

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 12,245,997

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

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Petitioner Owner Atossa Therapeutics, Inc. (“Atossa”) respectfully submits this Opposition to Jina Pharmaceuticals, Inc.’s (“PO”) Amended Request for Discretionary Denial (“Req.,” Pap.11).¹ PO’s Request does not identify a single case granting discretionary denial in a post-grant review (“PGR”). That is unsurprising: “petitions for post-grant review are favored because they must be filed no later than nine months from the grant of the patent (35 U.S.C. § 321(c)), are close in time to examination, and occur before expectations in the patent rights are strongly settled.” *LifeVac, LLC v. DCSTAR Inc.*, IPR2025-00454, Pap.11, 2 (July 11, 2025) (precedential); *Multi-Color Corp. v. Brook & Whittle Ltd.*, PGR2025-00025, Pap.10, 2 (July 16, 2025) (precedential). In addition, the absence of parallel proceedings also favors institution because there is no risk of inconsistent outcomes or duplication of effort here. PO’s four-page patent provides nothing to the public in exchange for the right to exclude others from using endoxifen to treat bipolar disorder, which is a serious and chronic condition. EX1001, 1:17-24. This is exactly the type of deficient patent that post-grant review was designed to address.

PO’s Request fails to mention most discretionary-denial considerations, tacitly acknowledging they do not support denial here. *See* Interim Director

¹ Sections are from 35 U.S.C./37 C.F.R. as context indicates, emphases are added, and internal quotations/citations omitted unless noted.

Discretionary Process (“IDDP”), §I.B. PO instead addresses only §325(d), and even then only as to one of the Petition’s four grounds. Req.2-10. And, despite the IDDP’s clear guidance and the Board’s caution against doing so, the rest of the Request is improperly directed to the *merits* of the Petition’s §112-based grounds. Req.8-20; Pap.9, 2 (“[a] patent owner should not treat a discretionary denial brief as an additional opportunity for merits briefing”); IDDP, §II.C.i (“A patent owner should not repeat its merits arguments verbatim but should briefly explain why the merits are relevant.”). PO’s merits assertions also fail, and rely on erroneous legal arguments and unsupported attorney argument.

The Request also makes a vague reference to “harassment” and “litigation gamesmanship,” but acknowledges PO’s development partner’s own challenges to Atossa’s patents and that there are no parallel proceedings here that could possibly raise any such concerns.² Req.1. PO’s Request should be denied.

I. The Lack of Settled Expectations Affirmatively Favors Institution

Multiple precedential decisions hold that petitions for post-grant review “are

² PO’s original, non-compliant Request argued that PO itself, rather than its development partner Intas, is the challenger in those proceedings. Pap.6, 1 n.1. Despite the Board’s order that PO’s new brief “may not include any new arguments” (Pap.9, 3), PO changed this in its Amended Request. Req.1 n.1.

avored” because they are filed “close in time to examination, and occur before expectations in the patent rights are strongly settled.” *Multi-Color*, 2-3; *LifeVac*, 2. Additionally, “[e]arly challenges favor robust, predictable patent rights and weigh against discretionary denial.” *Therabody, Inc. v. DataFeel Inc.*, PGR2025-00026, Pap.10, 2 (July 17, 2025).

So too here. The Petition was filed within nine months of the ’997 patent issuing. EX1001, 1; Pap.2 (“Pet.”). Adjudicating the validity of the four-page ’997 patent—including as to multiple §112 grounds not raised during examination (§III.C.1, *infra*)—close in time to examination and before PO’s expectations are settled will provide “robust, predictable patent rights” and thus favors institution. *Therabody*, 2.

II. The Lack of Parallel Proceedings Affirmatively Favors Institution

PO’s development partner, Intas, previously argued, and the Board found, that the lack of parallel proceedings ***favors institution***. *Intas Pharms. Ltd v. Atossa Therapeutics, Inc.*, PGR2025-00043, Pap.12, 2-3 (Aug. 29, 2025) (finding, where there was no parallel proceeding, “there is no concern of inconsistent outcomes or significant duplication of efforts resulting from two proceedings operating in parallel”); *see also Intas*, Pap.10, 3 (Aug. 7, 2025) (“That there is no current litigation favors *institution*, not denial....”) (emphasis original); *Ascend Elements, Inc. v. Duesenfeld GmbH*, PGR2025-00037, Pap.9, 2 (Aug. 14, 2025) (rejecting discretionary denial

request including because district court proceeding was stayed, so there was “no immediate concern of inconsistent outcomes or significant duplication of efforts”).

