**Written Statement of Jamie Simpson**
**Chief Policy Officer and Counsel, Council for Innovation Promotion (C4IP)**

**Before the Subcommittee on Courts, Intellectual Property,**
**Artificial Intelligence, and the Internet**
**Committee on the Judiciary, U.S. House of Representatives**

**Hearing on "Medicines and IP: Balancing Innovation and Access"**

**June 4, 2026**

Chairman Issa, Ranking Member Johnson, and Members of the Subcommittee:

Thank you for the opportunity to submit this statement on biopharmaceutical patents and the role of intellectual property in sustaining American leadership in medical innovation.

The Council for Innovation Promotion (C4IP) is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives. C4IP is chaired by two former Under Secretaries of Commerce for Intellectual Property and Directors of the U.S. Patent and Trademark Office: Andrei Iancu, who served in the first Trump administration, and David Kappos, who served in the Obama administration. Our board includes two retired judges of the U.S. Court of Appeals for the Federal Circuit, former Chief Judge Paul Michel (appointed by President Reagan) and former Judge Kathleen O'Malley (appointed by President Obama); former Governor of Washington, U.S. Secretary of Commerce, and U.S. Ambassador to China Gary Locke; and former U.S. Representative and House Judiciary Committee Chairman Lamar Smith. Our perspective draws on direct experience with the U.S. patent system across multiple administrations of both parties.

I want to begin by acknowledging that drug prices are a real and serious concern for American families. That concern deserves substantive engagement. C4IP is not here to suggest that the status quo is perfect. As described below in more detail, however, CBO has estimated that the types of patent reforms currently under consideration would have negligible overall effects on drug prices.

I am here to offer a different proposition: that the patent system is one of the principal reasons this country has the medical treatments it has, that the existing balance between innovation and competition is more effective than the current policy debate often acknowledges, and that several of the patent-based legislative proposals currently in circulation rest on empirical premises that the data does not support. Acting on those premises would impose lasting costs on American patients due to lost future treatments, cures, and improvements—costs that are harder to see than current drug prices, but no less real.

This statement addresses the success of our current system, and how that success depends on a robust and reliable patent system. It then turns to some common misconceptions and rhetoric that are often used to justify legislative proposals: "patent thickets," "evergreening," and the

regulation of "skinny labels." I urge the Subcommittee to look past these labels and consider the empirical evidence before enacting proposals that might cause, on balance, more harm than good.

## I. The American Biopharmaceutical Industry Has Delivered Extraordinary Benefits to Patients

The American biopharmaceutical industry has dramatically changed people's lives through rapid and sustained progress. Within living memory, an HIV diagnosis was a death sentence. Today, with appropriate antiretroviral therapy, HIV is a manageable chronic condition, and a person diagnosed in their twenties can reasonably expect a normal lifespan.[1] Hepatitis C, which once required liver transplantation in its advanced stages, is now curable in the great majority of cases with an oral course of treatment.[2] Many cancers that were uniformly fatal a generation ago are now treated with targeted and immunologic therapies that allow patients to continue working, remain with their families, and live years or decades longer than they otherwise would have.[3] Cystic fibrosis patients, who once rarely reached adulthood, now have transformative therapies that address the underlying genetic defect rather than just its symptoms.[4] Patients with rheumatoid arthritis, psoriasis, and a range of other chronic inflammatory conditions have access to biologic treatments that were barely conceivable thirty years ago.[5]

The story of insulin is particularly instructive, because it illustrates a pattern that recurs across therapeutic areas. The first insulin, isolated from cattle and pigs in the 1920s, was a remarkable scientific achievement — before its discovery, the average life expectancy after a type 1 diabetes diagnosis was less than three years.[6] But the early animal-derived insulins were difficult to dose precisely, caused allergic reactions in many patients because of the species mismatch, and offered nothing like physiologic glucose control. The biosynthetic human insulins introduced in the 1980s addressed the allergic reaction problem. The rapid-acting insulin analogues developed in the 1990s allowed patients to dose at mealtimes and dramatically reduced post-meal blood sugar excursions. The ultra-long-acting basal insulins introduced in the 2000s reduced the risk of nocturnal hypoglycemia and provided more consistent baseline glucose control. Each generation required substantial new investment, research, and clinical trials. Each was protected by new

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[1] Julia L. Marcus et al., *Comparison of Overall and Comorbidity-Free Life Expectancy Between Insured Adults With and Without HIV Infection, 2000-2016*, 3 JAMA Network Open e207954 (2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2767138.

[2] Ctrs. for Disease Control & Prevention, *Hepatitis C Questions and Answers for Health Professionals*, https://www.cdc.gov/hepatitis-c/hcp/clinical-overview/index.html.

