

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner

v.

SOLENO THERAPEUTICS, INC.,
Patent Owner

PGR2026-00034
U.S. Patent No. 12,419,895

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

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<i>Sotera Wireless, Inc. v. Masimo Corp.</i> , IPR2020-01019, Paper 12 (P.T.A.B. Dec. 1, 2020)	4, 14
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UPDATED EXHIBIT LIST

No.	Exhibit Description
EX1001	U.S. Patent No. 12,419,895 to Cowen
EX1002	U.S. Food & Drug Admin., <i>Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book): Vykat™ XR</i> , https://www.accessdata.fda.gov/scripts/cder/ob (last visited Feb. 9, 2026)
EX1003	Excerpts from Organic Chemistry 3 rd Ed. by L.G. Wade Jr. (1995)
EX1004	<i>Vykat™ XR</i> (diazoxide choline) [package insert]. Soleno Therapeutics; 2025.
EX1005	Declaration of Dr. Hollander
EX1006	Curriculum Vitae of Dr. Hollander
EX1007	Suzanne B. Cassidy & Daniel J. Driscoll, <i>Prader-Willi Syndrome</i> , 17 EUR. J. HUM. GENET. 3-13 (2009)
EX1008	International Patent Pub. No. WO 2014/197753 to Cotter
EX1009	International Patent Pub. No. WO 2009/006483 to Cowen <i>et al.</i>
EX1010	Frances M. Ashcroft, <i>ATP-Sensitive Potassium Channelopathies: Focus on Insulin Secretion</i> , 115 J. CLINICAL INVESTIGATION 2047 (2005)
EX1011	U.S. Food & Drug Admin., <i>Drugs@FDA: NDA 016996 (Hyperstat (diazoxide))</i> , https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=016996
EX1012	U.S. Food & Drug Admin., <i>Drugs@FDA: NDA 017453 (Proglycem (diazoxide))</i> , https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=017453
EX1013	<i>Remington: Essentials of Pharmaceutics</i> 52 (Linda A. Felton ed., 21st ed., Pharm. Press 2013)
EX1014	U.S. Food & Drug Administration, <i>Guidance for Industry: Exposure-Response Relationships — Study Design, Data Analysis, and Regulatory Applications</i> (2003)
EX1015	U.S. Patent No. 12,419,895 File History
EX1016	U.S. Patent Pub. No. 2014/0364367 to Cotter
EX1017	Miller <i>et al.</i> , <i>Nutritional Phases in Prader-Willi Syndrome</i> , 155 AM. J. MED. GENET A. 1040, 1040-49 (2011)

No.	Exhibit Description
EX1018	Excerpts from Physicians’ Desk Reference (2008) entry for Proglycem® at pp. 1191-1192
EX1019	Sneha S K, <i>US FDA Approves First Treatment for Rare Genetic Disorder Prader-Willi Syndrome</i> , REUTERS, https://www.reuters.com/business/healthcare-pharmaceuticals/us-fda-greenlights-first-ever-treatment-rare-metabolic-disorder-2025-03-26/ (Mar. 27, 2025)
EX1020	Andrew J. Shoffstall et al., <i>The High Direct Medical Costs of Prader-Willi Syndrome</i> , 175 J. PEDIATRICS 137 (2016)
EX1021	Merlin G. Butler et al., <i>Age Distribution, Comorbidities and Risk Factors for Thrombosis in Prader–Willi Syndrome</i> , 11 GENES 67 (2020)
EX1022	U.S. Patent No. 9,757,384 File History Excerpts
EX1023	U.S. Patent No. 10,058,557 File History Excerpts
EX1024	U.S. Patent No. 10,456,408 File History Excerpts
EX1025	U.S. Patent No. 10,874,676 File History Excerpts
EX1026	<i>Nomination of John A. Squires to be Under Sec’y of Com. for Intell. Prop. & Dir. of the U.S. Patent & Trademark Office: Questions for the Record Before the S. Comm. on the Judiciary</i> , 119th Cong. (2025)
EX1027	U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., <i>Estimating Cost Savings from New Generic Drug Approvals in 2023</i> , at 2 (Nov. 2025)
EX1028	U.S. Food & Drug Admin., Generic Drugs, https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs (last visited June 27, 2026)
EX1029	U.S. Food & Drug Admin., <i>Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices</i> (Dec. 2019).
EX1030	Hayden Dublois, <i>From Most Expensive to Most Favored: How the Trump Administration Is Bringing Down Prescription Drug Prices</i> , Found. for Gov’t Accountability (Feb. 3, 2026), https://thefga.org/research/most-favored-nation-bringing-down-prescription-drug-prices/ .
EX1031	Alexandra Hutzler et al., <i>Trump Unveils TrumpRx Website He Says Will Help Americans Buy Lower-Priced Prescription Drugs</i> , ABC News (Feb. 5, 2026), https://abcnews.go.com