Because there is no concern of inconsistent outcomes or duplication of efforts, PO’s assertion that there is no “concrete risk of infringement litigation” favors institution, not denial. Req.1. And PO’s handwaving about “harassment [and] litigation gamesmanship”—which PO’s case discusses in the context of the §315(b) one-year bar (inapplicable here)—is irrelevant. *Id.* (citing *Johnson Health Tech Co. v. Icon Health & Fitness, Inc.*, IPR2014-01242, Pap.16, 3 (Feb. 11, 2015) (“one-year deadline helps to ensure that [IPR] provides a quick and cost effective alternative to litigation, and is not used as a tool for harassment or litigation gamesmanship”)).

III. §325(d) Supports Institution, Particularly Given the Petition’s Additional §112-Based Grounds

The Request argues §325(d) only as to Ground 4 (a short 12-page argument asserting anticipation by Ahmad 2016 (EX1004)), ignoring the Petition’s three §112-based grounds (Grounds 1-3). Req.2-7 (citing *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Pap.6, 8 (Feb. 13, 2020) (“AB”)). The presence of these additional §112-based grounds supports institution such that it is not necessary to address *Advanced Bionics* as to any Ground. *See* §III.A, *infra*. But even if *Advanced Bionics* were considered, the Petition’s arguments were not previously presented (*AB* part one) and the Examiner materially erred because the claims cannot be valid under both §102 and §112 (*AB* part two).

A. The §112-Based Grounds Support Institution Under §325(d)

Grounds 1-3 showed the Challenged Claims are invalid under §112. Pet.31-75. PO does not address these Grounds in arguing §325(d) or assert they were previously considered. Req.2-7. That is because, where, as here, the “Examiner did not issue” any written description (Ground 1) or enablement (Ground 2) rejections, or any indefiniteness (Ground 3) rejections as to the relevant limitation, the Petition’s §112 arguments “could not have been presented previously to the office.” *Forte Biosciences, Inc. v. Univ. of Mass.*, PGR2023-00014, Pap.10, 13 (July 3, 2023).

When the Petition is considered as a whole, as it must be, this supports institution under §325(d). *Brunswick Corp. v. Volvo Penta of the Ams., LLC*, IPR2020-01512, Pap.15, 16-21 (Mar. 11, 2021) (granting institution where petition asserted two partially cumulative grounds not addressing all challenged claims and two non-cumulative grounds addressing all challenged claims, finding “[w]hen considering the Petition as a whole, we find that it does not sufficiently implicate the concerns addressed by § 325(d) to warrant discretionary denial”); IDDP, §I.E (“Director’s decision... will be based on a holistic review of the facts and circumstances”).

Thus, the Director need not reach *Advanced Bionics* as to any Ground. Additionally, as discussed below (§§III.B, III.C), even if the Petition’s arguments are evaluated under *Advanced Bionics*, those arguments were not the same or substantially the same as those considered during prosecution, and it was material error for

the Examiner to fail to issue a §112-based rejection on these Grounds while also finding claims 1-4 allowable over Ahmad 2016. The construction PO advanced to urge patentability in view of the prior art is fundamentally incompatible with patentability of the claims based on §112. Even in the present PGR, PO does not and cannot identify §112 support for the claims without *changing and the construction* of “wherein the method does not include a rescue medication” in an attempt to identify written description support in the specification. Req.9. But in prosecution, the examiner *rejected* the claims when applying a similar construction (and before adopting PO’s prosecution construction). Pet.8-10; EX1002, 169, 218-220.

