

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ATOSSA THERAPEUTICS, INC.,

Petitioner,

v.

JINA PHARMACEUTICALS, INC.,

Patent Owner.

Case PGR2026-00015

Patent No. 12,245,997

**PATENT OWNER'S AMENDED REQUEST FOR
DISCRETIONARY DENIAL OF INSTITUTION**

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I. INTRODUCTION

By its own admission, Petitioner's "business is focused on the treatment and prevention of breast cancer." IPR2025-00799, Paper 8 at 2. In contrast, the Challenged Claims are directed to a "method . . . for treatment of a patient with bipolar I disorder." Ex. 1001 at 3 (4:2-64). In no way, do these claims read on methods of treating breast cancer. Petitioner does not identify any concrete risk of infringement litigation arising from the Challenged Claims. The Board has recognized that PTAB proceedings should "not [be] used as a tool for harassment or litigation gamesmanship." *Johnson Health Tech. Co. v. Icon Health & Fitness, Inc.*, IPR2014-01242, Paper 16 at 3 (PTAB Feb. 11, 2015) (citing H.R. REP. NO. 112-98 at 48, as reprinted in 2011 U.S.C.C.A.N. at 78). Contrary to the Board's admonishment, the Petition does not identify any competitive or litigation concern that would warrant review.¹

¹ PO's development partner, Intas Pharmaceuticals Ltd., has challenged the validity of several patents owned by Petitioner. *See e.g.*, PGR2025-00043. However, unlike the claims here that are directed to a "method of treating patients with bipolar I disorder with endoxifen, Petitioner's claims are directed to all compositions of endoxifen and seek to preempt every use of endoxifen. Intas challenged those claims

And while early challenges weigh against discretionary denial, as explained below Petitioner simply rehashes rejected anticipation arguments and “Petitioner does not provide any persuasive reasoning why an [post grant] review is an appropriate use of Board resources.” *Dabico Airport Sols. Inc. v. AXA Power ApS*, IPR2025-00408, Paper 21 at 2–3 (Director June 18, 2025). Denying this Petition would further the goals of “maintain[ing] PTAB capacity to conduct AIA proceedings, reduc[ing] pendency in *ex parte* appeals,” and discourage duplicative or unnecessary proceedings.

II. DISCRETIONARY DENIAL IS APPROPRIATE UNDER 35 U.S.C. § 325(d)

Regarding anticipation ground 4, there can be no dispute that the Petition raises the very identical issues thoroughly examined during prosecution.

In considering institution denial under 35 U.S.C. § 325(d), the Board applies a two-part framework to determine: “(1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of [the] first part of the framework is satisfied, whether the Petitioner has

so that development could continue of methods of treating patients with bipolar I disorder using endoxifen.

demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13, 2020).

To apply this framework, the *Becton, Dickinson* (“BD”) factors “provide useful insight.” *Id.* at 9-10; *see also Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18 (P.T.A.B. Dec. 15, 2017).

“[BD] factors (a), (b), and (d) relate to the first part of the *Advanced Bionics* framework (whether the same or substantially the same art or arguments previously were presented to the Office), and [BD] factors (c), (e), and (f) relate to the second part of that framework (previous Office error).” *Autel Intelligent Technology Corp., Ltd., v. Orange Electronic Co., Ltd.*, IPR2021-01545, Paper 8 at 13 (P.T.A.B. Apr. 8, 2022). “If a condition in the first part of the framework is satisfied and the petitioner fails to make a showing of material error, the Director generally will exercise discretion not to institute inter partes review.” *Advanced Bionics*, IPR2019-01469, Paper 6 at 8-9.