No.	Exhibit Description
EX1032	Solenio Therapeutics, Inc., Annual Report (Form 10-K), for the Fiscal Year Ended December 31, 2025 (filed Feb. 25, 2026).
EX1033	Ass’n for Accessible Meds., <i>By the Numbers: IPR Speeds Patient Access to Lower-Cost Medicine</i> (2024), https://accessiblemeds.org/wp-content/uploads/2024/11/AAM-By-The-Numbers-IPR-Expedite-Lower-Cost.pdf

I. INTRODUCTION

This PGR is about the start of reining in a company that charges approximately **\$500,000 per year** for a drug that treats a life-threatening condition affecting *children*—and now seeks to use the Office’s discretionary authority to block the very competition that could make this treatment affordable. Patent Owner Soleno portrays itself as a benevolent company interested only in patient welfare, yet conspicuously omits that Vykat™ XR carries a price tag that “shocks the conscience.” *See* EX1019 at 2; *see also* EX1020 at 4-5, 7; EX1021 at Abstract. Worse still, Soleno admits it has cultivated a “patent thicket”—euphemistically termed a “mature patent family” (PO’s Brief at 2)—and continues expanding it with applications filed as recently as May 2026. As the Director has recognized, pharmaceutical companies deploy such thickets as barriers to generic entry, abusing the patent system. *See* EX1026 at 18, 24 (“I am aware of concerns of so-called **patent thickets** being abused in relation to the cost of prescription drugs . . . I am committed to ensuring the USPTO issues patents that meet the statutory requirements for patentability in every technological art area, including pharmaceuticals, and ensuring patents are not abused, including as thickets”).

Apotex makes no apologies for being a generic drug maker serving the public interest by bringing affordable generics to market. Indeed, Soleno conceded this by acknowledging that Apotex’s market entry would produce an “**immediate public-**

health benefit through earlier generic availability.” PO’s Brief at 19. This admission is fatal to Soleno’s discretionary denial request. Apotex’s challenge aligns with federal priorities: lowering prescription drug prices is a national objective including “[l]everaging the full weight and power of the United States of America” (<https://trumprx.gov/>) and bipartisan efforts to increase generic access. *See generally* EX1030; EX1031. This Petition advances that commitment.

Apotex is aware Soleno has erected a “patent thicket” and that “Apotex must deal with all the patents listed in the Orange Book for Vykat™ XR, not just the ’895 patent.” (PO’s Brief at 2). But addressing Soleno’s entire patent thicket takes time, and this PGR is the first step. In any event, Soleno’s brief undermines its position by acknowledging “Apotex could theoretically attempt to avoid certain patents by carving out portions of the label, i.e., file a skinny label.” PO’s Brief at 15 n.1; EX1032 at 34 (Soleno’s 2025 10-K recognizing potential carve-out strategy); *Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.*, 608 U.S. ___, slip op. at 4 (2026) (“In other words, the skinny label may not give instructions for uses that would infringe the patented methods of use”). If Soleno itself concedes other paths exist for Apotex to bring a generic to market—through challenging validity or a skinny-label strategy—it cannot credibly argue this PGR is futile or that Apotex lacks a true alternative to litigation.

