

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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PGR2025-00043  
Patent 12,071,391 B2

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Before SHERIDAN K. SNEDDEN, CHRISTOPHER C. KENNEDY, and  
JAMIE T. WISZ, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

DECISION  
Granting Institution of Post-Grant Review  
35 U.S.C. § 324

## I. INTRODUCTION

Intas Pharmaceuticals Ltd. (“Petitioner”) filed a Petition requesting a post-grant review of claims 1–44 of U.S. Patent No. 12,071,391 B2 (Ex. 1001, “the ’391 patent”). Paper 2 (“Pet.”). Atossa Therapeutics, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 9 (“Prelim. Resp.”).

We have authority under 35 U.S.C. § 324(a), which provides that a post-grant review may not be instituted “unless . . . the information presented in the petition . . . , if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” Upon considering the arguments and evidence presented by the parties, we determine Petitioner has demonstrated that it is more likely than not that at least one of the claims challenged in the Petition is unpatentable.

### *A. Real Parties-in-Interest*

Petitioner identifies itself and Accord Healthcare, Inc. (a U.S. subsidiary of Petitioner) as the real parties-in-interest to this proceeding. Pet. 1. Petitioner also states that

Other parties who may be interested in the outcome of this PGR include the National Cancer Institute/National Institutes of Health Clinical Center, Eli Lilly and Company, Pfizer Inc., Jina Pharmaceuticals Inc., Cheiljedang Corp., Alchem Laboratories Corporation, and Lambda Therapeutic Research Limited.

*Id.*

Patent Owner identifies itself as the real party-in-interest. Paper 4, 1.

### *B. Related Proceedings*

Petitioner has filed petitions challenging patents related to the ’391 patent in PGR2023-00043 (US 11,572,334; “the ’334 patent”) and IPR2025-00799 (US 11,261,151). Pet. 2; Paper 4, 1.

*C. The '391 patent*

The '391 patent, entitled “Methods for Making and Using Endoxifen,” was issued on August 27, 2024, and claims the benefit of several continuation and provisional applications, the earliest of which was filed September 11, 2017. Ex. 1001, codes [54], [60], [64]. According to the Abstract, the '391 patent “provides industrially scalable methods of making (Z)-endoxifen or a salt thereof, crystalline forms of endoxif[e]n, and compositions comprising them,” as well as “methods for treating hormone-dependent breast and hormone-dependent reproductive tract disorders.” *Id.*, Abstract.

Endoxifen is the active metabolite of tamoxifen, a selective estrogen receptor modulator that is used to treat endocrine responsive breast cancer, i.e., hormone-dependent or hormone-sensitive breast cancer. *Id.* at 1:63–2:9. Endoxifen has two isomers, (E)-endoxifen and (Z)-endoxifen. According to the Specification, “[i]t is widely accepted that (Z)-endoxifen is the main active metabolite responsible for the clinical efficacy of tamoxifen.” *Id.* at 2:36–43. “Several cytochrome P450 (CYP) mutations have been proposed to cause reduced conversion of tamoxifen to its active metabolite, endoxifen, and reduce tamoxifen efficacy and increase resistance to the drug,” but “changes in the CYP genotype do not fully explain the tamoxifen resistance and the reduced endoxifen levels observed in some subjects.” *Id.* at 2:7–22. Accordingly, the Specification states that several alternatives to tamoxifen are being developed for treating breast cancer. *Id.* at 2:28–29.

The Specification states that although hydrochloride and citrate salts of endoxifen are known in the art and being evaluated for metastatic cancer, “there remains [an] unmet medical need for new compositions and methods

for the treatment and/or prevention of hormone-dependent breast and reproductive tract (gynecologic) disorders.” *Id.* at 2:39–58.

