No. 25-1230

IN THE
Supreme Court of the United States

GOOGLE, LLC,
Petitioner,
v.
VIRTAMOVE, CORP., ET. AL.,
Respondents.

On Petition for Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

BRIEF OF THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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QUESTIONS PRESENTED

1. Whether the PTO lacks statutory authority to deny institution based on "settled expectations" where the patent statutes allow for administrative review at any time during the life of a patent.

2. Whether courts have power to review a PTO decision denying *inter partes* review on grounds that are contrary to statute.

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae the Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines.

In 2024 alone, generics and biosimilars saved U.S. patients over $467 billion.[2] AAM's members' products have saved patients and payers more than $3.4 trillion over the past ten years and are used to fill billions of prescriptions every year. *Id.*

Since the passage of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified at 35 U.S.C. §§ 311–19), AAM's members have regularly used *inter partes* review ("IPR") to challenge weak patents. In particular, IPRs have become a critical tool in fighting back against the

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[1] No counsel for a party authored this brief in whole or in part, and no person or entity other than *Amicus Curiae* or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. Counsel of record for all parties were provided timely notice of *Amicus Curiae*'s intent to file this brief.

[2] AAM, *The U.S. Generic & Biosimilar Medicines Saving Re-port, September 2025* at 10 (2025), https://accessiblemeds.org/wp-content/uploads/2025/09/AAM-2025-Generic-Biosimilar-Medicines-Savings-Report-WEB.pdf.

widespread proliferation of patent thickets, a strategy in which a branded company attempts to protect its monopoly with a large number of weak and duplicative patents. This abusive strategy attempts to elevate quantity over quality, hoping that the expense and uncertainty of challenging dozens of patents in court, rather than the strength of the patents themselves, will deter generics. But the patent thicket strategy only works by taking advantage of the cursory review given to most patent applications during primary examination. By subjecting patent claims to a more searching review by expert patent judges, IPRs are perfectly suited to efficiently correct the Patent Office's mistakes in having issued these patents in the first place—exactly as Congress intended.

As Petitioner has explained, the United States Patent and Trademark Office's ("USPTO") "settled expectations" policy creates a presumptive six-year deadline to file an IPR against an issued patent. If not corrected by this Court, this new, extra-statutory deadline effectively means the end of IPRs for pharmaceutical patents. The drug development process is long, taking 10-15 years or more before a new drug application ("NDA") is approved, meaning that the core patents protecting the Active Pharmaceutical Ingredient ("API") and formulation for a new drug have likely been in force for over six years by the time an NDA receives approval from the Food & Drug Administration ("FDA").

Under the USPTO's "settled expectations" policy, a generic or biosimilar applicant would have to file an IPR before the branded drug is even approved and marketed. This is simply untenable. In addition to

the practical reality that no company can identify the patents to challenge for a product that does not yet exist, even if a company wanted to file an IPR at that time, it would potentially lack standing to appeal any adverse decision while nonetheless creating collateral estoppel as to the validity of the patent. *See Momenta Pharms., Inc. v. Bristol-Myers Squibb Co.*, 915 F.3d 764, 769 (Fed. Cir. 2019). That is not a risk a generic or biosimilar applicant would ever take.

Moreover, when a branded drug company obtains approval for a new chemical entity ("NCE") or a new biological product, there is a four-year statutory exclusivity that prevents FDA from accepting abbreviated new drug applications ("ANDAs") or biosimilar applications referencing those products. This additional delay ensures that, even for patents that issued later in the development process, generic and biosimilar applicants will not have completed their own research and development work, let alone filed an application with FDA, before the "settled expectations" presumption kicks in and forecloses any IPR challenging those patents.

In short, the USPTO's use of "settled expectations" to impose a six-year deadline on IPRs all but ensures that pharmaceutical IPRs will be denied regardless of their merits. The result will be fewer affordable generic and biosimilar products, delayed generic and biosimilar entry, and substantially higher prescription drug prices for longer durations. As the trade association for the generic industry, AAM and its members have a strong interest in urging the Court to grant the Petition and review the decision below.