Soleno advances five grounds for discretionary denial: (1) 35 U.S.C. § 325(d); (2) settled expectations; (3) this Post-Grant Review not being a “true alternative” to litigation; (4) weakness of the merits; and (5) the public interest. Each fails:

Public Interest. The public interest favors institution. Prader-Willi Syndrome (PWS) is a genetic disorder that predominantly affects children. EX1021 at Abstract. The ’895 patent, by Soleno’s account, is listed in the Orange Book to block generic entry and extend Soleno’s monopoly to at least 2035, with Soleno claiming exclusivity “is expected to extend into the mid-2040s.” PO’s Brief at 2, 14. Allowing improperly issued patents to remain in force keeps drug prices high and delays patient access to lower-cost alternatives—precisely the harm President Trump, the Director and Congress have committed to preventing. EX1026 at 3; <https://trumprx.gov/>; *see generally* EX1033.

Section 325(d). Discretionary denial under 35 U.S.C. § 325(d) is unwarranted. Mere listing of Cotter,¹ Cowen, and Miller in the file history does not constitute substantive evaluation. The ’895 patent issued without a single prior art rejection, and the file history contains no discussion of these references. EX1015 at 225-33.

¹ Apotex notes that Cotter, WO 2014/197753, as cited by Apotex’s Petition, was not listed in the file history but rather, the U.S. equivalent of Cotter, U.S. Pat. Pub. No. 2014/0364367 (“U.S. Cotter”) was listed.

Soleno’s argument depends almost entirely on prosecution of a parent patent filed a decade ago—one Soleno admits has “different limitations” from the ’895 claims. PO’s Brief at 10. If claim scope changed such that non-infringement positions became available, the Office was required to examine the prior art anew. It did not. This constitutes material error.

Settled Expectations. Soleno has no settled expectations in a patent issued on September 23, 2025—barely six months before this Petition. PGRs exist precisely because challenges close in time to issuance “occur[] before expectations in the patent rights are strongly settled.” *Multi-Color Corp. v. Brook & Whittle Ltd.*, PGR2025-00025, Paper 10 at 2-3 (July 16, 2025) (precedential). Every case Soleno cites involves post-grant proceedings filed *at least two years* after issuance. Settled expectations attach to the challenged claims, not to a specification published in 2016 or a related patent issued in 2017.

True Alternative. This Petition is a true alternative to litigation. There are no pending, parallel proceedings regarding the ’895 patent—a fact Soleno concedes. PO’s Brief at 14. Apotex has agreed to a *Sotera* stipulation foreclosing the grounds of this Petition in any future district court proceeding. *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 18-19 (P.T.A.B. Dec. 1, 2020). Soleno’s argument that future litigation will “necessarily occur” fails on its own terms: Soleno

itself acknowledges Apotex could “avoid certain patents by . . . fil[ing] a skinny label.” PO’s Brief at 15 n.1.

Merits. The merits are strong. The Petition relies on express prior art disclosures—not expert gap-filling. *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004); 37 C.F.R. § 42.65. Cowen discloses treating hyperphagia in PWS patients by administering diazoxide choline, teaches once-daily administration, and describes a multidose regimen titrated from a starting dose to a maintenance dose. *See* Petition at 20-45. Cotter and Miller provide express teachings regarding food-related behaviors and the shift away from a hyperphagic phase in PWS patients. *Id.* at 45-86. Dr. Hollander’s declaration (EX1005) explains how a person of ordinary skill would have understood these references—proper and expected use of expert testimony. The alignment between the Petition and declaration underscores the strength of Apotex’s invalidity position, not impropriety.

For these reasons, set forth more fully below, the Director should decline to exercise discretionary denial authority and refer the Petition to the Board for review on the merits. The patent system exists to promote innovation—not to insulate high drug prices from competition through improperly examined patents.

