48-49; EX1033, ¶93. Petitioner makes no argument specific to the 8 mg claims (claims 29 and 35), which require an 8mg formulation (*e.g.*, an 8mg tablet or capsule). And the only range or reference to 8mg cited by Petitioner is a purported disclosure in Ahmad 2012 of “doses of 4.0-8.0mg.” Pet.48 (citing EX1002, 1-2). But this is not a disclosure of a single tablet or capsule or other formulated composition that contains an amount of (Z)-endoxifen between 4.0 and 8.0 mg. Indeed, Petitioner ignores the requirement that the 8 mg be in a single formulated dosage (*e.g.*, pill or capsule), and this cited Ahmad 2012 disclosure does not disclose an 8 mg tablet (*i.e.*, a composition of 8 mg of endoxifen). Petitioner also identifies no motivation to create an 8 mg tablet. Petitioner’s generic obvious to try assertion fails because it is premised on hindsight and ignores the absence of any showing that the claimed formulated compositions with 8 mg of (Z)-endoxifen were among a finite number of identified, predictable solutions that a

POSITA would have selected with a reasonable expectation of success. *See* EX2030, ¶59; *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1346-47 (Fed. Cir. 2021); *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1385 (Fed. Cir. 2019) *Sanofi v. Watson Lab'ys Inc.*, 875 F.3d 636, 641-42, 647-50 (Fed. Cir. 2017); *In re Antonie*, 559 F.2d 618, 620 (C.C.P.A. 1977).

For at least these same reasons (*i.e.*, the fact that the disclosures identified by Petitioner arguments are not directed towards the claimed amounts of (Z)-endoxifen in a single tablet or formulated composition, *see generally* EX1033, ¶93), Petitioner has also failed to establish the obviousness of claims 26-28 and 33-34.<sup>11</sup>

**IX. Claims 36-37 (Steady State Claims) Are Not Anticipated or Obvious (Grounds 1-3)**

Claims 36 and 37 depend from claim 32 and require that administering the claimed composition “maintains the subject’s plasma endoxifen at a steady state level above 30 nM” (claim 36) or “from 30 nM to 300 nM” (claim 37).

Petitioner challenges claims 36-37 under Grounds 1-3, but regardless of the interpretation of “composition,” Petitioner’s theories do not satisfy the strict requirements to establish inherency of the steady state requirements (Ground 1), and

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<sup>11</sup> While Petitioner asserts collateral estoppel for Ground 3 claim 26, Petitioner has not shown that about the issue regarding disclosure of individual tablets was actually litigated previously. *See* §IV.

its obviousness arguments either lack the required analysis (Ground 2) or improperly conflate unrelated pharmacokinetic disclosures in different formulations and contexts with the claimed steady state maintenance limitations (Ground 3). And as discussed in §IV.A above, collateral estoppel does not apply, and Petitioner concedes as much by never invoking it for these claims.

**A. Ahmad Does Not Inherently Disclose the Claimed Steady State Plasma Levels (Ground 1)**

The Petition acknowledges that Ahmad does not expressly disclose the claimed steady state plasma endoxifen levels. Instead, Petitioner argues that because Ahmad allegedly discloses the claimed composition, the claimed pharmacokinetics are “inherent in that composition.” Pet.33-34; EX1033, ¶80. That is legally and factually insufficient.

To prove anticipation by inherency, Petitioner must establish that the claimed pharmacokinetic results are the “natural result” of practicing Ahmad and are necessarily present, not merely probable or possible. *See, e.g., Endo Pharms. Sols., Inc. v. Custopharm Inc.*, 894 F.3d 1374, 1381 (Fed. Cir. 2018); *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981). The Board has *already* applied that standard to *reject Petitioner’s materially identical inherency theory regarding PK limitations* tied to Ahmad’s endoxifen formulation. In the ’334 PGR, the Board held that Petitioner and Dr. McConville “appear[ed] to assume without supporting evidence that the recited pharmacokinetic properties...would necessarily be the natural result of

