

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

HERON THERAPEUTICS, INC.,
Patent Owner.

Case PGR2025-00035
Patent No. 12,115,254

**PATENT OWNER'S BRIEF REQUESTING
DISCRETIONARY DENIAL OF INSTITUTION**

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LIST OF EXHIBITS

Exhibit No.	Description	Previously Submitted
2001	<i>Heron Therapeutics, Inc. v. Slayback Pharma LLC</i> (DNJ-2-24-cv-00423), D.I. 63 (“Defendants’ Reply Brief in Support of Motion to Transfer Venue to District of Delaware Pursuant to 28 U.S.C. § 1404(a) (Redacted)”)	
2002	<i>Heron Therapeutics, Inc. v. Azurity Pharmaceuticals, Inc.</i> (DDE-1-24-cv-01363), D.I. 81 (“Stipulation and Order to Amend Schedule”)	
2003	Prosecution History for U.S. Application Serial No. 18/418,030 which issued as the ’255 patent (“’255 Patent Prosecution History”)	
2004	<i>Heron Therapeutics, Inc. v. Slayback Pharma LLC</i> (DNJ-2-24-cv-00423), D.I. 1 (“Complaint for Patent Infringement”)	
2005	<i>Heron Therapeutics, Inc. v. Slayback Pharma LLC</i> (DNJ-2-24-cv-00423), D.I. 59 (“Opinion Granting Motion to Transfer Venue to District of Delaware”)	
2006	<i>Heron Therapeutics, Inc. v. Azurity Pharmaceuticals, Inc.</i> (DDE-1-24-cv-01363), D.I. 1 (“Complaint for Patent Infringement”)	
2007	<i>Heron Therapeutics, Inc. v. Azurity Pharmaceuticals, Inc.</i> (DDE-1-24-cv-01363), D.I. 30 (“Scheduling Order”)	
2008	<i>Heron Therapeutics, Inc. v. Azurity Pharmaceuticals, Inc.</i> (DDE-1-24-cv-01363), 12/30/2025 Hearing Transcript (Redacted)	
2009	<i>Heron Therapeutics, Inc. v. Azurity Pharmaceuticals, Inc.</i> (DDE-1-24-cv-01363), 01/13/2025 Defendants’ Invalidity Contentions	
2010	U.S. Patent 11,744,800 (“the ’800 patent”)	
2011	U.S. Patent 12,290,520 (“the ’520 patent”)	

2012	<i>Heron Therapeutics, Inc. v. Slayback Pharma LLC</i> (DDE-1-24-cv-00830), D.I. 80 (“Scheduling Order”)	
2013	<i>Heron Therapeutics, Inc. v. Azurity Pharmaceuticals, Inc.</i> (DDE-1-24-cv-01363), D.I. 46 (“Joint Stipulation and Order Regarding Claim Construction”)	
2014	04/28/2025 Email from J. Goldstein Regarding Reduction of Asserted Claims	
2015	Prosecution History for U.S. Application Serial No. 18/408,486 which issued as the ’254 patent (“’254 Patent Prosecution History”)	
2016	<i>Heron Therapeutics, Inc. v. Fresenius Kabi USA, LLC</i> (DDE-1-22-cv-00985), D.I. 182 (“Fresenius’s Opening Post-Trial Brief (Redacted)”)	

I. INTRODUCTION

Pursuant to Acting Director Stewart’s March 26, 2025 Memorandum on Interim Processes for PTAB Workload Management (“March 26 Memorandum”), Patent Owner Heron Therapeutics, Inc. (“Heron” or “Patent Owner”) submits this brief requesting discretionary denial of the petition for post-grant review (“PGR” or “Petition”) filed by Petitioners Azurity Pharmaceuticals, Inc., Azurity Pharma India LLP, Inc., and Slayback Pharma LLC (“Slayback” or “Petitioner”) challenging claims 1-30 of U.S. Patent No. 12,115,254 (the “254 patent”).

Slayback’s PGR warrants exercise of discretion because, *inter alia*, the United States District Court for the District of Delaware, as opposed to the PTAB, is the most logical venue for resolving the parties’ patentability dispute. The Delaware Court is intimately familiar with Heron’s patents and has previously adjudicated validity disputes very similar to those presented by Slayback’s PGR. Indeed, Slayback successfully moved to transfer the litigation from New Jersey to Delaware touting this familiarity and the efficiencies gained from having the Delaware Court resolve the parties’ disputes, including invalidity. Slayback should be held to its representations and not allowed to improperly use this PGR (and its companion,

PGR2025-00036)¹ to open a second front against Heron’s patents. This is particularly so when both the Delaware Court and the parties have invested (and are continuing to invest) significant resources into resolving the same disputes presented by Slayback’s PGR, and trial is scheduled for November 2025—more than eleven months before the projected October 2026 final written decision (“FWD”) date in this PGR (if instituted). Moreover, the Office has already considered the art and arguments presented in this PGR during prosecution of the ’254 patent.

First, pursuant to 35 U.S.C. § 324(a), the PGR should be denied in light of the fast-approaching trial date scheduled just one month after the deadline for an institution decision. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 1-6 (PTAB Mar. 20, 2020) (precedential) (“*Fintiv*”). Specifically, trial in the parallel district court litigation is scheduled for November 2025—eleven months before the projected October 2026 final written decision date in this PGR (if instituted). The parties and the Court will have nearly completed all work for the trial by the projected October 2025 institution decision date including completion of both fact and expert discovery by September 2025. The parties also agreed to adopt a number

¹ PGR2025-00036 challenges claims of related U.S. Patent No. 12,115,255 (the “’255 patent”).

of claim constructions from a prior litigation, and the Court granted the parties' claim construction stipulation in this regard. Moreover, Slayback is asserting in the district court the same prior art and invalidity theories raised in this PGR. Instituting the PGR in this instance therefore would be an extremely inefficient use of PTAB resources and would create potential for conflicting rulings on the same prior art and validity issues.