B. Ground 4: Denial Under §325(d) Is Not Appropriate

1. AB Part One: Ground 4 Does Not Advance the Same or Substantially the Same Arguments

PO asserts that Ground 4 raises issues already addressed in prosecution. Req.2. But during prosecution, PO overcame prior art rejections based on Ahmad 2016 (the basis for Ground 4 here) by arguing “the method does not include a rescue medication for the treatment of bipolar I disorder” positively excludes (prospectively prohibits) the administration of any rescue medication during the claimed course of endoxifen treatment. EX1002, 362; Pet.29-30, 76. This assertion is *inconsistent* with patentability under §112. Indeed, contrary to its assertions in prosecution, and faced with §112 written description challenges here (Ground 1), PO now attempts to broaden its prosecution interpretation (where BRI applied) in response to the

Petition's written description arguments (Ground 1), asserting that describing a clinical study "where the negative limitation is 'prospectively forbidden' 'during treatment'" is *not* required to adequately describe this limitation. Req.9. To the extent PO attempts to save its claims under §112 by arguing they do not require positive exclusion, as PO now appears to do, then the same or substantially the same arguments regarding the prior art were not considered during prosecution because PO advocated for, and the Examiner applied, a different construction in prosecution when addressing anticipation by Ahmad 2016. EX1002, 362, 434.

2. *AB* Part Two: If the Board Rejects PO's Prosecution Construction, the Examiner Committed Material Error by Applying the Wrong Construction

Because *AB* part one is not satisfied, it is not necessary to reach part two. *AB*, Pap.6, 8. And while the Board should reject PO's attempt to rewrite the prosecution history to save its claims under §112, to the extent the Board finds that PO's new construction is proper and that the claims are not invalid under §112, such a finding would also indicate that the Examiner applied the wrong construction in prosecution and that this error impacted the patentability of claims 1-4. *AB*, Pap.6, 8 n.9 ("An example of a material error may include... an error of law, such as misconstruing a claim term, where the construction impacts patentability of the challenged claims."). Indeed, as the Examiner found before adopting PO's argued-for prosecution construction, Ahmad 2016 discloses that at least some of its patients did not receive a

rescue medication. EX1002, 218; EX1004, 3; Pet.20, 80-81. If that is all the claims require, it cannot be said that “reasonable minds can disagree” as to whether Ahmad 2016 discloses this limitation, and thus the Examiner materially erred. *AB*, Pap.6, 9.

C. Grounds 1-3: Denial Under §325(d) Is Not Appropriate

1. *AB* Part One: Grounds 1-3 Are Not the Same or Substantially the Same

The Petition raises §112 arguments that were not addressed during prosecution; thus, the same or substantially the same arguments “could not have been presented previously to the office,” and *AB* part one is not satisfied. *Forte*, Pap.10, 13 (finding *AB* part one not satisfied where “the Examiner did not issue a rejection under 35 U.S.C. § 112, did not articulate any analysis of whether the specification provides written description and enablement support for the claims, and certainly did not do so in the context of Petitioner’s newly asserted arguments and evidence”); *Multi-Color*, Pap.9, 41-42 (petitioner’s opposition to discretionary denial, arguing that “[w]hile the Examiner had an obligation under MPEP §2173.01 to assess compliance with § 112(b)... the absence of any rejection or discussion of the particular issues raised in the Petition during the prosecution history confirms that the Examiner did not recognize or evaluate this fundamental defect before allowance.”); *Multi-Color*, Pap.10, 3 (“Petitioner also provides persuasive reasoning, supported by evidence, that discretionary denial under 35 U.S.C. § 325(d) is not appropriate.”).

Here, as in *Forte*, the Examiner did not issue any rejections under §112 for

lack of written description (Ground 1) or lack of enablement (Ground 2). Pet.8-13. While the Examiner did issue one indefiniteness rejection (Ground 3), that rejection was not related to the basis for the ground (claim 6’s “monitoring the dose administered to the patient no sooner than 21 days after commencement” of treatment), but instead to a different limitation in then-pending claim 1 that does not even appear in the issued claims. EX1002, 267-268. In fact, claim 6 was not present in the application when the indefiniteness rejection was made, and no other then-pending claim had that limitation or a similar limitation. EX1002, 417-422 (adding claim 6). And tellingly, the Examiner made no indefiniteness rejection—or any other rejection—after claim 6 and its dependent claims were added. EX1002, 426-429. Thus, the Petition’s §112 arguments (Grounds 1-3) were not previously considered, and *AB* part one is not satisfied by the Petition as a whole. *Brunswick*, Pap.15, 21.³