administering” Ahmad’s formulation, and emphasized that inherency “may not be established by probabilities or possibilities,” and that “[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *Intas Pharms. Ltd. v. Atossa Therapeutics, Inc.*, PGR2023-00043, Pap.37, 47-48 (quoting *Endo Pharms.*, 894 F.3d at 1381). Critically, the Board explained why Petitioner’s inherent assertion was unsupported on the record: differences in synthetic pathways and the resulting impurity profiles could impact pharmacokinetics, and Petitioner had not carried its burden to prove that administering Ahmad would necessarily yield the claimed PK ranges. *Id.* The Board concluded that, even though the claimed ranges there were broad, Petitioner still “failed to show that administering the 90% (Z)-endoxifen formulation of Ahmad would necessarily fall within those ranges.” *Id.*

Petitioner reprises the *same* flawed inherency theory here that the Board already rejected. Pet.33-34. Ahmad does not report any human plasma endoxifen concentrations, much less any steady state concentrations, and it provides no study or data from which a POSITA could conclude that administering Ahmad’s compositions necessarily maintains the required steady state plasma endoxifen levels. EX2030, ¶¶60-61. Petitioner again relies on Dr. McConville’s baseless assertion that the claimed PK properties are “merely inherent properties” arising from dosing with Ahmad’s formulation, but offers no evidence demonstrating that

administering Ahmad necessarily and inevitably maintains steady state plasma endoxifen above 30 nM (claim 36) or within 30 nM to 300 nM (claim 37) for the claimed method. Pet.33-34; EX2030, ¶61. As the Board has already recognized in rejecting Petitioner’s materially indistinguishable inherency theory, conclusory expert testimony that the claimed PK properties are “inherent,” without any supporting evidence showing inevitability, cannot satisfy Petitioner’s burden. PGR2023-00043, Paper 37 at 47-48.

That failure is especially applicable here because Petitioner’s own evidence (which it invokes for obviousness in Ground 3) confirms the *opposite* of inherency. Petitioner asserts that Ahmad 2012 provides “steady state plasma levels ranging from 65.5 to **359 nM**,” which falls *outside* of the claimed **300 nM** maximum of claim 37. Pet.51-52; EX1033, ¶99. If the asserted steady state levels can reach 359 nM, then Petitioner cannot establish that practicing the alleged prior art method necessarily “maintains” steady state plasma endoxifen within 30-300 nM as claim 37 requires. *See* EX2030, ¶62; *Endo*, 894 F.3d at 1381.

Indeed, even Petitioner’s expert Dr. McConville confirms the point: achieving a desired steady-state range requires adjusting dose/absorption and “play[ing] around with the formulation,” not an automatic or inevitable outcome. *See, e.g.*, EX2032, 36:22-37:12. Moreover, Dr. McConville admits that whether inclusion of “enteric material” would change PK metrics is something “you’d have to test,” and

he could not rule out differences without testing. *See, e.g., id.*, 23:21-24:5, 33:15-20, 35:4-10.

That lack of evidence is underscored by the '391 patent's own comparative steady state data, which shows that steady state exposure is formulation-dependent and can differ materially even at the same nominal dose. EX2030, ¶64. For example, the '391 patent reports side-by-side steady state concentrations from published literature (*including Ahmad 2010 and Ahmad 2012*) alongside steady state results for the '391 composition. *See* EX1001, Table 22; EX2030, ¶64. Critically, at the same nominal doses (e.g., 1 mg, 2 mg, and 4 mg), the '391 composition achieved materially higher (150% to 204%) average steady state concentrations than the published values. *See* EX1001, Table 22. Those data directly refute Petitioner's premise that the claimed steady state levels are an inevitable "inherent" consequence of administering endoxifen generally as described in the Ahmad-related references. EX2030, ¶64. If steady state concentrations vary substantially depending on formulation even at identical nominal doses, then Petitioner cannot meet its burden to prove that practicing Ahmad, without any reported human steady state data for Ahmad's specific formulation, necessarily and inevitably maintains steady state plasma endoxifen above 30 nM (claim 36) or within 30–300 nM (claim 37). *See* EX2030, ¶¶60-65; *Endo*, 894 F.3d at 1381.