SUMMARY OF ARGUMENT

The Petition for Certiorari presents exceptionally important questions about the scope of the USPTO's authority and the availability of judicial oversight—questions that directly affect the integrity of the patent system and significantly affect both the pharmaceutical industry and the public's timely access to affordable medications.

The Petition asks this Court to review the USPTO's aggressive and unprecedented assertion of authority to deny institution of IPRs based on a novel "settled expectations" criterion that lacks any statutory basis. The importance of this issue reaches far beyond this case, as discretionary denials have become the dominant mechanism by which the USPTO prevents review of meritorious IPR petitions while simultaneously shielding its decisions from judicial review.

This Court's review is critically important because the USPTO's use of "settled expectations" denials has had an outsized effect on the generic and biosimilar industry. The nature of the FDA approval process all but ensures that pharmaceutical IPRs will not be filed before the USPTO's arbitrary six-year deadline when the presumption of "settled expectations" kicks in. Thus, the presumptive deadline effectively ensures that the core patents protecting a branded drug product are immune from challenge through IPR.

Moreover, the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 301 *et seq.*), and the Biologics Price

Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148, 124 Stat. 804 (2010) (codified as amended at 42 U.S.C. § 262), structure patent challenges in ways that make it virtually inevitable that branded pharmaceutical patents will be contested—just not until after statutorily imposed exclusivity periods and other regulatory timing constraints expire. As a result of this statutory structure, branded pharmaceutical companies know that their patents will be challenged, just on a later timeline.

Thus, far from having "settled expectations" that their patents are safe from challenge, branded pharmaceutical companies in fact expect such challenges, having invited them by listing their patents in the FDA's Orange Book. And they expect them well into the patent term because exclusivity periods and regulatory requirements structure when generic and biosimilar companies can feasibly challenge patents. Yet, the USPTO has cited "settled expectations" in denying pharmaceutical IPRs at a much higher rate than for other IPRs, disregarding the regulatory context that determines the timing of when those IPRs must be filed.

These deleterious effects are unwarranted. The USPTO's "settled expectations" policy cannot be squared with the AIA's text and structure. The AIA contains carefully calibrated institution criteria and time limits, including a one-year deadline tied to service of an infringement complaint. 35 U.S.C. §§ 314(a), 315(b). Nothing in the statute authorizes the USPTO to impose a new, extra-statutory six-year presumption overriding the timing restraints set forth in the statute.

The denial of IPRs in deference to the supposed "settled expectations" of the patent owner is particularly egregious given that an IPR may only be instituted when the petitioner has shown "that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C, § 314(a). The USPTO's practice thus inappropriately elevates the patent owner's subjective "expectation" that its patent will not be challenged over the statutory directive for the USPTO to review its own work and rescind improperly granted patents. This Court's review is urgently needed.

BACKGROUND

I. THE HATCH-WAXMAN ACT AND THE BPCIA STRUCTURE THE TIMING OF CHALLENGES TO THE VALIDITY OF PHARMACEUTICAL PATENTS.

Under the Hatch-Waxman Act, an applicant seeking to market a new brand-name drug must prepare an NDA. Among other things, an NDA must identify any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted, and for which a claim of patent infringement could reasonably be asserted against an unauthorized user. 21 U.S.C. §§ 355(b)(1)(A)(viii), (b)(1)(B); 21 C.F.R. §§ 314.53(b)(1), (c)(2)(i). Upon approval of the NDA, patent information is submitted to the NDA and is subsequently published in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 U.S.C. §§ 355(c)(2), (j)(7)(A)(iii); 21 C.F.R. §§ 314.53(c)(2)(ii), (e); *see also* 21 C.F.R. § 314.3(b).

A pharmaceutical company seeking approval to market a generic version of a brand-name drug must submit an abbreviated new drug application to FDA. An ANDA must include a "certification" to each patent listed in the Orange Book in connection with the NDA for the brand-name drug. 21 U.S.C. §§ 355(j)(2)(A)(vii), (viii); 21 C.F.R. § 314.94(a)(12). A "Paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed, and on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

The Hatch-Waxman Act requires that an applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and NDA holder of each of its Paragraph IV certifications. 21 U.S.C. § 355(j)(2)(B). Upon receiving notice of the Paragraph IV certifications, the patent holder has 45 days to file an infringement suit against the generic manufacturer, which triggers an automatic 30-month stay on the approval of the ANDA. 21 U.S.C. §355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A). Under the Act, the 30-month stay can be terminated under certain circumstances, including if a district court enters a judgment "that the [asserted] patent is invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iii)(I).