2. The Examiner Materially Erred by Failing to Issue

³ Additionally, the Examiner also did not have before her Ahmad 2020 (EX1006), which confirmed that—contrary to the ’997 patent’s statements otherwise—the clinical trial discussed in the ’997 patent’s single example did include administration of “rescue medications” as that term is defined by the ’997 patent. Pet.40-41, 65 n.16; EX1001, 3:42-46; EX1006, 3. This fact, identified by the Petition, was not considered by the Examiner and is yet another reason why at least Ground 2 does not advance the same or substantially the same arguments. *See* Pet. §VII.B.2.

**Rejections on the §112 Grounds Because the Claims Cannot
Be Valid Under §112 and Patentable Over Ahmad 2016**

Because the Examiner did not consider the same or substantially the same arguments as to Grounds 1-3, proceeding to *AB* part two is unnecessary. *AB*, Pap.6, 8; *Forte*, Pap.10, 13. But even under part two, the Examiner materially erred because claims 1-4 cannot be both patentable under §112 and not anticipated by Ahmad 2016.

The Petition established material error: Grounds 1 and 2 showed, respectively, that the challenged claims are not supported and are not enabled. Pet.31-61 (Ground 1), 61-73 (Ground 2). And as shown in Ground 3, claims 6-10 are indefinite because the patent does not explain what “monitoring the dose administered to the patient” means. Pet.73-75. Neither PO nor Examiner addressed these issues during prosecution. The Examiner’s failure to reject the claims on these bases was material error. *See Forte*, Pap.10, 13-14 (“Even if we were to consider the second part of the [*AB*] framework, we nonetheless would find that Petitioner has demonstrated the Office erred... because, based on the current record, the claims should have been rejected for lack of enablement and written description....”). Thus, even if *AB* part two were reached as to Grounds 1-3, discretionary denial would not be appropriate.

IV. The Strength of the Petition’s Written Description Arguments Favors Institution (Ground 1)

PO’s written description merits arguments, which make up nearly half of its

brief, are riddled with unsupported attorney argument and flawed factual and legal analysis. PO's unsupported attorney argument should be given no weight and cannot overcome the Petition's prior-art literature and uncontested expert testimony. Pet.33-61 (citing EX1002; EX1003; EX1005; EX1006; EX1008; EX1009); *Pacificorp v. Birchtech Corp.*, IPR2025-00717, Pap.41, 20-21 (Feb. 10, 2026) ("Patent Owner's argument, however, is merely attorney argument without evidentiary support.... It does not, on this record and at this stage of the proceeding, undermine Petitioner's position, which is supported by uncontested testimony....") (citing *Icon Health & Fitness, Inc. v. Strava, Inc.*, 849 F.3d 1034, 1043 (Fed. Cir. 2017) ("Attorney argument is not evidence.")). And PO's merits-related arguments should be addressed in merits briefing rather than here. IDDP, §II.C.i ("A patent owner should not treat a discretionary denial brief as an additional opportunity for merits briefing.").

A. "The Method Does Not Include a Rescue Medication"

To overcome the Examiner's prior art rejections in prosecution, PO argued for and obtained a construction of this limitation requiring that it "positively excludes a rescue medication from the claimed method." EX1002, 362, 434; Pet.30. Under this construction, a method in which a patient is *permitted* to receive a rescue medication if breakthrough symptoms arise, even if no rescue medication is actually administered to that patient, does not satisfy this limitation. Pet.29-30; EX1002, 306, 343, 413; EX1003, ¶55.

PO does not identify any written description support for this limitation under the construction it successfully urged during prosecution to overcome the Examiner's prior art rejection. Req.9-10. Instead, in an attempt to find written description support, PO urges (without citation to intrinsic evidence) a different construction, insisting that under that construction, the patent need not "disclose[] a clinical study where the negative limitation is 'prospectively forbidden' 'during treatment.'" Req.9. But when the Examiner applied that understanding of the claims (before adopting PO's later, stringent, construction), it resulted in a prior art rejection over Ahmad 2016. EX1002, 169, 218-220.

