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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AZURITY PHARMACEUTICALS, INC.
AZURITY PHARMA INDIA LLP
SLAYBACK PHARMA LLC
Petitioner,

v.

HERON THERAPEUTICS, INC.
Patent Owner.

PGR2025-00035
Patent 12,115,254

PETITIONER'S OPPOSITION TO PATENT OWNER'S DISCRETIONARY DENIAL BRIEF

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Azurity Pharmaceuticals, Inc., Azurity Pharma India LLP, and Slayback Pharma LLC ("Azurity" or "Petitioner") respectfully submit that the request for post-grant review ("PGR") of claims 1-30 ("Challenged Claims") of U.S. 12,115,254 ("the '254 patent") (Ex. 1001) should not be subject to discretionary denial by the Board under 35 U.S.C. §314(a) or 35 U.S.C. §325(d).

I. INTRODUCTION

"Early challenges favor robust, predictable patent rights and weigh against discretionary denial." *Resmed Corp. v. Cleveland Medical Devices, Inc.*, IPR2025-00246, Paper 10 at 2 (P.T.A.B. Jun. 12, 2025). Azurity requested post-grant review of the '254 patent on February 28, 2025. That date was less than 3 months after Heron elected to assert the '254 patent against Azurity. And Azurity petitioned for review approximately four months after the '254 patent was issued. Under any measure, Azurity's petition was an early challenge which weighs against discretionary denial.

Moreover, Heron began its district court campaign by asserting numerous patents against Azurity. *See* Ex. 2004, ¶7; *id*. at 43 (claim 1); *id*. at 61 (claim 1); *id*. at 85 (claim 1); *id*. at 105 (claim 4); *id*. at 123 (claim 1); *id*. at 142 (claim 1); *id*. at 166 (claim 1); *id*. at 186 (claim 8); *id*. at 234 (claim 2). Nearly 11 months later, Heron asserted the '254 patent against Azurity. *See* Ex. 2006, ¶9. The '254 patent issued with claims reciting much broader ranges of emulsifier—and much higher

amounts—than the originally asserted patents. *See, e.g., id*. at 37 (claims 1-7). Heron's assertion of the '254 patent altered the district court litigation. *See* Ex. 2008 at 14:4-7 (Judge Bryson stating: "But the fact that this case seems to continue to get larger, the number of patents is greater, that does make things somewhat more complex."). Heron's actions precipitated Azurity's diligently filed request for post-grant review. *See Savant Tech. LLC v. Feit Electric Co., Inc.*, IPR2025-00260, Paper 16 at 3 (P.T.A.B. Jun. 12, 2025) (holding that diligent action "less than three months" after Patent Owner's assertion of new claims did not favor discretionary denial). The incorporation of the '254 patent into the schedule of the district court litigation does not make Azurity's request for review any less diligent.

Azurity's petition clearly establishes the unpatentability of Heron's claims as obvious and lacking written description and enablement because of the broadened limitations. Institution is respectfully warranted.

II. INSTITUTION IS WARRANTED

Under the procedure provided in the Acting Director's March 26, 2025, Memorandum Regarding Interim Processes for PTAB Workload Management ("Memorandum"), "the parties are permitted to address ***all relevant considerations***"[1] concerning requests for discretionary denial of institution.

[1] All emphases added unless otherwise indicated.

Memorandum at 2. For the following reasons, Azurity respectfully submits that this petition should not be subject to discretionary denial.

A. *Fintiv* Does Not Warrant Discretionary Denial

As explained below, none of the non-exclusive list of factors identified in *Fintiv* should warrant discretionary denial of Azurity's petition challenging each of the claims of the '254 patent. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 5-6 (P.T.A.B. Mar. 20, 2020) (precedential) ("*Fintiv*").

1. Factor 3 Does Not Favor Denial

Factor 3—which focuses on the investment in the co-pending district court litigation—directs against discretionary denial. *Fintiv*, Paper 11 at 6. According to *Fintiv*, this factor considers whether a district court has issued "substantive orders" related to the challenged patent. *Fintiv*, Paper 11 at 9-10. The district court has not issued any substantive orders related to the validity of the '254 patent. Heron concedes that there will be no summary judgment or *Daubert* motions concerning the '254 patent. *See* Patent Owner's Brief Requesting Discretionary Denial of Institution ("PODDB"), Paper 6 at 18 ("The parties also agreed they will not file any summary judgement or *Daubert* motions…."). And Heron admits that the construction of any disputed terms from the '254 patent will not occur until after the Board's institution decision. *See id*. ("[T]he Court also agreed with the parties to forgo Markman proceedings and address the single disputed term at the November

trial."). Such circumstances do not favor discretionary denial. *See Fintiv*, Paper 11 at 10 ("If, at the time of the institution decision, the district court has not issued orders related to the patent at issue in the petition, this fact weighs against exercising discretion to deny institution under *NHK*.").

Additionally, the Board has recognized with respect to this factor that when a petitioner "acted diligently and without much delay, this mitigates against the investment of the parties." *Dolby Labs., Inc. v. Intertrust Tech. Corp.*, IPR2020-00662, Paper 13 at 13 (P.T.A.B. Oct. 15, 2020); *see also Fintiv*, Paper 11 at 11. Azurity respectfully submits that it "acted diligently and without much delay" in preparing and filing its petition. The '254 patent issued on October 15, 2024, Heron asserted the '254 patent against Azurity in a complaint filed December 12, 2024, and Azurity filed its petition challenging the '254 patent a little more than two months later on February 28, 2025. Azurity's diligence in requesting review of such broadened claims should direct against discretionary denial as the Board has repeatedly found:

- *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 17 (P.T.A.B. Dec. 1, 2020) (finding timing of the Petition was reasonable even though "Petitioner filed its Petition approximately two months after serving its initial invalidity contentions, and ***approximately two weeks before the statutory deadline***.");