Slayback's offer to enter a *Sotera* stipulation if the PGR is instituted cannot overcome the eleven-month difference between the November 2025 trial date and projected October 2026 final written decision date. *See, e.g., Motorola Solutions, Inc. v. Stellar, LLC*, IPR2024-01205, Paper 19 at 3-4 (PTAB Mar. 28, 2025) (Director Review Decision) (denying institution despite a *Sotera* stipulation because the district court trial date was scheduled eleven months before the projected final written decision date and the parties and court had invested substantial amount of time and effort in the district court case). Indeed, the Acting Director has exercised her discretion to deny institution where the difference between the earlier scheduled trial date and projected final written decision date was as little as five months, despite *Sotera* stipulations. *Arm Ltd. et al. v. Daedalus Prime LLC*, IPR2025-00207, Paper

10 at 2 (PTAB May 16, 2025) (five-month difference)²; *Ericsson Inc. et al. v. Procomm Int'l PTE. Ltd.*, IPR2024-01455, Paper 15 at 2 (PTAB May 16, 2025) (nine-month difference).³

Moreover, an early challenge to a patent does not insulate it from discretionary denial under *Fintiv. Catalyst Orthoscience Inc. v. Shoulder Innovations, Inc.*, PGR2025-00001, Paper 8 at 12-14, 18 (PTAB Apr. 24, 2025) (discretionary denial of PGR in light of trial expected to take place before statutory deadline for FWD and substantial time and resources invested in parallel litigation by institution decision). Thus, this PGR should be denied and the PTAB's resources should be saved as trial in the parallel district court litigation is scheduled almost a year before the expected FWD date and nearly all work related to the trial will be complete by the time an institution decision is due.

Second, consistent with Acting Director Stewart's March 26 Memorandum, several factors (including the parties' settled expectations) favor exercise of

² *Arm Ltd. et al. v. Daedalus Prime LLC*, IPR2025-00207, Paper 9 at 9 (PTAB April 28, 2025) (petitioner's *Sotera* stipulation).

³ *Ericsson Inc. et al. v. Procomm Int'l PTE. Ltd.*, IPR2024-01455, Paper 13 at 3 (PTAB May 1, 2025) (petitioner's *Sotera* stipulation).

discretion. For example, the parties have a settled expectation that Federal Circuit Judge William Bryson, who is presiding over the district court litigation, will adjudicate the validity dispute for the '254 patent. Indeed, Judge Bryson is by far in the best position to handle the '254 patent validity dispute given his intimate familiarity with the technology at issue. He previously completed a four-day trial on very similar patents and his decision finding the patents valid is now on appeal. And he has noted that the '254 patent “looked . . . like [it] is very similar to several of the patents that went before.” (Ex. 2008 at 43:21-44:17.) Slayback successfully transferred the district court litigation from New Jersey to Judge Bryson’s court touting Judge Bryson’s extensive knowledge of the issues it now seeks to burden the PTAB with. For example, Slayback contended that “[Judge Bryson’s] prior decisions and familiarity with many, if not most, of the issues that will need to be decided in this case unquestionably will enable a more efficient and expeditious disposition of Heron’s claims.” (Ex. 2001 at 9.) Thus, it makes little sense for the PTAB to invest substantial resources into this case when the district court is far better situated to efficiently handle the validity issues raised in the PGR—a fact Slayback cannot dispute. *Advanced Micro Devices, Inc. v. Concurrent Ventures, LLC*, IPR2025-00223, Paper 9 at 2 (PTAB June 12, 2025) (denying IPR petition because of the efficiencies gained in district court in light of the meaningful investment made by the parties and court in the parallel litigation); *Shenzen Touzhu Tech. Co., Ltd. v.*

Stratasys, Inc., IPR2025-00354, Paper 11 at 2-3 (PTAB June 12, 2025).

Third, the PGR should be denied under 35 U.S.C. § 325(d), as the same or substantially the same prior art and arguments have been considered by the Office. Slayback’s primary reference, Zhou, was previously presented to the Office and carefully considered during prosecution of the ’254 patent. Slayback alleges that Zhou is “nearly anticipatory” while the other references (Washington, Bagwe, and Weng) “simply reflect common knowledge in the art regarding emulsion components/amounts” (Petition at 1-2.) Thus, the Office’s finding during prosecution that Zhou does not render the claims obvious should foreclose the PGR because Slayback offers no plausible basis for a finding of material error by the Office in its evaluation of Zhou.

Heron respectfully requests exercise of discretion and denial of institution.

II. BACKGROUND

A. CINV and NK-1 Receptor Antagonists

Chemotherapy-induced nausea and vomiting (“CINV”) is a debilitating side effect of chemotherapy experienced by patients already suffering from cancer. (Ex. 1007 at 6.) It can greatly impact the quality of life of patients with cancer, and in some cases can be so severe that patients are unwilling to continue chemotherapy treatment. (*Id.*) The optimal treatment for CINV is preventing it, which involves using antiemetic medications to block certain neurotransmitters (e.g., NK-1

receptors) associated with nausea and vomiting prior to administering chemotherapy. (*Id.* at 6-7.) The medications include a chemical, referred to as an “antagonist,” that inhibits the neurotransmitters. (*Id.*)

The first NK-1 receptor antagonist was aprepitant, which was discovered around 1993. (Ex. 1008 at 7.) In 2003, Merck obtained Federal Food and Drug Administration (FDA) approval for oral tablets of aprepitant for the treatment of CINV under the trade name Emend[®]. (Ex. 1007 at 7.) “Oral administration of aprepitant, however, presented [several] problems.” (*Id.* at 8.)

Merck thus pursued the development of an intravenous (IV) formulation of its Emend[®] product, but ultimately abandoned its efforts after many failed attempts, viewing the drug’s properties as precluding development altogether. (*Id.* at 8-9; Ex. 1008 at 5 (“The sparing water solubility of aprepitant precluded its formulation in a vehicle acceptable for intravenous administration in humans.”).) Merck instead pivoted to developing a derivate of aprepitant called fosaprepitant and received FDA approval in 2008 for an injectable fosaprepitant dimeglumine product for the treatment of CINV, which it marketed as Emend[®] for Injection (or Emend[®] IV). (*Id.*) In the more than 20 years following Merck’s discovery of aprepitant, no successful injectable **aprepitant** formulation was developed. (Ex. 1007 at 48-49.)

