Debunking Biopharmaceutical Patent Myths: An Evidence-Based Analysis

Authors: Lisa Mueller, Casimir Jones; Julie M. Lake, Merck; Mira A. Mulvaney, Eli Lilly and Company; Richard F. Kurz, Haug Partners LLP; Wan Chieh (Jenny) Lee, Haug Partners LLP; Gustavo de Freitas Morais, Dannemann Siemsen; Rob Rodrigues, RNA Law

Executive Summary

This white paper systematically refutes four pervasive myths about biopharmaceutical patent practices, utilizing empirical data, legal analysis, and economic research. These myths—that biopharmaceutical companies obtain excessive patents, create patent thickets, use patents to block generic competition, and leverage trivial post-approval innovations to "evergreen" their exclusivity—have become accepted conventional wisdom despite being contradicted by evidence from the U.S. Patent and Trademark Office (USPTO), the U.S. Food and Drug Administration (FDA), and independent academic research.

Key Findings:

Patent Counts Are Not Excessive: Biopharmaceutical companies represent only 2% of the top 300 U.S. patentees, filing fewer patents than the smartphone, semiconductor, and telecommunications industries. Moreover, the USPTO has confirmed that "simple counts of patents can be misleading" and does not provide a meaningful assessment of the intellectual property landscape or predict generic entry timelines.

Patent Thickets Are Not a Pharmaceutical Problem: The USPTO's June 2025 study on large patent application families found that large patent families are 2.5 times more common in semiconductors and electrical systems than in biopharmaceuticals. When multiple patents do exist, they typically reflect distinct, legitimate innovations—they are not artificial barriers to competition. Moreover, patent counting fails to account for the fact that generic manufacturers can "design around" patents and launch products before all follow-on patents expire.

Patents Enable, Not Prevent, Generic Competition: The Hatch-Waxman Act has enabled the United States to achieve generic competition with remarkable success—generics now account for 90% of prescriptions, compared to 13% in 1984. The USPTO's 2024 Drug Patent and Exclusivity Study found that follow-on patents do not "extend" earlier patents or systematically delay generic entry. Of 25 drugs studied, 13 had generic market entry during the study period, and the average exclusivity was 11.4 years—just over half of the 20-year patent term.

Post-Approval Innovations Deliver Genuine Clinical Value: These innovations offered substantial health benefits, including improved safety profiles, enhanced efficacy, expanded therapeutic applications, and improved patient adherence. For, example, between 2008 and 2018, 65% of oncology drugs received subsequent FDA approvals for new indications, with

approximately half in entirely new disease areas. Patents protecting these innovations must satisfy the same rigorous patentability requirements as initial patents and do not extend original patent terms. The patent laws safeguard against system prohibits evergreening through substantive doctrines.

Misinformation Has Undermined Policy Debate: Many pharmaceutical patent myths originate from methodologically flawed analyses by advocacy organizations that count abandoned applications, pending applications, and non-patent exclusivities as granted patents, which artificially inflate numbers by orders of magnitude. These counting errors have influenced legislative debates and shaped public perception despite being contradicted by official USPTO and FDA data.

The Stakes Are Significant: Weakening pharmaceutical patent protections based on false premises risks undermining the economic incentives that have made the United States the global leader in biopharmaceutical innovation. With drug development requiring investments typically exceeding $2 billion and success odds of only 1-2 in 10,000 candidates, robust patent protection is essential to justify the substantial financial risks inherent in pharmaceutical R&D. Policy grounded in accurate data, not flawed narratives, is crucial to preserving the incentives driving medical breakthroughs and maintaining American leadership in global pharmaceutical innovation.

Introduction

Operating at the intersection of scientific innovation, public health, and economic policy, the biopharmaceutical industry transforms groundbreaking research into life-changing therapies that improve and extend the lives of patients worldwide. In just the past 25 years, biopharmaceutical companies have delivered more than 1,200 new medicines to patients, including many first-in-class therapies for previously untreatable conditions.