- *Cellco Partnership v. Huawei Device Co, Ltd.*, IPR2020-01117, Paper 10 at 22 (P.T.A.B. Feb. 3, 2021) ("We also credit Petitioner's diligence in filing the Petition in this case within a relative short time ***(less than three months) after being served infringement contentions*** in the parallel case….");
- *Samsung Elecs. America, Inc. v. SNIK LLC*, IPR2020-01324, Paper 9 at 9 (P.T.A.B. Mar. 9, 2021) ("Moreover, Petitioner was diligent in filing its petitions ***nearly three months before the statutory bar***.");
- *Medtronic, Inc. et al. v. Teleflex Innovations S.À.R.L.*, IPR2020-01341, Paper 11 at 12 (P.T.A.B. Feb. 9, 2021) ("Medtronic") ("We do not consider, based on the current record, the filing of the Petition ***within 6 months of the filing of the Amended Complaint*** that asserted the '413 patent to be unjustified.");
- *Ability Opto-Elecs. Tech. Co., LTD., v. Largan Precision Co., Ltd.*, IPR2020-01339, Paper 10 at 22 (P.T.A.B. Feb. 22, 2021) (finding filing a petition ***three months after patent owner identified allegedly infringing claims*** was not a "significant delay" and noting that "it is often reasonable for a petitioner to wait to file its petition until learning specifics about infringement allegations, such as which claims are being asserted against it."); and

- *Medtronic Corevalve LLC v. Colibri Heart Valve LLC*, IPR2020-01454, Paper 11 at 14 (P.T.A.B. Mar. 10, 2021) ("We find no unreasonable delay in Petitioner's prompt filing of the Petition ***only four months after the complaint was served***.") (citing cases for support).

Heron makes no effort to relate the alleged "significant resources" of the district court litigation to the '254 patent as *Fintiv* directs. *See* PODDB at 18. Fact depositions, document production, invalidity and infringement contentions, and expert discovery were necessary efforts due to Heron's assertion of 12 patents ***other than the '254 patent*** in the district court litigation. The Board, however, has balanced such investment with whether substantive decisions on validity have in fact been made. For example, in *Medtronic Corevalve*, the Board recognized that "the parties and court have invested substantial time and resources" but also found "no evidence that any substantive determinations on validity issues have been made in the CDCA case." *Medtronic Corevalve*, Paper 11 at 15–16.

Heron did not—and cannot—contend that the resources expended to date by the parties or the district court are solely or even significantly a result of the '254 patent's belated assertion in the litigation. And Heron could have reduced any resource expenditure by eliminating redundancy as the district court asked nearly one year into the litigation. *See* Ex. 2008 at 15:1-6 ("Number one, are you really planning, Mr. Ashkenazi, to go to trial with 12 patents, or are you planning to reduce

the footprint of these patents to something that will reduce the redundancy and make the case more triable?"). Four months later, "Heron's latest list [of asserted claims] still contain[ed] 19 claims across 6 patents and include[d] the 'duplicative material' specifically addressed by Judge Bryson during the December 30, 2024 conference." Ex. 2014 at 1. The Board should not credit Heron's allegation of "significant resources" when Heron has controlled and caused any alleged expenditures.

Accordingly, factor three weighs in favor of institution.

2. Factor 4 Does Not Favor Denial

Factor 4 concerns the "overlap between issues raised in the petition and in the parallel proceeding." *Fintiv*, Paper 11 at 6. Heron concedes that Azurity offered to submit a *Sotera* stipulation upon institution. *See* PODDB at 21 (citing Petition at 71). Azurity has now done so. *See* Ex. 1051. Any concern regarding overlap between the petition and district court litigation concerning the '254 patent is mooted by Azurity's stipulation.

Despite this, Heron cites *Motorola Solutions, Inc. v. Stellar, LLC*, IPR2024-01205, Paper 19 at 3-4 (P.T.A.B. Mar. 28, 2025) to allege that Azurity's offer of a *Sotera* stipulation is not sufficient. *See* PODDB at 21-22. However, Heron ignores that in *Motorola*, "[p]etitioner's invalidity arguments in the district court [were] more expansive and include[d] combinations of the prior art asserted in these proceedings ***with unpublished system prior art***, which Petitioner's stipulation is not

likely to moot." *See Motorola* at 4. Azurity is not relying on "unpublished system prior art" in the district court proceeding. If Heron truly contends that Azurity's offer and filing of a *Sotera* stipulation would not moot validity of the '254 patent in the district court litigation, it made no effort to explain itself in its briefing.

Heron's additional argument regarding the chance of inconsistent rulings is speculative. *See* PODDB at 22. In December of last year, the district court asked if Heron intended to "reduce the redundancy" and ordered Heron "to make a realistic paring down of the case, and not leave a lot of duplicative material in there to just gum up the case." *See* Ex. 2008 at 15:1-6, 31:1-9. Azurity has no control over which claims Heron ultimately chooses to pursue at trial. If Heron elects to pursue what are effectively redundant claims and duplicative material in its case to create the possibility of inconsistent rulings, that is a needless circumstance of Heron's making that it was warned not to do. The Board should not allow Heron to benefit in this proceeding by intentionally creating redundancy in the district court litigation in contradiction of Judge Bryson's instruction.

Furthermore, the manner in which Heron presented its "overlapping subject matter" argument is disingenuous. *See* PODDB at 22-23. Heron chose to compare U.S. 12,290,520 (Ex. 2011, the "'520 patent") with the '254 patent (Ex. 1001). The '520 patent issued and was asserted mere weeks ago. *See* Ex. 2002. Pursuant to statute, Azurity has nine months from issuance of the '520 patent—until February

of next year—to request post-grant review of the '520 patent. *See* 35 U.S.C. §321(c). Heron's latest assertion of another patent does not change the timing afforded by statute. It is also telling that Heron tries to focus the Board's attention on the last asserted patent rather than the originally asserted patents for which it relies upon to try to insulate the claims of the '254 patent from the Board's review. *See* PODDB at 29 ("It is unfair for Heron to defend patent validity at the PTAB when Slayback did not previously opt for PTAB challenges for the other asserted patents….").

Heron also seeks to pre-empt the significant difference in claim numbers from the '254 patent challenged in this petition (claims 1-30) and the three claims that Heron, when it submitted its brief, was asserting in the district court litigation.[2] *See*

[2] Heron mischaracterizes the circumstances that resulted in its narrowing of the asserted claims in the district court litigation. *See* PODDB at 20 n.6. Judge Bryson asked Heron's counsel if they were "planning to reduce the footprint of these patents to something that will reduce the redundancy and make the case more triable?" Ex. 2008 at 15:1-6. Heron's counsel stated "we do plan on that" and Judge Bryson expressed the "hope that they would get narrowed earlier rather than later." *Id*. at 15:7-24. Heron's counsel was then told "to indicate how much you realistically expect to go to trial with" by April 15th. *Id*. at 31:1-9. Heron failed to do so, which is evidenced by the further reduction of asserted claims that were provided on April

PODDB at 19-20; Ex. 2014 at 2. However, four days after filing its request for denial, Heron further reduced the number of asserted claims from the '254 patent to a single one—claim 7. *See* Ex. 1052. Thus, Heron now asks the Board to hold that a single asserted claim should preclude the review of all thirty that were challenged.