B. Heron Overcame Merck's Failure

The inventors of the '254 patent did what Merck scientists and others failed to do: they overcame the very low solubility of aprepitant (which has been likened to “cement dust” (*e.g.*, Ex. 1007 at 7)) and created a safe and effective IV aprepitant drug product for the treatment of patients suffering from CINV. Specifically, the '254 patent claims aprepitant emulsion formulations of aprepitant suitable for intravenous administration for treatment of emesis. (Ex. 1001 at 1:22-24.) Heron's patents, including the '254 patent, claim an unprecedented amount of a particular excipient, ***an emulsifier such as egg yolk lecithin***, in combination with other specific ingredients and concentrations in an emulsion for intravenous use, including comprising the NK-1 receptor antagonist aprepitant. For example, the '254 patent discloses about “12 wt/wt % to 17 wt/wt %” emulsifier, such as egg yolk lecithin. (*E.g.*, Ex. 1001 at 3:49-58.) Additionally, the '254 patent discloses a ratio of the emulsifier, such as egg yolk lecithin, to the NK-1 receptor antagonist, such as aprepitant, of “about 20:1” or “20:1 to 25:1.” (*Id.* at 17:38-45.) Heron's discovery of using these amounts and ratios of emulsifier in an aprepitant emulsion for intravenous use are recited in the '254 patent claims. (*E.g.*, *id.* at claim 1 (“[a]n injectable pharmaceutical emulsion, comprising: about 0.7-0.8 wt % aprepitant . . . wherein the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1”),

claim 6 (“wherein the egg lecithin is present in the emulsion at about 16 wt/wt %”), claim 7 (“wherein the egg lecithin is present in the emulsion at about 17 wt/wt %”).)

Such formulations possess unexpected stability compared to the prior art aprepitant emulsions, and this stability confers significant clinical usefulness and benefit. For instance, Examples 1-3, and 6 of the '254 patent disclose embodiments of aprepitant emulsion that were stable for at least two months at room temperature. (Ex. 1001 at 19:38-20:17 (Example 1), 20:20-67 (Example 2); 21:1-46 (Example 3), 22:60-23:59 (Example 6).) In contrast, Examples 4 and 5 of the '254 patent, which used ingredients and concentrations of those ingredients that were disclosed in the prior art, including the Zhou reference asserted by Slayback as prior art, formed solid crystals of aprepitant within just four days at room temperature. (*E.g.*, Ex. 1040 at 2-3.) These crystals meant that these formulations were not suitable for administration into the veins of patients. The unexpected physical stability over the prior art is a key feature of Heron's claimed aprepitant emulsions.

**C. The USPTO Granted
Heron Several Patents, Including
the '254 Patent, Expressly Rejecting the Same
Prior Art Arguments that Slayback Proffers in this PGR**

As further discussed below in Section V.A, the Petition presents the same or similar prior art arguments that the USPTO has rejected numerous times. Specifically, the Petition presents Zhou as its primary reference alleging it is “nearly

anticipatory.” (Petition at 1.) But Zhou was considered by the Office (and Judge Bryson, *see infra* Section IV.B), and each time Heron’s inventions were found patentable and non-obvious over Zhou and other prior art. For example, when allowing the claims of the ’254 patent, the Office explained that the claims were not obvious based on Zhou given the stability properties imparted by the higher emulsifier concentration:

Zhou’s ratio of emulsifier to aprepitant (the NK-1 antagonist) is below the ratio required by the claimed invention. It appears that *the amount of emulsifier is critical* in the claimed invention because, according to the instant specification, the aprepitant emulsion possess[es] favorable stability properties[.]”

(Ex. 1022 at 39-40 (emphasis added).)

Examiners across several related patents arrived at the same conclusion: there was no motivation to increase the amount of emulsifier above Zhou, and Heron demonstrated criticality with respect to the amount of emulsifier in the claimed formulations. (*E.g.*, Ex. 1046 at 62 (“The wt. % of the egg yolk lecithin [in Zhou] is far too low, as is the ratio of egg yolk lecithin to aprepitant.”); Ex. 2003 at 160 (“Zhou’s disclosure does not provide sufficient guidance and motivation” to a POSA to “increase the amount of phospholipid to 13-20 wt/wt% and increase the ratio of the emulsifier to the NK-1 receptor antagonist to about 20:1 to 25:1 (wt/wt%).”).)

D. Judge Bryson Also Found Heron's Inventions Patentable over Zhou and Other Prior Art

Before Slayback's PGR (and the companion PGR-00036), others have tried and failed to invalidate Heron's patents. Fresenius was the first to challenge Heron's patents. The parties in the Fresenius litigation spent over two years litigating before Judge Bryson, ultimately culminating in a four-day trial in the District of Delaware. At trial, Fresenius advanced arguments *similar to those now raised by Slayback in this PGR*, primarily relying on the Zhou⁴ reference (with other background references) to support its obviousness theories. (Ex. 1007 at 26 ("In brief summary, Fresenius's theory of obviousness is that the Chinese patent application, CN845, disclosed an emulsion consisting of essentially the same components and prepared by the same process as the emulsion disclosed in [Heron's asserted patents].").) The Court found that "Fresenius has not proved by clear and convincing evidence that the asserted claims are invalid for obviousness under 35 U.S.C. § 103 or for the lack of adequate written description under 35 U.S.C. § 112." (Ex. 1007 at 57.) After a review of the prior art presented to the Court, including Slayback's primary reference Zhou, Judge Bryson found that "a POSA would not have had a motivation to increase the concentration of [*the emulsifier*] lecithin above 10%" as Heron's claimed 14%

⁴ The Zhou reference is referred to as "CN845" in the Fresenius Opinion.

was a “substantial departure from what was taught in the relevant prior art.” (Ex. 1007 at 39-40, 43 (emphasis added).) Judge Bryson also found that “a POSA . . . would not have had a reasonable expectation of success with an emulsifier level that high.” (Ex. 1007 at 40-41, 43.)

Mylan was the second challenger to Heron’s patents. Like Fresenius before it—and Slayback now—Mylan principally relied on the Zhou reference (with the same or similar background references) to support its obviousness arguments. Judge Bryson presided over all stages of the Mylan litigation for more than a year and a half, until the parties entered into a stipulated dismissal less than two weeks before trial was scheduled to begin.