PO next asserts that the Petition argued there is no written description support because the specification does not "explicitly disclaim" the use of rescue medication in the method. Req.10. That is not what the Petition—which nowhere mentions "disclaimer"—argues. Pet.39-41. Instead, the Petition argued that this limitation, as construed by PO during prosecution to require prospectively excluding rescue medication, lacks written description support under that construction. Pet.39-41.⁴

Finally, PO insists that written description support exists "when the specification describes a reason to exclude the relevant limitation." Req.10 (citing *Santarus*,

⁴ Consistent with the IDDP, Petitioner does not repeat its merits arguments verbatim but instead "briefly explain[s] why the merits are relevant." IDDP, §III.C.i.

Inc. v. Par Pharm., Inc., 694 F.3d 1344, 1351 (Fed. Cir. 2012) (finding written description support where “statements in the specification expressly list[ed] disadvantages” of using the excluded compound)). But, unlike *Santarus*, PO identifies no such reason described in the patent for affirmatively prohibiting rescue medications, and the patent does not disclose one. Pet.39-41; EX1001, 1:31-32 (“Background of the Invention” section discussing treatment of bipolar disorder, explaining “there is also a need of rescue medications”).⁵

B. “Maintaining a Therapeutically Effective Concentration of Endoxifen” by Administering a “Dose in a Range from 2 mg to 16 mg”

The Petition showed the specification simply parrots the claim language, which does not provide written description support for a dose range. Pet.43-45 (citing *Ariad Pharms. Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc)). In response, PO identifies the same specification language already addressed by the Petition, without addressing the Petition’s arguments as to those passages. Req.11; Pet.43-44. PO next mischaracterizes the Petition as simply arguing

⁵ If PO tries to (improperly) look outside the specification for support, the publication reporting the results of the study discussed in the patent (Ahmad 2020) disclosed “rescue medication” as defined by the patent (EX1001, 3:42-46) was administered. EX1006, 3, 4, (Table 3) (patients received diazepam and lorazepam); Pet.41.

“the absence of... testing data.” Req.11. But the Petition argued the patent does not disclose “evidence, experiments, studies, examples, or data, or other ‘descriptive means such as words, structures, figures, diagrams or formulas.’” Pet.43-44 (citing *Biogen Int’l GMBH v. Myland Pharms. Inc.*, 18 F.4th 1333, 1342 (Fed. Cir. 2021)).

PO next acknowledges the absence of “actual ‘scientific research to confirm that the full range of claimed doses’” would work, but asserts this is irrelevant, citing *United Therapeutics Corp. v. Liquidia Technologies, Inc.*, 74 F.4th 1360, 1370 (Fed. Cir. 2023). Req.12. That case, however, was not about whether the claimed range was described. Further, the patent there *did* provide “details on administration, concentrations, and dosages” of the drug at issue, as well as “an open label study upon acute safety, tolerability, and hemodynamic effects” of that drug and the record there included expert testimony from the patent owner (which is not present here). *United Therapeutics*, 74 F.4th at 1370-71. Contrary to PO’s suggestion, the sentence partially quoted by PO and referring to FDA guidance simply states that physicians’ treatment decisions are informed by FDA guidance. *Id.* at 1370. The patent owner in *United* did not argue, and the Federal Circuit did not hold, that FDA guidance dictated whether there was sufficient written description support in that case. *Id.*

Lastly, PO asserts “[n]either Petitioner nor its expert contend that repeating clinical trials with a different dosage strength is complex and highly unpredictable.” Req.12. To start, this is another acknowledgement of the patent’s missing data. It is

also wrong. Petitioner and its expert showed this field is unpredictable. Pet.48 (“That is particularly true in an unpredictable art such as this.”); EX1003, ¶108 (“the field of methods for successfully treating bipolar I disorder is unpredictable”).