The Board has found such a discrepancy to direct against denial, even if a trial precedes a final written decision. *Apple Inc. et al. v. Neodron Ltd.*, IPR2020-00778, Paper 10, 19 (P.T.A.B. Sept. 14, 2020) (weighing Factor 4 against discretionary denial because "the ITC will not consider the validity of challenged claims 13 and 14"); *PUMA North America, Inc. v. Nike, Inc.*, IPR2019-01043, Paper 8, 9–10 (P.T.A.B. Oct. 31, 2019) ("[T]he Litigation only addresses challenged claims 1, 5, and 6" whereas "the Litigation *does not address* challenged claims 9, 10, 13, 14, or 17.... Accordingly, even if trial in the Litigation were to conclude prior to the statutory due date for the Final Written Decision in this proceeding, questions regarding the patentability of the majority of challenged claims would remain unresolved.") (emphasis in original).

25, 2025. Ex. 2014 at 1-2. Azurity's repeated requests for Heron to comply with Judge Bryson's order has no bearing on discretionary denial. Heron's accusation in footnote 6 lacks merit.

Heron's cited authority on this issue is readily distinguished. *See* PODDB at 20 (citing *Fintiv*, Paper 11 at 13 and *Apcon, Inc. v. Gigamon Inc.*, IPR2020-01585, Paper 9 at 12-14 (P.T.A.B. Mar. 16, 2021)). *Fintiv* acknowledges that it "***may*** still be inefficient to proceed because the district court ***may*** resolve validity of enough overlapping claims to resolve key issues in the petition." *Fintiv*, Paper 11 at 13. *Fintiv* is not a bright line rule on this issue. Indeed, Heron has not admitted or offered to stipulate that the validity of every claim in every patent it has asserted during the course of the litigation with Azurity should rise or fall together with the one asserted claim of the '254 patent. That Heron continues to assert multiple claims over multiple patents suggests that differences exist despite any alleged overlap.

Furthermore, *Apcon* concerned duplicative validity challenges against ***the same patent*** before both the Board and the district court. *See Apcon*, Paper 9 at 14. Azurity's *Sotera* stipulation—which was not offered in *Apcon*—readily resolves this conflict. What Heron seeks to do is improperly leverage the holding of *Apcon* to preclude validity challenges between different patents. And it seeks to do so without stipulating that the validity of all claims across all patents should rise and fall together. The "highly fact dependent" weighing of the degree of overlap should be, as in *Apcon*, patent specific. Azurity's *Sotera* stipulation cures that overlap.

Accordingly, factor four weighs in favor of institution.

3. Factor 1 Should Not Weigh in Either Party's Favor

Factor 1 asks "whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted." *Fintiv*, Paper 11 at 6. Neither Heron nor Azurity have requested to stay the district court litigation. *See* PODDB at 15 (referring only to Slayback). Despite Heron's omission of itself in its briefing, Azurity agrees that it would be unlikely that such a motion would be granted.

Despite attempting to blame Azurity for not having petitioned for review of all thirteen patents that Heron has asserted at some point in the district court litigation (*see* PODDB at 16, 29), Heron has proven that it would have been wasteful and an inefficient use of the Board's resources to do so. That is because Heron has, at the insistence of the district court (*see* Ex. 2008 at 15:1-24; 31:1-9), slowly reduced claims and dropped patents from the district court litigation. *See* Ex. 2014; Ex. 1052 at 1 (continuing to reduce claims). Heron may or may not continue to do so in a manner relevant to this proceeding. But Heron—not Azurity—controls that decision.

Accordingly, factor one should be neutral.

4. Factor 5 Should Not Weigh in Either Party's Favor

Factor 5 concerns "whether the petitioner and the defendant in the parallel proceeding are the same party." *Fintiv*, Paper 11 at 6. The overlap here is self-evident. But even when there is not overlap, the Board may still deny review despite

it being requested by an unrelated petitioner. *See Fintiv*, Paper 11 at 14. Thus, the Board has seriously questioned the relevance of this factor. *See Apple Inc. v. Seven Networks LLC*, IPR2020-00156, Paper 10 at 20 n.12 (P.T.A.B. Jun. 15, 2020); *Cisco Sys., Inc. v. Ramot at Tel Aviv Univ. Ltd.*, IPR2020-00122, Paper 15 at 10 (P.T.A.B. May 15, 2020) (APJ Crumbley, dissenting). The existing overlap does not "strongly favor[] denial" as Heron asserts. PODDB at 23.

Moreover, because of the circumstances of the parallel district court litigation that led to the overlap, this factor should not weigh in either party's favor. Heron first brought Azurity into district court litigation not on the '254 patent, but instead on narrow claims from many other patents. Azurity diligently and expeditiously petitioned for post-grant review very soon after the broadened claims of the '254 patent issued and were asserted by Heron. But for the changed circumstances of the litigation—for which Heron is responsible—the Board may never have been involved. Even then, the Board has astutely recognized that "no litigant is required to adopt a strategy that increases judicial efficiency at a cost of reducing its likelihood of prevailing in the dispute." *Apotex Inc. v. UCB Biopharma SPRL*, IPR2019-00400, Paper 17 at 32-33 (P.T.A.B. Jul. 15, 2019).

Accordingly, factor five should be neutral.

5. Factor 2 Should Be Neutral

Factor 2 concerns the "proximity of the court's trial date to the Board's projected statutory deadline for a final written decision." *Fintiv*, Paper 11 at 6. There is no dispute that the '254 patent issued on October 15, 2024, Heron first asserted the '254 patent on December 12, 2024 and Azurity quickly petitioned the Board for review of the '254 patent on February 28, 2025. And there is no dispute that Heron is attempting to use the November 2025 trial date to insulate a later-asserted patent from post-grant review.