**E. Later This Year,
Slayback Will Litigate Before Judge Bryson
the Same Arguments and Prior Art It Presents in this PGR**

Slayback became the third challenger to Heron’s patents when, on December 11, 2023, it sent Heron a Paragraph IV Certification Letter providing written notice of its New Drug Application (“NDA”), which identified Heron’s Cinvanti[®] product as the reference listed drug. On January 24, 2024, Heron filed its patent infringement complaint against Slayback in the District of New Jersey, where Slayback had its headquarters at the time. (Ex. 2004.)

Slayback, subsequently moved its headquarters out of New Jersey and moved to transfer the litigation to the District of Delaware, touting Judge Bryson’s intimate

familiarity with Heron’s patents and the same issues that Slayback argues in this case. Slayback asserted that “[i]t makes no sense for [another] Court to duplicate the work that Judge Bryson has already done in the Delaware cases.” (Ex. 2001 at 4.) Slayback explained that Judge Bryson had “developed extensive knowledge of the facts and technology” through the pending litigations with Fresenius and Mylan, which concerned “[t]he same patents” and “technology.” (*Id.* at 4.) Slayback contended that “[Judge Bryson’s] prior decisions and familiarity with many, if not most, of the issues that will need to be decided in this case unquestionably will enable a more efficient and expeditious disposition of Heron’s claims.” (*Id.* at 9.) The patents-in-suit included related patents to the ’254 patent.

The District of New Jersey Court granted Slayback’s motion to transfer the litigation to the District of Delaware, agreeing that Judge Bryson’s familiarity with the related litigations involving the same or related patents meant that “it would be far more efficient for the District of Delaware to handle this matter.” (Ex. 2005 at 11.) Indeed, the District of New Jersey Court observed that “Judge Bryson in the District of Delaware has already gained detailed knowledge regarding the patents-in-suit.” (*Id.* at 13.)

On December 12, 2024, Heron filed suit against Slayback on the newly-issued ’254 and ’255 patents. (Ex. 2006 at 2.) Shortly afterwards, Judge Bryson ordered that the two litigations be coordinated with the same schedule,

including the same trial date. (Ex. 2007 at 1-2.) Judge Bryson explained that “I would like, absolutely, to get everything tied up together. Again, the new patents [i.e., the ’254 and ’254 patents] looked to me like they are very similar to several of the patents that” he adjudicated previously in the Fresenius litigation. (Ex. 2008 at 43:21-44:17.)

Since then, Slayback has asserted invalidity defenses in the district court based on references relied upon in its PGR, namely Zhou (Ex. 1003), Washington (Ex. 1004), Bagwe (Ex. 1005), and Weng (Ex. 1006). (*See, e.g.*, Ex. 2009 at 17 (Bagwe), 32-33 (Washington and Weng), 34-36 (Zhou), 48-75.) The PGR’s invalidity challenges for lack of written description and enablement under 35 U.S.C. § 112 are similarly included in Slayback’s district court invalidity contentions. (*Id.* at 82-85 (written description challenge), 85-89 (enablement challenge).)

The district court will hold a four-day trial on Slayback’s invalidity challenges no later than November 2025, almost one year before the anticipated final written decision date in this PGR. (Ex. 2002 at 2-3.)

**III. DENIAL OF INSTITUTION IS
WARRANTED UNDER 35 U.S.C. § 324(a)
AS THE *FINTIV* FACTORS FAVOR DENIAL**

The Director has discretion under 35 U.S.C. § 324(a) to decline institution of a post-grant review. *See, e.g., Catalyst Orthoscience Inc.*, PGR2025-00001, Paper 8 at 9-10. Discretionary denial of Slayback’s PGR is warranted under § 324(a) at

least because the *Fintiv* factors favor denial.

Fintiv identifies the following non-exclusive list of factors in consideration of whether a related, parallel district court proceeding provides a basis for discretionary denial under 35 U.S.C. § 324(a):

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
6. other circumstances that impact the Board's exercise of discretion, including the merits.

See Fintiv, Paper 11 at 5-6.

As discussed below, the *Fintiv* factors compel denial of Slayback's PGR.

**A. *Fintiv* Factor 1 Strongly
Favors Denial as There is Little
To No Chance the Related Litigation Will Be Stayed**

The parallel district court proceeding is charging ahead towards the trial scheduled in November 2025. Slayback has not moved to stay the district court proceeding. Even if Slayback were to move to stay the litigation, it is highly unlikely

that such a motion would be granted, especially because Slayback’s PGR petitions do not cover all asserted patents in the district court litigation.⁵ Judge Bryson, who is presiding over this case in the district court proceeding, has indicated to the parties that he wants the trial to take place by the end of this year (2025) so he has sufficient time to prepare and issue his decision(s) by June 2026. (Ex. 2008 at 12-14.) The June 2026 target date is tied to the 30-month regulatory stay initiated by the related litigation barring the U.S. FDA from approving Slayback’s generic application until the litigation resolves or the stay period expires.

Thus, factor one strongly favors exercise of the Acting Director’s discretion to deny this PGR.

**B. *Fintiv* Factor 2 Strongly Favors
Denial as Trial Will Occur Eleven Months
Prior To the Expected Final Written Decision Date**

Trial in the parallel district court litigation is scheduled for November 2025. (Ex. 2002 at 2-3.) If this PGR is instituted by the institution decision deadline of October 2025, a FWD would be due one year later—by October 2026. Thus, the

⁵ The district court litigation involves five additional patents that Slayback has not challenged at the PTAB. (Ex. 1030; Ex. 1044; Ex. 1031; Ex. 2010; Ex. 2011.)

trial in the district court case will occur eleven months before any FWD would be issued in this PGR (if instituted). And, as noted above, Judge Bryson has stated that he will issue a decision by June 2026. In fact, Judge Bryson moved the trial date forward to November 2025 from January 2026 to ensure he had sufficient time to prepare and issue a decision by June 2026. (*Compare* Ex. 2012 at 7, *with*, Ex. 2002 at 1-3.)