[3] *See, e.g.*, Nat'l Cancer Inst., *Targeted Therapy to Treat Cancer*, https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies; Nat'l Cancer Inst., *Immunotherapy to Treat Cancer*, https://www.cancer.gov/about-cancer/treatment/types/immunotherapy.

[4] Peter G. Middleton et al., *Elexacaftor-Tezacaftor-Ivacaftor for Cystic Fibrosis with a Single Phe508del Allele*, 381 N. Engl. J. Med. 1809 (2019), https://www.nejm.org/doi/full/10.1056/NEJMoa1908639.

[5] *See* Andrea Galluzzo et al., *Past, Present and (Foreseeable) Future of Biological Anti-TNF Alpha Therapy*, 12 J. Clinical Med. 7384 (2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9963154/ (reviewing the historical development of anti-TNF-α biologics and their transformation of treatment for rheumatoid arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and psoriasis).

[6] Am. Diabetes Ass'n, *The History of a Wonderful Thing We Call Insulin* (July 1, 2019), https://diabetes.org/blog/history-wonderful-thing-we-call-insulin ; Celeste C. Quianzon & Issam Cheikh, *History of Insulin*, 2 J. Cmty. Hosp. Internal Med. Persps. 18701 (2012), https://pmc.ncbi.nlm.nih.gov/articles/PMC3714061/.

patents that, contrary to popular narratives, did not "extend" the old ones. And each reflected precisely the type of innovations that the patent system was designed to encourage, delivering measurable improvements in life expectancy, quality of life, and reduction of long-term diabetic complications.

These are not abstractions. They are the lived experience of tens of millions of American patients. And they did not happen by accident.

## II. The Biopharmaceutical Industry Depends on the Patent System

The reason these treatments exist is straightforward. Developing a new medicine takes more than a decade on average and costs upwards of two billion dollars when the costs of failed candidates are properly accounted for.[7] The overwhelming majority of compounds that enter preclinical development never reach the market. Of those that enter human clinical trials, most fail—often in Phase III, after enormous investments have already been made.[8] The pharmaceutical industry is, in financial terms, a series of high-cost, high-failure-rate bets, justified only by the prospect that the bets that succeed will succeed substantially enough to fund the next round. This proposition does not work without reliable, robust patent protection.

Patents are the only mechanism we have ever found that consistently attracts private capital to that kind of high-risk, long-horizon scientific work. Investors fund early-stage biotechnology because they understand that a successful candidate, if patented, will enjoy a period of market exclusivity sufficient to recoup the investment, fund a return to investors, and finance the next generation of research. Scientists choose careers in industrial drug discovery because they know their work, if successful, will be commercialized, reach patients, and make meaningful improvements to their lives. Companies make multi-year, multi-billion-dollar commitments to clinical programs because they can model the post-approval economics with reasonable confidence.

Weaken the patent system, and the calculus of each of those decisions changes. Some early-stage investments do not get made. Some clinical programs do not get pursued. Some companies do not get formed. Scientists choose other fields of work.

This is not a feature unique to pharmaceuticals. The same logic governs every research-intensive sector of the American economy. Semiconductor manufacturers, aerospace companies, and renewable energy innovators all depend on patent protection to attract the capital required for fundamental research.

Notably, the patent system not only incentivizes invention and investment in R&D; it also requires the inventor to disclose the invention to the public. That is the quid pro quo of the patent system: disclosure in exchange for a limited period of exclusivity. And unlike the alternative of

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[7] Olivier J. Wouters et al., *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 JAMA 844 (2020), https://jamanetwork.com/journals/jama/fullarticle/2762311.

[8] *See* Michael Hay et al., *Clinical Development Success Rates for Investigational Drugs*, 32 Nature Biotechnology 40 (2014), https://www.nature.com/articles/nbt.2786 (finding that only about 10% of candidates entering Phase I trials ultimately receive FDA approval, with substantial attrition continuing through Phase III).

trade secret protection, that disclosure adds to the public store of knowledge and helps scientific progress advance faster.

## III. Congress Has Already Built a Remarkably Successful Framework for Generic Competition

A point that is often lost in the current debate is that the United States has the most robust generic drug market in the developed world. Approximately nine in ten prescriptions filled in this country are generic — a higher share than in any peer economy, including the European countries often cited as models of pharmaceutical affordability.[9] American patients, on the whole, receive their medicines in generic form, at generic prices, more reliably and more quickly than patients in almost any comparable system.

That outcome is the direct result of two laws specifically designed to balance innovators' need to invest in drug development, relying on strong patent rights, with incentives to encourage early generic competition: the Drug Price Competition and Patent Term Restoration Act of 1984—the Hatch-Waxman Act, for small-molecule drugs—and the Biologics Price Competition and Innovation Act of 2009 (BPCIA), for biologics.