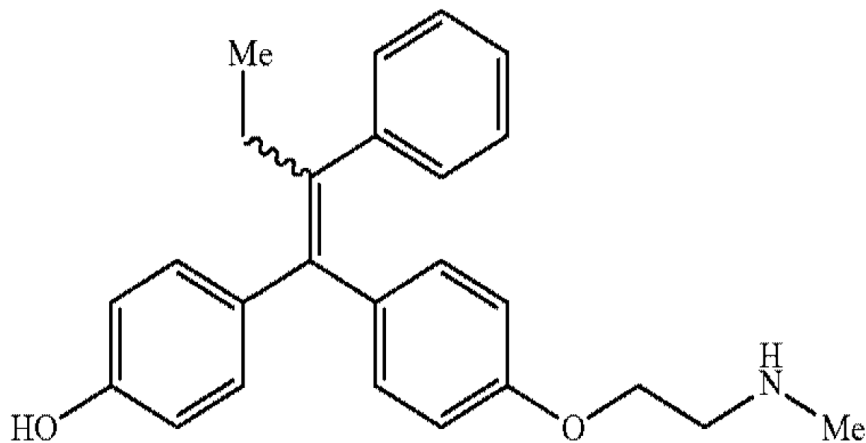
*D. Illustrative Claim*

Petitioner challenges claims 1–44 of the ’391 patent, of which claims 1 and 32 are independent. Claims 1 and 32 are illustrative and are reproduced below:

1. A composition comprising an endoxifen and an enteric material, wherein:

the endoxifen comprises a compound of Formula (III):

Formula (III)



or a pharmaceutically acceptable salt thereof, and

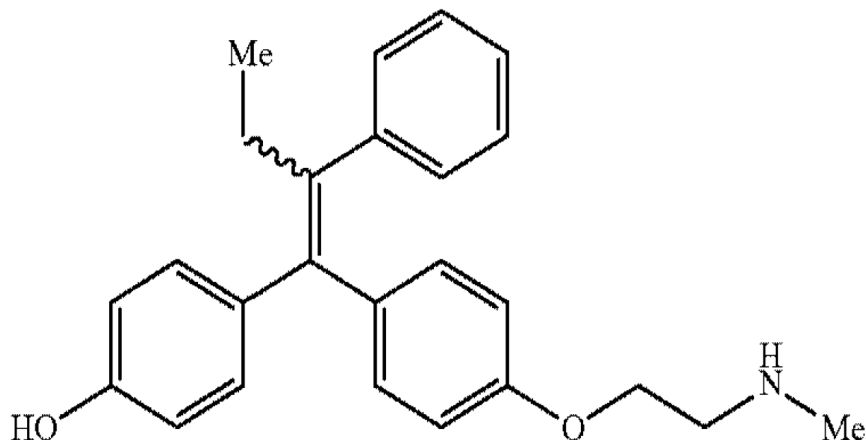
at least 90% by weight of the compound of Formula (III) is (Z)-endoxifen.

Ex. 1001, 96:20–40.

32. A method comprising administering to a subject a composition comprising an endoxifen and an enteric material, wherein:

the endoxifen comprises a compound of Formula (III):

Formula (III)



or a pharmaceutically acceptable salt thereof; and

at least 90% by weight of the compound of Formula (III)  
is (Z)-endoxifen.

*Id.* at 98:1–21.

#### *E. The Asserted Grounds of Unpatentability*

Petitioner challenges claims 1–44 of the '391 patent based on the grounds set forth in the table below.

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–6, 8, 9, 11–15, 20, 23, 26–37, 40–44	102	Ahmad <sup>1</sup>
2	1–6, 8, 9, 11–16, 20, 23, 26–37, 40–44	103	Ahmad

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<sup>1</sup> Ex. 1003, Ahmad et al., US 9,333,190 B2, issued May 10, 2016 (Ex. 1003, “Ahmad”).

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
3	26–29, 33–37, 40, 41	103	Ahmad, Ahmad 2010, <sup>2</sup> Ahmad 2012 <sup>3</sup>
4	7	103	Ahmad, Benameur <sup>4</sup>
5	10, 12–15, 30, 31	103	Ahmad, de Villiers, <sup>5</sup> Gandhi <sup>6</sup>
6	21–25	103	Ahmad, Stegemann, <sup>7</sup> HPE <sup>8</sup>
7	17–19, 38, 39	103	Ahmad, Cole <sup>9</sup>
8	10, 12–15, 30	112	Lack of Written Description
9	10, 12–15, 30	112	Lack of Enablement

<sup>2</sup> Ex. 1011, Ahmad, A. et al., *Endoxifen, a New Cornerstone of Breast Cancer Therapy: Demonstration of Safety, Tolerability and Systemic Bioavailability in Healthy Human Subjects*, 88(6) CLIN. PHARMACOLOGY & THERAPEUTICS 814-817 (2010) (“Ahmad 2010”).