The development of new medicines represents one of the most capital-intensive and risk-laden endeavors in modern industry. The average cost to develop a small-molecule drug is approximately $1-2 billion, spanning 8-10 years, while a biologic drug costs about $2-4 billion over 10-12 years.[1] These figures do not include the substantial investments in drug candidates that never reach the market.[2] The vast majority of drug candidates that appear promising in the laboratory never make it into clinical use, with only 12% of medicines that enter clinical trials receiving FDA approval.[3] Overall, only 1-2 of every 10,000 pre-clinical candidates tested ultimately reach patients.[4]

These extraordinary financial risks and lengthy development timelines are sustainable only because the U.S. intellectual property system provides innovators with a reliable, time-limited period of protection from copying. This exclusivity period allows biopharmaceutical companies to potentially recoup their massive upfront investments through future revenues from successful products, essentially enabling them to fund today's research with tomorrow's sales. Without this mechanism, the economic calculus of pharmaceutical innovation would collapse, as competitors would immediately copy successful products without bearing any development costs or risks.

Despite the patent system's critical role in sustaining pharmaceutical innovation, biopharmaceutical patents face persistent misunderstanding and mischaracterization in policy

---

[1] https://synergbiopharma.com/blog/biologics-vs-small-molecules/.
[2] The term "drug" refers to both small-molecule and biologic medicines.
[3] Donald L. Drakeman et al., From Breakthrough to Blockbuster: the Business of Biotechnology 38, 47, 48 (Oxford Univ. Press 2022) (citing Joseph A. DiMasi et al., Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, J. of Health Econ. 47 (May 2016): 20-33); see also Alexander Schuhmacher, Markus Hinder, Elazar Brief, Oliver Gassmann, Dominik Hartl, Benchmarking R&D success rates of leading pharmaceutical companies: an empirical analysis of FDA approvals (2006–2022), *Drug Discovery Today*, Volume 30, Issue 2, 2025, 104291, ISSN 1359-6446, https://doi.org/10.1016/j.drudis.2025.104291 (analyzing FDA approvals from 2006 to 2022 across 18 leading pharmaceutical companies and finding an average first approval rate of 14.3% (ranging from 8% to 23% across companies).
[4] https://pmc.ncbi.nlm.nih.gov/articles/PMC8165386/.

debates. This white paper addresses four pervasive myths that have shaped and distorted public discourse about pharmaceutical patents. These myths, propagated by advocacy organizations and repeated in legislative discussions, portray biopharmaceutical companies as manipulating the patent system to create artificial barriers to generic competition and extend patent protection indefinitely.

The narratives include claims that pharmaceutical companies obtain "excessive" numbers of patents, create "patent thickets" to block competition, use patents to prevent timely generic entry, and leverage trivial post-approval innovations to "evergreen" their exclusivity. Each of these characterizations has become conventional wisdom in certain policy circles despite being contradicted by empirical evidence from the U.S. Patent and Trademark Office (USPTO), the U.S. Food and Drug Administration (FDA), and independent academic research.

The stakes of this misinformation campaign extend far beyond rhetorical disputes. When policy decisions are based on false premises, they risk undermining the delicate balance that the patent system maintains between incentivizing innovation and ensuring competition. Weakening pharmaceutical patent protections based on flawed narratives could disable the primary economic engine that has powered America's translation of scientific breakthroughs into real therapies, jeopardizing the nation's leadership in global biopharmaceutical innovation.

By examining the structural mechanics of the U.S. patent system, analyzing empirical data on patent filings and generic competition, and reviewing the clinical evidence for post-approval innovations, this white paper provides a rigorous, evidence-based rebuttal to these myths. The analysis demonstrates that the patent system, working in conjunction with carefully designed regulatory frameworks, has successfully balanced the competing imperatives of fostering innovation and enabling competition. This balance has enabled the United States to become the global leader in both pharmaceutical innovation and the utilization of generic drugs.

Only through evidence-based policy—grounded in accurate data rather than misleading narratives - can we preserve the incentives that drive medical breakthroughs while ensuring that patients ultimately benefit from both innovative medicines and affordable generic alternatives.

Myth 1: Biopharmaceutical Companies Obtain "Excessive" Numbers of Patents

Myth: Pharmaceutical companies file an unreasonable number of patents compared to other industries, suggesting that this represents systematic abuse of the patent system.