Under these laws, innovators receive defined periods of regulatory exclusivity after their products are approved (for example, five years for a new chemical entity before a generic can drug application can be filed and twelve years for a new biologic before a biosimilar application can be approved), during which no generics, or biosimilars in the case of biologics, can rely upon innovator data to expedite their regulatory review. The laws also provide dispute-resolution procedures for generics or biosimilars that seek to enter the market while the product is still protected by patents. Under the Hatch-Waxman Act, a generic must address any listed "Orange Book" patents, which can lead directly to litigation if the generic seeks to challenge them. Under the BPCIA, a biosimilar may engage in the "patent dance" outlined in the statute, exchanging information with the originator company to determine which patents are in dispute.

These laws create a careful balance. Innovators receive an effective period of regulatory exclusivity which incentivizes them to conduct the costly clinical trials required to bring new medicines to market. Generic and biosimilar manufacturers receive a clear, expedited regulatory pathway and the ability to challenge innovator patents through purpose-built procedures, without the risk of damages, and with unique benefits such as the potential for 180 days of generic exclusivity. The result is a system that delivers world-leading innovation and robust generic competition—studies consistently show that the average period during which a branded drug faces no generic competition ranges between roughly 12 and 14 years, well short of the 20-year patent term.[10] The Hatch-Waxman Act, for example, took generics from roughly 13% of the

[9] Ass'n for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report 2024* (2024), https://accessiblemeds.org/2024-savings-report; Andrew W. Mulcahy et al., *Comparing Prescription Drugs in the U.S. and Other Countries: Prices and Availability*, U.S. Dep't of Health & Hum. Servs., Office of the Assistant Sec'y for Planning & Evaluation (Jan. 2024), https://aspe.hhs.gov/sites/default/files/documents/d5541b529a379d1f908ed2f9c00a9255/aspe-cover-idr-pricing-availability.pdf.

[10] U.S. Pat. & Trademark Off. & U.S. Food & Drug Admin., *Drug Patent and Exclusivity Study* (June 2024), https://www.uspto.gov/sites/default/files/documents/USPTO-FDA_Report_on_Drug_Patent_and_Exclusivity.pdf

market in 1983 to 90% today — it has been remarkably successful in bringing lower-cost alternatives to patients, but it strikes a thoughtful balance in doing so, and Congress should be careful not to upset that balance.[11]

## IV. American Leadership in Biopharmaceutical Innovation Is Recent, Deliberate, and Now Under Serious Pressure from China

It is easy to assume that American leadership in pharmaceutical innovation is the natural order of things. It is not. It is the product of policy choices made over the last forty years—and it can be weakened by policy choices made today.

The historical record is clear. In the late 1970s and early 1980s, fewer than 10% of new drugs were launched first in the United States, and European firms introduced more than twice as many new medicines as American firms. As recently as 1990, the global research-based pharmaceutical industry invested substantially more in Europe than in the United States. Biopharmaceutical innovation was centered in Europe, not America.[12]

By the 2010s, that picture had reversed. More than 60% of new drugs were launched first in the United States.[13] U.S.-headquartered firms accounted for a leading share of new molecular entities developed worldwide, and industry R&D investment in the United States had surpassed Europe by a wide margin. The United States became the global center of gravity for biopharmaceutical innovation.[14]

That shift did not happen by accident. It followed a series of policy decisions designed to make the United States the most attractive place in the world to discover, develop, and commercialize

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[hereinafter 2024 USPTO-FDA Study]; Benjamin N. Rome, ChangWon C. Lee & Aaron S. Kesselheim, *Market Exclusivity Length for Drugs with New Generic or Biosimilar Competition, 2012–2018*, 109 Clinical Pharmacology & Therapeutics 367 (2021), https://doi.org/10.1002/cpt.1983 (median exclusivity of 14.4 years); C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. Health Econ. 327 (2012) (average effective market life of approximately 12 years).

[11] *See* Cong. Budget Off., *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* xiii, 28 (July 1998), https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf (reporting that, in 1983, generic market share averaged just 13% for nonantibiotic drugs); *see also supra* note 9 and accompanying text (documenting that approximately 90% of prescriptions filled in the United States today are generic, the highest share in any developed economy).

[12] Stephen Ezell, *The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System*, Info. Tech. & Innovation Found. 4 (Mar. 2019), https://www2.itif.org/2019-bayh-dole-act.pdf.

