

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner,

v.

ALKERMES PHARMA IRELAND LIMITED,
Patent Owner.

Case IPR2025-00514
Patent No. 7,919,499

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

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LIST OF EXHIBITS

Exhibit No.	Description	Previously Submitted
2001	Patent Trial and Appeal Board Consolidated Trial Practice Guide – November 2019 (“CTPG”)	
2002	Request for <i>Ex Parte</i> Reexamination of U.S. Patent No. 7,919,499 in Reexamination Control No. 90/019,779 (Dec. 20, 2024)	
2003	Transmittal Form – Request for <i>Ex Parte</i> Reexamination of U.S. Patent No. 7,919,499 in Reexamination Control No. 90/019,779 (Dec. 20, 2024)	
2004	Notice of Reexamination Request Filing Date in Reexamination Control No. 90/019,779 (Dec. 20, 2024)	
2005	Order Granting Request for <i>Ex Parte</i> Reexamination of U.S. Patent No. 7,919,499 in Reexamination Control No. 90/019,779 (Jan. 28, 2025)	
2006	Office Action in Reexamination Control No. 90/019,779 (Apr. 30, 2025)	
2007	Ex. G to Argentum EPR Request – Johnson et al., “A Pilot Evaluation of the Safety and Tolerability of Repeat Dose Administration of Long-Acting Injectable Naltrexone (Vivitrex®) in Patients With Alcohol Dependence,” <i>Alcoholism: Clinical and Experimental Rsch.</i> , 28(9):1356-61 (Sept. 2004) (“Vivitrex Pilot Study”)	
2008	United States Patent and Trademark Office – Reexamination Operational Statistics (Updated 3/2025) (available at https://www.uspto.gov/sites/default/files/documents/reexamination-op-stats.pdf) (retrieved May 6, 2025)	
2009	Declaration of Kinam Park, Ph.D. in Support of <i>Inter Partes</i> Review of U.S. Patent No. 7,919,499 in IPR2018-00943	

I. INTRODUCTION

Pursuant to Acting Director Stewart's March 26, 2025 Memorandum on Interim Processes for PTAB Workload Management ("March 26th Memorandum"), Patent Owner Alkermes Pharma Ireland Limited ("Alkermes" or "Patent Owner") submits this brief requesting discretionary denial of institution of the petition for *inter partes* review ("IPR") filed by Petitioner Apotex Inc. ("Apotex" or "Petitioner") challenging claims 1-13 of U.S. Patent No. 7,919,499 (the "'499 patent").

In its IPR petition, Apotex argues that the U.S. Patent and Trademark Office ("Office") erred in issuing the '499 Patent. But Apotex filed its petition based on the same art previously presented to the Office and currently at issue in an *ex parte* reexamination filed by Argentum Pharmaceuticals LLC (Application No. 90/019,779, "Argentum EPR"). The Argentum EPR was filed over six weeks before Apotex filed its IPR. In fact, the Central Reexamination Unit ("CRU") issued an order granting Argentum's EPR Request two days before the Apotex IPR was filed, and issued an Office Action on April 30, 2025 rejecting the challenged claims based on the same art. In addition to being rejected based on the same art, the Office also rejected the challenged claims over several other grounds in the Office Action. As such, the Argentum EPR will provide for a more comprehensive, thorough review of the challenged claims relative to the Apotex IPR.

If the PTAB were to institute this IPR (which it should not), the institution

date would likely be around September 2025. The PTAB would then issue its final written decision (“FWD”) around September 2026. Even by the September 2025 institution deadline itself, however, prosecution of the Argentum EPR will be well underway given an Office Action has issued. Alkermes’ response will be on file (currently due June 30, 2025) and any subsequent responsive action by the CRU will more than likely also be completed. By the FWD deadline (September 2026), prosecution of the Argentum EPR will likely be complete. With these overlapping timelines, which Apotex failed to address, it makes little sense to duplicate efforts of the Office and Alkermes by instituting Apotex’s IPR.

Moreover, the Apotex IPR is a classic example of a follow-on, serial IPR petition that is discretionarily denied because it uses prior proceedings as a roadmap to craft its prior art grounds and harass patent owners like Alkermes. In particular, the Grounds in the Apotex IPR are the same as those litigated in a prior IPR filed by Amneal Pharmaceuticals LLC (IPR No. 2018-00943, “Amneal IPR”) challenging the same claims of the ’499 patent more than seven years ago. The Grounds in the Apotex IPR are also substantially similar to invalidity positions litigated in a prior district court litigation involving the ’499 patent in *Alkermes, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2:20-cv-12470 (D.N.J.) (“Teva litigation”) filed almost five years ago. The overlap between these prior proceedings and Apotex’s IPR petition was no mistake: Apotex used the parties’ and the PTAB’s briefing and

commentary from those litigations as a roadmap to revise the same prior art grounds that were litigated in those earlier cases. That is, years after Alkermes settled with both Amneal and Teva in a manner consistent with “strong public policy reasons to favor settlement between the parties to a proceeding” (Ex. 2001 at 86),¹ Apotex has emerged to harass Alkermes with a follow-on petition.

Such harassment is not what the IPR process was designed for and an important reason for the existence of discretionary denials. It would be highly prejudicial to Alkermes if it were required to relitigate issues from the prior Amneal IPR and Teva litigation where the '499 patent claims have now been in force for more than fourteen years. This is especially true when, as here, the same issues and more will be considered and decided by the Office in the Argentum EPR well before resolution of the Apotex IPR.

These factors and others discussed below counsel in favor of the Acting Director exercising her discretion to deny institution. As discussed below, this IPR should be denied for three independent reasons: (1) denial is warranted under 35 U.S.C. § 314(a); (2) denial is warranted under 35 U.S.C. § 325(d); and (3) denial is warranted due to other factors provided in the March 26th Memorandum.

¹ Citations to exhibits are to the documents' native pagination unless noted otherwise.

II. THE GROUNDBREAKING, INNOVATIVE VIVITROL® TREATMENT CLAIMED IN THE '499 PATENT

The invention claimed in the '499 Patent is a method for treating alcohol and opioid dependence, as exemplified by Alkermes' Vivitrol® product. The method administers a single injection of a long-acting formulation containing about 310-480 mg of naltrexone in PLGA (a biodegradable polymer). The formulation achieves a total blood exposure ("AUC") about three times greater than that of 50 mg/day of oral naltrexone, which was the standard of care for naltrexone treatment at the time of the invention.