II. ARGUMENT

A. Discretionary Denial Under 35 U.S.C. § 325(d) Is Not Warranted

As a preliminary matter, Soleno asserts Apotex “does not even allege Examiner error.” *See* Patent Owner’s Brief on Discretionary Denial (“PO’s Brief”) at 6. Petitioners are instructed not to address discretionary denial in their Petitions. *See* Interim Processes for PTAB Workload Management (March 26, 2025). Apotex’s compliance is not an admission.

Under the two-part *Advanced Bionics* framework, the Director asks (1) whether substantially the same art or arguments were previously presented to the Office and, if so, (2) whether the petitioner has shown material Office error. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential); *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18 (P.T.A.B. Dec. 15, 2017) (precedential in relevant part). Soleno satisfies neither step.

1. *Advanced Bionics* Step 1: The Examiner Never Substantively Evaluated Cowen, Cotter, or Miller in Regard to the Challenged Claims

Soleno’s reliance on *Ascentcare* is misplaced. *Ascentcare* denied institution where the petitioner “merely disagree[d] with the Examiner’s treatment of the art without showing material error.” *Ascentcare Dental Prods., Inc. v. Solmetex, LLC*, PGR2025-00058, Paper 10 at 3 (P.T.A.B. Oct. 17, 2025). Here, there is no

“treatment of the art” for Apotex to disagree with, as the Examiner never substantively evaluated Cowen, Cotter, or Miller against the challenged claims.

Soleno conflates the presence of a reference in the file history with substantive evaluation against the challenged claims. The two are not the same. Mere IDS listing does not demonstrate “meaningful evaluation and appreciation of the prior art.” *Dr. Reddy’s Lab’ys S.A. v. Eye Therapies, LLC*, IPR2024-00467, Paper 14 at 19 (P.T.A.B. Aug. 13, 2024). The ’895 patent issued without a single prior art rejection, and the file history contains no discussion of these references. The absence of any prior art rejection means “the asserted prior art was not a basis for rejection during examination, is not substantially the same as prior art the Examiner applied and includes specific teachings that ‘impact patentability of the challenged claims.’” *Ecto World, LLC v. RAI Strategic Holdings, LLC*, IPR2024-01280, Paper 13 at 5 (P.T.A.B. May 19, 2025) (precedential); EX1015 at 225-33. The Examiner’s only rejections were for double patenting—saying nothing about patentability over Cowen, Cotter, or Miller. EX1015 at 225-33. The Notice of Allowance likewise contains no analysis of these references. *Id.* at 257-63.

Soleno’s argument is weaker still because it depends almost entirely on prosecution of a parent patent, U.S. Patent No. 9,757,384 (“the ’384 patent”). The prior art Soleno contends was examined occurred a decade ago. EX1022 at 165-76. Furthermore, the ’384 patent and ’895 patent have substantially different claim

scope—something Soleno admits when it agreed that the '895 claims “contain different limitations” from the claims of the '384 patent. *See* PO’s Brief at 10. Soleno’s concession that claim scope has changed is also supported by its statement that Apotex could “theoretically attempt to avoid certain patents by carving out portions of the label.” *Id.* at 15 n.1.

Thus, the Examiner’s evaluation of the prior art—as it relates to the '384 patent—was directed to entirely different claim scope and cannot establish substantive evaluation of the prior art in view of the *challenged claims*. EX1022 at 106-08, 126-44, 147-72. The challenged claims have never been substantively examined against the prior art Apotex’s Petition presents, and the Director should not deny review of claims granted without proper examination. *Ecto World*, Paper 13 at 5. This aligns with the Director’s recognition that a “thorough and comprehensive prior art search is the foundation of every patent examination and the foundation of quality and confidence in the patent system,” and that society “benefit[s] . . . from patents ‘born strong.’” EX1026 at 23.