[13] *Id.*

[14] *See* Hui Yuan Hu et al., *Is the United States Still Dominant in the Global Pharmaceutical Innovation Network?*, 8 PLoS ONE e77247 (2013), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0077247 (finding that the United States dominated the global pharmaceutical innovation network, particularly with respect to essential core inventions, based on patent data for all FDA-approved drugs from 1996 through 2010); Charles River Assocs. for European Fed'n of Pharm. Indus. & Ass'ns, *Factors Affecting Location of Biopharmaceutical Investments and Implications for European Policy* (2022), https://www.efpia.eu/media/676753/cra-efpia-investment-location-final-report.pdf.

new medicines—including research tax incentives, increased federal support for basic science, and important reforms to patent policy.[15]

Critical reforms were made to boost the U.S. patent system. The Bayh-Dole Act enabled universities and federal grantees to commercialize federally funded inventions, strengthening the pipeline from laboratory research to real-world therapies. The Federal Courts Improvement Act created the Court of Appeals for the Federal Circuit and brought greater predictability and uniformity to patent law. And Hatch-Waxman reinforced the role of patents in supporting pharmaceutical innovation while establishing the modern generic framework. Together, these policies helped signal that the United States was the best place in the world to invest in medical innovation.

Today, the global competitive landscape is shifting again—and not in America's favor. The People's Republic of China has made biopharmaceutical innovation a national strategic priority through successive industrial plans, including *Made in China 2025*, *Healthy China 2030*, and the 14th Five-Year Plan. It has paired those plans with aggressive R&D investment and coordinated support for biotech development.[16]

The results are increasingly visible. China now leads the United States in pharmaceutical patent filings.[17] Chinese-headquartered companies sponsored roughly 30% of global Phase I–III clinical trials in 2024, up from just 1% in 2009, while the U.S. share has declined.[18] China's role in the market for new drug candidates is growing just as quickly, with Western companies increasingly licensing assets discovered there.[19]

The implications are strategic as well as economic. If the center of gravity for drug development shifts abroad, Americans will face difficult questions about supply, access, and resilience during periods of geopolitical tension. The domestic economic consequences would also be substantial. The U.S. biopharmaceutical industry directly supports more than one million high-skill, high-

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[15] *See generally* Sujai Shivakumar, Jeffrey Depp & Tisyaketu Sirkar, *Understanding the U.S. Biopharmaceutical Innovation Ecosystem*, Ctr. for Strategic & Int'l Stud. (Oct. 2024), https://www.csis.org/analysis/understanding-us-biopharmaceutical-innovation-ecosystem.

[16] Nat'l Sec. Comm'n on Emerging Biotechnology, *Charting the Future of Biotechnology: An Action Plan for American Security and Prosperity* (Apr. 2025), https://www.biotech.senate.gov/final-report ("Based on two years of research and consultation with private and public experts, this report comes to a sobering, even frightening, conclusion: China is quickly ascending to biotechnology dominance, having made biotechnology a strategic priority for 20 years."); Jack Burnham, *China's State Support and Pricing Practices in the Biotechnology Sector*, Found. for Def. of Democracies (May 27, 2026), https://www.fdd.org/analysis/2026/05/27/chinas-state-support-and-pricing-practices-in-the-biotechnology-sector/.

[17] *From Humble to Global: China's Biotechs Navigate the Demands of International Trials*, Clinical Trials Arena (Sept. 18, 2025), https://www.clinicaltrialsarena.com/features/from-humble-to-global-chinas-biotechs-navigate-the-demands-of-international-trials/.

[18] Oliver Wyman, *5 Reasons China Is Emerging as the Global Biopharma Leader* (May 2026), https://www.oliverwyman.com/our-expertise/perspectives/health/2026/may/china-hotspot-for-biopharma-innovation.html; *see also Washington Shouldn't Just Hand the Future of Biotech to Beijing*, The Hill (Oct. 2, 2025), https://thehill.com/opinion/healthcare/5530658-china-rising-biotech-leadership/.

[19] Laurel Oldach, *In the Rise of Chinese Biotech, Some See Opportunity. Others See a Threat*, Chem. & Eng'g News (Sept. 5, 2025), https://cen.acs.org/pharmaceuticals/drug-development/Chinas-biotech-industry-rise-reshape/103/web/2025/09.

wage jobs and millions more across the broader economy.[20] Innovation ecosystems are difficult to build—and once they relocate, they are even harder to bring back.

The lesson of the last forty years is straightforward: policy choices matter. They helped make the United States the world leader in biopharmaceutical innovation. Congress should recognize that they can just as readily determine whether America remains one.

**V. Congress Should Approach Changes to the Patent System with Particular Caution—and Not on Premises the Evidence Does Not Support**

Against this backdrop, C4IP urges the Subcommittee to approach proposed changes to weaken the patent system with particular caution. The stakes are high—not only for patients who depend on future medicines, but also for American economic strength and strategic competitiveness.

Before turning to several common misperceptions driving the current legislative debate, one threshold point is worth emphasizing: the Congressional Budget Office has already examined whether many of the patent-focused proposals now under discussion would meaningfully reduce drug prices. Its conclusion was clear—they would not.