However, Heron is mistaken in alleging that this factor "strongly favors" discretionary denial. *See* PODDB at 17. Numerous panels have instituted review even though the trial date preceded a final written decision by ***many months***:

- *Apple Inc. v. Seven Networks*, LLC, IPR2020-00506, Paper 11 at 7, 18-19 (P.T.A.B. Sept. 1, 2020) (although "trial is scheduled to begin on November 2, 2020, ***ten months before***" the final written decision deadline, factors such as 4 and 6 "outweigh the earlier scheduled trial date in the District Court and the investment in the District Court litigation.") (italics emphasis in original; internal quotes omitted);
- *Cellco Partnership*, IPR2020-01117, Paper 10 at 18-20 (instituting review even though parties agreed to trial date ***four months*** before the final written decision deadline);

- *Samsung Elecs. America*, IPR2020-01324, Paper 9 at 9-10 (declining to deny review where "the district court's scheduled trial predates our projected final written decision deadline by approximately ***seven months***");
- *Medtronic Corevalve*, IPR2020-01454, Paper 11 at 12-13 (instituting review even though the trial date preceded the final written decision by nearly ***six months*** and the district court conveyed that the trial date "would not move under any circumstances.") (internal quotation omitted);
- *Google LLC v. EcoFactor*, Inc., IPR2021-00054, Paper 9 at 9 (P.T.A.B. May 10, 2021) (not invoking Board's authority to deny institution even when scheduled trial date is "approximately ***five months*** before a Final Written Decision would be due."); and
- *Uniden America Corp. v. Escort Inc.*, IPR2019-00724, Paper 6 at 5-6, 10 (P.T.A.B. Sept. 17, 2019) (instituting review when the "Texas litigation is moving quickly towards a one week trial" scheduled "***three months*** *before* a final written decision likely will be issued . . . .") (italics emphasis in original).

Heron made no effort to analogize the cases it cites (*see* PODDB at 17) to the facts here. Moreover, in *Ericsson Inc. v. Procomm Int'l PTE. Ltd*, IPR2024-01455,

Paper 15 at 2 (P.T.A.B. May 16, 2025), the petitioner "waited nearly a year to file the Petition notwithstanding the early trial date." Azurity did no such thing and diligently petitioned for review upon Heron's assertion of the broadened claims of the '254 patent. The Board has previously noted that considering the petition's filing date "helps to analyze factor 2 on a sliding scale based on relative trial dates." *Seven Networks*, IPR2020-00506, Paper 11 at 9 n.6. Such a sliding scale should neutralize this factor under these facts. And in *Motorola* IPR2024-01205, Paper 19 at 3, the original panel had misapprehended the relevant inquiry by relying on the volume of infringement filings in the co-pending litigation. Azurity's arguments here do not rely on the volume of infringement filings.

Accordingly, factor two should be neutral.

6. Factor 6 Does Not Favor Denial

Factor 6 concerns "other circumstances that impact the Board's exercise of discretion, including the merits." *Fintiv*, Paper 11 at 6. As indicated above, Factors 1-5 do not favor discretionary denial, should not favor denial, and/or are neutral. Accordingly, the Board need not even consider the sixth factor. *Commscope Tech. LLC v. Dali Wireless, Inc.*, IPR2022-01242, Paper 23 (P.T.A.B. Feb. 27, 2023) (precedential) (holding that the Board must first address *Fintiv* factors 1-5, and should engage the compelling merits question only if that analysis favors discretionary denial).

Even if the Board considers Factor 6, Azurity respectfully submits that it also disfavors discretionary denial. "[W]hen determining whether there is a compelling unpatentability challenge, the Board evaluates whether the Petition presents challenges 'in which the evidence, if unrebutted in trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence.'" *Commscope*, Paper 23 at 3. That is the present situation.

a. The Challenged Claims Are *Prima Facie* Obvious

Azurity's petition explains in detail, with expert testimony in support, why the combination of Zhou (Ex. 1003) in view of one or more of Washington (Ex. 1004), Bagwe (Ex. 1005), and Weng (Ex. 1006) render the challenged claims obvious. Indeed, nine pages of the petition explain why Heron's broadly claimed range of emulsifier content is *prima facie* obvious. *See* Petition at 27-36. That meets, and the petition exceeds, *Commscope's* standard for a compelling unpatentability challenge concerning the petitions first ground.

Heron does not even address this standard. Instead, it alleges that Azurity's obviousness arguments "have been considered and rejected by the Office in the '254 and related patents." *See* PODDB at 23-24. This is clearly incorrect. As discussed in Section II.C.1, Washington and Bagwe were not even before the Office during prosecution of the '254 patent and no claims of the '254 patent were rejected for obviousness. Accordingly, there is no basis for Heron to allege that the Office has

"considered and rejected" such arguments. And as for Heron's reliance on "related patents," it was their burden to identify what it was referencing for the Board's consideration and it failed to do so. Heron's lack of specificity has failed to provide Azurity with any opportunity to rebut this allegation.

b. Heron's Understanding of the Written Description Requirement is Erroneous

Heron's assertions regarding the petition's written description arguments are equally deficient under *Commscope's* standard. *See* PODDB at 24. Heron's only rebuttal is that the argument "outright ignor[es] the explicit recitation of the claimed ratios of emulsifier to aprepitant in the specification." *Id*. That is a misstatement of fact. Azurity anticipated and addressed this argument in the petition. *See* Petition at 65-66. And Heron's focus on explicit recitation is a misstatement of the law concerning the written description requirement. *See id*. (collecting cases). In particular, precedent such as *Carnegie Mellon* and *Boston Scientific* expressly reject Heron's view of written description compliance. *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1126 (Fed. Cir. 2008) ("To satisfy the written description requirement in the case of a chemical or biotechnological genus, ***more than a statement of the genus is normally required***."); *Bos. Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1364 (Fed. Cir. 2011) ("An *ipsis verbis* disclosure of a claimed genus … is not *per se* sufficient to meet the written description requirement.") (emphasis in original).

Heron's argument also ignores the numerous admissions it made during the Fresenius litigation concerning the "critical," "unprecedented," "unexpected," "surprising," and "unpredictable" results for utilizing 14% (wt/wt) emulsifier and an emulsifier to aprepitant ratio of 20:1. *See* Petition at 55. As detailed in the petition, Heron's admissions expressly implicate—and undermine—factors that are considered under both the written description and enablement requirements. *Compare Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (identifying factors such as "the ***existing knowledge in the particular field***, ***the extent and content of the prior art***, the maturity of the science or technology, [and] ***the predictability of the aspect at issue***" affect "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date") (emphasis added) *with In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (identifying factors such as "(1) the quantity of experimentation necessary, (2) ***the amount of direction or guidance presented***, (3) ***the presence or absence of working examples***, (4) ***the nature of the invention***, (5) ***the state of the prior art***, (6) the relative skill of those in the art, (7) ***the predictability or unpredictability of the art***, and (8) the breadth of the claims.") (emphasis added).