2. *Advanced Bionics* Step 2: The Examiner Materially Erred in Allowing the Challenged Claims

Even assuming, *arguendo*, that the first step of the *Advanced Bionics* framework were satisfied, the second step independently supports institution. Under *Becton, Dickinson* factors (c), (e), and (f), the Director examines the extent to which prior art was evaluated during examination, whether Petitioner has shown how the

Examiner erred, and whether additional evidence warrants reconsideration. The prosecution history of the '895 patent reveals material Office errors that resulted in allowance of the challenged claims. The '895 patent issued without a single prior art rejection, and the file history contains no discussion of the prior art. EX1015 at 225-33, 257-63. This alone shows material Office error in view of Apotex's invalidity arguments. But it is not the only example.

The application leading to the '384 patent originally recited methods including: (i) treating PWS or Smith-Magenis Syndrome (SMS) patients with a K_{ATP} channel opener for at least ten weeks; and (ii) reducing aggressive behaviors by that same administration. EX1022 at 126-44. After the Applicant elected the second method and the Examiner rejected under § 103 over U.S. Cotter, Applicant amended the claims and argued U.S. Cotter disclosed neither the claimed population (aggressive-behavior subjects with PWS or SMS) nor sole administration of a K_{ATP} channel opener. *Id.* at 147-72. Both arguments led to material Office error.

First, while U.S. Cotter discloses a K_{ATP} channel opener *may* be coadministered with another therapy, it equally discloses administering a K_{ATP} channel opener *alone* to treat PWS. EX1016 at Abstract, [0001], [0003], [0008], [0010], [0057], Claims 9, 14, and 16. Although this error originated during prosecution of the '384 patent, it was not confined to that patent. The same incorrect characterization of U.S. Cotter recurred across prosecution of several related

applications, creating the illusion that substantive examination occurred throughout the '895 patent family when it did not. *See* EX1023 at 143-66; EX1024 at 133-57; EX1025 at 127-61. This lack of thorough examination is particularly concerning where the Director has recognized that branded pharmaceutical companies abuse patents to create “thickets” and “box out cheaper generic alternatives.” EX1026 at 24. Allowing a chain of improperly examined patents to insulate the challenged claims from review would reward precisely that practice.

Second, the Applicant obtained allowance of the '384 claims by arguing the claimed population (subjects with aggressive behaviors who have PWS or SMS) was not disclosed in U.S. Cotter. EX1022 at 170-72. The presently challenged claims, however, are directed to an entirely different patient population: subjects with hyperphagia who have PWS. Soleno concedes these claim limitations are different, further supporting this point by its statement that Apotex could theoretically pursue a carve-out, thus conceding that these patents have distinct claim scopes. *See* PO's Brief at 10, 15 n.1. This contrasts with *Cultec*, where the prosecution history showed analysis of the prior art over substantially similar claims. *Cultec, Inc. v. StormTech LLC*, IPR2017-00777, Paper 7 (P.T.A.B. Aug. 22, 2017). Because the challenged claims recite a substantially different patient population than the '384 patent claims, arguments distinguishing U.S. Cotter based on the “aggressive behaviors” population have no bearing on claims directed to the “hyperphagia” population. The

Office was required to conduct independent, substantive examination of the prior art with respect to the challenged claims. No such examination occurred, constituting material Office error and supporting institution.

In sum, discretionary denial under § 325(d) is unwarranted. The prior art and arguments presented in the Petition are not “substantially the same” as those previously presented to the Office because the Office never meaningfully evaluated Cowen, Cotter, or Miller against the challenged claims. *Ecto World*, Paper 13 at 5. Even if they were, the Office materially erred in allowing the challenged claims without any substantive prior art analysis and without correcting the improper characterizations of U.S. Cotter that were incorporated into the challenged patent from the ’384 patent.