In its October 2024 report, *Alternative Approaches to Reducing Prescription Drug Prices*, CBO evaluated several proposals intended to accelerate generic and biosimilar entry, including measures addressing so-called patent thickets, pay-for-delay settlements, and citizen petitions.[21] It concluded that each would reduce average drug prices only marginally—between 0.1% and 1.0%, or in some cases less than 0.1%, in 2031.

That matters because the patent changes Congress is being urged to make are unlikely, by CBO's independent analysis, to meaningfully change what Americans pay at the pharmacy counter. They are far more likely to affect investment decisions upstream—and therefore which medicines are developed at all.

With that in mind, it is important to separate evidence from rhetoric. Much of the current debate rests on recurring mischaracterizations of ordinary features of the patent system. Practices that are lawful, routine, and often pro-competitive are portrayed as inherently suspect, while isolated examples of abuse are invoked as though they reflect systemic failure—even where existing law and judicial doctrines already provide tools to address them. The Subcommittee should evaluate these claims carefully and based on evidence before making changes to a system that remains central to American biopharmaceutical innovation.

[20] TEConomy Partners LLC for PhRMA, *The Economic Impact of the U.S. Biopharmaceutical Industry: 2024 National and State Estimates* (May 2024), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.
[21] Cong. Budget Off., *Alternative Approaches to Reducing Prescription Drug Prices* (Oct. 2024), https://www.cbo.gov/publication/60812.

### A. The "Patent Thicket" Narrative Mistakes Patent Count for Patent Abuse

The central premise of so-called "patent thicket" legislation is that pharmaceutical innovators systematically obtain large numbers of patents on a single product to delay generic competition. The term "patent thicket" is not a legally defined concept and is frequently deployed as a rhetorical shortcut that obscures, rather than illuminates, how innovation ecosystem's function. The premise also mistakes a common feature of innovation for evidence of abuse. Multiple patents covering a single medicine are normal. Biopharmaceutical companies are not unusually heavy users of the patent system. And most importantly, the available evidence does not show that the number of patents on a drug determines how long that drug remains free from generic competition.

A single medicine often embodies multiple inventions developed over a lengthy development timeline, at substantial cost. Patents may cover the active ingredient, formulations, manufacturing processes, methods of use, delivery mechanisms, or device components associated with treatment. It should therefore not be surprising that multiple patent inventions may be embodied by a single product. The same is true across advanced technology sectors. Smartphones, semiconductors, and other complex products routinely implicate thousands—or even hundreds of thousands—of patents.[22] Complex products reflect multiple inventions, and each invention that satisfies the statutory standards for patentability is entitled to protection. There is no principled reason to treat pharmaceutical innovation differently.

Nor are pharmaceutical companies even particularly heavy users of the patent system. By the most direct available measure—the annual Intellectual Property Owners Association ranking of organizations receiving the most U.S. patents—almost every other sector of technology obtains more patents. The list is consistently dominated by electronics, semiconductor, software, telecommunications, and automotive firms.[23] Pharmaceutical and biotechnology companies appear much lower, if at all.

Most fundamentally, however, there is no correlation between the number of patents on a product and the timing of generic entry. This is the empirical claim on which the patent-thicket narrative depends, and the evidence does not support it.

The USPTO's 2024 drug patent and exclusivity study, conducted with FDA assistance at the request of Senator Tillis, examined the relationship between patents covering drug products and the actual timing of generic competition.[24] It found that actual periods of market exclusivity ranged from roughly 3 to 16 years—well short of the 20-year patent term. The study concluded

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[22] *See* RPX Corp., Amendment No. 3 to Form S-1, at 59 (Apr. 11, 2011), https://www.sec.gov/Archives/edgar/data/1509432/000119312511240287/ds1.htm (estimating, based on the company's own research as a defensive patent aggregator serving large technology companies, that approximately 250,000 active U.S. patents were relevant to modern smartphones); Proceedings of the 2010 ITU-T Kaleidoscope Academic Conf. (2010), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1619440 (estimating that a typical modern laptop incorporates implementations of approximately 251 interoperability standards, each of which may itself be covered by hundreds or thousands of patents).

[23] Intellectual Prop. Owners Ass'n & Harrity Analytics, *Top 300 Organizations Granted U.S. Patents in 2024* (Jan. 2025), https://ipo.org/wp-content/uploads/2025/01/2024-Top-300-Patent-Owners-List.pdf.

[24] 2024 USPTO-FDA Study, *supra* note 10.

that "patent expiration dates, like the number of patents, may not be predictive of the timing of actual launch of competing products." In several cases, generic products entered the market before all Orange Book–listed patents had expired. Patent count and patent term, in other words, do not reliably determine generic entry.

