Statement for the Record by the Association for Accessible Medicines
House Judiciary Subcommittee on IP, Hearing on Medicines and IP: Balancing Innovation and Access
June 4, 2026

The Association for Accessible Medicines and its Biosimilars Council (collectively, "AAM") thank the Subcommittee for convening this hearing on the critical role patents play in shaping prescription drug prices and patient access. At its core, this is not an abstract policy debate—it is about whether American patients can obtain the medicines they need at prices they can afford. Four decades of experience have proven a clear and durable truth: **robust, timely competition from generic and biosimilar medicines is the single most effective mechanism for lowering drug costs while preserving incentives for innovation**. That competition has delivered extraordinary benefits, generating more than $3 trillion in savings over the past decade alone, including $467 billion in 2024. Yet these savings—and the access they represent—are increasingly at risk. Abuses of the patent system are being used to delay or block competition, keeping lower-cost alternatives off the market and forcing patients, taxpayers, and the healthcare system to pay more for longer. Congress has both the authority and the responsibility to restore balance. Targeted, bipartisan reforms can protect innovation while ensuring that the patent system once again serves its intended purpose: promoting progress and expanding access—not entrenching monopolies at the expense of patients.

AAM urges Congress to act on three targeted reforms:

- Streamline patent thickets by **passing H.R. 3269, the ETHIC Act**, preventing the assertion of multiple overlapping patents that delay competition and raise costs.

- Restore and protect the "skinny label" pathway by **enacting H.R. 6485, the Skinny Labels, Big Savings Act**, ensuring that patents on limited uses cannot block access to affordable generics and biosimilars for unpatented indications.

- **Preserve a strong and effective *inter partes* review (IPR) system** by rejecting policies that limit access to PTAB review, ensuring weak or non-innovative patents can be efficiently challenged.

Eliminating Thickets to Increase Competition (ETHIC) Act (H.R.3269)

The U.S. patent system differs from its overseas counterparts in that it allows brand companies to prosecute and obtain more patents per medicine to create "patent thickets" that block generics and biosimilars from entering the market. Brand companies are able to develop these thickets through the use of terminal disclaimers, which allow duplicative patents to be asserted against competitors so long as the patent holder agrees that the subsequent patent will expire at the same time as an earlier, related patent. Even if the generic or biosimilar competitor invalidates the original patent, the generic competitor must ordinarily invalidate each duplicative patent separately before entering the market. Put simply, branded pharmaceutical companies' "patent

portfolio[s] emulate[] the many headed hydra from Greek mythology"[1] with generics and biosimilars facing multiple patent roadblocks.

Terminal disclaimer practice harms generic and biosimilar competition in the United States. While patents are meant to protect true innovations, terminal disclaimers encourage duplicative patents that do not represent improvements to an existing medicine yet provide the same threat of potential remedies (be it an injunction, automatic blocks on FDA approval, or damages exposure). Instead, these duplicative patents claim incremental differences, giving branded companies an additional but undeserved layer of protection. More specifically, because generics and biosimilars often must clear the field of all relevant patents before entering the market, duplicative patents require generics and biosimilars to engage in costly, serial litigation to invalidate every patent, adding greater uncertainty as to whether and when these generics and biosimilars may launch.

Unlike other countries, the United States permits patent holders to end-run the bar on duplicative patents through terminal disclaimers. Indeed, "on average, nine times more patents are asserted against biosimilars in the USA than in Canada, and 12 times more patents are asserted when compared to the UK."[2] "At the same time, . . . biosimilars enter the UK and Canadian markets more quickly than they do in the USA."[3] In the United States, "there is an average delay of 34 months between FDA approval and biosimilar launch," while the average delay in Canada and the United Kingdom is merely 7.4 and 4.7 months, respectively.[4] Put simply, "[o]n average, there is 4 times longer delayed launch of biosimilars in the USA compared to Canada and seven times longer compared to the UK."[5] In other words, because generic and biosimilar manufacturers in the United States face the more costly prospect of invalidating duplicative patents, they not only face lengthier delays in entering the market but must also incur significantly higher costs to do so. And given that litigation costs can skyrocket into the tens of millions of dollars, attempting to enter the market may be cost-prohibitive for generic and biosimilar manufacturers.[6]