Facts: Data from the Intellectual Property Owners (IPO) Association's 2023 Patent 300 list reveals that of the top 300 patentees in the United States, only six are biopharma companies, representing 2% of the total patents awarded.[5] In fact, all six biopharmaceutical companies *combined* were granted less than a third as many patents as the top patentee (2,748 vs. 9,036 for Samsung Electronics).[6,7]

The notion of an "excessive" number of patents is a fallacy. It assumes that there is a "right" number of patents and patent portfolios that exceed this arbitrary number are "excessive." But that is not how the patent system works. The patent laws do not limit patentees to a particular number of patents per product. Instead, innovators are awarded patents based on the inventions demonstrated to satisfy stringent patentability requirements. A single patent may protect a product patent, while others may be protected by dozens, hundreds, or even thousands of patents. The higher levels of this spectrum cannot be deemed to be "excessive" since every patent has been rigorously examined and found to claim a legitimate invention.

In any event, as the IPO data indicates, biopharmaceutical companies are not unique in their patenting practices. In fact, patentees in other industries obtain many more patents per product than biopharmaceutical companies. But that is beside the point, because, as the USPTO has pointed out, the numbers don't matter for pharmaceuticals: "simple counts of patents can be misleading," because "the number of patents does not provide a clear picture of the landscape."[8]

The reality is that products in complex technologies often include multiple inventions and, therefore, are protected by multiple patents.[9] As of 2012, the smartphone industry held more than 250,000 active U.S. patents,[10] accounting for approximately one in six active patents at that

---

[5] https://ipo.org/wp-content/uploads/2024/01/2024-Patent-300-IPO-Top-Patent-Owners-List.pdf.
[6] https://c4ip.org/debunking-patent-disinformation-insights-from-the-usptos-drug-patent-and-exclusivity-study/.
[7] In IPO's 2024 Patent 300 list, Samsung Electronics was again the top patentee with 9,304.
[8] Drug Patent and Exclusivity Study Report by the USPTO available at: https://www.uspto.gov/sites/default/files/documents/USPTO_Drug_Patent_and_Exclusivity_Study_Report.pdf.
[9] "With respect to multiple patents that cover a single product, multiple patents associated with a single marketed product are not unique to the pharmaceutical industry and are a common practice in many innovative industries, especially for complex products. United States Patent and Trademark Office. USPTO Drug Patent and Exclusivity Study Report. https://www.uspto.gov/sites/default/files/documents/USPTO_Drug_Patent_and_Exclusivity_Study_Report.pdf.
[10] An active patent is a patent that has issued and has not expired.

time.[11] A single smartphone may be covered by hundreds of thousands of active patents, including component-specific and design patents. Smartphone manufacturers including Samsung, Qualcomm, LG, Apple, and Alphabet (the parent company of Google), which are all among the top 10 patentees, maintain extensive patent portfolios that cover a wide range of technologies, from hardware design to software functionality. Similarly, the semiconductor industry holds over 53,000 granted U.S. patents,[12] demonstrating that large patent portfolios are characteristic of complex technologies in general, and patenting practices in the biopharmaceutical industry are modest relative to other innovative sectors.

Like smartphones and semiconductors, medicines are scientifically complex products. And just like smartphones and semiconductors, multiple patents on a medicine typically cover distinct inventions—the active compound, a method of treatment, a specific formulation that confers uniquely favorable properties, the delivery device, e.g., mirroring standard practice in other complex industries.

Activists organizations perpetuating myths surrounding drug patenting like Initiative for Medicines, Access & Knowledge (I-MAK)[13] inflate patent counts by including in their calculations expired patents, abandoned applications (which never issued as patents), pending applications (which have not yet issued and may never issue), and patents that are not listed in the Orange Book (which cannot trigger a stay of or enjoin regulatory approval).[14] Senator Thom Tillis specifically called attention to I-MAK's questionable methodology, which includes patents that are not a barrier to generic competition to artificially and meaninglessly inflate their numbers and create a misleading impression of the actual patent landscape.[15,16,17,18] For example,