That conclusion is consistent with a broader body of research. Studies by Grabowski and colleagues found that the average effective market life of branded drugs facing first generic entry was approximately 12 years.[25] A 2021 study by Rome, Lee, and Kesselheim examining small-molecule drugs found a median exclusivity period of 14.4 years.[26] Across methodologies and datasets, the findings point in the same direction: most branded drugs face competition years before patent expiration, and the number of patents associated with a product is not the principal driver of when that competition begins.

In short, the basic patent-thicket narrative mistakes numerosity for nefariousness. Multiple patents on complex products are a normal feature of innovation, not evidence of misconduct. They are more concentrated in many other industries than in pharmaceuticals, and the evidence does not show that more patents translate into longer periods of exclusivity. Legislation based on the assumption that patent quantity itself delays competition is therefore aimed at a problem the data do not show exists.

**B. A Terminal Disclaimer Cuts Patent Term Short; It Does Not Extend It**

A more specific version of the "patent thicket" argument focuses on patents linked by "terminal disclaimers" and the related claim that such patents enable "serial litigation" against generic challengers. That argument underlies the Eliminating Thickets to Increase Competition (ETHIC) Act (H.R. 3269) and related proposals. But once terminal disclaimers are understood, the premise for these reforms largely dissolves.

A terminal disclaimer shortens a patent; it cannot extend exclusivity. Critics often assume that more patents necessarily mean longer protection and delayed generic entry. Terminal disclaimers exist precisely to prevent that result.

To understand why, it helps to understand how these patents arise. Patent applicants frequently pursue different claims from the same underlying research through "continuation" applications — a longstanding and routine practice across industries. Those later claims may cover narrower or broader aspects of the same disclosed invention or other related embodiments described in the original application. Because the claims are related, a patent examiner may conclude that allowing the later patent to retain its own full term could improperly extend exclusivity. The examiner then issues an "obviousness-type double patenting" rejection.

The applicant overcomes that rejection by filing a terminal disclaimer: a binding commitment that the applicant agrees to voluntarily disclaim part of the later-filed patent's term such that the later patent will expire on the same date as the earlier patent and remain under common ownership. The entire purpose of the mechanism is to prevent any extension of exclusivity. A

[25] Hemphill & Sampat, *supra* note 10.
[26] Rome et al., *supra* note 10.

drug protected by ten terminally disclaimed patents reaches generic competition on the same date it would if protected by one.

Nor does a terminal disclaimer mean the later patent is meaningless or duplicative. "Obviousness-type double patenting" is fundamentally a timing doctrine. It prevents staggered expiration dates for closely related patents; it is not a determination that the later patent is invalid, trivial, or claims the exact same invention.

Indeed, because these patents commonly arise from continuation practice, they often already share the same priority date and expiration date before any disclaimer is filed. They are not a sequence of ever-later patents extending protection into the future. They are related claims drawn from the same body of research and expiring together. Whether any individual patent claim is valid or infringed is decided claim by claim, on the merits, as courts routinely do in Hatch-Waxman and BPCIA litigation.

More fundamentally, the evidence does not support the claim that these patents delay generic entry. As discussed above, the USPTO study and related scholarship have consistently found no relationship between the number of patents covering a drug and the timing of generic competition. Terminally disclaimed patents are simply a subset of that broader count. If the overall number of patents does not predict delayed generic entry, there is no reason to think terminally disclaimed patents do either.

Critics raise two more targeted objections, but neither justifies the proposed remedy. The first is that generic challengers at the Patent Trial and Appeal Board (PTAB) must generally file separate petitions against separate patents, increasing cost and complexity. But that reflects the PTAB's patent-by-patent design across all technologies, not any feature unique to pharmaceuticals or terminal disclaimers. More importantly, the PTAB was never intended to substitute for the already efficient Hatch-Waxman and BPCIA systems—it is only a supplemental forum. Drug-patent disputes are principally resolved in district court under the Hatch-Waxman Act and BPCIA, both of which are specifically structured to consolidate related patent disputes before a single court, often with representative claims.

The second objection concerns so-called "serial litigation": the claim that later-issued patents within the same family allow repeated suits against generic challengers. But both the Hatch-Waxman Act and BPCIA are designed to bring all already-existing patents into a single suit, and longstanding court doctrines already exist to address repetitive litigation, in addition to the patent-specific attorney fee-shifting rule that polices "exceptional cases" (35 U.S.C. § 285).

The common-ownership requirement associated with terminal disclaimers was never intended to guarantee that all related patents would be litigated in a single case. Its purpose is narrower: preventing patent fragmentation across multiple owners. A later-issued patent asserted by the same owner against the same defendant in the same court is not that abuse. And a newly issued patent, by definition, could not have been asserted before it existed.