<sup>3</sup> Ex. 1012, Ahmad et al., Endoxifen for breast cancer: Multiple-dose, dose-escalation study characterizing pharmacokinetics and safety in metastatic breast cancer patients, 30 J. CLINICAL ONCOLOGY 3089 (2012 ASCO Annual Meeting Abstract) (May 20, 2012) (Ex. 1007) (“Ahmad 2012”).

<sup>4</sup> Ex. 1006, Hassan Benameur, Capsule Technology: Enteric capsule drug delivery technology – Achieving Protection Without Coating, 15 DRUG DEVELOPMENT & DELIVERY 34–37 (June 2015) (Ex. 1010) (“Benameur”).

<sup>5</sup> Ex. 1007, Melgardt de Villiers, *Pharmaceutical Solvents & Solubilizing Agents*, in A PRACTICAL GUIDE TO CONTEMPORARY PHARMACY PRACTICE (3d ed., 2009) (“de Villiers”).

<sup>6</sup> Ex. 1022, WO 2011/107855, published Sept. 9, 2011 (“Gandhi”).

<sup>7</sup> Ex. 1008, Stegemann et al., *Hard gelatin capsules today – and tomorrow*, Capsugel Library 3–23 (2d ed., 2002) (Ex. 1011) (“Stegemann”).

<sup>8</sup> Ex. 1009, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS (Raymond C. Rowe et al. eds., 5th ed. 2006) (Ex. 1012) (“HPE”).

<sup>9</sup> Ex. 1010, Cole, et al., *Enteric coated HPMC capsules designed to achieve intestinal targeting*, 231 INTL. J. PHARMACEUTICS 83–95 (2002) (Ex. 1008) (“Cole”).

Petitioner relies on the Declarations of Jason McConville, Ph.D. (Ex. 1033) and Ron Bihovsky, Ph.D. (Ex. 1034) to support its asserted grounds of unpatentability.

*F. Collateral Estoppel*

Our reviewing court has held that “[c]ollateral estoppel protects a party from having to litigate issues that have been fully and fairly tried in a previous action and adversely resolved against a party-opponent.” *Nestle USA, Inc. v. Steuben Foods, Inc.*, 884 F.3d 1350, 1351–1352 (Fed. Cir. 2018) (quoting *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013)). “It is well established that collateral estoppel, also known as issue preclusion, applies in the administrative context.” *MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1376 (Fed. Cir. 2018) (citations omitted).

The party seeking to invoke collateral estoppel must show:

- (1) the issue is identical to one decided in the first action;
- (2) the issue was actually litigated in the first action;
- (3) resolution of the issue was essential to a final judgment in the first action; and
- (4) [the party against whom collateral estoppel is being asserted] had a full and fair opportunity to litigate the issue in the first action.

*In re Freeman*, 30 F.3d 1459, 1465 (Fed. Cir. 1994). It is well established that patent claims need not be identical for collateral estoppel to apply. *Soverain Software LLC v. Victoria’s Secret Direct Brand Mgmt., LLC*, 778 F.3d 1311, 1315 (Fed. Cir. 2015). Rather, collateral estoppel requires that the issues of patentability be identical. *Ohio Willow Wood*, 735 F.3d at 1342. Thus, collateral estoppel may apply even if the patent claims “use slightly different language to describe substantially the same invention,” so long as “the differences between the unadjudicated patent claims and

adjudicated patent claims do not materially alter the question of invalidity.” *Id.* Whether the differences between the patent claims materially alter the question of patentability is a legal conclusion based on underlying facts. *Google LLC v. Hammond Dev. Int’l, Inc.*, 54 F.4th 1377, 1381 (Fed. Cir. 2022).