The Hatch-Waxman Act also governs when a generic applicant may file its ANDA with FDA. Where a branded drug company obtains approval for a new chemical entity, the Hatch-Waxman Act provides that FDA will not accept a generic application for such a drug for a period of five years. 21 U.S.C.

§ 355(j)(5)(F)(ii). However, the Act allows generic pharmaceutical companies to file ANDAs with a paragraph IV certification one year before the expiration of NCE exclusivity, commonly referred to as the NCE-1 date. 21 U.S.C. § 355(j)(5)(F)(ii).

For biosimilars, the process is even more drawn out. Under the BPCIA, a biosimilar applicant may first submit an Abbreviated Biologics License Application ("aBLA") to FDA four years after the first licensure of the branded reference product. 42 U.S.C. § 262(k)(7)(B). Unlike an ANDA, however, the exclusivity period for a reference biological product is twelve years, meaning that even if the biosimilar applicant submits its application on the earliest possible date, it will still need to wait at least eight more years before the application can be approved. 42 U.S.C. § 262(k)(7)(A).

Under the BPCIA, biosimilar pharmaceutical companies may, within 20 days of the FDA's acceptance of the aBLA, notify the reference biologic product sponsor that it has filed an aBLA. 42 U.S.C. § 262(l)(2). Within 60 days of receiving such notice, the biologic product sponsor identifies a list of unexpired patents for which a claim of infringement could reasonably be made. *See* 42 U.S.C. § 262(l)(3)(A). The biosimilar applicant then has 60 days to provide detailed invalidity, unenforceability, and/or non-infringement contentions for each identified patent. 42 U.S.C. § 262(l)(3)(B). In response, the biologic product sponsor provides the factual and legal basis for its opinion that such patent will be infringed. 42 U.S.C. § 262(l)(3)(C). Over many months, the parties negotiate which patents could properly be subject to a

patent infringement suit, culminating in the reference product sponsor filing a complaint for patent infringement in district court. 42 U.S.C. §§ 262(l)(4)–(6). This extended process is known as the "patent dance," and regularly results in a large number of patents being asserted against the biosimilar applicant.

In short, under the Hatch-Waxman Act and the BPCIA, generic and biosimilar medicines are structured to follow their branded reference products. Their development—including the refinement of manufacturing processes, formulations, and labeling—necessarily occurs later. The filing of generic and biosimilar marketing applications with FDA likewise occurs later. And the identification of the patents relevant to those applications—often informed by the development process and FDA feedback—also occurs later in time. Yet throughout that period, the terms of the relevant patents continue to run. By the time it becomes feasible for a generic or biosimilar applicant to challenge these patents, several years may have elapsed since the branded reference product entered the market.

II. IPRs Are Critically Important in Ensuring Timely Access to Affordable Drugs.

A. Patent Thickets Are a Growing Problem in the Pharmaceutical Industry.

The Hatch-Waxman Act and the BPCIA require generic and biosimilar pharmaceutical companies to address most patent issues before launching a product through costly and protracted patent infringement litigation. These statutory schemes were

designed to create a robust generic and biosimilar drug marketplace, and, as a whole, have been successful in balancing the need for innovative drug therapies while enabling generic and biosimilar pharmaceutical companies to offer patients affordable medicines.

Despite these statutory schemes, some brand-name pharmaceutical companies have found ways to slow the availability of affordable generic and biosimilar medicines by leveraging the patent system and extending their patent-supported monopolies for years. Branded drug and biologic companies are increasingly assembling large estates of patents known as "patent thickets"—a problem uniquely plaguing the United States.[3] For example, data collected by FDA and court filings show that for six recently approved biosimilars in the United States, the brands asserted 11 to 65 patents per product. *Id.* at 9. Other analyses have shown that, as compared to patent disputes regarding 30 biosimilars in Canada and the United Kingdom, brands asserted an additional 300 patents against the biosimilar manufacturers when litigating in the United States. *Id.* at 8–9. In view of these patent thickets, it is no surprise that "biosimilars enter the UK and Canadian markets more quickly than they do in the USA."[4]

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[3] *See* AAM, *Anatomy of a Biosimilar Patent Litigation: Problems and Solutions* at 8–10 (July 8, 2025), https://accessiblemeds.org/wp-content/uploads/2025/07/White-Paper-Anatomoy-of-Biosimilar-Patent-Legislation-July-2025.pdf.