Moreover, courts already possess tools to address abusive repeat litigation. If a later patent merely repackages issues already resolved, doctrines such as claim preclusion and issue

preclusion can bar repetitive litigation. Indeed, the very similarity critics point to may strengthen the case for dismissal. Even absent dismissal, if later issued patents are indeed so similar to previously asserted ones, the same arguments used against the earlier ones could be raised against the later ones with little cost or burden. If, by contrast, the later patent survives those doctrines and requires new analyses because it claims something materially different, then the suit is not duplicative at all.

Those are fact-specific determinations better made by courts reviewing the full litigation history of a product than by a categorical statutory rule rendering entire classes of patents unenforceable regardless of their substance. If the litigation is truly vexatious or frivolous, a losing patent owner risks paying the other side's attorney fees under section 285. It also bears noting that the complexity of these disputes is often shaped in part by the generic challenger's own litigation choices, including which patents it elects to challenge and when.

Finally, legislation targeting continuation-and-disclaimer practice could create unintended consequences for the patent system itself. Continuation practice allows the Patent Office to examine complex inventions through multiple manageable applications rather than a single sprawling filing. If applicants risk forfeiting enforceability by using routine continuation procedures, they will rationally respond by filing larger, more cumbersome applications or restructuring prosecution strategies in ways that increase burdens on an already strained examination system. The likely result would be slower patent examination, greater administrative complexity, and delayed investment in new treatments—and ironically perhaps even more patents ultimately issued as filing strategies would change.

### C. The "Evergreening" Narrative Mischaracterizes Ordinary Product Improvement

A second category of criticism centers on so-called "evergreening"—the claim that pharmaceutical companies make trivial modifications to existing medicines in order to extend monopoly protection indefinitely and delay generic competition. That narrative misunderstands both how patent law works and how medicines improve over time.

A patent on an improved version of a medicine does not extend exclusivity over the original. Each patent stands on its own with its own filing and expiration date. When the original patent expires, generic manufacturers remain free to enter the market with the original formulation. They do not need a license to the improvement patent because they are not practicing the improvement; they are making the earlier product. The new patent protects only the improvement itself, and only if that improvement independently satisfies the patent law's requirements of novelty and non-obviousness.

What sometimes happens is that patients and physicians prefer the improved version after generics become available because it works better, causes fewer side effects, is easier to administer, or improves adherence. That is not anticompetitive conduct. It is the ordinary result of product improvement. If the newer version offers meaningful benefits, patients and doctors may choose it. If it does not, generic competition on the original product will prevail.

Indeed, what is labeled "evergreening" in pharmaceuticals is often the same kind of iterative innovation prevalent in every other advanced industry. The insulin example discussed earlier in this statement is illustrative: each successive generation required substantial investment, was protected by new patents, and delivered meaningful clinical improvements. The same pattern appears across medicine. HIV therapies evolved from complex multi-pill regimens into single-tablet daily treatments that dramatically improved adherence and patient outcomes. Cancer therapies advanced from broadly toxic chemotherapies to targeted medicines and immunotherapies with substantially better efficacy and fewer side effects. Improved inhalers and delivery devices have likewise made respiratory medicines easier and more effective for patients to use.

These are not cosmetic changes. A 2025 report from the Information Technology and Innovation Foundation found that follow-on pharmaceutical innovation routinely improves adherence, reduces side effects, simplifies administration, and lowers overall healthcare costs by preventing complications and hospitalizations.[27]

Legislation premised on the "evergreening" narrative would risk penalizing precisely the kind of iterative innovation that has produced some of the largest gains in patient outcomes over the last several decades. Proposals that broadly restrict or render follow-on patents unenforceable rest on the assumption that pharmaceutical improvements should be treated differently from iterative innovation in every other research-intensive sector of the economy. That is a significant policy judgment, and one that should require compelling empirical support. To date, that case has not been adequately made.

**D. The "Skinny Label" Debate Is Better Resolved by Courts than by Broad Legislation**

A final area of recent legislative interest concerns so-called "skinny labels." Here too, the case for sweeping legislation is weaker than the rhetoric surrounding it suggests.

Under the Hatch-Waxman Act, a generic manufacturer may seek a type of limited approval only for uses of a drug that are no longer protected by patents. In doing so, the generic will propose an amended "skinny label" that omits patented indications that remain protected by the brand manufacturer's method-of-treatment patents. Congress designed this limited generic-approval pathway to strike a careful balance: allowing generic competition on unpatented uses while preserving incentives to develop new patented indications.

The current controversy concerns what generic manufacturers may say about their products, including the label and other public statements. In *Amarin v. Hikma*, the Federal Circuit reversed a motion to dismiss the case on the pleadings, providing for an opportunity for the full case to proceed on the merits. The Supreme Court is now reviewing that decision, after hearing argument in April 2026.