Despite being safe and efficacious when used as directed, 50 mg/day oral naltrexone treatment was characterized by significant patient compliance issues. It was also associated with side effects including anxiety, nausea, and elevated liver enzymes and carried with it a black box warning. As early as 1981, researchers in the prior art tried to develop a long-acting naltrexone treatment that was safe, effective, and would improve compliance compared to oral naltrexone, but until Alkermes and Dr. Elliot Ehrich none succeeded.

The inventor of the '499 Patent, Dr. Ehrich, conceived of a long-acting naltrexone treatment based on a theory that brain dysregulation was the culprit for dependence disorders. Unlike the prior art and despite the black box warning, Dr. Ehrich favored a markedly higher total blood exposure of naltrexone compared to

the then-standard treatment of 50 mg/day oral naltrexone. Dr. Ehrich's approach departed from the established safety and efficacy of oral naltrexone. Clinical trials that included a single comparative pharmacokinetic study, however, surprisingly demonstrated that treating a patient in need of naltrexone with a single injection of a long-acting formulation containing PLGA and 380 mg of naltrexone, and also achieving an AUC that is about three times higher than that achieved by 50 mg/day oral naltrexone, was a safe and effective treatment. Today, Vivitrol[®] remains the first and only long-acting injectable naltrexone formulation shown to be effective in the treatment of alcohol and opioid dependence.²

III. DENIAL IS WARRANTED UNDER 35 U.S.C. § 314(a)

Institution of *inter partes* review is discretionary. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (stating that “the PTO is permitted, but never compelled, to institute an IPR proceeding”); 35 U.S.C. § 314(a). A decision whether to institute is within the Director's discretion. *See* 37 C.F.R. § 42.4(a); *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 273 (2016) (“[T]he agency's decision to deny a petition is a matter committed to the Patent Office's

² Vivitrol's approved indications are more specifically outlined in the prescribing information.

discretion.”); Ex. 2001 at 55 (“Sections 314(a) and 324(a) provide the Director with discretion to deny a petition.” (citations omitted)). Discretionary denial of the Apotex IPR is warranted under § 314(a) for at least two reasons: (1) to minimize duplication and conserve resources; and (2) Apotex should not be allowed to improperly use prior proceedings as a roadmap while not even acknowledging a currently pending proceeding.

A. The PTAB Will Duplicate or Waste Resources and Effort if the Apotex IPR Is Instituted in Light of the Argentum EPR

The Argentum EPR will proceed at a much faster pace than the Apotex IPR would (if instituted). Additionally, the Apotex IPR raises only issues that are the same as a mere subset of the issues now being considered in the Argentum EPR. The PTAB’s resources are better spent deciding cases where the same issues (and more) are not already being considered in a parallel Office proceeding, especially where the parallel Office proceeding is likely to conclude earlier than the IPR.

1. The Issues in the Apotex IPR Completely Overlap with the Issues in the Argentum EPR

All of the references and combinations presented in the Apotex IPR have been considered and are continuing to be considered by the Office in the Argentum EPR with respect to the challenged claims. Further, the Argentum EPR includes additional combinations and references that are being considered with respect to the challenged claims. Thus, as discussed below, there is no reason to institute the

Apotex IPR in which only a subset of the issues from the Argentum EPR would be considered.

The Apotex IPR presents the following three Grounds based on four references, namely **Comer** (Ex. 1004), **Nuwayser** (Ex. 1005), **Rubio** (Ex. 1006), and **Wright** (Ex. 1007):

- Ground 1: Claims 1, 3-5, and 12 anticipated by **Comer** as evidenced by **Nuwayser**.
- Ground 2: Claims 1-13 obvious over **Comer** in view of **Nuwayser**, **Rubio**, and **Wright**.
- Ground 3: Claims 1-13 obvious over **Nuwayser** in view of **Comer**, **Rubio**, and **Wright**.
 - Ground 3 merely flips the order of **Comer** and **Nuwayser** from Ground 2, and as discussed below in Section III.A.1.a, there is no meaningful difference between Grounds 2 and 3 in the Apotex IPR.

Paper 2 (Apotex IPR petition) at 6-7.

The Argentum EPR was ordered on the same substantial new questions of patentability (SNQs) as Grounds 1-3 above, along with additional SNQs. In particular, as shown below, the Argentum EPR's SNQs 1 and 3 raise the same issues as the Apotex IPR's Grounds 1-3 while the Argentum EPR's SNQs 2 and 4 present additional issues not presented in the Apotex IPR:

- SNQ 1: Claims 1, 3-5, and 12 anticipated by Comer as evidenced by Nuwayser.
 - Same issues as Ground 1 of Apotex IPR.
- SNQ 2: Claims 1, 3-5, and 10-12 anticipated by Vivitrex Pilot Study (Ex. 2007).
- SNQ 3: Claims 1-13 obvious over Comer in view of Nuwayser, Rubio, and Wright.
 - Same issues as Grounds 2-3 of Apotex IPR. *See infra* Section III.A.1.a.
- SNQ 4: Claims 1-13 obvious over Vivitrex Pilot Study in view of Comer, Rubio, and Wright.

Ex. 2002 at 15, 38, 45, 50, 59; Ex. 2005 at 5-13, 15.

Subsequently, on April 30, 2025, the CRU issued a first Office Action in the Argentum EPR rejecting the challenged claims based on eight total grounds. *See generally* Ex. 2006. As shown below, the grounds in the Argentum EPR Office Action include grounds 1 and 3 that raise the same issues as the Apotex IPR's Grounds 1-3, and include several additional obviousness grounds involving the four references at issue in the Apotex IPR.

- Ground 1: Claims 1, 3-5, and 12 anticipated by Comer as evidenced by Nuwayser.
 - Same issues as Ground 1 from Apotex IPR (and SNQ 1 from EPR Request).
- Ground 2: Claims 1, 3-5, and 7-12 anticipated by Vivitrex Pilot Study.³
 - Same as SNQ 2 from Argentum EPR Request, except claims 7-9 added to the ground in the Office Action.
- Ground 3: Claims 2, 6-11, and 13 obvious over Comer in view of Nuwayser.
 - Same issues as Grounds 2 and 3 from Apotex IPR (and SNQ 3 from Argentum EPR Request). *See infra* Section III.A.1.a.
- Ground 4: Claims 2 and 6 obvious over Vivitrex Pilot Study in view of Rubio.
- Ground 5: Claim 13 obvious over Vivitrex Pilot Study in view of Wright.
- Ground 6: Claims 1-13 rejected on ground of nonstatutory obviousness-type double-patenting over claims 1 and 14-18 of U.S. Patent No. 10,799,496 (Alkermes patent) in view of Comer and Nuwayser.
- Ground 7: Claims 1-13 rejected on ground of nonstatutory obviousness-type double-patenting over claims 1 and 9-13 of U.S. Patent No. 10,807,995 (Alkermes patent) in view of Comer and Nuwayser.
- Ground 8: Claims 1-13 rejected on ground of nonstatutory obviousness-type double-patenting over claims 1 and 9-13 of U.S. Patent No. 10,975,099 (Alkermes patent) in view of Comer and Nuwayser.