Indeed, the parties agreed (and the Court ordered) in May 2025 that Heron will additionally assert claims of a recently-issued patent in the parallel district court proceedings *while maintaining the same November 2025 trial date*. (Ex. 2002 at 1-3.) Thus, Judge Bryson will adjudicate Slayback's overlapping invalidity challenges months before a final decision in this PGR. Factor two, therefore, strongly favors exercise of the Acting Director's discretion to deny this PGR. *See, e.g., Motorola Solutions, Inc.*, IPR2024-01205, Paper 19 at 3-4 (exercising discretion to deny institution in the same circumstances, with eleven month difference between trial and projected final written decision date); *Arm Ltd. et al.*, IPR2025-00207, Paper 10 at 2 (discretionary denial with five-month difference between trial and projected final written decision date); *Ericsson Inc. et al.*, IPR2024-01455, Paper 15 at 2 (discretionary denial with nine-month difference between trial and projected final written decision date); *Catalyst Orthoscience Inc.*, PGR2025-00001, Paper 8 at 12-13 (finding factor two weighs in favor of denying a PGR in light of trial expected

to take place sometime before expected date for FWD date).

**C. *Fintiv* Factor 3 Strongly Favors
Denial Because the Parties and the Court
Have Significantly Invested in the Related Litigation**

The parties and the Court have already expended significant resources working towards the November 2025 trial. The parties have already exchanged invalidity and infringement contentions, conducted all fact depositions, and completed all document production. The parties will complete expert discovery by September 2025—one month before the projected institution decision date and more than a year before the projected FWD date. (Ex. 2002 at 2-3; *Fintiv*, Paper 11 at 9 (explaining that under factor three, the PTAB considers “the amount and type of work already completed in the parallel litigation by the court and the parties at the time of the institution decision.”).)

The Court also granted the parties’ stipulation regarding claim construction where the parties agreed to adopt a number of claim constructions from the prior Fresenius litigation. (Ex. 2013 at 2.) In light of the parties “seeking to efficiently adjudicate this case,” the Court also agreed with the parties to forgo *Markman* proceedings and address the single disputed term at the November trial. (*Id.*) The parties also agreed they will not file any summary judgement or *Daubert* motions, meaning that by the time of the projected institution decision date (October 2025), essentially all of the work towards the November 2025 trial will have been completed.

(Ex. 2002 at 2-3.)

Accordingly, factor three strongly favors denial. *Charter Comm., Inc. et al. v. Adaptive Spectrum and Signal Alignment, Inc.*, IPR2025-00088, Paper 14 at 10-12 (PTAB May 22, 2025); *Catalyst Orthoscience Inc.*, PGR2025-00001, Paper 8 at 13-14 (finding factor three weighs in favor of denying a PGR because “the parties will have invested substantial time and resources in the Parallel Proceeding by the time of institution”).

**D. *Fintiv* Factor 4 Favors Denial
Because Substantial Overlap of Issues Exists
Between This Proceeding and the Parallel Litigation**

Slayback asserts in the district court the same prior art and invalidity theories raised in this PGR. (*See supra* Section II.E.) For example, Slayback relies on Zhou (Ex. 1003), Washington (Ex. 1004), Bagwe (Ex. 1005), and Weng (Ex. 1006) in its invalidity contentions. (*See, e.g.*, Ex. 2009 at 17 (Bagwe), 32-33 (Washington and Weng), 34-36 (Zhou), 48-75.) Slayback also asserts lack of written description and enablement under 35 U.S.C. § 112 in its contentions. (*Id.* at 82-85 (written description challenge), 85-89 (enablement challenge).) Heron asserts claims 5, 6, and 7 (which depend from claim 1) in the parallel litigation and Slayback challenges each of those claims in the petition. Thus, there is substantial overlap of issues between this PGR and the parallel district court litigation.

Relative to the district court, Slayback additionally challenges claims 2-4 and

8-30 in the PGR; but this additional challenge does not favor institution.⁶ “If a petition involves the same prior art challenges but challenges claims in addition to those that are challenged in the district court, it may . . . 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; *see also, e.g., Apcon, Inc. v. Gigamon Inc.*, IPR2020-01585, Paper 9 at 12-14 (PTAB Mar. 16, 2021) (denying institution despite the petition challenging twenty claims compared to the two claims at issue in the district court, where factor 4 weighed in favor of denying institution due to similar subject matter of the claims and no additional prior art references necessary to challenge the non-overlapping claims).

Here, Slayback applies no additional prior art to challenge the

⁶ Slayback expressly requested that Heron limit the number of asserted claims and, in the spirit of cooperation, Heron has narrowed the number of asserted claims. (Ex. 2014 at 2 (arguing “88 claims across 7 patents” is not sufficient narrowing); *id.* at 1 (arguing “19 claims across 6 patents” with three and four claims for the ’254 and ’255 patents respectively, is still not sufficient narrowing).) Slayback cannot on one hand argue for Heron to narrow claims in the district court and turn around and use Heron’s claim narrowing against it as a basis for avoiding a discretionary denial.

non-overlapping claims (i.e., claims 2-4 and 8-30) because it uses the same combination of references (Zhou with the combination of Washington, Bagwe, and Weng) to assert obviousness for all challenged claims. (Petition at 12.) Furthermore, there are significant similarities between the asserted claims in the district court and the claims at issue in the PGR with a number of overlapping limitations. For example, claims 5, 6, and 7, which are asserted in the litigation, all depend from claim 1, which covers an aprepitant injectable emulsion with an emulsifier. Claim 22, which is not asserted but challenged in the Petition, differs from claim 1 in the ratio of emulsifier to aprepitant (“about 20:1 to 25:1” for claim 1 and “about 23:1” for claim 22). The significant overlap in the claims of the ’254 patent is equally apparent from Slayback’s petition. Much of Slayback’s analysis is focused on independent claim 1, which is heavily incorporated into the analysis for claim 22. (*See* Petition at 45-46.)

Slayback’s offer to submit a *Sotera* stipulation (Petition at 71) upon institution does not tilt factor four in favor of institution for at least two reasons. *First*, as discussed above under Section III.C, the district court proceeding is at an advanced stage with expert discovery due to be completed by September 2025. Thus, much if not all of the work towards invalidity issues will be completed in the month prior to the projected October 2025 institution date. Hence, Slayback’s offer to enter a *Sotera* stipulation if the PGR is instituted does not resolve the concerns animating

Fintiv, namely duplicating efforts in two venues and inefficient use of the PTAB's resources. *See, e.g., Motorola Solutions, Inc.*, IPR2024-01205, Paper 19 at 3-4 (denying institution despite a *Sotera* stipulation because the district court trial date was scheduled eleven months before the projected final written decision date and the parties and court had invested substantial amount of time and effort in the district court case).