**B. Ground 2 Does Not Cure (Or Even Address) Ahmad’s Failure to Disclose the Claimed Steady State Levels in Claims 36-37**

As discussed in §V.B above, Ground 2 is legally and factually deficient, including as applied to claims 36 and 37, because it is simply a catch-all, throwaway assertion for a sweeping list of claims and never addresses any limitation of those claims, let alone the pharmacokinetic steady state requirements. Petitioner fails to identify any specific teaching, motivation, or evidence showing that a POSITA would have targeted (or reasonably expected to achieve and maintain) the claimed steady state thresholds. Pet.38-39. Ground 2 should therefore be rejected as to claims 36 and 37 for failure to present any meaningful obviousness case directed to their pharmacokinetic limitations. *See* §42.204(b); *see also* V.B, *supra*.

**C. Ground 3 Fails Because Petitioner’s “Optimization to Target PK” Theory Is Unsupported and Does Not Establish a Motivation or Reasonable Expectation of Success**

Under Ground 3, Petitioner argues that “to the extent the claimed pharmacokinetics were not inherently achieved followed Ahmad,” a POSITA supposedly would have used the “target pharmacokinetics” discussed in Ahmad 2010 and Ahmad 2012 to “optimize a formulation to achieve them.” Pet.50-53. This does not satisfy Petitioner’s burden.

As discussed above (*supra*, §IX.A), Petitioner’s attempt to rely on inherency to supply the missing steady state limitations is legally and factually insufficient. EX2030, ¶¶60-65. Petitioner’s citations to *Santarus* and *In re Kao* do not change

that result. Pet.50. Those decisions stand for the unremarkable proposition that an otherwise obvious formulation does not become patentable merely because a patentee claims the resulting serum concentrations. *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1354 (Fed. Cir. 2012); *In re Kao*, 639 F.3d 1057, 1070 (Fed. Cir. 2011). They do not excuse Petitioner from proving that the specific “maintains...at steady state” limitations of claims 36 and 37 necessarily occur when administering Ahmad’s composition. Here, Petitioner offers no such proof, and the Board has already rejected Petitioner’s attempt to proceed by assumption rather than evidence. PGR2023-00043, Pap.37, 47-48.

Petitioner’s fallback obviousness “optimization” theory is results-driven hindsight and still fails to establish a reasonable motivation and expectation of success for achieving and maintaining the specific steady state thresholds of claims 36 and 37 using Ahmad’s composition. EX2030, ¶¶66-67. Petitioner asserts, without any evidence other than conclusory expert testimony, that a POSITA “would have been aware of the target pharmacokinetics expected to be efficacious” and would have “optimize[d] a formulation to achieve them.” Pet.52-53; EX1033, ¶¶97-100. But Ground 3 never identifies any prior art teaching that a POSITA would have targeted the particular steady state thresholds recited in claims 36 and 37, including the specific 30 nM reference point and the 300 nM ceiling. EX2030, ¶67. The ’391 Patent, by contrast, explains that maintaining steady state levels greater than 30 nM

is “advantageous” in reducing the likelihood of relapse. EX1001, 46:34-38; EX2030, ¶67. Petitioner does not identify any disclosure in any of the Ahmad references that recognizes that reference point as a target to be maintained through administration of an enteric-endoxifen composition. EX2030, ¶67; *see In re Antonie*, 559 F.2d at 620; *Mylan Pharms. Inc. v. Biogen MA Inc.*, IPR2018-01403, Pap.98, 16-17 (Feb. 5, 2020) (“However, for the optimization of a dosage within an established range to be obvious, the asserted prior art must teach that such an established effective range was known”).

Nor can Petitioner’s generic “optimization” assertions substitute for a reasonable expectation that the claimed steady state maintenance limitations would be achieved with Ahmad’s composition. *See Leo Pharm. Prods.*, 726 F.3d at 1356-57; *Pfizer*, 480 F.3d at 1365. The most Petitioner offers is a conclusory assumption that PK adjustment is “routine” and “straightforward” (Pet.52-53; EX1033, ¶96), which is precisely the sort of conclusory testimony the Board rejected in the ’334 proceeding when it faulted Petitioner for assuming PK outcomes from Ahmad without supporting evidence. *See PGR2023-00043*, Pap.37, 47-48.

