

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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IPR2025-00799  
Patent 11,261,151 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 *Inter Partes* Review  
35 U.S.C. § 314; 37 C.F.R. § 42.4

## I. INTRODUCTION

### *A. Background and Summary*

Intas Pharmaceuticals Ltd. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–21 of U.S. Patent No. 11,261,151 (“the ’151 patent,” Ex. 1001). Paper 2 (“Pet.”). Atossa Therapeutics, Inc (“Patent Owner”) filed a Preliminary Response. Paper 9.

Patent Owner filed a brief regarding Discretionary Denial. Paper 7 (Paper 8, redacted version). Petitioner filed an opposition to the Discretionary Denial Brief. Paper 10 (Paper 11, redacted version). Patent Owner filed a reply to Petitioner’s opposition to the Discretionary Denial Brief. Paper 11. After considering the parties’ arguments and the record, the Acting Director determined that discretionary denial was not appropriate and referred the Petition to the Board. Paper 12.

To institute an *inter partes* review, we must determine that the information presented in the Petition shows “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a) (2018). The Supreme Court has held that a decision to institute under 35 U.S.C. § 314 may not institute on less than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). After considering the information presented in the Petition and Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least 1 of the challenged claims of the ’151 patent is unpatentable.

*B. 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. 2. Petitioner also asserts 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.

Pet. 2.

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

*C. Related Matters*

Petitioner has filed petitions in PGR2023-00043 (US 11,572,334, a continuation of the '151 patent) and PGR2025-00043 (US 12,071,391, a continuation of the '151 patent). Pet. 2; Paper 4, 1.

The parties dispute whether collateral estoppel applies in this proceeding based on the Final Written Decision of PGR2023-00043. Pet. 24–25; Prelim. Resp. 35. Petitioner contends that many of the claims of the '151 patent present the same factual inquiries as those determined by the Board in PGR2023-00043. Pet. 25. Petitioner further contends that the same issues were actually litigated in PGR2023-00043, 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. *Id.* Patent Owner disagrees. Prelim. Resp. 35–37.

On the current record, we tend to agree with Patent Owner that the issues presented in this proceeding concern Liu's alleged inherency and the Form I or XRPD limitations recited in the challenged claims, which are

issues that are not identical to issues presented in the anticipation and obviousness grounds asserted in PGR2023-00043. Prelim. Resp. 35. That said, the parties are invited to address the issue of whether collateral estoppel applies in this proceeding based on the Final Written Decision of PGR2023-00043 during trial. Regardless of whether collateral estoppel applies, however, we determine for the reasons below that Petitioner shows a reasonable likelihood of prevailing in its challenge that at least 1 of the challenged claims of the '151 patent is unpatentable.

*D. The '151 patent (Ex. 1001)*

The '151 Patent, entitled “Methods for Making and Using Endoxifen,” issued on March 1, 2022, and claims the benefit of several continuation and provisional applications, the earliest of which was filed on September 11, 2017. Ex. 1001, codes [45], [54], [60]. According to the Abstract, the '151 Patent “provides industrially scalable methods of making (Z)-endoxifen or a salt thereof, crystalline forms<sup>1</sup> of endoxifen, and compositions comprising them,” as well as “methods for treating hormone-dependent breast and hormone-dependent reproductive tract disorders.” *Id.*, Abstract. The '151 Patent discloses polymorphic Form I of a compound of Formula (III), where Figure 10 “is an XRPD pattern obtained from a sample of Form I of the compound of Formula (III).” *Id.* at 11:62–63, 30:45–55, Fig. 10.

Endoxifen is the active metabolite of tamoxifen, a selective estrogen receptor modulator that is used to treat endocrine responsive breast cancer,

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<sup>1</sup> The Specification states that “[t]he terms ‘crystalline form’, ‘polymorph’ and ‘Form’ may be used interchangeably herein, and are meant to include all crystalline and amorphous forms of the compound . . . .” Ex. 1001, 12:60–63.

i.e., hormone-dependent or hormone-sensitive breast cancer. *Id.* at 1:61–2:9. According to the ’151 Patent Specification, “[i]t is widely accepted that (Z)-endoxifen is the main active metabolite responsible for the clinical efficacy of tamoxifen.” *Id.* at 2:36–38. “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 2:5–21. Accordingly, the Specification states that several alternatives to tamoxifen are being developed for treating breast cancer. *Id.* at 2:22–24.