Second, a *Sotera* stipulation does not foreclose the possibility that the district court and the PTAB could issue inconsistent rulings if the two proceedings move forward in parallel. *Samsung Electronics Co. v. Clear Imaging Research, LLC*, IPR2020-01399, Paper 13 at 23-24 (PTAB Feb. 3, 2021). The ongoing district court proceeding involves five other patents that Slayback has not challenged in post-grant proceedings. But those patents claim overlapping subject matter and present similar issues as the instant PGR petition. For example, the other patents in the district court proceeding claim ingredients and ingredient amounts that are either identical or closely related to those in the '254 patent. (*Compare, e.g., Ex. 1001* at claim 7 (an injectable pharmaceutical emulsion, comprising, among other things, about 0.7-0.8 wt % aprepitant, about 17 wt/wt % egg lecithin, and a ratio of aprepitant to egg lecithin of about 20:1 to 25:1), *with, Ex. 2011* at claim 14 (an injectable emulsion, comprising, among other things, about 0.7% aprepitant, 13-20 wt/wt % egg lecithin, and a ratio of egg lecithin to aprepitant of about 20:1 to 25:1).) Some claims cover

the emulsifier to aprepitant ratios as those recited in the '254 patent. (*Compare, e.g.,* Ex. 1001 at claim 1 (“wherein the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1”), *with,* Ex. 2011 at claim 1 (“wherein the ratio of egg lecithin to aprepitant is between about 20:1 to 25:1”).) Other patents also claim emulsifier concentrations of, for example, about 17 wt/wt % (*compare, e.g.,* Ex. 1001 at claims 4, 7 (“about 17 wt/wt %”), *with,* Ex. 2011 at claim 3 (“about 17 wt/wt %”)) similar to those recited in some of the '254 patent claims.

Accordingly, factor four favors denial of institution.

**E. *Fintiv* Factor 5 Strongly Favors Denial
as Slayback is Involved in Both Proceedings**

Factor five strongly favors denial of institution as there is complete overlap of the parties; Slayback is the defendant in the district court proceeding and the petitioner in this proceeding.

**F. *Fintiv* Factor 6 Strongly Favors
Denial as the District Court is the Most
Appropriate Venue To Litigate the PGR Grounds**

As discussed below in Section IV.B, the district court is far better situated to adjudicate the issues raised in this PGR given Judge Bryson’s extensive work in two prior litigations involving the same technology and issues.

Furthermore, the merits of Slayback’s invalidity challenge are not compelling. As discussed below in Section V.A, Slayback’s prior art (e.g., Zhou) and its arguments for modifying the formulations in Zhou have been considered and rejected

by the Office in the '254 and related patents. Similarly, Slayback's written description argument (Petition at 52-67) is misplaced, outright ignoring the explicit recitation of the claimed ratios of emulsifier to aprepitant in the specification. (*See infra* Section V.B.2.) And its enablement attack is barebones with no analysis of the relevant factors identified in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). (Petition at 68-71.)

Thus, factor six strongly favors denial.

G. The *Fintiv* Factors, Weighted Together, Strongly Favor Denial

As discussed above, each of the *Fintiv* factors favors denial and thus, when viewed holistically, discretionary denial is warranted in this case. If the PTAB institutes this PGR, it will unnecessarily duplicate efforts in view of the fast-approaching trial date and the extensive work that the parties and Court will have already completed before the projected institution decision date. Institution would thus be an extremely inefficient use of the PTAB's resources.

An early challenge to the patent alone does not preclude discretionary denial in light of all the *Fintiv* factors favoring denial. *Catalyst Orthoscience Inc.*, PGR2025-00001, Paper 8 at 12-14 (discretionary denial under *Fintiv* of an early challenge via PGR based on, among other things, an expected earlier trial date and significant investment in the parallel litigation). Indeed, this is precisely the type of

case where, “[t]o ensure that the PTAB continues to meet its statutory obligations as to *ex parte* appeals, while continuing to maintain its capacity to conduct AIA proceedings, the Director [should] exercise her discretion on institution.” *See* March 26 Memorandum at 1.

IV. THE PARTIES’ SETTLED EXPECTATIONS AND EQUITY WARRANT DENIAL

A. Judge Bryson is Intimately Familiar With the ’254 Patent and Zhou

Slayback cannot dispute that Judge Bryson is intimately familiar with the subject matter of the ’254 patent and the Zhou reference. As discussed in Section II.E, Slayback vigorously argued this exact point during the district court litigation. (*See, e.g.*, Ex. 2001 at 4 (“It makes no sense for this Court to duplicate the work that Judge Bryson has already done in the Delaware cases.”); *id.* at 7 (“Judge Bryson’s knowledge and experience with the underlying patents, issues, and technology will remain important and will help to efficiently decide this case.”).) Indeed, Judge Bryson ordered that the ’254 and ’255 patent litigation be coordinated with the initial litigation on the same schedule, explaining “I would like, absolutely, to get everything tied up together. Again, the new patents looked to me like they are very similar to several of the patents that went before.” (*Supra* Section II.E; Ex. 2008 at 43:21-44:17.)

**B. Judge Bryson Heard
and Decided the Same Defenses
in the Fresenius Trial That Slayback Raises Now**

Not only is Judge Bryson intimately familiar with the patents and technology at issue, but he already decided a litigation that had many of the same claims and defenses including, among other things, Zhou and many of the other prior art documents Slayback cites. As discussed above in Section II.D, Judge Bryson held a four-day trial in the Fresenius litigation with live testimony from expert witnesses on related patents, much of the same prior art (including the same primary reference Zhou that is put forth by Slayback), and the same or similar defenses. Following trial, Judge Bryson considered post-trial briefing, held oral arguments, and then decided the case in a detailed opinion that addressed many of the same issues raised by Slayback in its PGRs. In his decision, Judge Bryson rejected each invalidity attack on the asserted claims.

Even while asking that the patent office, instead of Judge Bryson, to adjudicate the parties' dispute on the '254 and '255 patents, Slayback substantively discusses the "litigation with Fresenius" (*e.g.*, at 54-57), cites documents from that litigation (*e.g.*, *id.* at 57), characterizes trial arguments (*e.g.*, *id.* at 64), and relies on cherry-picked statements from Judge Bryson's decision (*e.g.*, *id.* at 2, 44, 54). For example, Slayback quotes Judge Bryson's opinion, including the portion in which Judge Bryson wrote that "[t]he issue of obviousness in this case is a close one." (*Id.* at 2.)