As discussed above, the intrinsic record further confirms that the claimed compositions exhibit a distinct and improved pharmacokinetic profile compared to the Ahmad literature, underscoring why Petitioner cannot assume that a POSITA could simply “optimize” Ahmad to reach the claimed steady state maintenance

limitations. EX2030, ¶68. In Table 22, the '391 patent compares steady state concentrations from published literature, *including Ahmad 2010 and Ahmad 2012*, against the study results for the claimed formulation, and reports that the claimed formulation achieved higher average concentrations at steady state, with ratios of 154%, 204%, and 150% at 1 mg, 2 mg, and 4 mg, respectively. EX1001, Table 22; EX2030, ¶68. Those differences reflect tangible changes in bioavailability and steady state exposure, and confirm that Petitioner's asserted "optimization" path is not a predictable, routine exercise with a reasonable expectation of success for achieving and maintaining the specific steady state thresholds recited in claims 36 and 37. EX2030, ¶68.

Indeed, Petitioner's own cited data underscores the unpredictability problem for claim 37 in particular: the reported steady state values vary (*e.g.*, "65.5 to 359 nM") and can *exceed* the claimed 300 nM upper limit, defeating any claim that a POSITA would have expected, without hindsight, that administering Ahmad's composition would reliably maintain steady state within the required ranges. EX2030, ¶69.

For these reasons, claims 36 and 37 are not obvious over Ahmad and Ahmad 2010/2012 in view of the knowledge of a POSITA under Ground 3. EX2030, ¶¶66-70.

**X. Ground 8: Claims 10, 12-15 and 30 Are Described and Enabled Under §112**

Petitioner’s two-paragraph throw-away Ground 8 arguments conditionally assert lack of written description “and/or” enablement for claims 10, 12-15, and 30. Pet.73-74. Petitioner provides *no* expert support for this Ground, and does not provide *any* analysis in the Petition directed to enablement. But it is Petitioner’s burden to show, “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.” §322(a)(3); *see also Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). Here, Petitioner has failed its burden.

**A. Claims 10, 12-15 And 30 Are Enabled**

For enablement, the standard is whether “a patent’s specification describe[s] the invention ‘in such full, clear, concise, and exact terms as to enable any person skilled in the art’ to ‘make and use’ the invention.” *Amgen Inc. v. Sanofi*, 598 U.S. 594, 612 (2023) (citing §112(a)). “[A] specification may call for a reasonable amount of experimentation to make and use a patented invention.” *Id.* “Nor is a specification necessarily inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing.” *Id.* at 611. “Whether undue experimentation is needed is not a single, simple factual determination, but rather is

a conclusion reached by weighing many factual considerations.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Here, Petitioner merely recites the words “and/or are not enabled” but does not discuss or provide *any* argument, analysis, expert evidence, or application of the governing legal framework (including the *Wands* factors) for enablement. Pet.73-74. Accordingly, this Ground fails to satisfy Petitioner’s burden to demonstrate lack of enablement with the required particularity and should be rejected accordingly. *See, e.g.*, ID, 14 n.10 (declining to consider claim 3 under Ground 1 where Ground 1 analysis *did not discuss it*); *Yantai Jereh Petroleum Equip. & Techs. Co. v. BJ Energy Sol., LLC*, PGR2021-00103, Pap.46, 33 (Feb. 6, 2023) (finding challenged claims to be enabled after agreeing with “Patent Owner that Petitioner fail[ed] to provide a systematic analysis of the Wands factors in the context of this case.”).

**B. Claims 10, 12-15 And 30 Are Supported**

For written description support, “the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The “description requirement does not demand any particular form of disclosure,” or “that the specification recite the claimed invention *in haec verba*.” *Id* at 1352.