Ex. 2006 at 5-6, 8, 11-12, 14, 18, 21.

Thus, each of the four references and combinations of those references presented via the three Apotex IPR Grounds have been considered by the Office in the Argentum EPR at least twice already: first when determining whether to order the reexamination in response to Argentum's EPR Request, and then again when issuing the first Office Action. During prosecution of the Argentum EPR, the Office is also free to present the exact same combinations of references presented in the Apotex IPR, given it has already considered those combinations and references. There is simply no issue in the Apotex IPR that has not or will not be considered in the Argentum EPR. Moreover, as shown above, the Argentum EPR includes additional rejections based on references and theories not included in the Apotex IPR.

It makes little sense for the Office to institute the Apotex IPR when not just the same issues with respect to the challenged claims, but additional issues, will be considered and decided in the Apotex IPR. In other words, the Argentum EPR provides for a more comprehensive, thorough review of the challenged claims relative to the Apotex IPR.

The overlap between the issues raised in the Apotex IPR's Grounds 2-3 and the issues being considered in the Argentum EPR is discussed in more detail below,

³ The Vivitrex Pilot Study is also referred to as "Johnson" in the Office Action.

to the extent the Office would find it helpful.⁴

**a. There Is No Difference Between
Grounds 2 and 3 of the Apotex IPR
and the Obviousness Combinations Being
Considered and Applied in the Argentum EPR**

There is no meaningful difference between Grounds 2 and 3 in the Apotex IPR because Ground 3 merely flips the order of Comer and Nuwayser. *See supra* Section III.A.1. For example, Apotex relies on Figure 1 of Comer interchangeably with Figure 7 of Nuwayser in its IPR petition when attempting to map both Comer and Nuwayser to claim element [1.4] (“wherein the serum AUC of naltrexone is about three times greater than that achieved by 50 mg/day oral administration”). Paper 2 (Apotex IPR petition) at 33-36 (alleging that “the plot of Figure 1 of Comer discloses a serum AUC that is about three times greater than that achieved by 50 mg/day oral administration to the same extent as the ’499 Patent”), 57-58 (simply arguing that “since the plot of Nuwayser is superimposable with that of Comer, the AUC and the AUC differential for Nuwayser must be the same as for Comer”). Apotex’s assertion that Comer’s Figure 1 and Nuwayser’s Figure 7 are essentially the same demonstrates that, according to Apotex’s arguments, Comer-based Ground

⁴ As shown above, ground 1 of the Argentum EPR Office Action is the same as SNQ 1 and thus identical to Ground 1 of the Apotex IPR.

2 and Nuwayser-based Ground 3 are cumulative.

When ordering the Argentum EPR the Office considered SNQ 3, which is identical to the Apotex IPR's Ground 2. *See supra* Section III.A.1. As explained immediately above, the Apotex IPR's Ground 2 is no different than its Ground 3, and thus SNQ 3 is no different than Ground 3. Moreover, the Comer-Nuwayser combination is the basis for the Argentum EPR OA's ground 3. *See supra* Section III.A.1. Therefore, the same issues presented by way of Grounds 2 and 3 in the Apotex IPR are being considered and decided in the Argentum EPR.

Any argument by Apotex that the absence of the Rubio and Wright from ground 3 of the Apotex EPR OA would be a red herring. As discussed below, Apotex itself only relies on the Comer-Nuwayser combination for Grounds 2 and 3. Even when it cites to Rubio and Wright for a few dependent claims, it acknowledges that those references teach no more than what Comer or Nuwayser allegedly teach with respect to those claims.

In particular, for claims 1, 3-9, and 11-12, the references (i.e., Comer and Nuwayser) relied upon in Grounds 2 and 3 of Apotex's IPR petition are identical to the references relied upon in the EPR Office Action to address the same claims. *Compare* Paper 2 (Apotex IPR petition) at 38-52 (Ground 2), 53-61 (Ground 3) *with* Ex. 2006 at 5-6 (ground 1), 8-11 (ground 3). Thus, for claims 1, 3-9, and 11-12, there is no difference between the references relied upon by Apotex in Grounds 2

and 3 of the IPR, and the references the Office relies upon in the EPR Office Action.

While Grounds 2 and 3 of the Apotex IPR additionally cite to the Rubio reference for claim 2, Apotex asserts that Rubio is cumulative of Comer and Nuwayser for the claim element for which it is cited. *See* Paper 2 (Apotex IPR petition) at 48 (“Comer teaches that naltrexone had already been used for ‘chronic administration of over 1 year.’ Moreover, Rubio teaches that treatment protocols of 12 months in alcoholics were known.” (internal citation omitted)). The same applies to claims 10 and 13 in Grounds 2 and 3, where Apotex similarly argues the cumulative nature of Rubio and/or Wright relative to Comer and/or Nuwayser. *See* Paper 2 (Apotex IPR petition) at 51 (“Comer acknowledged that naltrexone had already been established to be safe and effective in alcoholics. . . . Rubio teaches treating alcoholics with naltrexone as well.”); *id.* at 61 (“While Nuwayser exemplifies a formulation that includes naltrexone in the amount of 54.4% by weight, Wright demonstrates that it was well-known to employ naltrexone drug loading in the range of 30-75% by weight of the formulation. Thus, the claimed naltrexone concentration is encompassed by the range contemplated by the prior art and is not patentable” (internal citation omitted)). Therefore, for claims 2, 10, and 13, there is no substantive difference between the references relied upon by Apotex in Grounds 2 and 3 of the IPR, and the references the Office relies upon in the