[4] Rachel Goode & Bernard Chao, *Biological patent thickets and delayed access to biosimilars, an American problem*, 9 J.L. &

For example, Humira®, a biologic indicated for the treatment of rheumatoid arthritis, was covered by over a hundred issued patents, with over sixty of those patents asserted in litigation. Often, branded pharmaceutical companies obtain evergreen patents long after their brand or biologic products have been approved, or even after generic and biosimilar manufacturers have sought approval of lower-cost versions of these products.[5]

Likewise, after generic manufacturers sought FDA approval of a generic version of the branded drug Myrbetriq, the branded pharmaceutical company repeatedly obtained new patents, subjecting those manufacturers to five rounds of patent litigation over nearly a decade. *Id.* at 8–10. In some instances, brand companies hold patents in reserve and assert them years later, underscoring that the scope of patent disputes surrounding a product may remain unsettled for several years. In other instances, brand-name pharmaceutical companies made certain arguments to FDA to gain approval of their NDAs and then performed an about-face," contradicting their own prior statements when prosecuting patents before the USPTO. *See Belcher Pharms., LLC v. Hospira, Inc.*, 11 F.4th 1345, 1353–54 (Fed. Cir. 2021) (holding patent unenforceable for inequitable conduct where the

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Biosci. 1 at 3 (2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC9439849/pdf/lsac022.pdf.

[5] *See, e.g.*, AAM, *Serial Patent Litigation White Paper* at 6–17 (Sep. 3, 2025), https://accessiblemeds.org/wp-content/uploads/2025/09/Serial-Patent-Litigation-White-Paper-Final-09032025.pdf (summarizing examples where brand and biologic companies have engaged in serial patenting).

brand company's chief science officer asserted a pH range was "old" to obtain FDA approval, then asserted the same pH range was a "critical innovation" to obtain patent rights (internal quotation marks omitted)).

The issue of patent abuse is pronounced in the United States. A recent analysis of 30 biosimilars found that "[i]n the USA, over 15 times more patents were asserted against these 30 biosimilars than in the UK."[6] It has been estimated that between 2015 and 2019 alone, "delayed entry of biosimilars due to patenting has cost the U.S. health care system an astounding $7.6 billion in lost savings."[7] Often, the later-filed patents claim small, incremental changes or minor aspects of a product that do not represent genuine innovation or benefit patients. Yet these low-quality—and often non-innovative—patents effectively delay generic and biosimilar competition and can force generic and biosimilar pharmaceutical companies into years of slow-moving and costly litigation.

B. IPRs Are an Important Tool to Address Pharmaceutical Patent Thickets.

District court litigation is not the only forum for challenging patent validity. In 2011, Congress passed the AIA to provide a "quick and cost effective alternative" to district court patent litigation through IPR

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[6] Goode & Chao, *supra* note 4, at 8–9.

[7] Biosimilar Council, *Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America's Patients: White Paper* at 4 (June 25, 2019), https://biosimilarscouncil.org/wp-content/uploads/2019/10/Failure-to-Launch-Part-1.pdf.

proceedings. H.R. Rep. No. 112-98, at 48 (2011). Consistent with Congress' goal to combat "overpatenting and its diminishment of competition" and allow parties to "weed out bad patent claims efficiently," *Thryv, Inc. v. Click-To-Call Techs., LP*, 590 U.S. 45, 54 (2020) (citations omitted), generic and biosimilar companies commonly employ IPRs to correct such patent abuses and trim down patent thickets.