Petitioner's entire written description argument is that "although the 391 patent mentions syrups, elixirs, alcohols, etc., nowhere does the 391 patent specification disclose a suspension that comprises such substances." Pet.73-74. But this misreads the disclosure and contradicts Petitioner's own view of what a "suspension" entails. In Ground 1, Petitioner itself asserts that "a suspension necessarily includes a fluid." Pet.28. The '391 patent likewise explains that its "compositions" may be "*prepared in...fluid* unit dosage forms," including "elixirs, suspensions, [and] syrups." EX1001, 36:10-16. The '391 further discloses that the "compositions" may "*further comprise*[]" one or more excipients," and such "excipients" can include "disintegrating agents" (e.g., "agar"), "lubricants" (e.g., "glycerin", "glycol" "mineral oil"), "plasticizers" (e.g., "plant oils"), and "any combination thereof." *Id.*, 35:13-14, 36:65-37:4, 37:63-38:44. Those disclosures convey possession of the recited suspension embodiments in which the suspension includes (*i.e.*, "comprises") a fluid vehicle/excipient of the types expressly identified for fluid dosage forms, and the endoxifen and enteric material is thus suspended in the fluid. EX2030, ¶¶72, 74. And Petitioner elsewhere confirms this same basic understanding when it argues (for obviousness) that syrups and elixirs are "common liquid vehicles" used to formulate suspensions. Pet.56. That is irreconcilable with any suggestion that the specification must separately spell out, *in haec verba*, "a suspension that comprises" such substances. *See Ariad Pharm.*, 598 F.3d at 1351

(noting that “the description requirement does not demand...that the specification recite the claimed invention *in haec verba*”).

With respect to claim 30, Petitioner asserts the '391 specification “fails to describe a formulation in which the enteric material is suspended in a fluid with the endoxifen.”<sup>12</sup> Pet.74. But Petitioner’s claim 30 theory fails for the reasons discussed above, including that the '391 patent expressly discloses “compositions” “*prepared in...fluid* unit dosage forms” (including “suspensions”) and that the “composition...*further comprises* one or more excipient,” and explains “[e]xamples of excipients that can be used *in the compositions* are described herein.” EX1001, 35:13-14, 36:65-37:4, 36:10-16. For example, the specification describes various exemplary liquid excipients including, *e.g.*, “lubricants” such as glycerin, glycol, mineral oil, plant oils, and “combinations thereof,” and further explains that “[a]dditional excipients may generally be found in Remington’s The Science and Practice of Pharmacy” (*id.*, 42:22-42), a widely used and comprehensive reference

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<sup>12</sup> Petitioner’s cursory written description argument is also inconsistent with its arguments for claim 9 (which claim 30 depends from) in Ground 1, where Petitioner *does not even acknowledge the requirement that the composition be a suspension that includes enteric material* in addition to endoxifen. See Pet.28; see §VI.A, *supra*.

that Petitioner does not address. EX1001, 37:63-38:44. These disclosures therefore provide ample written-description support for a method of “suspending the endoxifen and the enteric material in a fluid” as claim 30 recites. EX2030, ¶¶73-74.

Additional exemplary support for claims 10, 12-15, and 30 is provided in the table below:

<b>Claim</b>	<b>Examples of Disclosure in '391 Patent</b>
<p>[10] The composition of claim 9, wherein the suspension comprises a syrup or an elixir.</p>	<p><i>See, e.g.</i>, EX1001, 36:12-16 (“In at least some embodiments, the compositions are formulated for oral delivery as tablets, caplets, capsules, pills, powders troches, <b>elixirs</b>, suspensions, <b>syrups</b>, wafers, chewing gums, dragees, lozenges, and the like.”); 54:33-36 (“wherein the composition formulated for oral delivery is a tablet, a caplet, a capsule, a pill, a powder, a troche, <b>an elixir</b>, a suspension, <b>a syrup</b>, a wafer, a chewing gum, a dragee, and a lozenge.”).</p>
<p>[12] The composition of claim 11, wherein the fluid comprises an alcohol.</p>	<p><i>See e.g.</i>, EX1001, 39:1-16 (“Pharmaceutical preparations disclosed herein may comprise a control release agent. Examples of control release agent suitable for use include...<b>long chain alcohols</b>, such as stearyl alcohol, cetyl alcohol, and polyethylene glycol.”); 53:16-20; 54:10-24 (“wherein the composition comprises one or more control release agents selected from the group consisting of...<b>long chain alcohols</b>, such as stearyl alcohol, cetyl alcohol”); 81:22-39; 82:40-44 (“Results show the (Z)-endoxifen free base is surprisingly stable in <b>alcoholic</b> (for example ethanol</p>