A. The First *Advanced Bionics* Factor Is Met Because Petitioners’ References are the Same as the Prior Art Previously Presented to the Office

The application that issued as the 997 Patent was thoroughly examined by the Office. Indeed, the application was pending before the Office for *over three years*, and the claims of the application were rejected *no fewer than seven times* (three

non-final office action (“NFOA”) rejections, two final office action (“FOA”) rejections, and two advisory action rejections). *See* Ex. 1002. During the course of prosecution, the applicant submitted several references, including Ex. 1004 (“Ahmad”), which the Examiner considered extensively. *See* Ex. 1001 at 1. In the first NFOA and the first FOA, the Examiner rejected the claims as anticipated by or obvious over Ex. 1004. *See id.* at 502-532, 490-500. In the second NFOA, the Examiner rejected the claims as anticipated by Ex. 1004 and obvious over Ex. 1004 in view of Ali. *See id.* at 437-450. In the second FOA, the Examiner rejected the claims as obvious over Ex. 1004 in view of Ali. In the third NFOA, the Examiner rejected the claims as obvious over Ex. 1004 in view of WO 2008/048194 (“Yesilogluz”).

To argue anticipation, the Petition relies on Ex. 1004 (“Ahmad”). Thus, “the same ... art ... previously was presented to the Office.” Further, there is no daylight “between the arguments made during examination” and the arguments made in the Petition. By way of example, in the first NFOA, the examiner alleged that Ex. 1004 anticipated claim 1 and more specifically that “Ahmad teaches effectiveness of endoxifen 4 mg and 8 mg in alleviating depressive symptoms of mixed episode of BPD similar to that of divalproex (p 256, col.1 & Table 2) (claim 1).” Ex. 1002 at 168-169. The Petition parrots the same portions of Ex. 1004 when arguing that claim 1 is anticipated by Ex. 1004. Paper 1 at 77.

As another example, with regard to Element 1.b that recites, “wherein the method does not include a rescue medication for the treatment of the bipolar I disorder[,]” the Petition argues that “Ahmad 2016 teaches that ‘[a]ll psychotropic medications except benzodiazepines (lorazepam/diazepam only) were discontinued at least 2 days before randomization,’ and that ‘[b]enzodiazepines (lorazepam-/diazepam only) (up to 5 mg/day, preferably in divided doses) were allowed as adjunctive medication as needed at the discretion of the investigator from 2 days prior to randomization but not beyond the first 10 days of investigational medicinal product dosing.’” Paper 1 at 80 (citing Ex. 1004 at 3).

This argument is the same argument that the examiner made with respect to this claim limitation. Specifically, that “Ahmad teaches concomitant medications such as lorazepam have been discontinued before treatment and thus meet the instant claim limitation.” Ex. 1002 at 218. Thus, Petitioner simply makes materially the same arguments that were made during examination.

Based on the foregoing, the record demonstrates that there are no “differences between the asserted art and the prior art involved during examination,” (BD factor (a)), which means that “the asserted art and the prior art evaluated during examination” is “cumulative” (BD factor (b)), and there is extensive “overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art[.]” (BD factor (d)).

As the Director has stated, “the first part of the *Advanced Bionics* framework is satisfied if either substantially the same prior art or substantially the same arguments were previously presented to the Office.” *Nokia of America Corp. v. Alexander Soto and Walter Soto*, IPR2023-00680, Paper 18 at 4 (PTAB Mar. 4, 2024) (Director Review). The record demonstrates both elements.

B. Petitioners Have Not Shown the Office Erred Materially

Because the first part of the *Advanced Bionics* framework is satisfied, Petitioners are required to show that the Office erred in a manner material to the patentability of the Challenged Claims. In doing so, Petitioners “must explain, ‘with reference to Becton, Dickinson factors (c), (e), and (f), how the Examiner erred in overlooking the prior art’ and ‘if the Examiner applied the asserted prior art or substantially the same prior art during examination, then a petitioner must demonstrate that...the previously presented art teaches the limitations of the challenged claims, and that no reasonable examiner could have found otherwise.’” *Ecto World*, Paper 13 at 5-6; *see also Advanced Bionics*, Paper 6 at 9 (“If reasonable minds can disagree regarding the purported treatment of the arts or arguments, it cannot be said that the Office erred in a manner material to patentability.”). Petitioners have made no effort to meet this burden and cannot meet it.

Regarding BD Factor (c) – the extent to which the asserted art was evaluated during examination – the Examiner thoroughly examined the claims of the 997

Patent, issuing multiple NFOAs and FOAs. As part of that thorough examination, the Examiner considered Ex. 1004.