Reforming terminal disclaimer practice would help dismantle patent thickets and facilitate the ability of generics and biosimilars to enter the market, all of which would help level the playing field between prices in the United States and prices in other countries. To cut down on duplicative patents, the U.S. Patent and Trademark Office could link the validity of patents with terminal disclaimers to the validity of the earlier, related patent. Under that system, if a competitor invalidates the earlier, related patent, the duplicative patent would be deemed unassertable. Indeed, the PTO itself suggested this change in 2024 to help "reduc[e] litigation and administrative proceeding costs" and "increas[e] predictability."[7] Relatedly, permitting patent holders to assert only one patent per duplicative group against a generic or biosimilar competitor would likewise reduce litigation costs and increase predictability by cutting down on serial litigation as to substantively identical patents.

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[1] *See* Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars, an American Problem*, 9 J. Law Biosci. 16-22 (2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC9439849/pdf/lsac022.pdf.

[2] *Id.*

[3] *Id.*

[4] *Id.*

[5] *Id.*

[6] *Mylan Inc. v. Comm'r,* 76 F.4th 230, 241 (3d Cir. 2023) (noting that Mylan incurred "nearly $130 million of legal expenses" from 2012 to 2014 in connection with ANDA litigation).

[7] Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting, 89 Fed. Reg. 40,439, 40,441 (May 10, 2024).

The ETHIC Act (H.R.3269) addresses these issues and will enhance patient access by preventing brand-name pharmaceutical companies from asserting multiple duplicative patents in patent litigation. These duplicative patents create a numbers game for generic and biosimilar companies that ultimately harms patients. Challenging a large patent estate requires generic and biosimilar manufacturers to engage in years of slow-moving and costly patent litigation to bring their lower-cost medicines to market. The net result is delayed patient access to lower-cost generics and biosimilar medicines. This legislation helps address this patent litigation bottleneck—while also respecting innovation—by requiring brand name pharmaceuticals to assert only non-duplicative patents in patent litigation. The ETHIC Act is supported by a wide variety of stakeholders, including AHIP, PCMA, the ERISA Industry Committee, Public Citizen, Generation Patient, Consumer Action, American Consumer Institute, Transparency-Rx, PIRG, and AARP.

While other proposed legislation, such as the Affordable Prescriptions for Patients Act (S.1041), also attempts to address the important issue of patent thickets, it does not go far enough to protect patient access. This legislation would "cap" the number of patents that can be asserted in biosimilar litigation but does not apply in the context of Hatch-Waxman litigation. The proposed 20-patent cap is still a significant number of patents for a single litigation and is subject to several exceptions that could effectively swallow the rule. For example, method of treatment and some device patents are excluded from the cap, as are certain older patents. In addition, the cap may be lost for even minor non-compliance with procedural rules and may be enlarged for a variety of loosely defined reasons. Simply stated, the ETHIC Act provides a more meaningful and impactful way to address the problem of patent thickets.

Skinny Labels, Big Savings Act (H.R. 6485)

Since the enactment of the Hatch-Waxman Amendments in 1984, Congress has provided that a narrow patent on one way of *using* a drug should not block access to generic substitutes entirely. When a drug's formulation and one or more ways of using it have moved into the public domain, patents on other uses should no longer prevent the marketing of a generic version for the non-patented uses. As the Supreme Court has rightly recognized, Congress provided for carve-outs so "that one patented use will not foreclose marketing a generic drug for other unpatented ones."[8]

Hatch-Waxman accomplished that goal through the "skinny labeling" mechanism, which has allowed generic manufacturers to bring numerous generic drugs to the market. A skinny label permits the generic manufacturer to "carve-out" a brand drug sponsor's patented methods of use from the generic's FDA-approved labeling. For example, if a brand-name drug is approved for treating four different diseases, only one of which is covered by a patent, generic manufacturers can "carve-out" that patented use, gain FDA approval for the remaining three diseases, and bring to market a more affordable generic alternative.

The rationale for Hatch-Waxman's carve-out process is straightforward: it facilitates generic competition on unpatented uses of brand-name drugs and ensures patients have timely access to more affordable medicine. Indeed, Hatch-Waxman's carve-out process has served the public interest for over 40 years by increasing access to generic medicines, saving the healthcare system billions of dollars. In 2010, Congress added a pathway for biosimilars, which achieve similar savings through alternatives to some of the most expensive biologic medicines. Biosimilars, too, can sometimes avoid a patent block by omitting portions of the labeling of the brand-name reference product and so make the biosimilar available for those indications where there is no such block.