	<p>and isopropanol (data not shown)) <b>solutions</b> even at elevated temperatures (40° C.) at higher concentrations over 10 days.”).</p>
<p>[13] The composition of claim 12, wherein the alcohol comprises an ethanol.</p>	<p><i>See, e.g.,</i> EX1001, 81:22-39; 82:40-44 (“Results show the (Z)-endoxifen free base is surprisingly stable in alcoholic (for example <b>ethanol</b> and isopropanol (data not shown)) solutions even at elevated temperatures (40° C.) at higher concentrations over 10 days.”).</p>
<p>[14] The composition of claim 9, wherein the suspension comprises an alcohol, a plant oil, a mineral oil, a glycol, an agar, or a mixture thereof.</p>	<p><i>See, e.g.,</i> EX1001, 36:10-12 (“Compositions intended for oral use may be prepared in solid or fluid unit dosage forms.”); 36:26-33; 36:65-37:3 (“Examples of excipients that can be used in the compositions formulated for oral administration are provided herein and can include...disintegrating agents, lubricants...plasticizers...”); 37:63-38:2 (“Disintegrants that can be used in the pharmaceutical compositions provided herein include, but are not limited to, <b>agar...and mixtures thereof</b>”); 38:3-11 (“Lubricants that can be used in the pharmaceutical compositions provided herein include, but are not limited to, calcium stearate, magnesium stearate, <b>mineral oil, light mineral oil</b>, glycerin, sorbitol, mannitol, <b>polyethylene glycol, other glycols</b>, stearic acid, sodium lauryl sulfate, talc, <b>hydrogenated vegetable oil (e.g., peanut oil, cottonseed oil, sunflower oil, sesame oil, olive oil, corn oil, and soybean oil)</b>, zinc stearate, magnesium stearate or potassium stearate, ethyl oleate, ethyl laureate, <b>agar</b>, and <b>mixtures thereof</b>.”); 38:24-39 (“Suitable plasticizers, include...<b>plant</b></p>

	<p><i>oils</i>, (e.g., <i>olive oil, camelia oil, castor oil, tall oil</i>, and <i>a peanut oil</i>),...<i>diethylene glycol, polyethylene glycols, polypropylene glycol...or mixtures thereof</i>").</p>
<p>[15] The composition of claim 9, wherein the suspension comprises ethanol, mineral oil, glycerin, sorbitol, mannitol, polyethylene glycol, vegetable oil, stearic acid, sodium lauryl sulfate, or a mixture thereof.</p>	<p><i>See, e.g.</i>, EX1001, 35:13-14 (“In some embodiments, the compositions comprising endoxifen further comprise an <i>excipient</i>.”); 36:26-33; 36:65-37:3 (“Examples of excipients that can be used in the compositions formulated for oral administration are provided herein and can include...<i>lubricants...plasticizers...</i>”); 37:27-36; 38:3-11 (“Lubricants that can be used in the pharmaceutical compositions provided herein include, but are not limited to, calcium stearate, magnesium stearate, <i>mineral oil, light mineral oil, glycerin, sorbitol, mannitol, polyethylene glycol, other glycols, stearic acid, sodium lauryl sulfate</i>, talc, <i>hydrogenated vegetable oil (e.g., peanut oil, cottonseed oil, sunflower oil, sesame oil, olive oil, corn oil, and soybean oil)</i>, zinc stearate, magnesium stearate or potassium stearate, ethyl oleate, ethyl laureate, agar, and <i>mixtures thereof</i>.”); 38:24-39 (“Suitable plasticizers, include...<i>plant oils</i>, (e.g., <i>olive oil, camelia oil, castor oil, tall oil</i>, and <i>a peanut oil</i>),...<i>diethylene glycol, polyethylene glycols, polypropylene glycol...or mixtures thereof</i>”); 38:48-51.</p>
<p>[30] A method of making the composition of claim 9, the method comprising suspending the endoxifen and the enteric material in a fluid.</p>	<p><i>See, e.g.</i>, EX1001, 14:18-24 (“‘pharmaceutically acceptable carrier’ or ‘carrier’ means a pharmaceutically acceptable material, composition, or vehicle, such as a liquid or solid filler,</p>