According to USPTO data, between September 16, 2012, and July 31, 2025, over 1,600 IPR petitions challenged patents listed in the Orange Book, patents covering biologics, or patents that are otherwise in the field of biologics/pharmaceuticals.[8] During this timeframe, the institution rates for these categories of patents was just over 60%. *Id.* at 13.

The proliferation of patent thickets, full of duplicative and weak patents, makes it imperative that IPRs be available to generic and biosimilar manufacturers. Indeed, many generic and biosimilar pharmaceutical companies have used IPR proceedings to successfully remove patent roadblocks and accelerate the launch of lower-cost products, providing patients with earlier access to more affordable medications.

For example, successful IPRs brought by Noven Pharmaceuticals Inc. paved the way for generic competition to Exelon® Patch (indicated for the treatment of Alzheimer's and Parkinson's disease). *Novartis AG*

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[8] USPTO, *PTAB Orange Book patent/biologic patent study: FY 25 Update* at 6 (July 31, 2025), https://www.uspto.gov/sites/default/files/documents/Orange_Book_Biologics_Trial_Stats_July_2025.pdf.

v. Noven Pharms. Inc., 853 F.3d 1289 (Fed. Cir. 2017) (affirming IPR decisions). Similarly, generic pharmaceutical companies successfully defeated the claims of a patent covering the drug Zytiga®, allowing for the launch of generic versions to treat prostate cancer. *BTG Int'l Ltd. v. Amneal Pharms. LLC*, 923 F.3d 1063 (Fed. Cir. 2019) (affirming IPR decisions). As a result of this successful IPR, patients saved an average 81% on this life-saving medicine due to the availability of generic Zytiga®.[9] A generic pharmaceutical company similarly invalidated all claims of four patents covering the drug Kerydin® pursuant to four IPRs. *See Anacor Pharms., Inc. v. Flatwing Pharms., LLC*, 825 F. App'x 811, 812 (Fed. Cir. 2020) (affirming IPR decisions).

Numerous other patents relating to brand drug or biologic products have been invalidated—in whole or in part—through IPRs, including patents for Lantus®, Herceptin®, Rituxan®, Avastin®, and Neulasta®.[10] IPRs have also been instrumental in driving early settlements, such as a settlement a biosimilar received relating to Stelara® shortly after filing an IPR. *See Samsung Bioepsis Co. v. Janssen Biotech, Inc.*, IPR2023-01103, Paper 8 (PTAB Aug. 9, 2023). Settlements such as these promote competition and enable earlier patient access to lower-cost alternatives.

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[9] *See* AAM, *Statement for the Record: House Judiciary Subcommittee on the Courts, Intellectual Property, and the Internet Hearing on "The Patent Trial and Appeal Board After 10 Years: Impact on Innovation and Small Businesses* at 1 (June 23, 2022), https://www.congress.gov/117/meeting/house/114937/documents/HHRG-117-JU03-20220623-SD026.pdf.

[10] *See* AAM, *Statement for the Record*, *supra* note 9 at 1.

Indeed, a recent analysis of patent settlements between 2014 and 2024 estimated that patent-related settlements saved the healthcare system $422.9 billion and allowed generic or biosimilar entry an average of 64 months before patent expiry.[11]

III. THE USPTO'S INCREASING USE OF "SETTLED EXPECTATIONS" TO SHIELD DENIALS OF MERITORIOUS IPRS FROM JUDICIAL SCRUTINY DISPROPORTIONATELY AFFECTS PHARMACEUTICAL PATENTS.

As Petitioner explains, the USPTO has increasingly relied on discretionary denials to avoid even having to consider meritorious IPRs. Recent analysis shows that from "May to September 2025, 60% of 506 requests for discretionary denial were granted, triple historical levels, including one-third involving drug patents."[12] For example, IPRs challenging patents protecting Mounjaro®, Opdivo®, and Yervoy® have recently been denied based on the allegedly "strong settled expectations of the Patent Owner" because the challenged patents had been in force for more than six years. *Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601 & IPR2025-00602, Paper 9, at 3 (PTAB July 24, 2025); *Empower Clinic Servs. v. Eli*

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[11] *See* AAM, *Assessment of the Impact of Settlements: Analysis Results* at 5–6 (June 2025), https://accessiblemeds.org/wp-content/uploads/2025/06/202506-AAM-Impact-of-Patent-Settlements-IQVIA-Study.pdf.