[8] *Caraco Pharm Labs v. Novo Nordisk*, 132 S. Ct. 1670, 1682 (2012).

Despite this well-established practice, a 2021 decision from the U.S. Court of Appeals for the Federal Circuit has undermined Hatch-Waxman's carve-out process. That decision, *GSK v. Teva*, holds that a generic can be liable for inducing doctors to infringe the brand's patented method that the generic carved out from its label, based on arguments that the carve-out was supposedly not broad enough and thus evidence intent to induce infringement.[9] The Federal Circuit also relied on evidence that the generic publicly described its product as the equivalent of the brand product—something that is true of *every* generic. Although the federal government filed a brief to the Supreme Court explaining that the Federal Circuit's decision was wrong, the Supreme Court declined to review the decision.

The Federal Circuit's *GSK* decision threatens to nullify the longstanding carve-out mechanism that allows generic manufacturers to quickly get affordable, FDA-approved medicines to patients. Many well-known generics currently on the market (including Crestor® and Abilify®) were able to launch years before expiration of the brand's method patents because of the carve-out mechanism. With the viability of carve-outs thrown into uncertainty, manufacturers have been discouraged from attempting early launch of generic drugs and biosimilars, which is forcing patients to wait longer for lower-cost generics to be approved.[10]

Seizing on the opening created by the Federal Circuit's *GSK* decision, another branded manufacturer, Amarin, filed suit against a generic manufacturer, Hikma, arguing that Hikma's skinny-labeled icosapent ethyl product infringed Amarin's patents. Despite Hikma's carved out label, Amarin relied on press release statements in which Hikma identified its product as a generic version of Amarin's branded Vascepa® product. The district court rightly dismissed the case for failing to plausibly allege induced infringement. The Federal Circuit, however, reversed and held, on reasoning similar to *GSK*, that Hikma could be liable for induced infringement based on a skinny label that carved out the claimed indication and press release and website statements characterizing Hikma's product as a generic version of Vascepa.

Hikma petitioned the Supreme Court for certiorari. After receiving a brief from the federal government, urging the Court to take up the case and overturn the decision below,[11] the Supreme Court granted certiorari. As the government noted in its amicus brief, uncertainty regarding skinny labels "will deter generic manufacturers from invoking that mechanism, thereby threatening the availability of lower-cost generic drugs, in contravention of the statutory design."[12] Several amici, including AAM, filed briefs in support of Hikma.[13] Other notable amici supporting Hikma included Henry Waxman, co-author of the original Hatch-Waxman Act,[14] as well as the United States.[15] Rep. Waxman argued in his brief that the "Federal Circuit's decision [] threatens to decimate the compromise at the heart of the Hatch-Waxman Act, which in turn threatens to undermine the generic

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[9] *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021).

[10] *See generally* Michael A. Carrier, *Skinny Labels' Importance for Drug Competition*, 2026 Wis. L. Rev. F. 11-25, available at https://wlr.law.wisc.edu/wp-content/uploads/sites/1263/2026/04/Carrier-Final.pdf.

[11] Brief for the United States as Amicus Curiae, *Hikma Pharms USA Inc. v. Amarin Pharma, Inc.*, No. 24-889 (Dec. 5, 2025), Brief for the United States as Amicus Curiae.

[12] *Id.* at 13.

[13] Brief for The Association for Accessible Medicines as *Amicus Curiae* Supporting Petitioners, *Hikma Pharms USA Inc. v. Amarin Pharma, Inc.*, No. 24-889 (Feb. 25, 2026), AAM Amicus Brief.

[14] Brief of *Amicus Curiae* Former Congressman Henry A. Waxman in Support of Petitioners, *Hikma Pharms USA Inc. v. Amarin Pharma, Inc.*, No. 24-889 (Feb. 25, 2026), Waxman Amicus Brief.