The parties dispute whether collateral estoppel applies in this proceeding based on the Final Written Decision of PGR2023-00043 involving the ’334 patent (the ’334 PGR). Pet. 14–55; Prelim. Resp. 26–27. Petitioner contends that many of the claims of the ’391 patent present the same factual inquiries as those determined by the Board in the ’334 PGR. Pet. 15. Petitioner further contends that the same issues were actually litigated in the ’334 PGR, necessary to the final judgment, and that Patent Owner had a full and fair opportunity to litigate them. *Id.* Thus, Petitioner contends that collateral estoppel applies to the issues presented in its Petition and that Patent Owner “may not reargue factual findings resolved against it in the 334 PGR.” *Id.*

Patent Owner disagrees. Prelim. Resp. 26–27. Patent Owner contends that “[t]he issues and claims presented also differ from the previous PGR such that collateral estoppel does not apply.” *Id.* at 4. Patent Owner also contends that the issues here were not “actually litigated.” *Id.* at 26. In particular, Patent Owner notes that the ’334 patent claimed a dosage form where endoxifen is encapsulated in an enteric capsule. *Id.* at 26–27 (citing Ex. 2014, cl.1). Patent Owner contends that “the ’334 claims have no requirement that the composition itself contain an enteric material or even that there be an enteric material somewhere within the enteric capsule.” *Id.* In contrast, “the ’391 Patent claims the underlying composition itself, where the enteric material is an ingredient combined with the endoxifen.” *Id.*

Because Patent Owner's arguments, at this stage of the proceeding, do not implicate collateral estoppel, we need not address whether Petitioner has demonstrated sufficiently that collateral estoppel applies here. The parties are encouraged to further develop this issue over the course of trial including questions such as whether estoppel should be applied on a limitation-by-limitation basis, claim-by-claim basis, or otherwise.

## II. ELIGIBILITY FOR POST-GRANT REVIEW

We must first determine whether the '391 patent is eligible for post-grant review. Section 6(d) of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011) ("AIA") sets forth the post-grant review provisions, which apply only to patents subject to the first-inventor-to-file provisions of the AIA. AIA § 6(f)(2)(A) (stating the provisions of Section 6(d) "shall apply only to patents described in section 3(n)(1)"). Post-grant reviews are only available for patents that issue from applications "that contain[] or contained at any time . . . a claim to a claimed invention that has an effective filing date . . . on or after" March 16, 2013. AIA § 3(n)(1). Moreover, "[a] petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent or of the issuance of a reissue patent (as the case may be)." 35 U.S.C. § 321(c). Petitioner has the burden of demonstrating eligibility for post-grant review. *See Mylan Pharms. Inc. v. Yeda Res. & Dev. Co.*, PGR2016-00010, Paper 9 at 10 (PTAB Aug. 15, 2016).

The '391 patent claims the benefit of several provisional applications, the earliest of which was filed on September 11, 2017. Ex. 1001, code (60). Thus, for purposes of this proceeding, the '391 patent claims have an effective filing date after March 16, 2013.

Moreover, the '391 patent issued on August 27, 2024, and the Petition was filed on April 3, 2025. Ex. 1001, code (45). Thus, the Petition was filed less than nine months after the date the patent was granted.

We, therefore, determine that the challenged claims are eligible for post-grant review. Patent Owner does not assert otherwise. *See generally* Prelim. Resp.

### III. ANALYSIS OF GROUNDS

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

Petitioner asserts that a person of ordinary skill in the art (“POSA”) would be “someone with a graduate degree in organic chemistry, medicinal chemistry, pharmaceutical chemistry, or a related field, and four to six years of experience in the synthesis, purification, analysis, design, and/or formulation of pharmaceutical compounds and derivatives.” Pet. 7 (citing Ex. 1034 ¶ 21; Ex. 1033 ¶ 25). Petitioner also asserts that a person of ordinary skill in the art “would have worked with a team of professionals with training in related disciplines, such as pharmacology, pharmacokinetics, formulation, drug discovery and/or drug development as of the date of the claimed inventions.” *Id.* at 7–8.