[12] Sean Tu et al., *Recent changes in discretionary denials of drug patent challenges*, 3 Health Affs. Scholar at 1 (Nov. 2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12638723/pdf/qxaf215.pdf

Lily & Co., IPR2025-01024, Paper 15 (PTAB Oct. 10, 2025).

Where the patent owner has asked the USPTO to dismiss a pharmaceutical IPR on "settled expectations" grounds, over ***85 percent*** of those requests have been granted, a much larger percentage than for non-pharmaceutical IPRs.[13] This discrepancy is hardly surprising—because of the unique features of the Federal Food, Drug, and Cosmetic Act, the Hatch-Waxman Act, and the BPCIA, generic and biosimilar applicants are almost never in a position to challenge the core patents protecting a branded product within six years of patent issuance due to the application of statutory exclusivities and the drug development timeline. Thus, the USPTO's new practice of denying IPRs based on "settled expectations" has the practical effect of ensuring that weak pharmaceutical patents cannot be challenged by IPRs. This result is clearly contrary to Congress's intent in passing the AIA, and this Court's review is needed to ensure that discretionary denials are subject to judicial review and oversight.

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[13] Tu et al., *supra* note 12, at 2 (showing that 21 pharmaceutical IPRs were denied institution on "settled expectations" grounds compared to only 3 pharmaceutical IPRs in the same time period that were allowed to proceed despite "settled expectations" being raised).

ARGUMENT

I. THE USPTO'S "SETTLED EXPECTATIONS" POLICY HAS EFFECTIVELY ELIMINATED IPRS FOR GENERICS AND BIOSIMILARS.

The USPTO's denial of any IPR filed against a patent more than six years after issuance has drastically curtailed the use of IPRs by generic and biosimilar manufacturers. This will predictably result in the delayed entry of lower-cost drug products and higher prescription drug prices.

The drug development process is long, beginning with development of a candidate compound, followed by preclinical testing and formulation development. The drug sponsor then submits an Investigational New Drug ("IND") application to FDA for approval to begin phased clinical trials of increasing size to establish safety, dosing, and efficacy. If the clinical trial results support approval, the sponsor submits an NDA, which is reviewed by FDA. The entire process can take 10-15 years or longer.

As a result, the window between when a branded drug or biologic company obtains its core patents and when it receives approval of its product can be quite long, often longer than the six years the USPTO assumes creates "settled expectations." Indeed, Congress explicitly recognized this difference between patent issuance and FDA approval when it passed the Hatch-Waxman Act, which grants patent owners an extension of up to five years to cover the regulatory review period when the company's application was pending before FDA. *See* 35 U.S.C. § 156(a).

Moreover, generic and biosimilar applicants are constrained by statutory exclusivity rules from filing applications on most drugs and biologics until at least four years after the original product application was approved. Every NDA approval based on a new chemical entity comes with a five-year exclusivity, during which FDA is not allowed to accept generic drug applications. 21 U.S.C. § 355(j)(5)(F)(ii). Under the Hatch-Waxman Act, generic drug applicants may submit their applications one year prior to the expiration of this exclusivity, on the NCE-1 date, if the application contains a Paragraph IV certification challenging the infringement or validity of one of the branded company's patents. *Id.* The vast majority of patents covering an NCE pharmaceutical product are challenged at this time.

Likewise, under the BPCIA, a new biologic is granted twelve years of exclusivity. 42 U.S.C. § 262(k)(7)(A). As with small molecule drugs, FDA is allowed to receive a biosimilar application beginning four years after the reference product was first licensed. 42 U.S.C. § 262(k)(7)(B).

Collectively, the length of the drug and biologic development and approval process combined with statutory exclusivity effectively ensures that no IPRs will ever be filed on the core patents protecting branded drug and biologic products before the USPTO's arbitrary six-year cutoff. Indeed, in order to meet that deadline, generic and biosimilar applicants would often need to file their IPR petitions before they even know whether the branded product will receive FDA approval—years before they will decide on whether to even pursue a generic version of that product.