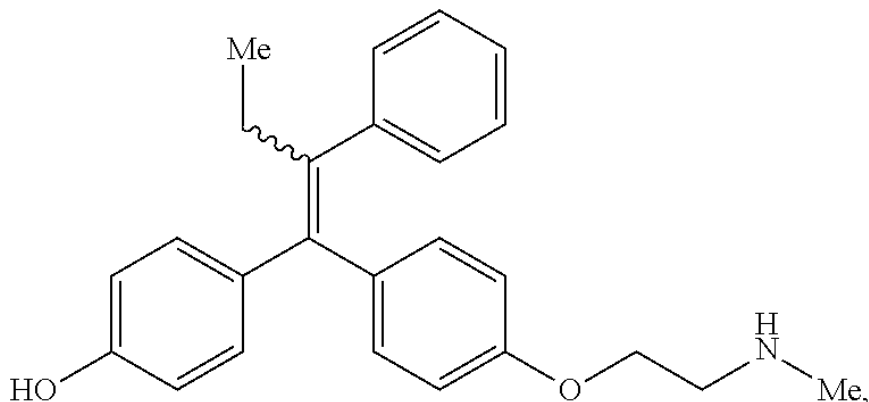
The ’151 Patent states that although hydrochloride and citrate salts of endoxifen are known in the art and being evaluated for metastatic cancer, “there remains [an] unmet medical need for new compositions and methods for the treatment and/or prevention of hormone-dependent breast and reproductive tract (gynecologic) disorders.” *Id.* at 2:50–53.

#### *E. The Challenged Claims*

Petitioner challenges claims 1–21 of the ’151 Patent, of which claims 1 and 16 are independent. Claims 1 and 16 are illustrative and are reproduced below:

1. A composition comprising a crystalline form of a compound of Formula (III):

Formula (III)

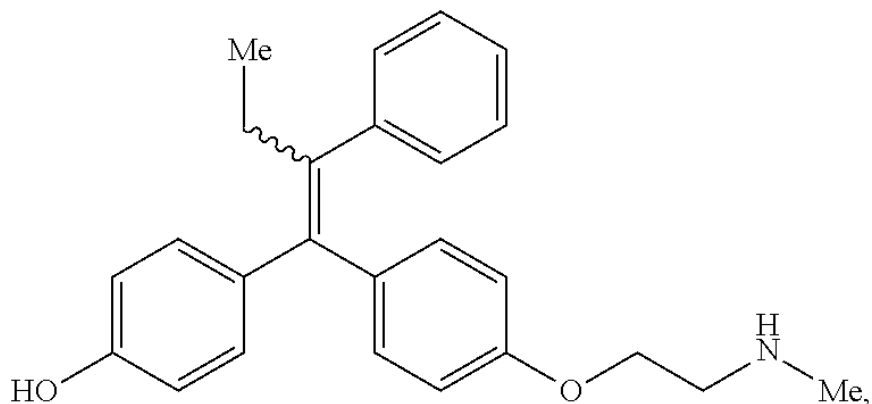


wherein at least 90% by weight of the compound of Formula (III) in the composition is the (Z)-isomer, and wherein the crystalline form of the (Z)-isomer is Form I, characterized by an x-ray powder diffraction pattern comprising major peaks at  $16.8 \pm 0.3^\circ$ ,  $17.1 \pm 0.3^\circ$  and  $21.8 \pm 0.3^\circ$  two theta.

Ex. 1001, 98:28–50.

16. A method of treating a hormone-dependent breast disorder or a hormone-dependent reproductive tract disorder in a subject, the method comprising administering to the subject a composition comprising a crystalline form of a compound of Formula (III):

Formula (III)



wherein at least 90% by weight of the compound of

Formula (III) in the composition is the (Z)-isomer, and wherein the crystalline form of the (Z)-isomer is Form I, characterized by an x-ray powder diffraction pattern comprising major peaks at  $16.8 \pm 0.3^\circ$ ,  $17.1 \pm 0.3^\circ$  and  $21.8 \pm 0.3^\circ$  two theta, thereby treating the hormone-dependent breast disorder or the hormone-dependent reproductive tract disorder.