B. Soleno Has No Settled Expectations in the ’895 Patent

Soleno cannot establish settled expectations in a patent that issued on September 23, 2025—roughly six months before this Petition was filed. PGRs are favored precisely because they “must be filed no later than nine months from the grant of the patent,” “are close in time to examination,” and necessarily “occur[] before expectations in the patent rights are strongly settled.” *Multi-Color Corp. v. Brook & Whittle Ltd.*, PGR2025-00025, Paper 10 at 2-3 (P.T.A.B. July 16, 2025) (precedential). A newly issued patent challenged within the statutory PGR window is the exact case in which settled expectations are absent. In contrast, every case

Soleno cites in support of its allegation of settled expectations involves post-grant procedures occurring *at least two years* after patent issuance. *See Empower Clinic Servs., L.L.C. v. Eli Lilly & Co.*, IPR2025-01024, Paper 15 (P.T.A.B. Oct. 10, 2025); *Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, Paper 9 (P.T.A.B. July 24, 2025); *Dabico Airport Sols. Inc. v. AXA Power ApS*, IPR2025-00408, Paper 21 (P.T.A.B. June 18, 2025).

Soleno’s attempt to backdate its expectations to “ten years ago” fails because settled expectations attach to the *challenged claims*, not to a specification published in 2016 or a related patent that issued in 2017. Soleno concedes the ’895 claims “contain different limitations” from the ’384 claims, and thus any settled expectations in the challenged claims could not exist until their allowance in August 2025. *See* PO’s Brief at 10.

Moreover, Soleno’s claimed settled expectations are further undermined by its ongoing expansion of its patent thicket. The ’895 patent is one of many continuations in an extensive patent family, one of which was filed as recently as May 2026 and remains pending. Petition at 5. This Petition will inform the Office as prosecution continues. Soleno cannot credibly claim that its expectations in the ’895 patent are settled when it is simultaneously pursuing additional claims, because filing continuations signals that Soleno views the boundaries of its patent protection as *unsettled*. Indeed, Soleno acknowledged in its public filings it has no “settled

expectations” because it was expecting a PGR as it expanded its “patent thicket”. EX1032 (Solenio 10K) at 31 (As “more patents are issued . . . the risk increases that our commercialization of VYKAT XR . . . may be subject to . . . requests for inter partes review and **post-grant review**.”).

Turning to Soleno’s investment in developing Vykat™ XR, this also does not establish settled expectations in the challenged claims. The Director has cautioned that even substantial investment does not create settled expectations where the challenged patent issued recently. *See Amgen*, Paper 9 at 3.

Finally, Soleno’s assertion that Apotex “sat on its hands” and should have challenged the family “years ago” is belied by the facts. PO’s Brief at 1-2. As Soleno states, “Vykat™ XR has orphan drug exclusivity until March 26, 2032, and no other company can market a generic version of Vykat™ XR before then regardless of patent status.” PO Brief at 19. Thus, the time for Apotex to act, given the orphan drug exclusivity, is now, not “years ago.” Furthermore, the present Petition is directed only at the ’895 patent claims, which issued on September 23, 2025. Apotex could not have filed a PGR before issuance and cannot be said to have delayed when filing occurred within the statutorily required nine-month period. Because Apotex promptly and diligently filed the Petition within *six* months of the PGR window opening, Soleno cannot credibly argue that any delay occurred.

C. The Petition Is an Alternative to Litigation

Soleno’s “no true alternative” argument fails on both the facts and the law. Soleno’s reliance on *Magnolia Medical Technologies* is misplaced because there are no parallel proceedings regarding the ’895 patent. *Magnolia Med. Techs., Inc. v. Kurin, Inc.*, IPR2026-00097, Paper 17 at 3-4 (P.T.A.B. May 14, 2026). Indeed, Soleno admits litigation “has not yet begun.” *See* PO’s Brief at 14.

Moreover, Apotex has agreed to a *Sotera* stipulation: if the Board institutes and Apotex is ever involved in district court litigation for the ’895 patent, Apotex “will not pursue the same grounds as in the Petition or any grounds that could have reasonably been raised in this Petition.” *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 18-19 (P.T.A.B. Dec. 1, 2020). Soleno cannot leverage unchallenged and unasserted patents to shield the ’895 patent from review that Apotex has expressly stated will not be duplicated in court.