Regarding BD Factor (e), Petitioner retreads the same arguments that the Examiner made during examination. Accordingly, Petitioner cannot credibly argue that the Examiner erred in evaluating Ex. 1004 or the other art of record that is cumulative of Ex. 1004 – despite having the burden of doing so. *Nespresso USA, Inc. v. K-Fee Sys. GmbH*, IPR2021-01223, Paper 9 at 29 (P.T.A.B. Jan. 18, 2022) (“Petitioner bears the burden of showing that the Office erred”). That alone is sufficient to deny institution. *See Sony Interactive Entm’t LLC v. Terminal Reality, Inc.*, IPR2020-00711, Paper 15 at 11-12 (P.T.A.B. Oct. 13, 2020) (denying institution under § 325(d) where Petitioner was silent on BD Factors (e) and (f)).

Finally, regarding BD Factor (f), the Board “look[s] for some explanation of how or why ‘the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.’” *Nespresso*, Paper 9 at 30. Here, Petitioner points to no additional evidence or facts in the Petition that warrant a do-over based on Petitioner’s duplicative art.

Denial is therefore appropriate under the *Advanced Bionics* framework.

III. WEAKNESS OF THE WRITTEN DESCRIPTION GROUND COUNSELS IN FAVOR OF DENIAL

Having failed to present any viable prior art unpatentability position, Petitioner relies on equally deficient grounds under 35 U.S.C. § 112.

The written description requirement of 35 U.S.C. § 112, ¶ 1 provides that “[t]he specification shall contain a written description of the invention.” 35 U.S.C. §112. “The essence of the written description requirement is that a patent applicant . . . must describe his or her invention so that the public will know what it is and that he or she has truly made the claimed invention.” *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1298 (Fed. Cir. 2014). However, “written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010).

Petitioner spills much ink arguing that the specification lacks actual reduction to practice. However, Petitioner does not meaningfully address whether the specification identifies the claimed invention with reasonable clarity. Because Petitioner bears the burden of proving invalidity and Petitioner failed to demonstrate that the specification does not provides a “constructive reduction to practice,” the Board should reject the written description challenges.

A. Petitioner's argument that there is no written description support for a method for "treatment of a patient with bipolar I disorder," "wherein the method does not include a rescue medication" fails as a matter of law

The relevant claim limitation recites "wherein the method does not include a rescue medication for the treatment of the bipolar I disorder." The specification defines rescue medication as "an additional medication necessary to treat breakthrough or recurring symptoms." Ex. 1001 at 3 (3:42-44). With this definition, the claim limitation recites "wherein the method does not include an additional medication necessary to treat breakthrough or recurring symptoms."

While Petitioner admits that the specification describes a trial where "no rescue medications were administered to any of the patients," (Ex. 1001 at 3 (4:57-59)), Petitioner complains that this legally does not meet the written description requirement because a "POSITA reading the specification would not have understood the description of this trial to be conveying that it positively excluded (prospectively prohibited) all rescue medication as the claims require." Paper 1 at 41. First, assuming *arguendo* that Petitioner's interpretation of "the description of the trial" is correct, Petitioner provides no legal support for the seemingly novel proposition that a negative limitation in a claim directed to a method of treatment has written description support if and only if the specification discloses a clinical study where the negative limitation is "prospectively forbidden" "during treatment."

Second, Petitioner's argument that there is no written description support because the specification does not explicitly disclaim a method where a rescue medication is included does not square with the law. *See* Paper 1 at 40 (arguing that statement in the specification "is not a statement that rescue medication were positively (prospectively) prohibited."); *see also id.* at 39 (asserting that "passage . . . does not convey to POSITA that PO possessed the claimed method in which rescue medication is completely positively excluded.") (citing Ex. 1001 at 3 (3:42-46)). The limitation is properly understood as a negative limitation. "Negative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation." *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012). However, "[s]uch written description support need not rise to the level of disclaimer," as Petitioner argues. *Id.* Accordingly, Petitioner's sole argument that the absence of "a statement that rescue medication were positively (prospectively) prohibited" leaves this limitation bereft of written description support cannot carry the day.