*Id.* at 100:1–26. Claims 2–15 depend directly or indirectly from claim 1. *Id.* at 98:51–99:46. Claims 17–21 depend directly or indirectly from claim 16. *Id.* at 100:27–44.

*F. Asserted Grounds of Unpatentability*

Petitioner asserts that claims 1–21 would have been unpatentable on the following grounds:

| Ground | Claim(s)<br>Challenged | 35 U.S.C. § <sup>2</sup> | Reference(s)/Basis      |
|--------|------------------------|--------------------------|-------------------------|
| 1      | 1–6, 16, 18,<br>21     | 102                      | Liu <sup>3</sup>        |
| 2      | 1–21                   | 103                      | Liu, Ahmad <sup>4</sup> |

Petitioner relies on the Declarations of Jason McConville, Ph.D. (Ex. 1032), Ron Bihovsky, Ph.D. (Ex. 1033), and Steven Miller, Ph.D. (Ex. 1034) to support its asserted grounds of unpatentability.

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<sup>2</sup> The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the application leading to the ’151 patent claims priority to an application filed after March 16, 2013, we apply the AIA version of 35 U.S.C. §§ 102 and 103.

<sup>3</sup> Ex. 1003, Liu, WO 2017/070651, published April 27, 2017 (“Liu”).

<sup>4</sup> Ex. 1004, Ahmad et al., US 9,333,190, issued May 10, 2016 (“Ahmad”).

*G. Claim Construction*

We interpret a claim “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b) (2019). Under this standard, we construe the claim “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.*

Petitioner states that “all terms should be given their plain and ordinary meaning.” Pet. 10. Patent Owner does not propose construction of any terms. *See generally* Prelim. Resp.

Having considered the parties’ positions and evidence of record, we determine that no express construction of any claim term is 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))).

*H. Level 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, material science, 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. 9. 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.*

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, Bihovsky, and Miller are qualified to opine from the perspective of a skilled artisan as they all are persons of at least ordinary skill in the art, based on our adopted definition. *See* Ex. 1032 ¶¶ 3–15; Ex. 1033 ¶¶ 3–10; Ex. 1034 ¶¶ 3–7.

## II. ANALYSIS

### *A. Ground 1: Asserted Anticipation of Claims 1–6, 16, 18 and 21*

Petitioner asserts that Liu anticipates claims 1–6, 16, 18 and 21. Pet. 25–37. To support its contentions, Petitioner directs our attention to the disclosure of Liu and provides a detailed claim analysis addressing how Liu discloses each element of claims 1–6, 16, 18 and 21. *Id.* (citing Ex. 1032; Ex. 1033; Ex. 1034). Patent Owner disagrees and contends that Petitioner fails to establish that Liu inherently discloses each element of independent claims 1 and 16. Prelim. Resp. 8–26.

In view of the following, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on this ground. We begin with a summary of Liu.

*1. Summary of Liu (Ex. 1003)*

Liu is an international patent application publication titled “Process for Preparing (Z)-Endoxifen of High Purity.” Ex. 1003, 1. Liu teaches that “Endoxifen exists as two forms, E and Z, with the Z form more active at the estrogen receptor” and that “there is a need in the art for a practical, scalable synthesis that gives access to highly pure (Z)-endoxifen.” *Id.* at ¶ 4.