That is obviously untenable. Not only is it wholly impractical to file an IPR at that stage, it would also severely prejudice any company that even attempted to do so. Before filing an application with FDA, a generic or biosimilar applicant has not engaged in any possibly infringing activities. Thus, under Federal Circuit precedent, the petitioner would potentially lack Article III standing to appeal an adverse decision but would still be subject to estoppel as to the validity of the patent if the patent were asserted against it in the future. *See Momenta Pharms.*, 915 F.3d at 769. No company would be willing to take that risk.

Moreover, Congress provided generic and biosimilar applicants with a safe harbor to allow them to complete the research, development, and testing supporting their applications without liability for patent infringement. 35 U.S.C. § § 271(e)(1). This safe harbor operates as part of the Hatch–Waxman Act's broader calibrated framework. Congress paired permission to engage in research, development, and testing during the term of a patent with mechanisms that allow patent disputes to be litigated at the appropriate time. The USPTO's "settled expectations" denials upset this carefully crafted balance by requiring generic applicants to either litigate the validity of the brand company's patents before completing its research and development work or forgo the ability to file IPRs altogether. *See, e.g.*, *Amgen Inc.*, IPR2025-00601 & IPR2025-00602, Paper 8, at 28 (July 10, 2025) ("When the '320 Patent granted in 2018, Petitioner had not even begun its clinical trials on its biosimilar product[.]").

For biosimilar applicants, the situation is even worse. When the reference product is eligible for twelve-year exclusivity, the lengthy review period for such applications means that the patent landscape will have radically changed by the time of approval. In addition, at the point a biosimilar applicant would have to file an IPR to meet the "settled expectations" deadline, the applicant would not have the benefit of the information exchanged in BPCIA's "patent dance," which is designed to narrow the patents asserted in litigation to the relevant patents. *See* 42 U.S.C. § 262(l).

Moreover, the AIA specifically contemplates that parties would choose to file IPRs after being sued for patent infringement. 35 U.S.C. § 315(b). The AIA provides a defendant with a one-year period from the date of service of a patent infringement complaint to decide whether to file an IPR against the patents asserted in the litigation. *Id.* The USPTO's "settled expectations" denials effectively nullify this statutory decision period by requiring generic and biosimilar applicants to file IPRs long before they are actually sued.

Under the agency's approach, branded pharmaceutical patents are functionally insulated from administrative review—even where strong prior art demonstrates invalidity. That outcome directly frustrates the Hatch–Waxman Act's framework, which is designed to accelerate, not defer, the resolution of patent disputes affecting FDA-regulated products.

In short, the USPTO's practice of issuing discretionary denials on "settled expectations" grounds

requires any generic or biosimilar applicant who wants to file IPRs against a branded company's drug to take a shot-in-the-dark guess about which patents are potentially relevant at a time when they might not even be sure they will ultimately seek to market a competing product. Given the difficulty and expense of an IPR challenge, that is effectively a death knell to the use of IPRs to challenge weak core pharmaceutical patents. And without IPRs to clear the thickets protecting many new branded products, the result will be fewer validity challenges and fewer generic and biosimilar drugs brought to market.

II. THE USPTO'S "SETTLED EXPECTATIONS" POLICY FAILS TO ACCOUNT FOR THE REALITY THAT BRANDED PHARMACEUTICAL PATENT OWNERS EXPECT THAT THEIR PATENTS WILL BE CHALLENGED.

The USPTO's frequent denials of pharmaceutical IPRs based on "settled expectations" have failed to account for the impact of the Hatch-Waxman Act and BPCIA. In light of the framework provided by these statutes, it is a virtual certainty that the branded company's patents will be challenged. Indeed, a recent report noted that "[i]n the USA, no biosimilars launched free from patent litigation or a pre-litigation settlement."[14] Thus, branded pharmaceutical companies never have any reasonable expectation that their patents are safe from challenge, let alone a "settled" one.

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[14] Goode & Chao, *supra* note 4, at 13.