[15] Brief for the United States as Amicus Curiae Supporting Petitioners, *Hikma Pharms USA Inc. v. Amarin Pharma, Inc.*, No. 24-889 (Feb. 25, 2025), United States Merits Amicus Brief.

pharmaceutical industry."[16] The government's brief further explained that skinny labels "encourage[] the introduction of low-cost drugs for American consumers and helps avoid exploitative and anticompetitive practices by brand-name manufacturers."[17] A unifying theme across the briefs was that clarification of the law was needed because "[u]ncertainty about [skinny labels] will deter generic manufacturers from invoking that mechanism, thereby threatening the availability of lower-cost generic drugs, in contravention of the statutory design."[18]

The Supreme Court heard oral argument in April 2026 and a decision is expected in late June 2026. While questions posed during oral arguments suggested that at least some justices understand the critical importance of skinny labels and the need for generic manufacturers to have unfettered access to this pathway, many commentators believe that the Court may rule on narrower procedural grounds.

Considering the likelihood of a narrow, procedural ruling in *Amarin v. Hikma*, legislative action remains imperative to preserve access to more affordable medicines and to ensure that biosimilars—which the Supreme Court did not address—have labeling carve-out protections. AAM and 19 other organizations have urged Congress to "advance crucial legislation to help reduce costs for America's patients."[19] The Skinny Labels, Big Savings Act (H.R. 6485) will ensure that the Hatch-Waxman Act's longstanding provisions regarding skinny labels are not undermined and that patients can continue to access lower-cost medicines as quickly as possible. The carve-out process has served the public interest for over 40 years by increasing access to generic medicines, saving the healthcare system billions of dollars. According to The American Journal of Managed Care (AJMC), from 2015 to 2020, 15 skinny labels alone generated $14.6 Billion in Medicare savings.[20] Without explicit protection for carve-outs, the existence of a single, indication-specific patent could block generic and biosimilar versions from entering the market. The Skinny Labels, Big Savings Act would reverse the U.S. Court of Appeals for the Federal Circuit's misplaced *GSK* decision and restore this vital pathway for bringing generic medications to market. The Skinny Labels, Big Savings Act is supported by a wide variety of stakeholders, including AHIP, PCMA, the ERISA Industry Committee, Public Citizen, Generation Patient, Consumer Action, American Consumer Institute, Transparency-Rx, PIRG, and AARP.

Preserving a Robust *Inter Partes* Review (IPR) System

Congress created IPR as part of the AIA to provide an efficient and cost-effective forum to "weed out bad patent claims efficiently."[21] Consistent with Congress' goal that IPR would combat "overpatenting and its diminishment of competition,"[22] generic and biosimilar companies regularly employ IPR to efficiently challenge non-innovative patents that should never have been granted. According to the Patent Office's data, between September 16,

[16] Waxman Amicus Brief at 15-16.

[17] United States Merits Amicus Brief at 17-18.

[18] *Id.* at 20.

[19] *See* Letter to Chairmans Jordan and Issa, and Ranking Members Raskin and Johnson, RE: Skinny Labels, Big Savings Act (H.R. 6485), Eliminating Thickets to Increase Competition (ETHIC) Act (H.R. 3269), April 6, 2026, Letter from 20 Organizations.

[20] Laura Joszt, Competition from Skinny-Label Generics Saved Medicare Nearly $15B over 5 Years, Am. J. Managed Care (Apr. 29, 2024), available at https://www.ajmc.com/view/competition-from-skinny-label-generics-saved-medicare-nearly-15b-over-5-years.

[21] H.R. Rep. No. 112-98, pt. 1, at 40 (2011).

[22] *Id*.

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.[23]

Indeed, many generic and biosimilar pharmaceutical companies have used IPR proceedings to successfully remove patent roadblocks and accelerate 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 the Exelon® patch for the treatment of Alzheimer's and Parkinson's disease.[24] Similarly, generic pharmaceutical companies successfully defeated the claims of a patent covering the drug Zytiga®, allowing for the launch of generic versions of the drug to treat prostate cancer.[25] As a result of this successful IPR, the system saved an average 81% on this life-saving medicine due to the availability of generic Zytiga®.[26] Over the course of four IPRs, generic pharmaceutical companies also invalidated all challenged claims of several patents covering OxyContin® in response to infringement allegations asserting over a dozen patents.[27] A generic pharmaceutical company similarly invalidated all claims of four patents covering Kerydin® pursuant to four IPRs.[28] Numerous other patents relating to brand drug or biologic products have been invalidated—in whole or in part—through IPR, including patents for Lantus®, Herceptin®, Rituxan®, Avastin®, and Neulasta®.[29]

IPRs have also been instrumental in driving early settlements, such as a settlement a biosimilar received relating to Stelara® shortly after filing an IPR.[30] Settlements such as these promote competition and enable earlier patient access to lower-cost alternatives. 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.[31]