Liu discloses multi-step protocols for synthesizing (Z)-endoxifen. *Id.* at 19–55, 56–59, 61–77. For example, Liu discloses a first recrystallization step, which “can be carried out in a first solvent in which the E isomer (2) crystallizes well and is significantly less soluble than the Z isomer (1).” *Id.* at ¶ 21. Liu discloses that it “has been unexpectedly discovered that toluene, isopropyl acetate, methyl ethyl ketone, and methyl isobutyl ketone are particularly useful first solvents for carrying out this step, with isopropyl acetate particularly preferred.” *Id.*

“The second step (ii) in the disclosed process is recrystallizing a solid produced by concentrating the first mother liquor, or by removal of the first solvent from the first mother liquor, from a second solvent to give a second crystalline solid and a second mother liquor.” *Id.* at ¶ 25. “Generally, this recrystallizing can be carried out in a second solvent in which the Z isomer (1) crystallizes well and in which enrichment of the Z isomer can be increased upon crystallization.” *Id.* at ¶ 26. “It has been unexpectedly discovered that acetone is a particularly useful second solvent for carrying out this step.” *Id.*

“The third step (iii) is optionally recrystallizing the second crystalline solid from the second solvent one or more additional times to give a third crystalline solid, wherein the third crystalline solid has a ratio of (Z)-endoxifen (1) to (E)-endoxifen (2) greater than 20:1.” Ex. 1003 ¶ 28.

Liu further teaches that (Z)-endoxifen can be prepared via isomerization of (E)-endoxifen (or a mixture of (E)- and (Z)-endoxifen) followed by recrystallizations. *Id.* at ¶¶ 46–55.

Liu teaches that its method achieved “1698 g (34%) of (Z)-endoxifen, with an isomeric purity of 99% (HPLC analysis).” *Id.* at ¶ 76.

## *2. Independent claims 1 and 16*

### *a) Petitioner’s Contentions*

Both independent claims 1 and 16 of the ’151 patent require a composition wherein “the crystalline form of the (Z)-isomer is Form I.” Ex. 1001, claims 1 and 16. Petitioner acknowledges that Liu does not expressly disclose the claimed Form I of (Z)-endoxifen or provide an XRPD characterization of the resulting crystalline solids. Pet. 29. Rather, Petitioner contends that “Liu inherently teaches the claimed Form I of (Z)-endoxifen.” *Id.* To support its contention, Petitioner relies on the declarations of Dr. Bihovsky and Dr. Miller, where Dr. Bihovsky reproduced Liu’s synthesis and crystallization procedures to purify (Z)-endoxifen from a mixture of (E)- and (Z)-endoxifen and sent the resulting crystals to Dr. Miller for XRPD testing. *Id.* at 27–29 (citing Ex. 1003 ¶¶ 73–76; Ex. 1033 ¶¶ 43–77; Ex. 1034 ¶¶ 23–25, 29). Petitioner contends that Dr. Bihovsky successfully produced crystalline solids of (Z)-endoxifen following Liu’s recrystallization and Liu’s isomerization/recrystallization procedures that exhibited XRPD patterns consistent with the claims of the

'151 patent. *Id.* at 29 (citing Ex. 1034 ¶¶ 23–25, 29–31). Dr. Bihovsky testifies that by following Liu's purification scheme, he was able to achieve (Z)-endoxifen with 93% isomeric purity. Ex. 1033 ¶¶ 71–72. Thus, according to Petitioner, Liu inherently teaches the claimed Form I of (Z)-endoxifen with greater than 90% purity and characterized by an XRPD comprising major peaks at  $16.8 \pm 0.3^\circ$ ,  $17.1 \pm 0.3^\circ$  and  $21.8 \pm 0.3^\circ$  two theta. *Id.* at 27–29; Ex. 1034 ¶ 31; Ex. 1033 ¶¶ 43, 71–72.