Under the Hatch-Waxman Act, generic drug manufacturers include certifications that the brand company's patents are invalid or not infringed as part of their ANDAs. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(4)(A). Generic manufacturers are required to give notice to the brand company that they have made such a certification, after which the brand company has 45 days to sue the generic applicant for patent infringement. 21 U.S.C. § 355(j)(2)(B), (j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A). The BPCIA "patent dance" likewise culminates with the reference product sponsor filing a complaint for patent infringement in district court. 42 U.S.C. §§ 262(l)(4)–(6). In these litigations, generic and biosimilar applicants seek to invalidate the branded companies' patents.

These inevitable challenges to the validity of the branded company's patents, however, do not come immediately. As discussed above, drug approval is a lengthy, multi-year process, and generic and biosimilars applicants are constrained by statutory exclusivity from filing applications on NCEs and new biological products until at least four years after the original product application is approved.

As a result, branded pharmaceutical companies know that their patents will inevitably be challenged when they obtain them, but that the challenge will come four or more years after their own applications are approved by FDA. Far from creating a "settled expectation" that their patents are immune from challenge, the very nature of the Hatch-Waxman Act and BPCIA ensures that the only reasonable expectation

the branded company can have is that the validity of their patents will be tested.

Yet despite the fact that branded pharmaceutical companies never have any reasonable expectation that their patents are safe from challenge, the USPTO has repeatedly denied IPRs challenging pharmaceutical patents on "settled expectations" grounds at a higher rate than other IPRs. *See supra* n.13.

The Federal Circuit's decision below, holding that these discretionary denials are unreviewable, all but ensures that the USPTO will continue to deny pharmaceutical IPRs based on a wholly arbitrary and capricious application of its "settled expectations" policy. This Court's review is warranted.

III. THE DECISION BELOW ALLOWS THE USPTO'S ARBITRARY USE OF "SETTLED EXPECTATIONS" DENIALS TO GO UNCHECKED.

In addition to the arguments presented by Petitioner, which AAM endorses fully, the denial of IPRs on "settled expectations" grounds is especially flawed when applied to pharmaceutical patents. As discussed above, branded companies expect that their patents will be challenged. Denying IPRs challenging those patents based on "settled expectations" without considering the impact of statutory exclusivities is arbitrary and capricious. The Federal Circuit's decision holding that discretionary denials are unreviewable will simply breed more arbitrary and capricious agency action. This Court's review is therefore needed.

The USPTO's denial of IPRs on "settled expectations" grounds is also contrary to law. The AIA sets both prohibitions and thresholds for institution of IPRs. For example, the AIA specifically prohibits institution when a petitioner was served with a complaint more than one year earlier. 35 U.S.C. § 315(b). And the AIA permits institution only if the petition shows a reasonable likelihood that the petitioner will succeed on at least one challenged claim. 35 U.S.C. § 314(a). Yet despite setting a strict deadline to file an IPR within a certain amount of time after service of a patent infringement complaint, nothing in the AIA suggests that Congress wanted to create a different presumptive deadline that IPRs must be filed no more than six years after a patent issues.

The AIA does not authorize the creation of a new, extra-statutory criterion for institution. The use of "settled expectations" to deny IPRs is completely unmoored from the statutory criteria set forth in the AIA, yet discretionary denials now make up the majority of all IPR denials. That fact alone suggests something is seriously amiss at the Patent Office and that this Court's review is warranted to ensure that the USPTO's exercise of its discretion does not exceed the scope of discretion granted by Congress.

Congress enacted the Administrative Procedure Act "'as a check upon administrators whose zeal might otherwise have carried them to excesses not contemplated in legislation creating their offices.'" *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 391 (2024) (quoting *United States v. Morton Salt Co.*, 338 U.S. 632, 644 (1950)). As this Court noted in *Loper Bright*, the APA "specifies that courts, not agencies,

will decide '*all* relevant questions of law' arising on review of agency action . . . and set aside any such action inconsistent with the law as they interpret it." *Id.* (quoting 5 U.S.C. § 706) (emphasis added by the Court). By holding that the USPTO's imposition of an extra-statutory deadline for filing IPRs is unreviewable, the Federal Circuit's decision did what this Court forbade in *Loper Bright*: it deferred to the agency to decide what the law is. In doing so, the decision below conflicts with the decisions of this Court. Certiorari should be granted for this additional reason.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

May 29, 2026

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