Patent Owner does not dispute Petitioner’s definition of a person of ordinary skill in the art. *See generally* Prelim. Resp.

We adopt Petitioner’s definition as it is consistent with the level of ordinary skill in the art as reflected by the prior art in this proceeding. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown” (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755

F.2d 158, 163 (Fed. Cir. 1985))). To the extent the parties dispute the level of ordinary skill and its impact on the analysis of the challenged claims, we encourage the parties to address this issue further during trial.

Moreover, at this stage of the proceeding, we find that Drs. McConville and Bihovsky are qualified to opine from the perspective of a skilled artisan as both are persons of at least ordinary skill in the art, based on our adopted definition. *See* Ex. 1033 ¶¶ 3–15; Ex. 1034 ¶¶ 3–10.

### *B. Claim Construction*

The Board applies the same claim construction standard that would be used to construe the claims in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 42.200(b) (2021). Under that standard, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Petitioner states that “all terms should be given their plain and ordinary meaning.” Pet. 8. Patent Owner does not propose construction of any terms except for the language in the preamble of claims 1 and 32 reciting “[a] composition comprising an endoxifen and an enteric material.” Prelim. Resp. 5–9.

Having considered the parties’ positions and evidence of record, we determine there is a need to construe the term “[a] composition comprising an endoxifen and an enteric material” as recited in the claims of the ’391 patent to resolve the dispute between the parties, which we address below. We determine that the express construction of other claim terms are not necessary to determine whether to institute *inter partes* review. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed.

Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

1. *Scope of the term “[a] composition comprising an endoxifen and an enteric material”*

Both independent claim 1 and 32 of the ’391 patent recites “[a] composition comprising an endoxifen and an enteric material.” Ex. 1001, cl.1, cl.32. As noted above, Petitioner does not construe the term “enteric material,” except to note that “enteric material” is broader than the ’334 patent’s recitation of “enteric capsule.” Pet. 19.

Patent Owner attempts to distinguish the scope of the claims between the related ’334 patent and ’391 patent, where the claims of the ’334 patent recite a “an endoxifen composition encapsulated in an enteric capsule.” Prelim. Resp. 11. Patent Owner contrasts this with the scope of the claims of the ’391 patent and contends that the challenged claims are directed to “the underlying composition itself, where the enteric material is an ingredient of the composition combined with the endoxifen.” *Id.* To support its contentions, Patent Owner attempts to apply the doctrine of claim differentiation across patents, noting that

[t]he related ’334 describes a composition where the enteric requirement is not part of the composition, reciting “[a]n oral formulation comprising an **endoxifen composition encapsulated in an enteric capsule.**” EX2014, cl.1. In other words, the enteric aspect of the ’334 claims is not part of the composition itself. In contrast, the ’391 requires “[a] **composition comprising an endoxifen and an enteric material.**”

Prelim. Resp. 6–7. Additionally, Patent Owner argues that the claims of the ’391 patent “plainly require that the two named components—endoxifen and enteric material—be part of the same composition itself (a composition

which, in turn, can further be, e.g., formed into a tablet (claim 5), or formulated as, e.g., part of a suspension (as in claim 30)).” Prelim. Resp. 5.

Having considered the parties’ positions and evidence of record, summarized above, we find Petitioner to have the better position. The doctrine of claim differentiation creates a presumption that an independent claim differs in scope from a dependent claim, which, under 35 U.S.C. § 112(d), must be further limiting. *See Free Motion Fitness, Inc. v. Cybex Int’l, Inc.*, 423 F.3d 1343, 1351 (Fed. Cir. 2005) (“The doctrine of claim differentiation creates a presumption that each claim in a patent has a different scope.”); 35 U.S.C. § 112(d) (“a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed”). That presumption “is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004). Here, claims 1 and 32 of the ’391 patent recite “[a] composition comprising endoxifen and enteric material” and dependent claims 5 and 6, for example, further define the composition as a tablet (claim 5) or a capsule (claim 6). Thus, under the doctrine of claim differentiation, the recitation of “[a] composition comprising endoxifen and enteric material” must be broad enough to encompass a capsule, consistent with Petitioner’s interpretation. Pet. 19. Patent Owner, at this stage of the proceeding, does not attempt to distinguish the scope of claim 6 from the scope of the claims in the related ’334 patent, for example. The parties are encouraged to further develop this issue over the course of trial.