For all these reasons, AAM has long been a supporter of IPR and efforts to implement IPR proceedings efficiently and effectively. For example, in connection with the Senate Judiciary Committee Hearing for the STRONGER Patents Act, AAM emphasized the importance of IPR, explaining it provides "cost-effective, efficient procedures . . . to ensure that questionable, non-innovative patents may be efficiently invalidated."[32] AAM explained why IPR is "critically necessary to help get invalid patents—including those blocking more affordable

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[23] USPTO, *Orange Book patent/biologic patent study and district court pharma litigation study*, at 6 (July 31, 2025), https://www.uspto.gov/sites/default/files/documents/Orange_Book_Biologics_Trial_Stats_July_2025.pdf.

[24] *Novartis AG v. Noven Pharm. Inc.*, 853 F.3d 1289 (Fed. Cir. 2017) (affirming IPR decisions).

[25] *BTG Int'l Ltd. v. Amneal Pharm. LLC*, 923 F.3d 1063 (Fed. Cir. 2019) (affirming IPR decisions).

[26] *See* AAM, Competition Matters. That's Why We Need to Further Improve IPR, https://accessiblemeds.org/resources/blog/competition-matters-thats-why-we-need-further-improve-ipr/.

[27] *See Amneal Pharm., LLC v. Purdue Pharma, L.P. et al.*, Case Nos. IPR2016-01412, (Feb. 8, 2018), IPR2016-01413, (Jan. 17, 2018), IPR2016-01027, (Nov. 8, 2017), and IPR2016-01028, (Nov. 8, 2017).

[28] *See Anacor Pharms., Inc. v. Flatwing Pharms., LLC*, 825 F. App'x 811, 812 (Fed. Cir. Aug. 27, 2020) (affirming IPR decisions).

[29] *See* AAM, Statement for the Record, Senate Judiciary Committee Hearing on the "Support Technology and Research for Our Nation's Growth and Economic Resilience Patents Act of 2019 ('STRONGER')," at 2-3 (Sept. 11, 2019).

[30] *See Samsung Bioepis Co. v. Janssen Biotech, Inc.*, IPR2023-01103, Paper 8 (PTAB Aug. 9, 2023).

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

[32] AAM, Statement for the Record, Senate Judiciary Committee Hearing on the "Support Technology and Research for Our Nation's Growth and Economic Resilience Patents Act of 2019 ('STRONGER')," at 2 (Sept. 11, 2019).

generic and biosimilar medicines—declared invalid as quickly as possible."[33] At another Senate Judiciary Committee Hearing, AAM highlighted some of the ways IPR has improved the patent system as compared to examination or district court litigation.[34] In particular, IPR "allows a patent owner's arguments to be tested through cross-examination and the submissions of opposing experts in a way that examination does not allow," and "allows invalidity issues to go before experts from within the Patent Office, rather than lay jurors or generalist federal trial judges."[35] AAM likewise has frequently expressed its views in response to recent proposed rulemaking by the Patent Office.

Recently, however, the viability of IPR has been under attack in proposed legislation and administrative rulemaking. For example, the PREVAIL Act (S.1553) includes provisions that would materially undermine the availability of IPR, especially for generic and biosimilar challengers. AAM has expressed its concerns with the PREVAIL Act and the way in which it would "diminish[] the viability of IPR challenges and disproportionately harm[] generic and biosimilar companies."[36] AAM has also been a vocal opponent of recent proposed Patent Office rulemaking that would undermine IPR and thereby "thwart the public's access to generic and biosimilar medicines."[37]

In addition to formal rulemaking efforts, IPR has been subject to recent practices that have resulted in a troubling number of IPR petitions being denied without substantive review. Since early last year, the Acting Director—and now the Director—have made incredibly frequent use of "discretionary denials" of institution. Between January and September 2025, the Acting Director denied approximately 400 IPRs purely on procedural grounds that were rarely supported by more than one or two paragraphs of analysis in the decision that generally cannot be appealed.[38] Between June and September 2025, the Acting Director denied over 142 petitions—more than 1 per day—under a new "settled expectations" discretionary denial principle that was seemingly crafted out of thin air in 2025.[39] According to the Patent Office's most recent statistics, 385 more petitions were discretionarily denied between October 2025 and April 2026.[40] These sweeping denials, based on policies that were implemented absent any formal rulemaking, significantly limit IPR as a viable pathway for challenging weak patents. Moreover, these practices are already having a chilling effect on the number of IPR challenges being brought.[41] IPRs have fallen off so much that the number of IPRs filed in April 2026 was a mere 15.[42]

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[33] *Id.* at 2-3.