Soleno’s argument that future litigation will necessarily occur due to other patents listed in the Orange Book for Vykat™ XR similarly fails. Soleno undermines its own position by contending Apotex could “attempt to avoid certain patents by carving out portions of the label, i.e., by filing a skinny label.” *See* PO’s Brief at 15 n.1. Soleno’s “skinny label” argument highlights that any future patent issues may concern infringement allegations alone, which the PTAB cannot address.

Accordingly, this Petition, if instituted, constitutes a true alternative to district court litigation because it materially narrows the scope of any future dispute between

the parties and eliminates overlap between the grounds raised here and any validity issues that could be litigated in court—the exact purpose of post-grant proceedings. *See Magnolia*, Paper 17 at 2.

D. The Merits Are Strong and Favor Institution

Soleno’s reliance on *Xerox* is misplaced. In *Xerox*, the expert declaration was given little weight because it merely “repeat[ed] verbatim the conclusory assertion for which it [was] offered to support” where the prior art *failed to expressly teach* the claim limitation. *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (P.T.A.B. Aug. 24, 2022) (precedential). Here, by contrast, key teachings are expressly disclosed by the prior art. Cowen discloses treating hyperphagia in PWS patients by administering diazoxide choline, teaches “reduced rates of hyperphagia” and “inhibition of hyperphagia,” once-daily administration, and a multidose regimen titrated from a subtherapeutic starting dose to a therapeutic maintenance dose. *See* Petition at 20-45. Cotter and Miller provide additional express teachings regarding food-related behaviors and the shift away from a hyperphagic phase in PWS patients taking diazoxide choline. *Id.* at 45-86.

Dr. Hollander’s expert declaration explains how a person of ordinary skill in the art would have understood the cited prior art references—a proper use of expert testimony. Soleno’s attempt to question the overlap between the Petition and Dr. Hollander’s declaration is unavailing. Rather than burying material information

and forcing the Office to search for needles in a haystack, Apotex presented its invalidity positions in a straightforward manner that allows the Office to efficiently evaluate the Petition's merits. *Ecto World*, Paper 13 at 6 n.2 ("Judges are not like pigs, hunting for truffles buried [in the record]." (quoting *Gross v. Cicero*, 619 F.3d 697, 702 (7th Cir. 2010))); *Am. Acad.*, 367 F.3d at 1368 (citing cases). The alignment between the Petition and expert declaration reinforces Apotex's invalidity position by underscoring express disclosures in the cited prior art, contrary to Soleno's veiled suggestion of impropriety.

Finally, Soleno's argument regarding the Petition's merits conspicuously fails to address the threshold requirement under 35 U.S.C. § 324(a). Soleno does not argue Apotex has failed to demonstrate a likelihood of unpatentability. Instead, Soleno asks the Director to exercise discretion to deny institution without engaging with the statutory threshold. This omission is telling: Soleno cannot rebut Apotex's *prima facie* showing and thus seeks protection in discretionary denial. Discretionary denial is not, however, a substitute for a substantive defense against Apotex's invalidity positions. Where, as here, a petition satisfies the "more likely than not" standard under § 324(a) and the patent owner fails to rebut that showing, institution is favored.

E. The Public Interest Favors Institution, Not Denial

The '895 patent claims a known use of an old drug and, by Soleno's own account, is listed in the Orange Book to block generic entry, extending a monopoly to November 2035.² *See* PO's Brief at 2. The Director has recognized that allowing improperly issued patents to remain in force keeps drug prices high and delays patient access to lower-cost alternatives. EX1026 at 3 (recognizing post-grant review should "promote and improve patent quality nearer the time of issuance," and that issuing "flawed drug patents . . . delays generic entry and increases drug prices for Americans").