*C. Ground 1: Alleged Anticipation by Ahmad*

In Ground 1, Petitioner asserts that claims 1, 2, 4–6, 8, 9, 11–15, 20, 23, 26–37, and 40–44<sup>10</sup> of the '391 patent are anticipated by Ahmad. Pet. 19–37. Patent Owner opposes. Prelim. Resp. 30–40.

Having considered the evidence and argument presented by the parties, we determine Petitioner has shown it is more likely than not that the challenged claims are anticipated by Ahmad.

*1. Ahmad (Ex. 1003)*

Ahmad is a U.S. patent entitled “Endoxifen Compositions and Methods,” which issued on May 10, 2016. Ex. 1003, codes (54), (45). Ahmad describes “compositions containing endoxifen, formulations and liposomes of endoxifen, methods of preparation of such agents and formulations, and use of such agents and formulations for the treatment of breast cancer and other diseases susceptible to endoxifen.” Ex. 1003, Abstract. Ahmad explains that “[r]ecently, endoxifen has been shown to be anti-estrogenic in breast cancer cells and to be more potent than Tamoxifen,” which is a widely-used, anti-estrogenic drug prescribed for long-term, low-dose therapy of breast cancer. *Id.* at 1:64–66; *see also id.* at 1:36–39.

Ahmad describes methods of preparing a composition containing a therapeutically active amount of endoxifen in its free base or salt form. *Id.* at 2:21–26. Ahmad explains that the endoxifen can be crystallized and/or

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<sup>10</sup> The Identification of Grounds table in Section IV of the Petition also lists claim 3 as being challenged under Ground 1 as being anticipated by Ahmad; however, the analysis of this ground in the Petition does not include a discussion of claim 3. *See* Pet. 3, 19–37. Therefore, we do not consider claim 3 to be challenged under Ground 1 and do not discuss it in our analysis of Ground 1.

chromatographically treated to produce a purified preparation that contains predominantly E-isomer, predominantly Z-isomer, or a mixture of E- and Z-isomers of endoxifen. *Id.* at 3:55–61, 11:17–23 (“The separation of E- and Z-isomers of endoxifen in the present invention can be done, e.g., by crystallization, or purification by liquid chromatography (LC), or high pressure liquid column chromatography (HPLC).”). In some embodiments, the composition comprises a tablet or a filled capsule that optionally comprises an enteric coating material. *Id.* at 3:62–4:44.

Ahmad states that “[o]ne object of the present invention is to provide E-endoxifen or Z-endoxifen with at least 80% purity, such as at least 90% pure or at least 95% pure or at least 98% pure or at least 99% pure or at least 100% pure.” *Id.* at 12:14–17.

## 2. *Independent Claims 1 and 32*

Regarding claim 1, Petitioner asserts that Ahmad discloses each limitation of the claim. Pet. 19–23 (citing Ex. 1033 ¶¶ 54–60). For example, Petitioner asserts that Ahmad discloses “the endoxifen composition . . . of Formula (III)” as Ahmad “depicts the same chemical structure” (albeit depicted slightly differently). *Id.* at 22 (citing Ex. 1003, cover, Fig. 1). Petitioner also asserts that Ahmad discloses “at least 90% by weight of the compound of Formula (III) is (Z)-endoxifen” because Ahmad teaches that “[o]ne object of the present invention is to provide E-endoxifen or Z-endoxifen with at least 80% purity, such as at least 90% pure.” *Id.* at 23 (citing Ex. 1003, 12:14–17, 2:24–40, 3:55–61; Ex. 1033 ¶¶ 58–59). Ahmad further teaches that the purification can be accomplished using crystallization or chromatography. *Id.* (citing Ex. 1003, 11:17–23). Finally, Petitioner asserts that Ahmad discloses “endoxifen and an enteric material”

because Ahmad teaches that its formulations may be “encapsulated in enteric-coated capsules to protect it from acids in the stomach.” *Id.* at 20 (citing Ex. 1003, 18:19–21; Ex. 1033 ¶ 54).