Argentum EPR.⁵

Like the Apotex IPR, the Argentum EPR Office Action relies on the combination of Comer and Nuwayser in ground 3 of the EPR Office Action and does not additionally include Rubio and Wright (which the Office considered in SNQ 3 when ordering the EPR). Specifically, the Office first considered and ordered the Argentum EPR based on, amongst other grounds, the Comer-based anticipation ground under SNQ 1 (which is identical to Ground 1 in the Apotex IPR) and the Comer-Nuwayser-Rubio-Wright obviousness ground under SNQ 3 (which raises the same issues as Grounds 2-3 in the Apotex IPR, as discussed above). After further consideration of these completely overlapping references and grounds, when issuing the Office Action, the Office maintained SNQ 1 as ground 1 and revised SNQ 3 as ground 3, finding Comer and Nuwayser sufficient to address the remaining challenged claims. Ex. 2006 at 8. This revision, however, does not change the fact

⁵ To the extent that the Rubio and Wright references are non-cumulative over Comer and Nuwayser, Rubio and Wright have already been (and continue to be) considered by the Examiner in the EPR proceeding as evidenced by the Argentum EPR Order which found SNQs 1 and 3 presented in the EPR request to be persuasive. Ex. 2005 at 5-6, 9-11.

that Ground 2 and 3 for the Apotex IPR raise the same issues as ground 3 of the Argentum EPR Office Action because, as discussed above, Apotex does not cite to Rubio or Wright for any additional disclosures that are not allegedly part of Comer and/or Nuwayser.

Put another way, there is simply no combination of references in the Apotex IPR that has not already been considered, or will not be considered, by the Office in the Argentum EPR to address the challenged claims. During prosecution of the Argentum EPR, the Office is also free to rely on Rubio and Wright in the same way that Apotex relied on those references in the Apotex IPR. Given the additional grounds of rejection in the Argentum EPR based on references not at issue in the Apotex IPR, instituting the Apotex IPR—which presents only a narrow subset of the issues being considered in the Argentum EPR—would be an inefficient use of the PTAB’s resources, contrary to the objectives of the March 26th Memorandum. *See* March 26th Memorandum at 3.

**2. The Same Issues from the Apotex IPR Will Be Decided
in the Argentum EPR Well in Advance of the Apotex IPR**

The Argentum EPR is being “conducted with special dispatch.” Ex. 2006 at 26. In other words, the Argentum EPR is being expedited and prioritized “over all other cases except reexaminations or reissues involved in litigation.” *See* MPEP 2261; *see also* 35 U.S.C. § 305; 37 C.F.R. § 1.550(a).

Consistent with this prioritization, the CRU issued an Office Action in the Argentum EPR on April 30, 2025 (within five months of Argentum filing its EPR Request, and just three months after the EPR was ordered). Ex. 2006 at Cover.

Alkermes' response to the Office Action is currently due June 30, 2025. Ex. 2006 at 25; *see also* MPEP 2263. At that time, Alkermes will present its arguments responding to the grounds along with any supporting evidence. Given the "special dispatch" processing of the EPR, it is more than likely that the CRU will issue a responsive action within a month or two of Alkermes' response, i.e., by August 2025. A substantive reexamination of **the same claims** at issue in Apotex IPR based on the same issues presented in the Apotex IPR, as well as additional grounds, will therefore be well underway in the Argentum EPR by August 2025.

The PTAB's institution decision in the Apotex IPR, on the other hand, is not due until September 2025. By that time, e.g., after Alkermes' response to the Argentum EPR Office Action, the patentability of the claims of the '499 patent may already be confirmed after the Office considers the same issues presented in the Apotex IPR (along with additional issues). The CRU's confirmation of the '499 patent claims' patentability in view of the same issues raised in the Apotex IPR counsel in favor of discretionary denial. *See* March 26th Memorandum at 2 ("Whether the PTAB or another forum has already adjudicated the validity or patentability of the challenged patent claims" is relevant to discretionary denial); *see*

also Intramedic Co., Ltd. v. Given Imaging Ltd., IPR2015-00579, Paper 9 at 7-10 (Aug. 5, 2015) (PTAB denying institution in light of advanced stage of a parallel *inter partes* reexamination proceeding).

If the claims of the '499 Patent challenged in the Apotex IPR petition are instead rejected in a final Office Action by the Examiner which may be expected within about two months of Alkermes' response (e.g., around August 2025), the same claims may nonetheless come before the PTAB in an appeal from the Examiner's final rejection. That is, Alkermes could file a notice of appeal from the Examiner's final rejection as early as August 2025. In this scenario, tasking the PTAB with two separate proceedings (the Apotex IPR, and an appeal from the EPR) on the patentability of the same claims, in view of the same prior art references (if not more), at the same time, would certainly not be an efficient use of the PTAB's resources in view of the "current workload needs of the PTAB." *See* March 26th Memorandum at 3.

Based on the CRU's operational statistics for fiscal year 2025, a reexamination certificate from the EPR should be expected around April 2026 (approximately 16 months after filing of the EPR Request, which was filed in December 2024). *See* Ex. 2008 at 2. On the other hand, if trial is instituted in the Apotex IPR, the PTAB's FWD would not be expected until around September 2026. The issuance of a reexamination certificate for the '499 patent approximately halfway through the

Apotex IPR proceedings would upend the parties' and the PTAB's efforts in the IPR (if instituted) and likely result in a significant volume of wasted effort. Allocating the PTAB's resources to an *inter partes* review on a patent that will more than likely be fully reexamined before the PTAB can issue its FWD would simply undermine the goals and objectives for managing the PTAB's workload as set out in the March 26th Memorandum. *See* March 26th Memorandum at 3. Moreover, the CRU and Alkermes have already invested significant resources into the EPR given its advanced stage. *See* Ex. 2005; Ex. 2006.

Instituting the Apotex IPR would also lead to potentially conflicting results, because there is no guarantee that the PTAB and the CRU would reach the same outcome in the two proceedings. Regulating the PTAB's workload by denying the institution of a duplicative and potentially conflicting IPR, on the other hand, would "improve PTAB efficiency, maintain PTAB capacity to conduct AIA proceedings, [and] reduce pendency in *ex parte* appeals" *See* March 26th Memorandum at 3.

Thus, Alkermes respectfully requests the Acting Director exercise her discretion and decline to institute the Apotex IPR, so the PTAB's resources can be allocated to other deserving cases where they are less likely to go to waste.

**B. The Follow-on Nature of the Apotex
IPR Is Highly Prejudicial to Alkermes**

Apotex's IPR is a classic example of abuse of the review process by repeated attacks on a patent that Congress was concerned about when it gave the Director discretion to institute IPRs. Indeed, Congress specifically recognized the potential for abuse of the *inter partes* review process by repeated attacks on patents to harass patent owners. See H.R. Rep. No. 112-98, pt. 1, at 48 (2011) ("While this amendment is intended to remove current disincentives to current administrative processes, the changes made by it are not to be used as tools for harassment or a means to prevent market entry through repeated litigation and administrative attacks on the validity of a patent. Doing so would frustrate the purpose of the section as providing quick and cost effective alternatives to litigation.").