B. Petitioner's argument that there is no written description support for "maintaining a therapeutically effective concentration . . . with a dose in a range from 2 mg to 16 mg" fails as a matter of law

The specification repeatedly recites "administering to the patient, a dose of 2 mg to 16 mg of endoxifen citrate in an enteric coated tablet once per day [.] Ex. 1001 at 3 (3:7-10). Petitioner claims that this is not enough. And while Petitioner

concedes “that the inventor need not disclose a particular type of information, such as experimental data” to establish that the inventor was in possession of the claimed invention, Petitioner complains that “POSITA would not have understood the named inventors to have been in possession of the claimed invention based on the specification and would instead have needed to conduct their own scientific research to confirm that the full range of claimed doses[.]” Paper 1 at 45. In essence, Petitioner argues that “the absence of . . . testing data” for the entire range means that the range lacks written description support. This argument is legally flawed.

The law does not require “an actual reduction to practice” to comply with the written description requirements. *Univ. Of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 926 (Fed. Cir. 2004) (“We of course do not mean to suggest that the written description requirement can be satisfied only by providing a description of an actual reduction to practice.”). “Constructive reduction to practice is an established method of disclosure.” *Id.* “[A] constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010). Petitioner does not dispute that the specification “identifies the claimed invention,” and more specifically, “2 mg to 16 mg.” Accordingly, at minimum the specification “in a definite way identifies the claimed invention.”

Separately, the absence of actual “scientific research to confirm that the full range of claimed doses would be suitable to maintain a therapeutically effective concentration of endoxifen for treatment of patients with bipolar I disorders,” (Paper 1 at 45), does not mean that the limitation lacks written description support, as Petitioner argues. “The decision [concerning therapeutic effectiveness] would be informed by FDA guidance, not the written description in the specification.” *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1370 (Fed. Cir. 2023).

Finally, “the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.” *Regents of the Univ. of California v. Broad Inst., Inc.*, 136 F.4th 1367, 1383 (Fed. Cir. 2025) (citations omitted). “When the technology at issue is ‘complex’ and ‘highly unpredictable’ . . . the level of detail required to satisfy the written description requirement may be greater.” *Id.* (citations omitted). Neither Petitioner nor its expert contend that repeating clinical trials with a different dosage strength is complex and highly unpredictable.

C. Petitioner’s argument that there is no written description of administering endoxifen for “up to 21 days” is without merit

Petitioner’s complaint is the claim recites “up to 21 days” and the specification recites “for at least 21 days.” This, in Petitioner’s view renders the claim invalid. As

an initial matter, “the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*,” as Petitioner suggests. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (citation omitted).

Separately, “claim construction is inherent in any written description analysis.” *In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1319 (Fed. Cir. 2011). Yet Petitioner myopically focuses its attention on the phrase “up to 21 days” without considering the effect of the “wherein” clause that recites the negative limitation “wherein the method does not include a rescue medication.” The specification explains that in the clinical study, endoxifen was administered for “at least 21 days” and “at EOT . . . no rescue medications were administered to any of the patients.” Ex. 1001 at 3 (4:57-58). The claimed method recites “administering to the patient . . . endoxifen citrate . . . for up to 21 days, wherein the method does not include a rescue medication.” Ex. 1001 at 3 (4:65-5:1). By disclosing treating a patient for 21 days without providing rescue medication, the specification reasonably conveys to a POSITA treating the patient for *up to* 21 days without providing rescue medication.

D. Petitioner's argument that there is no written description of "monitoring the dose administered to the patient no sooner than 21 days after commencement of the administration to the patient" is incorrect

The limitation is properly understood as a negative limitation. "Negative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation." *Santarus*, 694 F.3d at 1351. However, "[s]uch written description support need not rise to the level of disclaimer," as Petitioner argues. *Id.* "Rather, as with positive limitations, the disclosure must only reasonably convey to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Novartis Pharm. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013, 1020 (Fed. Cir. 2022) (cleaned up).