C. Administering Endoxifen for “Up to 21 Days”

PO does not contend that the ’997 patent anywhere discloses administering endoxifen citrate for “**up to**” 21 days or any duration less than 21 days. Req.12-13; Pet.49. Instead, PO’s only argument is that the single example disclosing treatment for “**at least** 21 days” is a disclosure of the full range of treatment, which includes administration from the outset of the method through 21 days. Req.13; Pet.48. The Petition (supported by case law and expert testimony) addressed this argument. Pet.49-52 (citing, *e.g.*, *Indivior UK Ltd. v. Dr. Reddy’s Laby’s S.A.*, 18 F.4th 1323, 1328-30 (Fed. Cir. 2021) (holding claimed range of “about 40 wt % to about 60 wt %” was not supported by disclosure of “at least 50%”)); EX1003, ¶¶86-87. PO, on the other hand, provides unsupported attorney argument about POSITA’s understanding of the specification and does not address the Petition’s cases showing “at least 21 days” does not provide support. Req.13; Pet.51-52. PO’s unsupported arguments should receive no weight and cannot support denial, *Pacificorp*, Pap.41, 20-21, and PO’s failure to respond to the Petition’s cases also counsels against denial.

D. “Monitoring the Dose Administered to the Patient No Sooner Than 21 Days After Commencement of the Administering to the Patient”

The Request acknowledges that the “monitoring” limitation is a negative

limitation and for written description support the specification must “describe[] a reason to exclude the relevant limitation.” Req.14. Yet the Request points to no such reason. Req.14-15. It instead identifies the very same irrelevant background discussion already addressed by the Petition. Req.14 (citing EX1001, 1:33-35, 1:60-63); Pet.54-55. The Petition showed why these passages—neither of which PO cited when adding claim 6 (EX1002, 420)—do not provide support (Pet.54-56) and why the specification does not provide a reason to exclude monitoring (Pet.57-58).

E. Treating Patients with the Additional Conditions Required by the Dependent Claims

The Petition showed the specification provides no support for treating patients with the additional conditions of dependent claims 2-5 and 7-10. Pet.58-61. Instead, the specification parrots the claim language and provides a single generic, unsupported statement about the PKC signaling pathway. Pet.59. But mere recitation of the claim language is not enough because there is nothing in the specification showing the inventors “actually invented” and possessed the claimed method. *Nuvo Pharms. (Ir.) Designated Activity Co. v. Dr. Reddy’s Lab’ys Inc.*, 923 F.3d 1368, 1380 (Fed. Cir. 2019); *Centocor Ortho Biotech, Inc. v. Abbott Laby’s*, 636 F.3d 1341, 1348 (Fed. Cir. 2011); Pet. 59. The Request does not challenge this proposition. Req.15-16. It instead simply recites the very same specification passages the Petition showed are insufficient. Req.15.

PO also contends that the claimed “clinical features are inherent components

of bipolar I diagnostic criteria.” Req.15. To the extent that argument can even be understood, it is certainly not an assertion that the patent provides any data, evidence, explanation, or description of treating patients with these conditions. Req.15. And the specification’s single example (Req.15), which makes no mention of these additional symptoms, does not provide support. Pet.58-59.

V. The Strength of the Petition’s Enablement Arguments Favors Institution (Ground 2)

As to enablement, PO does not actually dispute that the ’997 patent fails to disclose the numerous teachings that the Petition shows are missing from the specification. Req.16-17; Pet.62-68. This includes that the patent does not disclose “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 “doing so in the absence of any possibility of using rescue medication or with all of the doses and schedules claimed.” Req.16 (citing Pet.63, 67).

PO instead: (1) claims the Petition’s arguments are inconsistent with precedent, but fails to identify any error of law; and (2) advances unsupported attorney argument about the *Wands* factors, which should receive no weight. Req.16-17.

First, PO claims the Petition fails to use the exact phrases “merely routine” and “known or commonly used techniques” but ignores that both Petitioner’s and PO’s cases state the *Wands* factors—which the Petition analyzed in detail—address and account for these issues. Req.17; e.g., Pet.61 (citing *Amgen Inc. v. Sanofi*,

Aventisub LLC, 987 F.3d 1080, 1084-85 (Fed. Cir. 2021) (“the factors set forth in *Wands* then provide the factual considerations that a court may consider when determining whether the amount of that experimentation is either ‘undue’ or **sufficiently routine**”), 67 (citing *Medytox, Inc. v. Galderma S.A.*, 71 F.4th 990, 998 (Fed. Cir. 2023) (relying on *Wands* factors to analyze whether it was “routine to **clinically confirm**” whether compositions satisfy the claims)), 68-72 (discussing *Wands* factors); EX1003, ¶¶100-103; Req.17 (citing *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013) (analyzing *Wands* factors to determine whether “a reasonable amount of **routine experimentation** [is] required”)).