It is of no moment that Heron tries to spin these devastating admissions as "the shortcomings of prior art" as opposed to the "patent specification." *See* PODDB

at 35. As the precedent cited above makes clear, both are relevant to the legal issues of lack of written description and lack of enablement. Moreover, the petition explains precisely why the "***patent specification***" is deficient concerning these legal issues and is particularly so in view of "a laundry list of how Heron characterized ***the shortcomings of prior art*** in a previous litigation." *Id*.

c. Heron Ignores the Interrelatedness of Written Description and Enablement Jurisprudence

The extent of Heron's criticism of the petition's lack of enablement ground is the assertion it "is barebones with no analysis of the relevant factors identified in *In re Wands*." *See* PODDB at 36. But Heron ignores that the petition explains why overlapping facts and arguments need not be re-hashed: "Because of the interrelatedness of their legal criteria, 'written description and enablement often rise and fall together.' *Ariad*, 598 F.3d at 1352; *Capon v. Eshhar*, 418 F.3d 1349, 1360 (Fed. Cir. 2005)." Petition at 68. The petition addressed the *Wands* factors. Arguably, it did so twice. *See* Petition at 68-69 (explaining: "Thus, Petitioner has already addressed many of the factors that support a finding of lack of enablement for the full scope of the Challenged Claims when setting forth Heron's failure to satisfy the written description requirement."). Heron only misses the analysis because the weight of it counsels towards institution.

d. Policy Favors Institution

There is no denying that Azurity diligently and expeditiously requested review of the ’254 patent. Having successfully worked the broadened claims of the ’254 patent into the district court schedule and trial date, Heron is essentially arguing that the Board should allow the earlier assertion of narrow claims to prevent the Board from reviewing later asserted, broader claims. Azurity respectfully requests that the Board preclude Heron from insulating such claims from post-grant review.

Accordingly, the sixth factor would favor institution even if the Board were to consider it.

7. The *Fintiv* Factors, Weighted Together, Strongly Favor Institution

As discussed above, none of the *Fintiv* factors favor denial and thus, when viewed holistically, institution is warranted in this case. Azurity’s expeditious request for post-grant review of the broadened claims of the ’254 patent is precisely the type of request that that the Board is encouraging petitioners to make. *See Resmed*, Paper 10 at 2 (“Early challenges favor robust, predictable patent rights and weigh against discretionary denial.”). Azurity respectfully submits that discretionary denial is not warranted.

B. There Are No Settled Expectations Regarding the ’254 Patent

Heron cannot credibly contend that the ’254 patent is entitled to “settled expectation” that warrant discretionary denial. The Acting Director’s March 26,

2025, Memorandum Regarding Interim Processes for PTAB Workload Management ("Memorandum") explicitly refers to "the length of time the claims have been in force" when considering "[s]ettled expectations of the parties." Memorandum at 2. The Acting Director's recent decisions also explicitly refer to the time in which the challenged patent has been in force. *See Dabico Airport Solutions Inc. v. AXA Power APS*, IPR2025-00408, Paper 21 at 2 (P.T.A.B. Jun. 18, 2025); *iRhythm Tech., Inc. v. Welch Allyn, Inc.*, IPR2025-00363, Paper 10 at 3 (P.T.A.B. Jun. 6, 2025) ("Petitioner's awareness of Patent Owner's applications and failure to seek early review of the patents favors denial and outweighs the above-discussed considerations."). Heron's arguments regarding "settled expectations" concerning the '254 patent make no reference to time and should be outright rejected on this basis.

It should be obvious that for an expectation to become "settled," time is an important factor. The '254 patent issued on October 15, 2024. *See* Ex. 1001 at (45). Azurity filed its petition for post-grant review of the '254 patent on February 28, 2025. That is a four-month window of existence for the '254 patent. "Although there is no bright-line rule on when expectations become settled," no party can credibly argue that four months' time settles any expectation that warrants discretionary denial. *See Daibco*, Paper 21 at 3. Heron's argument expressly contradicts the special timing rules and deadlines for the filing of post-grant review

that Congress authorized. *See* 35 U.S.C. §321(c) ("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)."). In fact, rather than taking the full statutorily permitted time to bring a petition for post-grant review, Azurity petitioned 5 months early. Azurity also did so within 10 weeks of the '254 patent's assertion by Heron. *See* Ex. 2006 (Complaint filed December 12, 2024). Azurity's diligence in seeking review of the '254 patent does not warrant discretionary denial on the basis of any purported "settled expectation."

1. Heron Mischaracterizes Earlier Statements

Having failed to address any aspect of timing concerning "settled expectations," Heron hangs its hope for denial on Judge Bryson's supposed intimate familiarity with the '254 patent and the Zhou reference. *See* PODDB at 25. Azurity does not presume to know the mind of Judge Bryson as it relates to the '254 patent or Zhou. However, Heron falsely alleges that "Slayback vigorously argued this exact point during the district court litigation." *Id*. Heron's only cited evidence is Ex. 2001. This is a document dated June 10, 2024—four months before the '254 patent issued and six months before Heron asserted it in district court litigation. Azurity could not have "vigorously argued" any point during district court litigation that concerned a patent not yet in existence. No settled expectations could arise under such a scenario.

2. The Fresenius Litigation Did Not Create Settled Expectations

Heron also attempts to leverage the earlier Fresenius litigation to support its "settled expectations" argument. *See* PODDB at 26. Yet nowhere does Heron explain how Fresenius's litigation—which did not involve the '254 patent—created a settled expectation concerning the unlitigated '254 patent which would warrant discretionary denial. To the contrary, Azurity's substantive discussion of documents, trial arguments, and the Fresenius trial opinion in its petition provides the Board with a framework and understanding to reach a favorable merits determination regarding the obviousness, lack of written description, and lack of enablement of the '254 patent's claims reciting a broad range of emulsifier content. Indeed, Heron's statements regarding the earlier litigated claims reciting 14% (wt/wt) emulsifier and the '254 patent's claims that greatly exceed this value are central tenants of Azurity's grounds for lack of written description and lack of enablement. *See* Petition at 52-71. The difference in claim scope matters for the petition's arguments. Narrow claims as litigated in Fresenius should not settle any expectations concerning the broader, later issued claims found in the '254 patent.