*b) Patent Owner's Contentions*

Patent Owner presents detailed argument that challenges Petitioner's assertion that Liu's process necessarily, unavoidably, and inevitably results in the Form I polymorph of (Z)-endoxifen as required by the claims of the '151 patent. Prelim. Resp. 8–26 (citing *In re Montgomery*, 677 F.3d 1375, 1380 (Fed. Cir. 2012) (“The inherent result **must inevitably result** from the disclosed steps . . .”); *Millennium Pharms., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1367 (Fed. Cir. 2017) (“fact that a certain thing **may** result” is insufficient (quoting *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981))); *Azurity Pharms., Inc. v. Exelixis Inc.*, IPR2025-00210, Pap.11, 28 (June 4, 2025) (“That is not, however, the standard for inherency. It **must be the necessary result, not a possible expected result.**”); *Celltrion, Inc. v. Chugai Seiyaku Kabushiki Kaisha*, IPR2022-00579, Pap.72, 27 (Aug. 29, 2023) (“A reference may anticipate inherently if a claim limitation that is not expressly disclosed ‘is **necessarily present**, or inherent, in the single anticipating reference.’”) (quoting *Verizon Servs. Corp. v. Cox Fibernet Va., Inc.*, 602 F.3d 1325, 1337 (Fed. Cir. 2010)); *Arbutus Biopharma Corp. v. Modernatx, Inc.*, 65 F.4th 656, 662 (Fed. Cir. 2023) (“A limitation is inherent if it is the ‘**natural result flowing from**’ the prior art's explicit disclosure.”) (citations

omitted); *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1383 (Fed. Cir. 2009) (holding that the “very essence of inherency is that one of ordinary skill in the art would recognize that a reference **unavoidably teaches** the property in question”); *PersonalWeb Techs., LLC v. Apple, Inc.*, 917 F.3d 1376, 1382 (Fed. Cir. 2019) (“The mere fact that a certain thing **may** result from a given set of circumstances is not sufficient.”) (quoting *PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1195 (Fed. Cir. 2014))).

Notably, Patent Owner contends that “Petitioner and all three of its experts concede that Liu fails to disclose the claimed Form I with the x-ray powder diffraction pattern.” Prelim. Resp. 10 (citing Pet. 29; Ex. 1032 ¶ 65; Ex. 1033 ¶ 33; Ex. 1034 ¶ 29). Patent Owner further contends that Dr. Bihovsky’s modified reproduction of Liu is legally insufficient to establish inherency. *Id.* at 11–26. In particular, Patent Owner contends that Dr. Bihovsky did not follow Liu’s recrystallization and Liu’s isomerization/recrystallization procedures, but rather “modified Liu, filled in gaps, and made choices among various available implementation options in Liu’s disclosure.” *Id.* at 11 (emphasis omitted). Patent Owner contends that there are nine instances where Dr. Bihovsky did not follow Liu’s procedure as written. *Id.* at 12–18. For example, Liu specifies that a particular reaction was performed under argon atmosphere, while Dr. Bihovsky chose to perform the reaction under a nitrogen atmosphere. *Id.* at 14 (citing Ex. 1033 ¶ 54n.5); Ex. 1003 ¶ 65. Patent Owner notes that while Dr. Bihovsky testifies that certain changes would have no effect on the final crystal form (*see, e.g.*, Ex. 1033 ¶ 54n.5), he fails to cite evidence or provide more than a conclusory explanation for why his modifications would not alter the results achieved in Liu. Prelim. Resp. 19–23.

Moreover, Patent Owner contends that Dr. Bihovsky's lab notebook entries show that certain samples produced in his experiments were shown not to be Form I. *Id.* at 24–25 (citing Ex. 1033, 89, 91). Patent Owner contends that “neither Petitioner nor any of its three experts make any attempt to explain or even acknowledge these failed results, which are conspicuously omitted from the declarations’ main text and buried only in an appendix.” *Id.* at 25 (emphasis omitted).

*c) Discussion*

A claim to a specific polymorph is not inherently anticipated by a prior art reference describing a process that does not always result in the polymorph. *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047–48 (Fed. Cir. 1995); *see also In re Armodafinil Pat. Litig. Inc.* (’722 Pat. Litig.), 939 F. Supp. 2d 456, 465 (D. Del. 2013) (citing *Glaxo*, 52 F.3d at 1047-48) (finding no inherent anticipation where testing evidence demonstrated that the prior art example could yield crystals of either the claimed polymorph or a different polymorph).