---

[11] https://www.techdirt.com/2012/10/18/there-are-250000-active-patents-that-impact-smartphones-representing-one-six-active-patents-today/.
[12] https://www.upcounsel.com/semiconductor-patents#:~:text=Memory%20chips%20represent%20more%20than%2053%2C000%20granted%20patents%20and%20more%20than%2042%2C600&text=The%20Semiconductor%20Industry%20Patent%20Scorecard.
[13] https://www.i-mak.org/.
[14] https://ipwatchdog.com/sessions/myths-ip-pharma-sector-ls2023/; https://ipwatchdog.com/2024/05/19/fda-uspto-ignoring-requests-info-i-mak/id=176620/; https://s3.amazonaws.com/media.hudson.org/Mossoff_Unreliable%20Data%20Have%20Infected%20the%20Policy%20Debates%20Over%20Drug%20Patents.pdf.
[15] https://ipwatchdog.com/wp-content/uploads/2022/04/4.1.2022-TT-Ltr-to-USPTO-FDA-re-IMAK-patent-data-Final.pdf.
[16] www.i-makexposed.com.
[17] https://ipwatchdog.com/2025/09/21/amgen-attacks-academics-false-claims-about-biologic-patents/id=192344/.
[18] https://c4ip.org/fact-check-separating-fact-from-fiction-in-recent-ftc-doj-listening-sessions-on-patents-in-the-drug-industry/.

I-MAK has asserted that 73 U.S. patents cover the Novartis drug Gleevec, but when pending, expired, and abandoned patents are excluded, the number of patents that actually cover Gleevec is five, with another one to four possibly covering some ways of making it that generic manufacturers could but do not have to use.[19] It is no surprise, then, that contrary to I-MAK's claim that patents would prevent generic competition for Gleevec until at least 2029, generic versions of Gleevec began launching in 2016.[20] All told, the total amount of time Gleevec spent on the U.S. market without generic competition was less than 15 years, and not 35 years as I-MAK's asserted. Another example of I-MAK's misleading counting tactics is its April 2025 report entitled "The Heavy Price of GLP-1 Drugs." There, I-MAK again counted pending, expired, and abandoned applications based on exceptionally broad search terms applied across the title, abstract, specification, *or* claims of patents to assert that Novo Nordisk filed 320 U.S. patent applications and granted 154 patents "related to" its three semaglutide products Ozempic, Rybelsus, and Wegovy, and Eli Lilly filed 53 U.S. patent applications and granted 16 patents "related to" its two tirzepatide products, Mounjaro and Zepbound.[21] Importantly, absent from I-MAK's report is any analysis of whether any of the results they deemed "related to" these products actually claim the products at issue or present a barrier to generic entry. Indeed, a proper analysis has confirmed that many of the patents identified by I-MAK as conferring 49 years of patent protection for semaglutide and 44 years of patent protection for tirzepatide do not claim these products.[22] Likewise, setting aside pending and abandoned applications would further undermine I-MAK's numbers. About a third of the identified issued patents expired before these products even gained regulatory approval and could therefore not be a barrier to generic entry.[23]

Conclusion: The notion of an "excessive" patent count is fundamentally flawed—it presupposes an arbitrary ceiling that has no basis in patent law. The patent system rewards innovation based on rigorous examination of patentability requirements, not predetermined numerical quotas. As the USPTO's 2024 Drug Patent and Exclusivity Study unequivocally

[19] Statement of Corey Salsberg, Vice President and Global Head Intellectual Property Affairs for Novartis "Listening Session on Joint USPTO-FDA Collaboration Initiatives" January 19, 2022, Clara Barton Auditorium, USPTO, page 6, available at: https://ipwatchdog.com/wp-content/uploads/2023/01/Novartis-comments.pdf.
[20] *Id.*
[21] https://www.i-mak.org/glp-1/.
[22] https://ipwatchdog.com/2025/10/21/counting-patents-not-progress-misdiagnosis-i-mak/.
[23] *Id.*

concluded, "simple counts of patents can be misleading" and fail to provide meaningful assessment of the intellectual property landscape. Complex technologies inherently involve multiple distinct inventions meriting separate patent protection, and biopharmaceutical products—like smartphones and semiconductors—reflect this legitimate scientific complexity. In any event, representing merely 2% of the top 300 U.S. patentees, biopharmaceutical companies file substantially fewer patents than other technology sectors. The "excessive patents" narrative persists primarily through methodologically flawed analyses by advocacy organizations that artificially inflate patent counts. Policymakers must reject such misleading metrics and recognize that the number of patents protecting a medicine reflects the legitimate scope and complexity of innovation, rather than an abuse of the patent system.