Heron also wrongly asserts that Judge Bryson "already decided a litigation that had many of the same claims and defenses." *See* PODDB at 26. If Heron is referring to patent claims, the timing of the '254 patent's issuance refutes this assertion. Moreover, Azurity's obviousness ground is not the same as the previous

litigation. The petition goes to great lengths to explain why the claims—including the broad range of emulsifier—would have been obvious despite any contrary finding on a different record in the earlier Fresenius litigation. *See* Petition at 27-36. Nine pages of the petition (nearly one-third of the obviousness arguments) were devoted to why the broad range of emulsifier would have been obvious. The petition's obviousness ground is certainly not the "same" argument Fresenius presented earlier. The petition's secondary references that are relied upon to address the obviousness of this range are not even alleged to be the same. *See* PODDB at 28 (arguing references "line up closely"). As technical experts, the Board is particularly well-suited to address the scientific merits of Azurity's arguments. *See* FAQs for Interim Processes for PTAB Workload Management at 21 ("As the judges have technical and legal expertise, it is not necessary for an expert to explain every aspect of the prior art.").[3] The Board should choose to do so here.

Similarly, the lack of written description and enablement for the '254 patent's claims are not the "same" defenses that Judge Bryson considered in the Fresenius litigation. Heron made no effort to even argue that written description and enablement were the "same." *See* PODDB at 26-29. And with respect to

[3]https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management (accessed June 25, 2025).

enablement, that issue is not even mentioned in the trial opinion. *See* Ex. 1007. Additionally, Azurity's petition focuses on the broadly claimed range of emulsifier in the '254 patent as undermining written description. *See* Petition at 52-67. The Fresenius litigation was concerned with pH values. *See* Ex. 1007 at 53-57. Indeed, it would have been odd for the Fresenius litigation to assert a lack of written description for a broadly claimed range of emulsifier content as Azurity has here when the asserted claims against Fresenius recited only 14% (wt/wt) and not a range. *See* Ex. 1007 at 5. No "settled expectations" could exist in the face of the different issues presented in Azurity's petition.

Timing is also, yet again, an issue for Heron. Judge Bryson issued his decision in the Fresenius litigation in December of 2024. That was three months before Azurity filed its petition. No "settled expectation" could exist from such a short interval.

3. Heron's Appeal To Equity Lacks Merit

Heron also argues that it is "unfair" to defend patent validity at the PTAB when Azurity has allegedly "touted Judge Bryson's suitability to resolve the parties' disputes, including patent validity." PODDB at 27. Notably, Heron cites no evidence for this allegation. That said, Judge Bryson is a fine jurist and has resolved many disputes, including patent validity, during his distinguished career.

But if Heron is referring to Azurity's requested venue transfer that was granted in July of 2024 (*see* Ex. 2005) as the reason for equity, Heron's rationale lacks merit. At the time of transfer, "[t]he Delaware litigation concern[ed] the same patents" as those asserted in the Fresenius litigation. Ex. 2005 at 7. The situation changed when Heron obtained broader claims in the '254 patent and asserted them against Azurity five months after transfer. Azurity explained this to both Heron and Judge Bryson in December of 2024:

> The primary difference between these two patents and the older patents are the numbers that are in the various ratios and concentrations in the aprepitant emulsion claims. And there are, as a result of those number being different, there are different defenses and different arguments with respect to the two new patent than with respect to the earlier patents. I mean, they're similar, but they're different.

Ex. 2008 at 20:21-21:7. Heron's assertion of broader claims precipitated Azurity's request for post-grant review. There is nothing unfair regarding Azurity's response to the new circumstances that Heron created. "[E]quity generally favors blameless plaintiffs and punishes blameworthy defendants." *Overall v. Est. of Klotz*, 52 F.3d 398, 404 (2d Cir. 1995). Heron has not shown either. The Board should reject Heron's plea for equity as unwarranted.

Similarly, the Board should give no weight to Heron's attempt to insulate the broader '254 patent claims using the narrower claims of the originally asserted

patents as a shield. *See* PODDB at 29 ("Equity and the parties' settled expectations also warrant denial here because of Slayback's voluntary decision not to file IPRs challenging the other asserted patents."). Courts have already curtailed similar behavior in the context of infringement under the doctrine of equivalence—an equitable remedy. Under this doctrine, a patentee is precluded from claiming narrowly and asserting broad claim scope. *See Tanabe Seiyaku Co. v. Int'l Trade Comm'n*, 109 F.3d 726, 732 (Fed. Cir. 1997) (narrow language in the claims and specification can preclude use of doctrine of equivalents to reach beyond what is literally claimed); *see also Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 955 (Fed.Cir.2006) ("A claim that contains a detailed recitation of structure is properly accorded correspondingly limited recourse to the doctrine of equivalents."). Accordingly, equity should not foreclose Azurity's expeditious challenge of these broad claims in post-grant review.

Heron's sole support for its equitable plea—*Tessell, Inc. v. Nutanix, Inc.*, IPR2025-00322, Paper 14 at 2-3 (P.T.A.B. Jun. 12, 2025) ("*Tessell*")—does not compel a different outcome. *Tessell* held that "[i]t is not an appropriate use of Office resources where the inventors applied for and were issued a patent, but, as is the case here, now advocate for its unpatentability." *Id*. at 2. Heron made no effort to analogize this holding to the present situation and none exists. Azurity did not invent the '254 patent. Azurity did not assign the '254 patent to Heron. The "unfair

dealings" in *Tessell* that tipped the balance in favor of discretionary denial are absent here.

If Heron was truly concerned about the fairness of defending the '254 patent before the Board and the district court, Heron could drop its assertion of this patent and rely on four of the originally asserted patents in the district court litigation. It has refused to do so. *See* Ex. 2014 at 1-2; Ex. 1052 at 1. It is illogical for Heron to suggest that to preserve the right to challenge the later issued '254 patent before the Board, Azurity needed to first petition the Board for review of all 10 prior patents that were asserted in the district court litigation. *See* PODDB at 29. That would have been a wasteful use of Board resources when Heron subsequently dropped six of those patents from the litigation. *See* Ex. 1052 at 1. It is especially wasteful when the differences between the '254 patent and the originally asserted patents are what precipitated Azurity's petition for post-grant review.

C. *Advanced Bionics* Does Not Favor Denial

In determining whether to exercise discretion to deny institution under §325(d), the Board applies *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020) (precedential) ("(1) whether the same or substantially the same art … or … arguments previously were presented to the Office; and (2) if either condition of first part of the framework

is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.").

Heron argues that the Petition should be denied under 35 U.S.C. §325(d) because "it presents the same or similar prior art, and the same arguments that the Office has rejected." PODDB at 30-31. Heron is wrong. There is no reason to exercise discretionary denial under §325(d) because there is either no previous Office evaluations of the evidence of record or the Office erred in regards to the patentability of the challenged claims. As explained herein, the petition provides novel art combinations, grounds, and arguments that the Examiner did not raise or consider. The Examiner's failure to do so during prosecution was both a legal and factual error. *Advanced Bionics* does not favor denial.