We have considered Patent Owner's arguments that Dr. Bihovsky's alleged “modified reproduction” of Liu's recrystallization and isomerization/recrystallization procedures cannot support a determination that Liu inherently anticipates the challenged claims. On this record, however, we are persuaded that Petitioner has sufficiently shown, for purposes of this decision, that Liu inherently discloses the subject matter of independent claims 1 and 16. Petitioner relies on the declaration of Dr. Bihovsky, who testifies that he reproduced the methods of synthesis and purification of (Z)-endoxifen taught by Liu, and that in his opinion, the methods described by Liu “would have been routine and well within the skill

of a POSA . . . to follow Liu and synthesize 90% (Z)-endoxifen” without “extraordinary skill or undue experimentation.” Ex. 1033 ¶ 44–45. As noted by Patent Owner, Dr. Bihovsky acknowledged that he made “minor adjustments” compared to the procedure disclosed in Liu. *Id.* at 47. Dr. Bihovsky testifies, however, that

Each of these adjustments were routine adjustments a POSA following Liu would have likely made. In my opinion, none of the modifications had any impact on the resulting crystalline solids. Importantly, the polymorphic form that a crystal adopts is driven by the final crystallization of the material. With respect to Liu’s crystallization of a mixture of (E)- and (Z)-endoxifen to produce greater than 90% (Z)-endoxifen, I followed Liu extremely closely. Thus, to the extent that I made any adjustments compared to the large-scale synthetic protocols described in Liu’s Examples, these adjustments did not impact the final crystalline form of (Z)-endoxifen (e.g., “Form I”).

Ex. 1033 ¶ 47.

Patent Owner’s arguments may have merit; however, its arguments are largely unsupported on the current record. For example, we acknowledge Patent Owner’s argument that Dr. Bihovsky’s experimental lab notebook identifies certain samples as “XRPD – Not Form I,” however, the current record lacks sufficient information for us to discern what those samples represent. That is, on the current record, we are unable to conclude that the referenced samples are evidence of attempts at following Liu’s process resulting in a polymorph other than Form I.

Accordingly, upon review of the contentions of Petitioner, and of the evidence offered in support thereof, we are persuaded that Petitioner has established a reasonable likelihood of prevailing in showing that claims 1 and 16 of the ’151 patent are anticipated by Liu.

*3. Dependent claims 2–6, 18 and 21*

Petitioner also identifies where Liu discloses the limitations of dependent claims 2–6, 18 and 21 of the '151 patent. Pet. 30–37. In support of these arguments, Petitioner provides a detailed analysis of the disclosure of Liu, as well the supporting testimony of Dr. Bihovsky (Ex. 1033) and Dr. Miller (Ex. 1034). *Id.*

Patent Owner does not address Petitioner's specific arguments with respect to claims 2–6, 18 and 21. *See generally*, Prelim. Resp.

Upon review of Petitioner's arguments, as well as Dr. Bihovsky's and Dr. Miller's supporting testimony, we determine that Petitioner has identified sufficiently the manner in which Liu inherently discloses every limitation of dependent claims 2–6, 18 and 21. Thus, Petitioner has demonstrated a reasonable likelihood that these claims are anticipated by Liu.

*4. Conclusion*

Having considered the parties positions and evidence of record, summarized above, we determine that Petitioner has established a reasonable likelihood of prevailing in demonstrating the unpatentability of claims 1–6, 16, 18 and 21 with respect to Ground 1.

III. CONCLUSION

After considering the evidence and arguments presented in the current record, we determine that Petitioner has demonstrated a reasonable likelihood of success in establishing that at least one challenged claim of the '151 patent is unpatentable. We therefore institute trial on all challenged claims under the grounds raised in the Petition. 37 C.F.R. § 42.108(a); *see also PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018)

(indicating that a decision whether to institute an *inter partes* review “require[s] a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition”) (citing *SAS*, 138 S. Ct. at 1355).

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. *See TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting in the context of an *inter partes* review that “there is a significant difference between a petitioner’s burden to establish a ‘reasonable likelihood of success’ at institution, and actually proving invalidity by a preponderance of the evidence at trial”) (quoting 35 U.S.C. § 314(a) and comparing § 316(e)).

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).

#### IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–21 of the '151 patent is instituted with respect to the grounds set forth in the Petition; and

FURTHER ORDERED, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), that the *inter partes* review of the '151 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

IPR2025-00799  
Patent 11,261,151 B2

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