Myth 2: Biopharmaceutical Companies File Multiple Patents on The Same Invention to Create "Patent Thickets"

Myth: Biopharmaceutical companies create dense webs of large patent families to block generic competition through sheer volume.

Facts: The USPTO's June 2025 study on large patent application families ("USPTO June 2025 Study") found that large patent families are not common in pharmaceutical applications.[24] From November 2021 to May 2025, the USPTO reviewed 2,458 allowed applications across eight technology centers. Among applications with more than 10 parent applications, pharmaceuticals represented only 8 out of 609 total cases (1.3%) in biotechnology (TC 1600), and zero cases in chemical and materials engineering (TC 1700). By comparison, semiconductors, electrical and optical systems (TC 2800) had 125 such cases, and computer networks and communications (TC 2400 and TC 2600) had 114 and 73 cases, respectively. The study found that such families are 2.5 times more common in the context of semiconductors, electrical, and optical systems and components (TC 2800) than they were for pharmaceutical applications.[25]

Although large patent families are common across complex technology sectors, they are not common in the biopharmaceutical sector. Large patent families exist extensively in

[24] https://www.uspto.gov/sites/default/files/documents/USPTO_Hour_Large_Patent_Family_Study_Final_06042025_CleanCopy_brand508c.pdf.

[25] *Id.*

telecommunications, where companies hold extensive patents on wireless standards and network infrastructure. In the smartphone industry, overlapping patents have led to numerous legal disputes between companies such as Apple and Samsung, which have extensive patent portfolios covering various components and features. The semiconductor industry similarly demonstrates patent complexity, with companies like Macronix, Micron Technology, and Advanced Micro Devices leading patent filings in electric digital data processing, electric solid-state devices, semiconductor devices, and static storage.[26]

Complex biopharmaceutical products legitimately incorporate multiple distinct innovations, each of which merits separate patent protection. The Council for Innovation Promotion ("C4IP") explains that "the practice of filing multiple patents to protect a product is not nefarious – or unique to the drug industry. Complex technologies like drugs and electronics work by combining multiple inventions, which must be patented to prevent illicit copying."[27] Indeed, biopharmaceutical innovations often occur over many years, necessitating the filing of multiple patent families. Such innovations include essential advances, such as new medical uses, improved formulations, and innovative manufacturing methods.

Conclusion: The empirical evidence decisively refutes the claim that biopharmaceutical companies create "patent thickets" to impede generic competition. The USPTO's June 2025 study on large patent application families reveals that biopharmaceutical applications account for only 1.3% of cases involving more than 10 parent applications. Moreover, when multiple patents do protect a single biopharmaceutical product, they typically represent distinct, legitimate innovations developed over many years, including new medical uses. This practice of securing multiple patents for complex products is neither nefarious nor unique to the pharmaceutical industry; it reflects the standard approach across all technology sectors for protecting products that incorporate multiple inventions. Moreover, many follow-on patents result from the procedural requirements of the patent system itself, such as continuation and divisional applications mandated by USPTO's examination practices. These mechanisms ensure clarity and fairness but do not extend patent terms or create artificial barriers. The "patent thicket" narrative fundamentally mischaracterizes legitimate innovation as systematic abuse, ignoring both the scientific complexity of modern medicines and the structural realities of patent law.

[26] https://www.einfolge.com/blog/Understanding-Patentability-in-the-Semiconductor-Industry.
[27] https://c4ip.org/fact-check-debunking-myths-about-patents-in-the-pharmaceutical-industry/.

Myth 3: "Patent Thickets" and Patent "Gaming" Prevent Generic Entry

Myth: Biopharmaceutical companies use multiple overlapping patents to create impenetrable barriers that systematically delay generic drug market entry, while simultaneously manipulating patent laws and FDA processes to block legitimate generic competition.