1. Generic Competition Lowers Prices and Expands Patient Access

The public interest in this proceeding is inseparable from the public interest in generic competition—even Soleno concedes this. PO Brief at 19 ("immediate public-health benefit through earlier generic availability."). The FDA has repeatedly found that greater generic competition "can help affordability and improve access to drugs for American patients and consumers," with prices continuing to decline as additional competitors enter. EX1029 at 2, 5; *see also* EX1028. The FDA estimated

² While Soleno initially contends its market exclusivity extends until 2035, it later undermines this statement by stating its market exclusivity "is expected to extend into the mid-2040s", further illustrating Soleno's patent thicket to keep out generic competition. *See* PO's Brief at 14.

that the 773 generic drugs approved in 2023 generated \$18.6 billion in savings, with \$2.4 billion attributable to first-generic entrants whose “market entry . . . disrupts monopolies held by brand name drugs and induces price reductions.” EX1027 at 2. This benefit extends to therapies serving small patient populations like PWS, where generic approvals deliver “sharp price reductions for drugs that were previously prohibitively expensive” and represent “a lifeline” for patients. *Id.* at 3. VykateTM XR is the only marketed drug to treat hyperphagia in PWS and costs approximately \$500,000 per year. EX1019. Challenging improperly issued patents provides a path for price-lowering competition in a market where patients already face significant financial strain. Soleno’s contention that institution would yield no “immediate” public-health benefit misunderstands the relevant interest. The public benefits from reduced market exclusivity and introduction of generics generally. This benefit does not depend on a generic reaching pharmacy shelves the day a patent is invalidated. The mere availability of a path to generic entry—even one maturing only after regulatory exclusivity lapses—is itself a public benefit that weighs against discretionary denial. Challenging an invalid patent shortens the period of monopoly pricing and hastens the day generic competition can enter the market. *See generally* EX1033. The FDA confirms this, stating that “without the first entry, no generic alternatives would exist and brand-name prices would remain in place.” EX1027 at 3, 8-10.

Federal policy also affirms this public interest. The government has made lowering prescription drug prices a national priority, including through the “Most Favored Nation” initiative, the TrumpRx platform,³ and bipartisan efforts to increase generic drug access and reduce out-of-pocket costs. *See generally* EX1030; EX1031. These initiatives recognize that unsustainably high drug pricing is contrary to the public interest. Maintaining improperly issued patents that block generic competition runs contrary to the public interest and frustrates these objectives.

2. Soleno’s Argued “Equities” Do Not Favor Denial

Soleno has already been rewarded for its innovation through orphan-drug exclusivity for Vykat™ XR and other granted patents. *See* EX1002. These mechanisms are precisely the tools Congress designed to reward pharmaceutical innovation. The public’s interest in ensuring only valid patent rights issue should not be compromised to further bolster Soleno’s commercial position or to continue its pursuit of patent thickets aimed at blocking generic entry. This is consistent with the Director’s commitment to ensuring patents are not abused. EX1026 at 24.

Soleno’s remaining points similarly miss the mark. Orphan-drug exclusivity running to March 2032 is a regulatory consideration independent of patent validity. Moreover, the fact that current regulatory exclusivities expire before the ’895 patent

³ <https://www.trumprx.gov>

underscores the harm of not instituting Apotex's petition, because Soleno will extend market exclusivity significantly beyond regulatory exclusivity. Soleno also contends its domestic manufacture of Vykat™ XR should weigh against institution. This argument fails because domestic manufacture does not outweigh anti-competitive harm caused by Soleno's monopoly, which inflates healthcare costs for PWS patients. The public interest favors institution.

III. CONCLUSION

For the foregoing reasons, Apotex respectfully requests that the Director decline to exercise his discretion to deny institution and refer the Petition to the Board for a decision on the merits.

Dated: July 22, 2026

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this Petitioner's Brief Opposing Discretionary Denial complies with the page limit requirements of the Interim Director Discretionary Process. This brief contains 20 pages, which is consistent with the page limit applicable to a Petitioner's Brief Opposing Discretionary Denial filed on or after September 1, 2025.

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing, Petitioner's Brief Opposing Discretionary Denial, was served on July 22, 2026, via electronic mail at the following email addresses:

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