Here, the patent specification recognizes that one of the disadvantages of prior art methods of treating bipolar disorders included "a continuous need to observe the therapeutic dose monitoring in patients during the treatment." Ex. 1001 at 2 (1:33-35). The inventors recognized that "[t]argeting the PKC signalling pathway for bipolar disorder can improve the patient compliance, *when therapeutic dose monitoring is not required in patient.*" *Id.* (1:60-63) (emphasis added). This disclosure provides an affirmative reason to exclude continuous monitoring prior to 21 days. The study was carried out for 21 day and "[a]t the EOT, none of the patient required rescue medications, no rescue medications were administered to any of the

patients,” and none of the patients discontinued from the study. *Id.* (2:57-59). Petitioner does not analyze these portions of the specification in view of the law relating to written description in the context of negative limitations.

E. Petitioner’s argument that there is no written description support for treating patients with additional conditions described in the dependent claims is without merit

The patent specification explains “the present application provides a method for maintaining a therapeutically effective concentration of endoxifen for treatment of bipolar I disorder in a patient, wherein the patient *has manic episodes with or without mixed features*. In another embodiment the present application provides a method for maintaining a therapeutically effective concentration of endoxifen for treatment of bipolar I disorder in a patient, wherein the patient *has depression or associated with depressive episodes*.” Ex. 1001 at 2 (3:66-4:8). A POSITA would know that “[t]he bipolar I disorder criteria represent the modern understanding of the classic *manic-depressive disorder*[.]” Ex. 1009 at 7 (emphasis added). These clinical features are inherent components of bipolar I diagnostic criteria. The specification provides that “[t]he clinical study was a multicenter, randomized, double-blind, double-dummy, active controlled, parallel study to assess the efficacy and safety of endoxifen enteric coated tablet 8 mg and divalproex sodium extended release tablet 1000 mg in patients of bipolar I disorders.” Ex. 1001 at 3 (4:50-54).

Accordingly, Petitioner's argument that the dependent claims that recite the clinical features of bipolar I disorder, i.e., "depression" and "manic episodes with mixed features" lack written description support is without merit.

IV. WEAKNESS OF LACK OF ENABLEMENT GROUND COUNSELS IN FAVOR OF DENIAL

Petitioner argues that the claims are not enabled because:

[T]here is simply nothing in the specification telling POSITA how to determine, without undue experimentation, whether a therapeutically effective concentration of endoxifen has been reached, or even an example or description of what that concentration is or may be in any patient—and certainly no disclosure of doing so in the absence of any possibility of using rescue medication or with all of the doses and schedules claimed.

Paper 1 at 63; *see also id.* at 67 ("POSITA would have needed to test administration of various doses and the resulting concentrations and evaluate patients' need for rescue medications across those doses to arrive at the full scope of the claimed methods."). Petitioner's argument is inconsistent with Federal Circuit precedent.

"The question of undue experimentation is a matter of degree, and what is required is that the amount of experimentation not be unduly extensive." *Cephalon, Inc. v. Watson Pharm., Inc.*, 707 F.3d 1330, 1338 (Fed. Cir. 2013) (citations

omitted). “[T]he fact that a clinician’s involvement may be necessary to determine effective amounts of the single compound . . . does not itself constitute undue experimentation.” *Id.* In fact, “[e]ven ‘a considerable amount of experimentation is permissible,’ as long as it is ‘merely routine’ or the specification ‘provides a reasonable amount of guidance’ regarding the direction of experimentation.” *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1386 (Fed. Cir. 2013) (citing *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1360–61 (Fed.Cir.1998)); see also *Cephalon*, 707 F.3d at 1338 (“extensive experimentation does not necessarily render the experiments unduly extensive where the experiments involve repetition of known or commonly used techniques.”).

Neither Petitioner nor its expert claims that the experimentation required to practice the full scope of the claim requires something more than “merely routine,” “known or commonly used techniques.” That being the case, Petitioner cannot carry its burden of showing that the full scope of the claims is not enabled. Under the Wands factors, the claimed methods involve predictable dose optimization, routine pharmacokinetic measurement, and established clinical assessment tools. These considerations weigh strongly against any finding of undue experimentation.