diluent, excipient, solvent, or encapsulating material, involved in carrying or transporting one or more of the compounds”); 35:13-14 (“In some embodiments, the compositions comprising endoxifen further comprise an excipient.”); 36:10-16 (“Compositions intended for oral use may be *prepared in* solid or *fluid* unit dosage forms. In at least some embodiments, the compositions are formulated for oral delivery as tablets, caplets, capsules, pills, powders, troches, elixirs, *suspensions*, syrups, wafers, chewing gums, dragees, lozenges, and the like.”); 36:65-37:4 (“Examples of excipients that can be used in the compositions formulated for oral administration are provided herein and can include...lubricants...control release agents...”); 38:3-23 (“Lubricants that can be used in the pharmaceutical compositions provided herein include...”); 38:56-67; 39:1-16 (“Pharmaceutical preparations disclosed herein may comprise a control release agent. Examples of control release agent suitable for use include, without limitation, pH-dependent polymers”); 39:22-51 (“compositions may comprise one or more of pH-dependent polymers such as acid insoluble polymers”); 39:22-38 (“In some embodiments, *compositions may comprise* one or more of *pH-dependent polymers* such as acid insoluble polymers... Non-limiting examples of acid-insoluble polymers include... acrylic acid-methylacrylic acid copolymers (commercially available...

	as a powder or a 30% aqueous dispersion...”); 39:52-67; 42:17-31 (“... compositions disclosed herein may comprise one or more of the excipients known in the art... Additional excipients may generally be found in Remington's The Science and Practice of Pharmacy, Meade Publishing Co., United States Pharmacopeia/National Formulary.”); 42:54-59 (“liquid or fluid formulations”); 53:60-67 (“compositions comprising (Z)endoxifen or salts thereof...control release agent”); 54:7-24 (“a composition comprising (Z)-endoxifen or salts thereof...wherein the composition comprises one or more control release agents”); 54:30-36 (“suspension”); 56:29-57:19; 81:22-39; 82:1-77.
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For these reasons, the Board should reject Ground 8’s written description and enablement challenges to claims 10, 12-15, and 30.

## **XI. Conclusion**

Petitioner has failed to demonstrate that any of the Challenged Claims are unpatentable. Its core theory depends on misreading the claims to cover compositions that lack the required combination of endoxifen and an enteric material, contrary to the plain claim language, Federal Circuit precedent and the intrinsic record. Once properly construed, Petitioner’s anticipation and obviousness arguments collapse, particularly because Ahmad discloses only enteric-coated

capsules, not compositions in which endoxifen and enteric material are mixed together. The dependent claims, including those directed to suspension formulations, dosage amounts, steady state levels, and stability, likewise fail under Petitioner's legally insufficient analysis regardless of the interpretation of "composition". Petitioner also fails to support its written description and enablement arguments with any expert testimony or meaningful analysis. Accordingly, for the reasons set forth above, the Board should find all Challenged Claims not unpatentable.

Respectfully submitted,

Dated: January 26, 2026

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**CERTIFICATE OF WORD COUNT**

The undersigned certifies that the foregoing Patent Owner's Response complies with the type-volume limitation in 37 C.F.R. §42.24(c)(1) and the "Interim Processes for PTAB Workload Management" (Mar. 26, 2025). According to the word-processing system's word count, the brief contains 15,903 words, excluding the parts of the brief exempted by 37 C.F.R. §42.24(a)(1).

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of Patent Owner’s Response and the accompanying exhibits have been served in their entirety on January 26, 2026, by causing the aforementioned documents to be electronically mailed to the following attorneys of record for the Petitioner listed below.

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