Yet, Slayback ignores where Judge Bryson plainly wrote that “I find that a POSA would not have had a motivation to increase the concentration of lecithin above 10%, including a concentration of at least 14%, and would not have had a reasonable expectation of success with an emulsifier level that high” and Heron’s claimed 14% was a “substantial departure from what was taught in the relevant prior art.” (Ex. 1007 at 39-41, 43.) Slayback misleadingly referenced Judge Bryson’s opinion multiple times, including by omitting contrary findings. There is a settled expectation that Judge Bryson is the appropriate adjudicator of the parties’ disputes as he is in the best position to know what factual findings he made, what arguments were raised in the litigation he adjudicated, and the trial he oversaw. (*Supra* Sections II.D, III.B.1.) Equity compels the same outcome as it would be unfair for Heron to defend patent validity at the PTAB when Slayback has repeatedly touted Judge Bryson’s suitability to resolve the parties’ disputes, including patent validity. *Tessell, Inc. v. Nutanix, Inc.*, IPR2025-00322, Paper 14 at 2-3 (June 12, 2025). Slayback’s efforts to rely on the Fresenius litigation while seeking adjudication by another tribunal would only invite confusion and the possibility of error.

Slayback’s arguments in its petitions line up closely with the arguments that Judge Bryson already heard and rejected. Indeed, the primary reference (Zhou) that Slayback relies on for its obviousness defense was the primary reference that Fresenius relied on its for its obvious defense. (Petition at 21; *see, e.g.*, Ex. 1007 at

26.) Fresenius made the same misplaced arguments that Zhou disclosed various claim limitations (but not, *e.g.*, the claimed concentration of emulsifier) and that the other claim limitations would have been obvious in view of other literature and/or “routine experimentation.” (Petition at 15, 34-36; Ex. 2016 at 32-37, 46.)

The secondary references that Slayback relies on “in view of” Zhou, also line up closely with the references that Fresenius relied on at trial. For example, Fresenius had also argued that a POSA would have been motivated to improve the stability of an aprepitant emulsion based on Washington. (Petition at 27-28; Ex. 2016 at 24, 36.) Fresenius also made the same scientifically-invalid argument that decreasing the diameter of the emulsion droplets would have created more surface area to load aprepitant, while ignoring, among many things, the fact that small droplet diameters were achieved in the prior art with much less than the claimed amount of emulsifier. (Petition at 31; Ex. 2016 at 24, 26, 31.)

A total of approximately 14 hours of testimony was considered by Judge Bryson from experts in pharmaceutical formulations and the inventors of the patents-in-suit. As examples of what was discussed during that testimony, Zhou was mentioned 357 times, and Washington was mentioned 72 times. Judge Bryson also considered approximately 11 hours of testimony from medical doctors, expert economists, and corporate witnesses on objective indicia that demonstrated the non-obviousness of the asserted claims.

In sum, Judge Bryson's years-long experience with the subject matter of Slayback's PGRs makes him uniquely qualified to resolve these issues. Slayback's repeated acknowledgments of Judge Bryson's familiarity with the subject matter, and the parties' position that all issues should be addressed concurrently at the November 2025 trial, indicates Slayback does not disagree on this point. (*See supra* Section II.D.) To the contrary, it confirms the parties' settled expectations that Judge Bryson will resolve the validity disputes, and equity demands the same.

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. In particular, the fact that Slayback could have, but elected not to, file IPRs challenging claims of the other asserted patents in the district court litigation is yet another reason why the parties have a settled expectation of the validity issues being resolved in district court. Slayback had ample time to prepare and file IPRs challenging these other patents. In the absence of such challenges, there was undoubtedly a settled expectation that the disputes, including the validity disputes, would be resolved in district court, not the PTAB. 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, especially given it is raising arguments that have been previously rejected. *Tessell, Inc.*, IPR2025-00322, Paper 14 at 2-3.

For all these reasons, the district court, and not the PTAB, is the proper venue

for adjudicating Slayback's validity challenge.

**V. DENIAL OF INSTITUTION IS
WARRANTED UNDER 35 U.S.C. § 325(d)**

In determining whether to institute a PGR, if another proceeding or matter involving the patent is before the Office, "the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. § 325(d). In evaluating arguments under § 325(d), the Office applies the two-part framework set forth in *Advanced Bionics*:

- (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 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.

Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential); *see also Becton, Dickinson and Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18 (PTAB Dec. 15, 2017) (precedential as to Section III.C.5, first paragraph) (listing factors to consider in evaluating the applicability of § 325(d), referred to herein as the *Becton-Dickinson* factors).

Slayback's petition should be dismissed under *Advanced Bionics* because it

presents the same or similar prior art, and the same arguments that the Office has rejected. As explained below, Slayback’s § 103 argument in its petition relies on Zhou as its primary reference alleging it is “nearly anticipatory.” (Petition at 1.) But the Office considered Zhou and did not make a material error in allowing the ’254 patent claims over Zhou.

Slayback’s § 112 attacks fare no better. The Office necessarily considered compliance of the claims with § 112. *See* M.P.E.P. § 2103 (2024) (stating that the Office will consider “each claim . . . for compliance with every statutory requirement for patentability,” including those under § 112). Thus, step one of *Advanced Bionics* is satisfied. And Slayback provides no explanation as to what the Office missed or misconstrued in the specification. In fact, it is evident that the Office did not miss anything when it allowed the claims with the limitations that are the subject of Slayback’s § 112 attack as they are expressly disclosed in the specification.

**A. The Petition Presents the Same
or Substantially the Same Art and
Arguments Previously Considered by the Office**

1. Obviousness Challenge

The Petition’s obviousness challenge involves a four-reference combination: Zhou in view of Washington, Bagwe, and Weng. (Petition at 12.) Zhou was carefully considered by the Office, which ultimately found that the claims were not obvious based on Zhou. (Ex. 1022 at 39-40; *supra* Section II.C.) In particular, the

Office found that the aprepitant emulsions disclosed in Heron's patents had significantly improved stability profiles. (Ex. 1022 at 39-40.) Weng was also considered by the Office via an IDS. (See Ex. 1001 at 2 (listing Weng in list of References Cited); Ex. 2015 at 150.) While the Office did not issue any rejection over Weng, a reference considered via an IDS is considered "previously presented to the Office" under the *Advanced Bionics* framework. *Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13 at 4 (PTAB May 19, 2025) (precedential).