V. WEAKNESS OF INDEFINITENESS GROUND COUNSELS IN FAVOR OF DENIAL

Petitioner argues that claim 6 is indefinite “because the patent never explains what ‘monitoring the dose administered to the patient’ actually means, and it is also unclear from the plain language of the claim.” Paper 1 at 74. Petitioner’s argument is misguided. The claimed method requires “maintaining a therapeutically effective concentration of endoxifen” by administering the dose and *refraining* from “monitoring the dose administered” for 21 days. Any method that allows for “monitoring the dose administered” falls within the scope of that claim term and is excluded from the claim as it is a negative limitation. The Petition shows that a POSITA knows the methods of monitoring the dosage form. *See* Paper 1 at 75 (identifying various methods of monitoring). A POSA would understand that monitoring includes measuring plasma concentrations, evaluating symptom scales such as YMRS, or adjusting dosage based on clinical response—each standard clinical practice. The claim excludes performing all of them for at least 21 days. Thus, the Petition fails to show that the claim is not reasonably certain.

That certainty is further enforced by the prosecution history, which Petitioner erroneously ignores. *See Ancora Techs., Inc. v. Apple, Inc.*, 744 F.3d 732, 738 (Fed. Cir. 2014) (in context of indefiniteness an “an ordinarily skilled artisan must consult the prosecution history to confirm the proper understanding of a claim term’s

meaning”). During prosecution Patent Owner distinguished Ahmad (2016), making clear “the monitoring of the patients necessary in Ahmad (2016) is not necessary in the method of claim I.” Ex. 1002 at 243. Ahmad (2016) teaches “Efficacy and safety assessments were done based on evaluation parameters on Days 4, 7, 14, and 21 (end of treatment).” Ex. 1004 at 3 (describing testing of blood plasma and YMRS symptom scales). A POSA would thus understand the negative limitation on monitoring to clearly exclude any and all such monitoring. *See, e.g., Grace Instrument Indus., LLC v. Chandler Instruments Co., LLC*, 57 F.4th 1001, 1009 (Fed. Cir. 2023) (finding claims sufficiently definite where “prosecution history supports this understanding”); *Ironburg Inventions Ltd. v. Valve Corp.*, 64 F.4th 1274, 1287 (Fed. Cir. 2023) (finding claims definite and noting prosecution history “provides some additional data to a person of ordinary skill, at minimum confirming that an ‘elongate member’ in the context of the '525 patent cannot be circular”).

Under *Nautilus*, a claim is indefinite only if the patent claim, specification, and prosecution history fails to inform a POSITA, with reasonable certainty, of the scope of the invention. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). A POSITA would understand “monitoring the dose administered” to include measuring plasma concentrations, evaluating symptom scales such as YMRS, or adjusting dosage based on clinical response—each standard clinical practice. *Contrast HZNP Medicines LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 690 (Fed.

Cir. 2019) (finding term “impurity A” not reasonably certain and rejecting patentee’s argument it meant USP Compound A where patentee did “not cite to any part of the specification, the claims, or the prosecution history that defines or directly connects ‘impurity A’ to USP Compound A.”); *IBSA Institut Biochimique, S.A. v. Teva Pharms. USA, Inc.*, 966 F.3d 1374, 1379 (Fed. Cir. 2020) (finding indefiniteness only after “turn[ing] to the prosecution history”).

Patent Owner’s incomplete analysis, which fails to even consider the prosecution history, cannot demonstrate indefiniteness.

VI. CONCLUSION

For all of the reasons discussed above, Patent Owner respectfully requests that the Director exercise his discretion to deny institution.

Dated: March 9, 2026

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CERTIFICATE OF SERVICE

I certify that the Patent Owner's Amended Request for Discretionary Denial in connection with Post Grant Review Case PGR2026-00015 was served on March 9, 2026 by electronic mail to:

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned attorney for the Patent Owner, Jina Pharmaceuticals, Inc., declares that Patent Owner's Amended Request for Discretionary Denial of Institution complies with the 20-page limit provided by the Board in its direction of March 5, 2026 (Paper 9).

Dated: March 9, 2026

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