As discussed below, principles of undue inequities and prejudices to Alkermes along with the *General Plastic* factors the PTAB considers for repeated attacks on a patent counsel denial of Apotex's IPR. *General Plastic Indus. Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 17 (Sept. 6, 2017) (precedential as to § II.B.4.i) ("*General Plastic*").

**1. Apotex's Use of the Prior Amneal
IPR as a Roadmap Warrants Denial**

Prior to Apotex filing the instant IPR in January 2025, the '499 patent was subject to an IPR by Amneal Pharmaceuticals LLC almost seven years ago in April

2018. *Amneal Pharmaceuticals LLC v. Alkermes Pharma Ireland Ltd.*, IPR2018-00943 (“Amneal IPR”), Paper 1 (Apr. 20, 2018). The Amneal IPR included grounds identical to those presented in the Apotex IPR, including reliance on Nuwayser for understanding Comer’s disclosures. *See, e.g.*, Amneal IPR, Paper 1 (Apr. 20, 2018) at 22-23. Alkermes filed a preliminary response. Amneal IPR, Paper 7 (Aug. 9, 2018). The PTAB instituted the Amneal IPR. Amneal IPR, Paper 8 (Nov. 7, 2018). During trial, the parties submitted significant briefing and evidence, including a patent owner response, petitioner’s reply, and patent owner’s reply along with supporting expert declarations (the experts were also deposed). *See* Amneal IPR, Paper 10 (Jan. 8, 2019); Amneal IPR, Paper 14 (Feb. 7, 2019); Amneal IPR, Paper 18 (May 7, 2019); Amneal IPR, Paper 20 (May 20, 2019); Amneal IPR, Paper 22 (June 21, 2019). The parties settled the matter before the PTAB issued a final written decision, and the PTAB terminated the IPR. Amneal IPR, Paper 29 (July 31, 2019).

The ’499 patent was also involved in district court litigation in *Alkermes, Inc. v. Teva Pharmaceuticals USA*, No. 2:20-cv-12470 (D.N.J.) (“Teva litigation”) filed almost five years ago. Like the Apotex IPR, Teva also primarily relied upon Comer in its invalidity grounds, and relied on Nuwayser’s disclosures for a POSITA’s understanding of Comer. The court held a bench trial and received post-trial briefing, but the parties settled the matter before the district court issued its opinion. *See Alkermes, Inc. v. Teva Pharmaceuticals USA*, No. 2:20-cv-12470 (D.N.J.), D.I. 260

(Sept. 15, 2023) (Stipulated Consent Judgment and Injunction).

Now, in the Apotex IPR, Apotex essentially copies grounds 1, 3, and 4 from the Amneal IPR (and the similar Comer-based positions from the Teva litigation). *See, e.g.*, Paper 2 (Apotex IPR petition) at 28 n.1, 38 n.2, 53 n.3. Moreover, Apotex attempts to fix certain issues that were raised, *e.g.*, with respect to the Amneal IPR grounds, based on the PTAB's institution decision and the parties' positions during the prior proceedings. *See, e.g.*, Paper 2 (Apotex IPR petition) at 6-7, 21-22. For example, Apotex attempts to address a claim construction presented by Alkermes during the Amneal IPR (and the Teva litigation) that the Amneal IPR grounds did not account for. *See, e.g.*, Paper 2 (Apotex IPR petition) at 21-22. Apotex also does not include claims 10 and 11 in Ground 1 of the Apotex IPR because of the weaknesses with the prior art highlighted with respect to those claims during the Amneal IPR proceeding. *Compare* Amneal IPR, Paper 1 (Feb. 7, 2019) at 22 ("Ground 1: Comer Teaches Every Element of Claims 1, 3-5, And 10-12") *with* Paper 2 (Apotex IPR petition) at 28 (Ground 1: Claims 1, 3-5, and 12 Are Anticipated by Comer as evidenced by Nuwayser"). Apotex similarly does not include certain grounds from the Amneal IPR whose deficiencies were noted during the Amneal IPR proceeding. *Compare* Amneal IPR, Paper 1 (Feb. 7, 2019) at 4 *with* Paper 2 (Apotex IPR petition) at 6-7.

Put another way, Apotex comes along many years later and uses the now-

settled Amneal and Teva litigations as a roadmap to harass Alkermes with this follow-on petition. But Alkermes should not be penalized for settling with Amneal prior to final resolution of that IPR, consistent with “strong public policy reasons to favor settlement between the parties to a proceeding.” Ex. 2001 at 86.

This is the classic road-mapping concern the PTAB has with respect to multiple, staggered petitions challenging the same patent and same claims, raising the potential for abuse. *General Plastic* at 17. Moreover, as the PTAB has noted, serial petitions challenging the same patent allow petitioners “the opportunity to strategically stage their prior art and arguments” which is “unfair to patent owners and is an inefficient use of the *inter partes* review process and other post-grant review processes.” *General Plastic* at 17-18. Thus, the Acting Director should exercise her discretion and deny institution.

2. The *General Plastic* Factors Favor Denial

In *General Plastic*, the PTAB articulated the following list of factors to be considered in evaluating whether to exercise discretion under 35 U.S.C. § 314(a) to deny a petition that challenges a patent that was previously challenged before the PTAB.

1. whether the same petitioner previously filed a petition directed to the same claims of the same patent;
2. whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it;
3. whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition;
4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition;
5. whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent;
6. the finite resources of the Board; and
7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.

General Plastic at 15-16. As discussed below, these *General Plastic* factors favor denial.

Regarding factor 1, Apotex did not previously file an IPR directed to the same claims of the same patent. Apotex argues incorrectly that this factor is dispositive in light of former Director Vidal's decision in *Videndum Prod. Sols., Inc. v. Rotolight Ltd.* ("Videndum"), IPR2023-01218, Paper 12 (Vidal Apr. 19, 2024). See Paper 2

(Apotex IPR petition) at 63-65. In *Videndum*, Director Vidal held that “[u]nder USPTO policy and precedent, *General Plastic* has not been extended to any cases in which the first and second petitioners do not have a significant relationship.” *Videndum* at 6; *see also id.* at 5-6 (determining based on “existing USPTO policy and precedent” that “where, as here, the first and second petitioners are neither the same party, nor possess a significant relationship under *Valve*, *General Plastic* factor one necessarily outweighs the other *General Plastic* factors.”).