Second, the Request advances only unsupported attorney argument about what was “routine” or “predictable” or “established” clinical practice under the *Wands* factors. Req.17. These are expert opinions masquerading as attorney argument and should be given no weight, and demonstrate that trial on a full record is appropriate to resolve these factual issues. *Pacificorp*, Pap.41, 20-21.

VI. The Strength of the Petition’s Indefiniteness Arguments Favors Institution (Ground 3)

The Petition showed claim 6’s “monitoring the dose administered to the patient no sooner than 21 days after commencement of the administering to the patient” is indefinite because the “intrinsic record”—which includes the specification and prosecution history—does not provide “clear notice of what is claimed.” Pet.74-75 (citing *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 899 (2014)).

PO does not identify any specification statements that it contends provide guidance as to the scope of this term. Req.18-20. Instead, PO contends the Petition “ignores” the prosecution history. Req.18. Not so. The Petition specifically references the relevant prosecution history, explaining that “when adding claim 6 immediately before allowance” PO did not “point to any supporting disclosure.” Pet.75 (citing EX1002, 418-420). PO ignores this, instead pointing to prosecution statements about *claim 1* (which does not contain this limitation), made before claim 6 was added. Req.19 (citing EX1002, 243).⁶

In fact, the portion of the prosecution history relied on by PO (which is about claim 1) illustrates the problem with claim 6. PO relies on the prosecution-history statement that “the monitoring of the patients necessary in Ahmad (2016) is not necessary in the method of *claim 1*” and argues that this monitoring included “testing

⁶ PO’s case are distinguishable. Unlike here, each involved specification guidance as to the term at issue. *Grace Instrument Indus., LLC v. Chandler Instruments Co.*, 57 F.4th 1001, 1009 (Fed. Cir. 2023) (no indefiniteness where “specification guides us to the term’s meaning”); *Ironburg Inventions Ltd. v. Valve Corp.*, 64 F.4th 1274, 1287 (Fed. Cir. 2023) (“the specification instructs a person of ordinary skill” about term scope, thus “even if Valve were correct that [POSITA] would find nothing meaningful in the prosecution history, our conclusion would remain” the same).

of blood plasma and YMRS symptom scales.” Req.19. Elsewhere, however, PO provides an open-ended list of possible conduct prohibited by claim 6, which includes additional conduct PO did not identify during prosecution: “monitoring includes measuring plasma concentrations, evaluating symptom scales such as YMRS, or *adjusting dosage based on clinical response*.” Req.18. The inconsistency between PO’s identified prosecution history and PO’s own attempt to explain what is covered by the claim (without actually placing any limits on what is covered) confirms the patent’s complete lack of guidance as to the “monitoring” limitation. Pet.74.

Lastly, as with PO’s arguments about written description and enablement, PO relies on unsupported attorney argument as to what POSITA would understand about the scope of the claims. Req.19 (“A POSA would thus understand...”; “A POSITA would understand ‘monitoring the dose administered’ to include...”). This unsupported attorney argument should be given no weight. *Pacificorp*, Pap.41, 20-21.

VII. Conclusion

PO’s request for discretionary denial should be denied.

Respectfully Submitted by:

Dated: March 26, 2026

/s/ Megan Raymond (Reg. No. 72,997)

CERTIFICATE OF PAGE COUNT

The undersigned certifies that the foregoing PETITIONER'S OPPOSITION TO PATENT OWNER'S AMENDED REQUEST FOR DISCRETIONARY DENIAL OF INSTITUTION complies with the twenty-page limit for this brief.

Dated: March 26, 2026

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of PETITIONER'S OP-
POSITION TO PATENT OWNER'S AMENDED REQUEST FOR DIS-
CRETIONARY DENIAL OF INSTITUTION has been served in its entirety
by causing the aforementioned document to be electronically mailed to the
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