Against that backdrop, legislation is premature. While a Supreme Court decision will hopefully put an end to any remaining confusion in this area, legislation, such as the Skinny Labels, Big

[27] Stephen Ezell, *The Crucial Importance of Follow-On Pharmaceutical Innovation*, Info. Tech. & Innovation Found. (Mar. 2025), https://itif.org/publications/2025/03/follow-on-pharmaceutical-innovation/.

Savings Act (H.R. 6485) would go much further, creating a broad statutory safe harbor by excluding certain categories of conduct from consideration in induced-infringement cases, regardless of the surrounding facts.

The evidence does not suggest a widespread problem requiring that kind of intervention. Skinny-label launches are common—roughly half of first-generic small-molecule launches reportedly use section viii carve-outs.[28] Yet the number of induced-infringement disputes arising from those launches remains small, consisting primarily of a handful of fact-specific cases such as *GSK v. Teva* and *Amarin v. Hikma*. Even in *Amarin* itself, the originator company, Amarin, noted that it had only accused Hikma of infringement, not other seven other generics, because the others stayed within the carve-out.[29] Amarin concluded that the others were appropriately marketing their generic versions consistent with their skinny label—as opposed to Hikma, who Amarin alleged was marketing its generic beyond its skinny label to knowingly profit from sales for the patented indication. That pattern—with very few disputes over skinny labeling—is more consistent with a system functioning as intended than with one experiencing systemic failure.

Nor is broad legislation well-tailored to the underlying issue. Induced infringement has always been a fact-intensive inquiry focused on intent, and courts traditionally evaluate the totality of a defendant's conduct. A categorical evidentiary safe harbor risks creating room for "wink-and-nod" promotion that formally complies with the statute while informally encouraging use for patented indications. The result could be more boundary-testing behavior and more litigation over what conduct remains permissible.

Most importantly, Congress should be cautious about legislating while the Supreme Court is actively considering the governing legal standard. The Court's decision in *Hikma v. Amarin* will provide a clearer framework for evaluating whether any legislative adjustment is necessary and, if so, how narrowly it should be crafted. Acting now risks creating a statutory solution to a problem the Court may already resolve, or doing so more broadly than necessary.

The existing Hatch-Waxman framework has generally succeeded in balancing generic competition with incentives for follow-on innovation. The better course is to allow the courts to continue refining the line between permissible skinny-label competition and improper inducement, rather than replacing that fact-specific inquiry with categorical rules.

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Over the past several decades, Congress has helped build a pharmaceutical innovation system that is unmatched in the world. The United States today produces both the world's most innovative biopharmaceutical products and its most robust generic drug market. Nine in ten

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[28] *See* Bríd M. Walsh, Ameet Sarpatwari & Aaron S. Kesselheim, *Frequency of First Generic Drug Approvals with "Skinny Labels" in the United States*, 181 JAMA Internal Med. 995 (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC8008438/ (cohort study examining first generic drug approvals between 2015 and 2019 and finding that approximately 43% of brand-name small-molecule drugs experienced first generic competition under a skinny label during the study period).

[29] Brief for Respondent at 4, Hikma Pharma. USA Inc. v. Amarin Pharma, Inc., Case No. 24-889 (2026), https://www.supremecourt.gov/DocketPDF/24/24-889/401523/20260320195333332_2026.03.20%20Amarin%20-%20Merits%20Response%20Brief.pdf.

prescriptions in this country are filled with generics, while patients continue to benefit from breakthroughs that have transformed the treatment of HIV, hepatitis C, cancer, cystic fibrosis, diabetes, and many other serious diseases.

Those outcomes are the product of deliberate policy choices. Strong but time-limited patent protection has allowed investors, scientists, and companies to undertake extraordinarily risky and expensive research with some confidence that successful innovations can be commercialized. At the same time, Hatch-Waxman and the BPCIA have created clear pathways for generic and biosimilar competition that begin well before the expiration of the nominal twenty-year patent term.

Drug affordability remains a serious issue, and Congress is right to examine potential solutions carefully. But many of the patent-focused proposals currently under consideration would, by CBO's own assessment, produce little measurable effect on overall drug prices while weakening incentives for future innovation. More importantly, several rest on empirical claims about "patent thickets," "evergreening," and skinny-label abuse that the evidence does not support.

The United States did not become the global leader in biopharmaceutical innovation by accident, and that leadership should not be taken for granted. At a moment when other countries are investing aggressively to overtake the United States in biotechnology and pharmaceutical development, Congress should approach changes to the patent system with particular caution.

C4IP respectfully urges the Subcommittee to distinguish carefully between rhetoric and evidence, to preserve the innovation ecosystem that has delivered extraordinary benefits to patients, and to address any genuine abuses through targeted reforms rather than broad rules that risk undermining the development of future medicines.