Putting aside the fact that *Videndum* is not a precedential decision, the facts of *Videndum* are distinguishable from the instant case and a different precedential decision by former Director Vidal compels a different result.

First, the underlying facts in *Videndum* were starkly different. There, a first party (Arnold & Richter Cine Technik GMBH & Co. Betriebs KG) filed a first IPR against the relevant patent. *Videndum Prod. Sols., Inc v. Rotolight Ltd.*, IPR2023-01218, Paper 9 at 2-3, 7-9, 21 (Jan. 25, 2024); *Videndum Prod. Sols., Inc v. Rotolight Ltd.*, IPR2023-01218, Paper 11 at 2-4, 8-9, 11-12 (Feb. 23, 2024). After the first IPR was instituted and the one-month window for joinder passed, patent owner Rotolight filed a patent infringement complaint against Videndum. IPR2023-01218, Paper 9 at 21; Paper 11 at 2, 4, 11-12. At this time, Videndum could not join the instituted first IPR. IPR2023-01218, Paper 9 at 21; Paper 11 at 4, 11-12. Before a final written decision issued in the first IPR, Rotolight settled with the first party and

filed a motion to terminate the first IPR. IPR2023-01218, Paper 9 at 7-8, 21; Paper 11 at 3-4. Videndum attempted to intervene and oppose the motion. IPR2023-01218, Paper 9 at 7-8, 21; Paper 11 at 3-4. The PTAB granted the motion to terminate and noted that Videndum was free to pursue its own IPR in the future. Paper 9 at 7-8, 21; Paper 11 at 3-4, 8-9. Subsequently, Videndum filed its own IPR (the second IPR) in light of the PTAB guidance. Paper 9 at 21; Paper 11 at 3-4. But the PTAB, over a dissent, denied the IPR on discretionary grounds, relying on the *General Plastic* factors. IPR2023-01218, Paper 9 at 10-18, 21; IPR2023-01218, Paper 11, 2.

Given these unusual facts, none of which are present with respect to the Apotex IPR, former Director Vidal's *Videndum* decision is not applicable here.

Second, former Director Vidal's precedential decision in *Code200, UAB v. Bright Data Ltd.*, compels a different result. IPR2022-00861, Paper 18 (Vidal Aug. 23, 2022) (precedential). There, former Director Vidal noted that "General Plastic factor 1 must be read in conjunction with factors 2 and 3. Where the first-filed petition under factor 1 was discretionarily denied **or otherwise was not evaluated on the merits**, factors 1-3 only weigh in favor of discretionary denial **when there are 'road-mapping' concerns** under factor 3 or other concerns under factor 2." *Id.*

at 5 (citing *General Plastic* at 17).⁶

Here, factor 3 heavily favors denial. The Apotex IPR presents three Grounds which are identical to the grounds presented in the Amneal IPR. *See supra* Section III.B.1. Based on positions (e.g., claim construction) taken by Alkermes in its briefing both pre- and post-institution, and the PTAB’s preliminary findings in the institution decision, Apotex revised its Grounds and arguments in an attempt to bolster them. *See, e.g.*, Paper 2 (Apotex IPR petition) at 42-48 (adding a backup obviousness argument based on a “single injection” claim construction position not advanced by Amneal but presented by Alkermes during the Amneal IPR); 6 (not challenging claims 10-11 under Ground 1, at least in light of the PTAB’s preliminary findings in the Amneal IPR institution questioning the propriety of Amneal’s challenge to those claims under the same ground); 6-7 (not including the Nuwayser-based anticipation ground from the Amneal IPR in light of the PTAB noting weaknesses with that ground in the Amneal IPR institution decision). This is the classic type of road-mapping that the PTAB is concerned leads to harassment of patent owners and abuse of the post-grant review process. *General Plastic* at 17-18. Thus, factor 3 heavily favors denial.

⁶ In *Code200*, “the Board found ‘no evidence of road-mapping.’” *Code200* at 5.

To the extent factors 2, 4, and 5 are relevant, while Apotex had an opportunity to do so, Apotex did not provide any explanation or evidence regarding these factors. Regarding factor 2, for example, Apotex does not explain when it knew of the prior art asserted in the Amneal IPR. Thus, factor 2 favors denial.

Factor 4 concerns the length of time elapsed between the time Apotex learned of the prior art asserted in its IPR petition and the filing of its IPR petition, and factor 5 inquires whether Apotex provided adequate explanation for the elapsed time between the Amneal IPR and its own IPR. Thus, factors 4 and 5 strongly favor denial.

Factor 6 relates to finite resources of the PTAB and factor 7 relates to the one-year deadline from the institution decision to issue a final written decision. The PTAB should not waste its finite resources and impose a one-year deadline on itself by instituting review of the Apotex IPR, given Apotex used the prior Amneal IPR (and the Teva litigation) as a roadmap to prepare its own IPR, and given the same issues are being considered and decided in the Argentum EPR which is proceeding at a much faster pace than the expected timeline of the Apotex IPR (if instituted). *See supra* Section III.A. Indeed, instituting review here would encourage further harassment of patent owners, contrary to the goals and objective of the AIA. Thus, factors 6 and 7 favor denial.

The Acting Director should exercise her discretion and deny institution

because all of these *General Plastic* factors favor denial.

IV. DENIAL IS WARRANTED UNDER 35 U.S.C. § 325(d)

In determining whether to institute an IPR petition, 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 PTAB set forth a **two-part framework** in its precedential *Advanced Bionics* opinion:

- (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).

Both prongs of *Advanced Bionics* and the related *Becton-Dickinson* factors

favor exercising discretion to deny institution here, especially given Apotex does not even acknowledge, much less address, the currently pending Argentum EPR.

A. *Advanced Bionics* First Prong: The Apotex IPR Presents the Same or Substantially the Same Art and Arguments Previously Presented in the Argentum EPR

As part of the analysis under the first prong of the *Advanced Bionics* framework, the PTAB evaluates *Becton-Dickinson* factors (a), (b), and (d):

Factor (a): “the similarities and material differences between the asserted art and the prior art” presented to the Office during a proceeding pertaining to the challenged patent,

Factor (b): “the cumulative nature of the asserted art and the prior art” presented to the Office during a proceeding pertaining to the challenged patent, and

Factor (d): “the extent of the overlap between the [prior] arguments” and “the manner in which petitioner relies on the prior art.”