1. *Advanced Bionics* Step 1: The Asserted Arguments Have Not Been Previously Presented to the Office

a. Obviousness Challenge

First and most importantly, the Examiner only considered Zhou (Ex. 1003) as a potential anticipatory reference from an information disclosure statement ("IDS"), not as part of an obviousness combination. Ex. 1022 at 39. In fact, the Examiner never considered any obviousness combination during prosecution of the '254 patent. Ex. 1022 at 8-24. The petition, on the other hand, asserts obviousness with respect to Zhou ***in view of*** Washington (Ex. 1004), Bagwe (Ex. 1005), and Weng (Ex. 1006). Obviousness under 35 U.S.C. §103 and anticipation under 35 U.S.C.

§102 are completely distinct and separate arguments. *See* M.P.E.P. §2145 IV ("Arguing Against References Individually") ("One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.") (citing *In re Keller*, 642 F.2d 413 (CCPA 1981)). The fact that the petition used the phrase "nearly anticipatory" with respect to Zhou is both factually accurate and irrelevant to step 1. In sum, the Office never considered any obviousness combinations with Zhou.

Second, each of the other prior art references in Petitioner's obviousness combination was either not considered by the Office or simply listed in an IDS with no further analysis by the Examiner. Specifically, Heron admits that "the Office did not issue any rejection over Weng" and Weng was only considered in an IDS. PODDB at 32. Azurity is also cognizant of the Director's recent order as it relates to the first prong of the *Advanced Bionics* framework. *See Ecto World, LLC v. Rai Strategic Holdings, Inc.*, IPR2024-01280, Paper 13 at 4 (P.T.A.B. May 19, 2025) (precedential). The Director cautioned that discretionary denial may not be warranted if the IDS containing the reference was atypically large. *See id.* at 7. Indeed, "[m]ost IDS submissions contain fewer than 25 references" and "approximately 87% of applications contain 50 or fewer applicant-provided items of information…" *Id*. at 7 n.3 (internal citations omitted). Here, Weng and Zhou both were part of an IDS with 63 references (Ex. 2015 at 127-130) – an IDS larger

than 87% of applications submitted to the Office. Thus, discretionary denial is not warranted under this factor.

Third, Washington and Bagwe were never considered by the Office and therefore the Examiner could not have evaluated any arguments based on Washington and Bagwe. While the petition does acknowledge that Washington and Bagwe contain information that a POSA would have known, that does not mean that the references are somehow less important or not part of the obviousness combination, which they are. "The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the relevant time." M.P.E.P. §2141(II)(C). That does not mean that one can ignore a cited reference. Indeed, Heron fails to cite a single case that states certain references in obviousness combinations should somehow be treated differently if they are not the primary obviousness reference. Therefore, the Office never considered Bagwe or Washington and presented no rejection based on Weng. At bottom, the Office never considered any obviousness combinations whatsoever and did not consider Bagwe, Washington, or Weng in any rejection.

Accordingly, there is no "overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishe[d] the prior art." *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18 (P.T.A.B. Dec. 15, 2017).

Different art and different arguments warrant different conclusions. Heron has not demonstrated that "substantially the same arguments" were previously considered.

b. Section 112 Challenge

With respect to Ground II (written description) and Ground III (enablement), Heron's specious arguments should be given no weight. As an initial matter, there were simply no §112 rejections made during prosecution – full stop. As a result, Heron first argues that the Examiner "should be ***presumed*** to have considered enablement and written description for the challenged claims during prosecution and *Advanced Bionics* part one should be deemed to have been satisfied." PODDB at 33. On this argument, Heron cannot be correct because otherwise, every single §112 argument made in a PGR petition – regardless of whether there were any §112 rejections made during prosecution – should be disregarded under the *Advanced Bionics* analysis.

This cannot be the law and Heron cites no authority to support such an unwarranted blanket assertion. And, in fact, it is not the law. Heron is not the first patent owner to make such a strained argument. The Board has long ago dismissed this sort of argument, holding "the mere absence of a rejection does not reflect that the Examiner already considered the specific arguments presented in the Petition." *Lifescan Glob. Corp. v. Ikeda Food Rsch., Ltd.*, PGR2019-00032, Paper 11 at 14 (P.T.A.B. Aug. 15, 2019).

Heron next argues that a minor typographical objection made during prosecution somehow qualifies as the Examiner fully evaluating enablement and written description under §112. Not so. Here, the Examiner merely objected to an informality suggesting "it would be better if Applicant use consistent claim dependency language. That is, for claim 7 recite 'wherein the egg lecithin' instead of 'wherein the phospholipid' or change the dependency of claim 7." Ex. 1022 at 8-9. Such a correction has nothing to do with whether the claims comply with the enablement or written description requirements. In contrast, Azurity set forth fulsome non-enablement and lack of written description arguments for each of the Challenged Claims which have nothing to do with whether claim 7 recites "egg lecithin" or "phospholipid." *See, e.g.*, Petition at 52-71. Thus, the Examiner never considered the §112 arguments made in the Petition.

2. Advanced Bionics Step 2: Material Error Exists

a. Obviousness Challenge

Azurity has demonstrated material error under the second prong of *Advanced Bionics*. Contrary to Heron's flawed assertions (PODDB at 33-36), analysis of *Becton, Dickenson* Factors (c), (e), and (f) does not support denial.

Becton, Dickenson Factor (c) does not support denial. *See Commscope Tech. LLC v. Dali Wireless, Inc.*, IPR2020-01473, Paper 18 (P.T.A.B. Mar. 12, 2021) ("*Commscope II*") at 13 ("Whether the prior art was the basis for a rejection is

significant to this analysis."); *Ecto*, Paper 13 at 5-6 ("A petitioner also may point to the fact that even though the asserted prior art is listed on an IDS, the Examiner did not issue any prior art rejections during examination, so the Examiner materially erred by overlooking certain teachings in the prior art on the IDS."); *Cisco Systems, Inc. v. Portsmouth Network Corp.*, IPR2024-00505, Paper 7 at 18-19 (P.T.A.B. Aug. 6, 2024) (disclosure of reference and acknowledgement by Examiner insufficient to favor denial under factor (c)).

Despite their inclusion in Heron's omnibus IDS, the challenged claims were not substantively evaluated using the combined teachings of Zhou and Weng. Indeed, with respect to Weng, Bagwe, and Washington, none of the references are cumulative of art or arguments cited during prosecution and Heron makes no arguments to the contrary. In such circumstances, the Board has found that Factor (c) favors the petitioner. *See Becton, Dickinson*, Paper 8 at 23; *Bowtech, Inc. v. Mcp Ip, LLC*, IPR2019-00382 Paper 12 at 12 (P.T.A.B. Aug. 6, 2019) ("*Becton, Dickinson* expressly distinguished the situation 'where the prior art was simply listed in an IDS during prosecution.'").