[34] *See* AAM, Statement for the Record, Senate Judiciary Committee Hearing on the "Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition," at 2-3 (May 7, 2019).

[35] *Id.* at 3.

[36] *See* AAM, Letter to Chairman Durbin and Ranking Member Graham, March 14, 2024, at 3, https://accessiblemeds.org/wp-content/uploads/2024/12/AAM-Letter-PREVAIL-Act.pdf.

[37] *See, e.g.*, Comments from the Association for Accessible Medicines Regarding Docket No. PTO-P-2025-0025, "Revision to Rules of Practice before the Patent Trial and Appeal Board," at 13 (Dec. 2, 2025).

[38] *See In re Sandisk Techs., Inc.*, No. 25-152, D.I. 9 at 2 (Fed. Cir. Sept. 22, 2025) (Amicus Brief of Intellectual Property and Innovation Professors).

[39] *See In re Sandisk Techs, Inc.*, No. 25-152, D.I. 11 at Addendum (Fed. Cir. Sept. 22, 2025) (Amicus Brief of US*Made, et al.).

[40] PTAB Trial Statistics (April 2026), at 6, https://www.uspto.gov/sites/default/files/documents/April_2026_Trial_Statistics.pdf.

[41] *Id.* at 7 (showing an average of more than 110 petitions filed per month from Apr.-Sept. 2025 declining to an average of less than 30 petitions filed per month between Feb.-Apr. 2026).

[42] Dennis Crouch, Inter Partes Review in 2026, https://patentlyo.com/patent/2026/05/inter-partes-review-in-2026.html.

The Patent Office's recent practice of denying IPR petitions based on "settled expectations" of the patent owner is particularly problematic for generic and biosimilar manufacturers. In a March 26, 2025 memorandum, Interim Director Stewart set out Interim Processes for PTAB Workload Management identifying "settled expectations of the parties, such as the length of time the claims have been in force" as one factor that could support discretionary denial of an IPR petition.[43] Subsequent decisions revealed that settled expectations were generally invoked when a patent had been in force for more than six years. Given regulatory exclusivities and the timing of generic development, which often post-dates the brand's launch by several years, generic and biosimilar challengers are regularly challenging patents that are more than six years old. Relying on "settled expectations" thus provides a non-substantive basis for disposing of legitimate IPR challenges to older patents covering brand name drugs.

This is not merely a theoretical concern. The PTAB has recently denied IPR challenges to patents covering high-priced medications based on settled expectations. In July 2025, for example, the PTAB denied two IPR petitions directed to patents covering Opdivo®—a $7-billion-per-year cancer immunotherapy—on the basis that "the challenged patents have been in force for seven and six years, respectively, creating strong settled expectations for Patent Owner."[44] As another example, the PTAB denied an IPR against a patent covering Mounjaro®, a diabetes and weight loss medication that costs more than $1,000 per month, on the basis of settled expectations.[45] In both cases, the brand patents escaped IPR review, which was intended by Congress as an efficient and cost-effective way to "weed out bad patent claims," simply because of the age of the patents, not because of any weakness in the substantive arguments for their invalidity.

In light of the above, legislative action is needed to restore IPR to align with Congress' intent and ensure that it remains a viable pathway for challenging bad patents that nonetheless prevent generic and biosimilar competition to the detriment of patients and payors.

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Meaningful patent reform is essential to restore balance to a system that too often delays competition and keeps lower-cost medicines out of reach for American patients. Congress can address these harms by curbing patent thickets that prolong monopolies, protecting the longstanding skinny-label pathway that enables timely access to generic and biosimilar medicines for unpatented uses, and preserving a robust IPR system so weak patents can be challenged efficiently.

[43] USPTO, Interim Processes for PTAB Workload Management (Mar. 26, 2025), https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf.

[44] *Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, 602, 603, Paper 9 (July 24, 2025).

[45] *Empower Clinic Services, L.L.C (Empower Pharmacy) v Eli Lilly & Co*, IPR2025-01024, Paper 15 (Oct. 10, 2025).