Regarding claim 32, Petitioner asserts that claim 32 is anticipated by Ahmad for the same reasons as claim 1, because it recites a “method of delivering (Z)-endoxifen to a subject” comprising administering to the subject a composition that is identical to the oral formulation of claim 1. Pet. 25 (citing Ex. 1033 ¶¶ 62–63; Ex. 1003, 18:1–7 (disclosing administering orally)). For example, Ahmad discloses “methods for treating and preventing breast cancer and other breast related diseases by administering novel formulations or compositions comprising a therapeutically effective amount of endoxifen.” *Id.* (citing Ex. 1003, Abstract, 19:27–30).

Patent Owner relies on its claim construction of claims 1 and 32 to distinguish the preamble language reciting “[a] composition comprising an endoxifen and an enteric material” from Ahmad. Prelim. Resp. 13–16. Specifically, Patent Owner contends that Petitioner’s arguments rely on Ahmad’s alleged disclosure of endoxifen encapsulated in enteric-coated capsules. *Id.* at 14. For example, Patent Owner contends that “every portion of Ahmad relied upon by Petitioner describes a ‘composition containing endoxifen’ that can then be coated with a separate external ‘enteric coating.’” *Id.* at 15. Patent Owner further contends that

these disclosures ***fail to disclose an enteric material that is a component (with endoxifen) of the composition itself.*** At most, these disclosures purport to describe (1) a pharmaceutical composition of endoxifen (2) encapsulating the finished composition in a separate 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.”).

Prelim. Resp. 15. Patent Owner therefore concludes that “Petitioner identifies no teaching in Ahmad that the enteric material is a component of the endoxifen composition, as claimed.” *Id.* at 16.

Based on our preliminary construction of the term, “[a] composition comprising an endoxifen and an enteric material” discussed above, and, having considered the arguments and evidence presented by the parties at this stage of the proceeding, summarized above, we find that Petitioner has shown it is more likely than not that Ahmad discloses each limitation of claims 1 and 32 for the reasons stated in the Petition, which we adopt for purposes of this Decision. *See* Pet. 19–25; Ex. 1003, 2:24–40, 3:55–61, 8:47–63, 9:1–20, 11:17–23, 12:14–17, 18:19–29, 19:27–30; Ex. 1033 ¶¶ 54–64. Accordingly, we find Petitioner has shown that it is more likely than not that claims 1 and 32 are anticipated by Ahmad.

#### IV. CONCLUSION

Upon consideration of the evidence and arguments in the record, we determine that the information presented shows that it is more likely than not that Petitioner would prevail with respect to at least one of the challenged claims. We thus institute a post-grant review on all challenged claims on all asserted grounds. 37 C.F.R. § 42.208(a) (“When instituting post-grant review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.”); *SAS Inst. Inc. v. Iancu*, 584 U.S. 357, 362–63, 369–70 (2018).

Our determination in this Decision is not a final determination on the patentability of the challenged claims and, thus, leaves undecided any factual issues necessary to determine whether sufficient evidence supports

Petitioner's contentions by a preponderance of the evidence in the final written decision. Patent Owner is cautioned that any argument not raised in a timely Patent Owner Response to the Petition, or as permitted in another manner during trial, shall be deemed waived even if asserted in the Preliminary Response. *See In re Google Tech. Holdings LLC*, 980 F.3d 858, 862–64 (Fed. Cir. 2020) (holding an argument forfeited when not timely raised before the Board); *In re NuVasive, Inc.*, 842 F.3d 1376, 1380–81 (Fed. Cir. 2016) (holding Patent Owner waived an argument addressed in the Preliminary Response by not raising the same argument in the Patent Owner Response).

#### V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 324(a), a post-grant review of claims 1–44 of the '391 patent is *instituted* with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 324(c) and 37 C.F.R. § 42.4(b), post-grant review of the '391 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

PGR2025-00043  
Patent 12,071,391 B2

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