See Advanced Bionics, Paper 6 at 9-10, 9 n.10 (citing *Becton, Dickinson*, Paper 8 at 17-18).

The PTAB emphasized that these factors “should be read **broadly** . . . to apply to **any situation** in which a petition relies on the same or substantially the same art or arguments previously presented to the Office during a proceeding pertaining to the challenged patent.” *Advanced Bionics*, Paper 6 at 10; *see also id.* at 8 (noting that “[t]he proceedings in which the art was previously presented include, for

example: examination of the underlying patent application, **reexamination of the challenged patent**, a reissue application for the challenged patent, and AIA post-grant proceedings involving the challenged patent” (emphasis added)).

As discussed below, each of *Becton-Dickinson* factors (a), (b), and (d) favor exercise of discretion to deny institution.

Regarding factors (a) and (b), as discussed above, the four references relied upon by Apotex, namely Comer, Nuwayser, Rubio, and Wright, are all presented to the Office in the pending Argentum EPR—there are no differences between the art asserted in the IPR and the art previously presented in the EPR. *See supra* Section III.A.1; *see also* Paper 2 (Apotex IPR petition) at 6-7, *see also id.* at B-1 (Appendix B, identifying the references as Exhibits 1004-1007); Ex. 2002 at 15 (identifying SNQs 1 and 3 based on the same references); *see also id.* at 14-15 (identifying the same references as Exhibits E, F, W, and N); Ex. 2005 at 3 (identifying the same references in the order granting the Argentum EPR), 5-6 (ordering reexamination on SNQ 1, which raises the same issues as Ground 1 in the Apotex IPR), 9-11 (ordering reexamination on SNQ 3, which raises the same issues as Ground 2 in the Apotex IPR), Ex. 2006 at 5 (anticipation rejection based on Comer), 8 (obviousness rejection based on Comer and Nuwayser), 11 (obviousness rejection based in part on Rubio), 12 (obviousness rejection based in part on Wright). Given the same art was previously presented to the Office in the Argentum EPR and the Apotex IPR does

not rely on any additional art in its prior art Grounds relative to the art presented in the Argentum EPR, factors (a) and (b) are necessarily met.

Moreover, Comer was also considered by the Examiner during prosecution by way of an IDS filed May 26, 2010 (and initialed July 7, 2010). Ex. 1002 at 145.⁷ Similarly, Wright was considered by the Examiner during prosecution by way of an IDS filed August 29, 2005 (and initialed April 29, 2009). Ex. 1002 at 355.

Thus, there are no differences between the art previously presented to the Office and the art being presented in the Apotex IPR, and so factors (a) and (b) favor exercising discretion to deny institution.

Factor (d) considers “the extent of the overlap between the [prior] arguments” and “the manner in which petitioner relies on the prior art.” *Becton, Dickinson*, Paper 8 at 17-18. As discussed above, there is complete overlap between the issues raised by Grounds 1-3 in the Apotex IPR and the issues being considered in the Argentum EPR. *See supra* Section III.A.1.

Accordingly, the first prong of *Advanced Bionics* is met since the art and arguments presented in the Apotex IPR petition are the same or substantially the

⁷ Citations to Ex. 1002 refer to the stamped page numbers added by Petitioner at the bottom of each page of the exhibit.

same as those presented in the Argentum EPR.

B. *Advanced Bionics* Second Prong: Apotex 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):

Factor (c): “the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;”

Factor (e): “whether petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art;” and

Factor (f): “the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.”

See Advanced Bionics, Paper 6 at 9-10, 9 n.10 (citing *Becton, Dickinson*, Paper 8 at 17-18). The PTAB emphasized *Becton-Dickinson* factors (c), (e), and (f) all “relate to whether the petitioner has demonstrated a material error by the Office.” *Id.*, Paper 6 at 10.

As discussed below, each of factors (c), (e), and (f) favor exercise of discretion to deny institution.

With respect to factor (c), the CRU has not only issued an order granting Argentum’s EPR Request (prior to Apotex’s IPR filing), but also issued an Office

Action rejecting the challenged claims based on several grounds including grounds that raise the same issues presented in the Apotex IPR. *See supra* Section III.A.1. Thus, factor (c) is met because the same or substantially the same prior art is the basis for the rejections in the Argenteum EPR.

Regarding factor (e), Apotex simply failed to address the Argenteum EPR despite the EPR having been filed and ordered prior to the Apotex IPR filing. Ex. 2004 at 1 (confirming December 16, 2024 filing date of Argenteum EPR); Ex. 2003 at 3; Ex. 2005 at 1 (Argenteum EPR Order showing Argenteum EPR Request granted on January 28, 2025); Paper 5 at 1 (confirming January 30, 2025 filing date of Apotex IPR). Moreover, given the Argenteum EPR's SNQs 1 and 3 raised the same issues as the issues raised by the Apotex IPR's Grounds 1-3, and given the Office has granted Argenteum's EPR Request on those SNQs and has now issued an Office Action, Apotex can hardly argue that the Office erred in granting the EPR Request. If anything, the fact that the CRU ordered the Argenteum EPR and issued an Office Action with a subset of the grounds raising the same issues as the Apotex IPR Grounds leaves nothing for Apotex to argue about regarding any potential error by the Office. Ex. 2005 at 5-6, 9-11; Ex. 2006 at 5-6, 8, 11-12, 14, 18, 21.

Additionally, as discussed above, the Argenteum EPR record will be significantly developed by September 2025 (Apotex IPR institution deadline) and it should most certainly be fully developed by September 2026 (Apotex IPR FWD

deadline, if IPR is instituted). *See supra* Section III.A.2. Thus, any argument that the issues in the Apotex IPR were not previously presented or were not fully developed for Apotex to address are blunted by the fact that the Argentum EPR will proceed at a much faster pace relative to the Apotex IPR. *Id.* Apotex should have addressed the complete overlap between its proposed IPR Grounds and the SNQs not only presented in the Argentum EPR Request, but granted by the CRU Examiner before Apotex filed its IPR petition.