Becton, Dickenson factors (e) and (f) also do not favor denial. Azurity has explained in detail how Zhou in view of Weng, Bagwe, and Washington would have rendered the challenged claims obvious. Zhou clearly taught emulsions meeting most of the challenged claim limitations including the aprepritant, oil, emulsifier,

co-surfactant, protective agent, and water for injection limitations. *See e.g.*, Petition at 15. Weng taught certain emulsion preparations including the use of a co-emulsifier and pH modulator including sodium oleate. *Id*. at 44. Indeed, the Examiner did not even consider Bagwe and Washington. Importantly, nine pages of the petition explain why the broad range of emulsifier that Heron claims would have been obvious. *See id*. at 27-36. Bagwe—which was not before the Examiner—is prominently featured in this explanation for why the broad range of emulsifier is *prima facie* obvious.

Thus, the material error made by the Examiner was the misapprehension of the obviousness of the challenged claims, not the alleged novelty over Zhou that resulted in the mistaken allowance of the challenged claims. Azurity submits that the Board can adopt verbatim the reasoning of *Commscope II* to find in Azurity's favor on these factors: "Given the fact that the Examiner did not expressly rely on [Zhou] and [any of Weng, Bagwe, or Washington] in rejecting the claims during prosecution or in the Examiner's explanation of the reasons for allowance, and given the description and explanation provided by [Zhou] and [Weng, Bagwe, and Washington] as discussed *infra*, we find that the Examiner erred by either overlooking, or failing to appreciate, the materiality of the disclosures of [Zhou] and [any of Weng, Bagwe, or Washington]." *Commscope II*, Paper 18 at 16. As such, *Becton, Dickenson* Factors (c), (e), and (f) do not support denial.

b. Section 112 Challenge

With respect to step two of the *Advanced Bionics* analysis, here, Heron ineffectively attacks the merits of Azurity's §112 arguments and fails to acknowledge that the Examiner did not have the benefit of Heron's prior admissions and expert's statements regarding the complexity of the broadly claimed emulsions. PODDB at 34-36. The challenged claims recite a range of emulsifier weight percentages that greatly exceed 14% (wt/wt) and emulsifier to aprepitant ratios that are often greater than 20:1. *See* Petition at 58-63. Yet it was lesser amounts of emulsifier that Heron and its expert alleged were "critical," "unprecedented," "unexpected," "surprising," and "unpredictable." *See id*. at 56-57. Inexplicably, the Examiner never questioned the challenged claims satisfaction of the written description and enablement requirements—particularly for claimed values that departed from the exemplified emulsions of the specification. The Examiner plainly erred by relying solely on a theory of obviousness-type double patenting to reject the claims. Ex. 1022 at 8-24. Accordingly, the two-step *Advanced Bionics* test does not disfavor institution.

Heron's arguments concerning the written description and enablement grounds do not exonerate the Examiner's error. *See* PODDB at 34-36. First, Heron's prior litigation admissions clearly bear on whether its specification satisfies the written description and enablement requirements for the challenged claims. *See*

PODDB at 35. Authority specifically contradicts Heron's argument for both written description and enablement. *Ariad*, 598 F.3d at 1351 (identifying factors such as "the ***existing knowledge in the particular field***, ***the extent and content of the prior art***, the maturity of the science or technology, [and] ***the predictability of the aspect at issue***" affect "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date"); *Wands*, 858 F.2d at 737 (identifying factors such as "(1) the quantity of experimentation necessary, (2) ***the amount of direction or guidance presented***, (3) ***the presence or absence of working examples***, (4) ***the nature of the invention***, (5) ***the state of the prior art***, (6) the relative skill of those in the art, (7) ***the predictability or unpredictability of the art***, and (8) the breadth of the claims.").

On the merits, Heron's only rebuttal concerning the lack of written description is that "it is undisputed that the '254 patent discloses the claimed amounts of emulsifier and the claimed ratios of emulsifier to aprepitant." PODDB at 36. But the petition clearly explains that *ipsis verbis* generic statements and laundry lists of values in the specification do not satisfy the written description requirement. *See* Petition at 67 (collecting cases). If Heron is suggesting that the Examiner applied such an incorrect understanding of the law, that would also be error under *Advanced Bionics*.

And Heron's allegation that the "enablement attack is barebones with no analysis of the relevant factors identified in *In re Wands*" does not even address whether the Examiner erred. *See* PODDB at 36. It is also incorrect. Azurity addressed many of the factors that support a finding of lack of enablement when setting forth Heron's failure to satisfy the written description requirement—as expressly indicated in the petition. *See* Petition at 70. It also does not take many words to explain the absence of guidance, lack of working examples, or even address the other *Wands* factors when Heron's admissions (cited and quoted ad nauseum) render enablement impossible.

III. CONCLUSION

Given that the discretionary denial considerations support institution as discussed above, Petitioner respectfully requests that the Board reach the merits of the petition.[4]

[4] The Office's discretionary denial practices are currently being challenged in *Apple Inc. v. Stewart*, No. 24-1864 (Fed. Cir. May 17, 2024) as well as other cases. Azurity respectfully requests the benefit of any relief that may be granted in that appeal or other challenges to the Office's discretionary denial practices.

Respectfully submitted,

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Dated: July 16, 2025

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Azurity Pharmaceuticals, Inc.
Azurity Pharma India LLP
Slayback Pharma LLC

Azurity v. Heron
PGR2025-00035 – U.S. 12,115,254

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that foregoing **PETITIONER'S OPPOSITION TO PATENT OWNER'S DISCRETIONARY DENIAL BRIEF** complies with the type-volume limitation of 37 C.F.R. §42.24(a)(1). According to Microsoft Office Word 2016's word count, this Petition contains 9041 words, exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a).

Respectfully submitted,

WINDELS MARX LANE & MITTENDORF, LLP

Dated: July 16, 2025

By: /Andrew E. Morrell/

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITIONER'S OPPOSITION TO PATENT OWNER'S DISCRETIONARY DENIAL BRIEF** and **EXHIBITS 1051-1052** are being served on July 16, 2025, via e-mail, as consented to by Patent Owner, on the following attorneys of record:

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Dated: July 16, 2025 By: /Andrew E. Morrell/

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