Additionally, according to Slayback, Washington and Bagwe are simply background references on the knowledge in the art. Indeed, Slayback contends that Zhou is "nearly anticipatory" while the other references (Washington, Bagwe, and Weng) "simply reflect common knowledge in the art regarding emulsion components/amount" (Petition at 1-2.) Thus, Slayback cannot rely on Washington and Bagwe to negate *Advanced Bionics* step one.

2. Section 112 Challenge

For Grounds II (written description) and III (enablement) in the Petition, the Examiner is presumed to have considered "each claim . . . for compliance with every statutory requirement for patentability," including those under § 112. M.P.E.P. § 2103 (2024). Indeed, the Examiner is presumed to have "reviewed [the application] to make certain that the whole application meets all formal and substantive (*i.e.*,

statutory) requirements and that the language of the claims is enabled by, and finds adequate descriptive support in, the application disclosure as originally filed,” when the application was ready for allowance. M.P.E.P. § 1302.01 (2024). The Examiner, therefore, 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. Regardless, the Examiner of the ’254 patent did consider compliance with § 112. For example, the Examiner objected to the claims for informalities, evaluating the application for § 112 (Ex. 1022 at 8-9), and entered amendments to the pending claims, again suggesting the claims were compliant with § 112 (*Id.* at 37 (“Objection to claim 7 is withdrawn in view of Applicant’s amendment submitted on 05/24/2024.”)).

**B. Slayback Failed to Demonstrate
that the Office Erred in a Manner
Material to the Patentability of Challenged Claims**

As part of the analysis under the second prong of the *Advanced Bionics* framework, the PTAB evaluates *Becton-Dickinson* factors (c), (e), and (f), which all “relate to whether the petitioner has demonstrated a material error by the Office.” *See Advanced Bionics*, Paper 6 at 9-10, 9 n.10 (citing *Becton, Dickinson*, Paper 8 at 17-18). “[I]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.” *Advanced Bionics*, Paper 6, at 9.

1. Obviousness Challenge

Slayback does not and cannot show that the Office materially erred in allowing the claims of the '254 patent over Zhou. Slayback contends that the Office erred because the Examiner relied “solely on a theory of obviousness-type double patenting rejection.” (Petition at 73.) But the Examiner carefully evaluated Zhou and explained why no prior art (including Zhou) discloses or suggests the claimed emulsion to a prepatent ratio. (Ex. 1022 at 39-40.) The Office similarly conducted a prior art search for a motivation to increase the amount and/or concentration of emulsifier disclosed in Zhou in a related patent and found that “there would have been no motivation by one of ordinary skill to modify the ratio [in the Zhou reference] to those recited by the claimed invention” based on the prior art it found. (Ex. 1039 at 70.)

Thus, it simply is not the case that the Office materially erred in allowing the claims over Zhou.

2. Section 112 Challenge

Slayback has made no effort to demonstrate an error material to patentability with respect to Grounds II and III. Instead, Slayback primarily argues an erroneous legal theory that there is no written description support, and no enablement, based

on how a POSA would view the prior art.⁷ To support its erroneous theory, Slayback dedicates nearly five pages of its brief summarizing statements Heron made during the Fresenius litigation related to how emulsions are more complicated than other systems, and how using a high emulsifier amount (*e.g.*, 14%) was a departure from anything that had been done previously in the prior art. (Petition at 54-58.) But a laundry list of how Heron characterized *the shortcomings of prior art* in a previous litigation does not bear on written description and enablement, which analyze whether a POSA would find the *patent specification* as providing the requisite support and enablement for the claims.

When Slayback finally arrives at the merits of its written description argument, it only faults the specification for an alleged lack of disclosure of apreitant emulsions having more than 15% emulsifier or a ratio of emulsifier to apreitant

⁷ Slayback suggests that after previous patents were allowed with a range of 11 to 15 wt/wt % emulsifier, the Examiners got confused and mistakenly allowed Heron's more recent patents directed to greater than 15 wt/wt % emulsifier believing they were commensurate with Heron's previous patents. (Petition at 61-63.) There is no evidence supporting Slayback's speculation, which is also unfounded given the extensive disclosures in the specification covering the claims.

greater than 20:1. (Petition at 65.) But it is undisputed that the '254 patent discloses the claimed amounts of emulsifier and the claimed ratios of emulsifier to aprepitant. (E.g., Ex. 1001 at 3:49-58 (about “12 wt/wt % to 17 wt/wt %”), 17:38-45 (“about 20:1” or “20:1 to 25:1”).) And its enablement attack is barebones with no analysis of the relevant factors identified in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). (Petition at 68-71.) Thus, Slayback cannot demonstrate any material error by the Office.

In sum, forcing Heron to litigate this PGR, where the same issues have been considered and decided during prosecution of the '254 patent and related patents would be highly prejudicial to Heron. As such, Heron respectfully requests the Acting Director exercise her discretion and decline institution of this PGR under § 325(d).

VI. CONCLUSION

For the foregoing reasons, Heron respectfully requests that the Acting Director exercise her discretion to deny Slayback's PGR petition.

Respectfully submitted,

Dated: June 16, 2025

By: /Naveen Modi/
Naveen Modi (Reg. No. 46,224)
Counsel for Patent Owner

CERTIFICATE OF COMPLIANCE

Pursuant to Acting Director Stewart's March 26, 2025 Memorandum on Interim Processes for PTAB Workload Management, the undersigned certifies that the foregoing Patent Owner's Brief Requesting Discretionary Denial of Institution contains, as measured by the word-processing system used to prepare this paper, 8,151 words. This word count does not include the items excluded by 37 C.F.R. § 42.24.

Respectfully submitted,

Dated: June 16, 2025

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CERTIFICATE OF SERVICE

I certify that I caused to be served on the counsel identified below a true and correct copy of the foregoing Patent Owner's Brief Requesting Discretionary Denial of Institution by electronic means on June 16, 2025:

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