Regarding factor (f), as noted above, the prior art Grounds in the Apotex IPR raise the same issues as those being considered in the pending Argentum EPR. *See supra* Section III.A.1. In the IPR, Apotex addresses Alkermes' "single injection" interpretation of the claimed "step of parenterally administering a long acting formulation . . ." by way of its Grounds 2-3. Paper 2 (Apotex IPR petition) at 21-22, 42-48, 54 (Ground 3 briefly addressing the issue, and relying on the same arguments from Ground 2). In particular, while both the Argentum EPR and Apotex IPR disagree with the "single injection" interpretation (*see* Ex. 2002 at 26-27; Paper 2 (Apotex IPR petition) at 21-22), Apotex additionally attempts to address Alkermes' interpretation under its prior art Grounds. *See, e.g.*, Paper 2 (Apotex IPR petition) at 42-48, 54. But this issue will also be considered by the Examiner in the Argentum EPR, and the Examiner will have an opportunity to similarly address Alkermes' claim construction arguments, including with prior art rejections. Notably, Apotex

does not rely on any additional prior art reference(s) to address the “single injection” interpretation, and thus, there is no reason for the PTAB to waste its resources in considering arguments that are either being considered, or will be considered, in the Argentum EPR.⁸ Moreover, as explained earlier, Apotex did not carry its burden of

⁸ There is also no meaningful difference between the expert testimony being relied on in the Argentum EPR and the Apotex IPR, absent for Apotex using the prior Amneal IPR as a roadmap. The Argentum EPR resubmits Amneal’s expert declaration from the Amneal IPR. Ex. 2002 at 18. The Apotex IPR submits two expert declarations, with one presenting the same positions and analysis as Amneal’s expert. *Compare generally* Ex. 1046 *with* Ex. 2009. Many portions of Apotex’s expert declaration are nearly verbatim copied from Amneal’s expert declaration. *Compare* Ex. 1046 at ¶¶ 34-37 *with* Ex. 2009 at ¶¶ 29-32; Ex. 1046 at ¶¶ 38-49 *with* Ex. 2009 at ¶¶ 14-24; Ex. 1046 at ¶¶ 63-93 *with* Ex. 2009 at ¶¶ 51-77. Apotex’s other expert declaration is focused on addressing obviousness under the “single injection” construction, which is a classic abuse of the post-grant review process under *General Plastic*. *See supra* Section III.B.2. In fact, Apotex’s failure to provide “focused expert testimony” also weighs against institution. *See* FAQs for Interim

explaining why the PTAB should reconsider the issues here. *Advanced Bionics*, Paper 6 at 8.

Thus, the second prong of *Advanced Bionics* is met since the issues raised by the art and arguments presented in the Apotex IPR petition are the same or substantially the same as those presented and being considered in the Argentum EPR.

In sum, all of the *Becton-Dickinson* factors, as reviewed from the lens of the two prongs of *Advanced Bionics*, weigh in favor of discretionary denial. Forcing Alkermes to prosecute the Argentum EPR and litigate the Apotex IPR in parallel, where the same issues would be considered, would be highly prejudicial to Alkermes. As such, Alkermes respectfully requests the Acting Director exercise her discretion and decline institution of the Apotex IPR.

V. OTHER FACTORS DICTATE DENIAL OF THE APOTEX IPR

Discretionary denial considerations under the March 26th Memorandum include “[s]ettled expectations of the parties, such as the length of time the claims have been in force” and “[a]ny other considerations bearing on the Director’s

Processes for PTAB Workload Management at Question 21 (available at <https://www.uspto.gov/sites/default/files/documents/reexamination-op-stats.pdf>).

discretion.” *See* March 26th Memorandum at 2-3. Alkermes’ respectfully submits that relevant facts here further support discretionary denial of the Apotex IPR for additional reasons.

First, the ’499 patent issued on April 5, 2011, and thus the ’499 patent claims have been in force for more than fourteen years. *See* Ex. 1001 at Cover. In that time, as discussed above, the challenged claims were subject to invalidity attacks in both the Teva district court litigation and the Amneal IPR, both of which settled and were dismissed. *See supra* Section III.B.1. Thus, Alkermes has settled expectations regarding the validity of the ’499 patent claims given the length of time they have been in force and the prior proceedings involving the claims. Now, many years after those proceedings, Alkermes is being harassed by multiple post-grant challenges to the ’499 patent claims in the form of the Argentum EPR and the Apotex IPR. Allowing this type of abusive behavior by patent challengers would encourage further abusive post-grant challenges by other parties and unduly disturb the settled expectations of parties such as Alkermes regarding the validity of their patents.

Second, Apotex’s complete and utter failure to address the Argentum EPR in its IPR petition should also bear on the Acting Director’s discretion to deny this IPR. The Argentum EPR was filed six weeks prior to the Apotex IPR, and also ordered prior to the Apotex IPR. Ex. 2004 at 1; Ex. 2005 at 1; Paper 5 at 1. Apotex therefore had the opportunity to address the overlap between its IPR Grounds and the

Argentum EPR SNQs when filing its IPR petition, but chose not to. *See, e.g.*, Paper 2 (Apotex IPR petition) at 67-68. This omission is particularly notable because Apotex's IPR petition includes a section addressing discretionary denial under § 325(d), but that section only addresses the '499 patent's prosecution history during examination. *Id.*

Apotex did not conduct even a minimum amount of due diligence regarding matters related to the '499 patent as it failed to identify the Argentum EPR in the mandatory notices filed with its IPR petition. Paper 2 (Apotex IPR petition) at 3-5. The Office should not reward Apotex for neglecting its duty under 37 C.F.R. § 42.8(b)(2) to file mandatory notices which “[i]dentify any other judicial or administrative matter **that would affect, or be affected by**, a decision in the proceeding” (emphasis added). And given Alkermes identified the Argentum EPR in its mandatory notices three weeks after Apotex filed its IPR petition and about five weeks prior to the March 26th Memorandum, Paper 4 at 1 (listing Application No. 90/019,779), Apotex should have recognized its oversight.

Considering and crediting any of Apotex's belated arguments regarding the Argentum EPR at this juncture would essentially give Apotex, and other parties in the future, a free pass to overlook related matters and multiple bites at the apple to address issues that they should have known about at the time of an IPR filing. The Office should not encourage this type of behavior, particularly in the context of

abusive post-grant challenges harassing patent owners such as here.

For these additional reasons, discretionary denial of the Apotex IPR is warranted.

VI. CONCLUSION

For the foregoing reasons, Alkermes respectfully requests that the Acting Director exercise her discretion to deny the Apotex IPR petition.

Respectfully submitted,

Dated: May 6, 2025

By: /Naveen Modi/
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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, 8,911 words. This word count does not include the items excluded by 37 C.F.R. § 42.24.

Respectfully submitted,

Dated: May 6, 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 May 6, 2025:

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