Facts: Patents enable both innovation and timely generic competition. By precluding copying for a limited period, patents incentivize the high-risk, high-cost research necessary to discover life-saving medicines. Once those patents expire, generic manufacturers can rely on that same costly research to immediately produce lower-cost copies.

The Hatch-Waxman Act of 1984 is the U.S. statutory framework that governs generic entry of small-molecule drugs in the United States. The entry of biosimilar drugs is governed by a similar framework known as the Biologics Price Competition and Innovation Act, or BPCIA. These frameworks include provisions specifically designed to drive timely generic entry, including:

- Abbreviated approval pathways, allowing generic manufacturers to rely on an innovator's safety and efficacy data when seeking FDA marketing approval, avoiding duplicative and expensive trials and accelerating FDA approval.
- Safe Harbor provisions allow generic manufacturers to develop their products, submit their marketing authorization applications, and receive FDA approval before patent expiration without the threat of infringement liability.

Coupled with the requirement that patents must disclose sufficient details to enable others to reproduce the invention—essentially to provide a roadmap for copying—these mechanisms allow generic drugs to enter the market the day patent protection expires. Due to the minimal development expense needed to create generic copies, the average brand-to-generic price reduction exceeds 85%. The Hatch-Waxman Act has been extraordinarily successful. Today, generics account for 90% of U.S. prescriptions, compared to 13% in 1984, before the passage of the legislation, and 41% in other developed nations, highlighting the U.S. system's success in balancing innovation with affordability.[28] This balance is necessary for the system to function because generics can only be brought to market if innovative drugs that can be copied are first marketed. Without investments being made to bring new innovator drugs to market, there also

[28] https://phrma.org/blog/40-years-of-hatch-waxman-how-does-the-hatch-waxman-act-help-patients.

would be no new generic drugs to market. The pipeline of future generic copies of drug products is wholly dependent on the development of new innovator drugs.

The "patent thicket" myth simplistically focuses on the number of patents protecting a medicine and argues that more patents mean a longer period before generic competition. But the data shows otherwise. A recent study conducted by the USPTO entitled "Drug Patent and Exclusivity Study" ("USPTO 2024 Patent Exclusivity Study") confirmed that so-called "patent thickets" are not delaying generic competition in the U.S. The USPTO's study concluded that simply counting the number of granted pharmaceutical patents does not meaningfully assess the patent landscape nor is it indicative of the length of exclusivity when it comes to pharmaceuticals: "The results illustrate that simply quantifying raw numbers of patents and exclusivities is an imprecise way to measure the intellectual property landscape of a drug product because not every patent or exclusivity has the same scope . . . [S]imple counts of patents can be misleading when every patent is counted equally, because the number of patents does not provide a clear picture of the landscape without a review of the scope of the claims in each patent."[29]

Indeed, of the 25 new drug applications (NDAs) that the USPTO reviewed,[30] 13 had generic market entry *during the study period*. The average period of exclusivity[31] across these products was 11.4 years – *significantly less than the 20-year length of a full patent term*, and not "multiple decades" as some critics have baldly (and falsely) claimed.[32]

The USPTO also concluded that follow-on patents do not "extend" earlier patents and do not block the introduction of generics, identifying several examples where "a generic competitor drug was approved and launched, while later patents directed to follow-on innovation and listed in the Orange Book were still in force."[33] In the case of products for which primary protection had not ended during the study, the USPTO noted that "later patents may have claims directed only to specific aspects of the [innovator company's] product, and may not block a generic from

[29] Drug patent and exclusivity study (uspto.gov) (page 57).
[30] All the NDAs studied by the USPTO were included in the Orange Book at some point between 2005 and 2018.
[31] According to the USPTO 2024 Patent Exclusivity Study, "exclusivity", for purposes of the study, included both patent protection and the FD&C Act exclusivities (page 3).
[32] See, https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.
[33] USPTO 2024 Patent Exclusivity Study, page 5.

launching a competing product once the earlier patents have expired."[34,35] Finally, the study highlighted instances where no generic was launched despite the expiry of all applicable patents.

This finding is consistent with those of other studies.[36] A 2025 study by IQVIA examining biosimilar competition found that "only 14 out of 62 biologics without patent protection as of the end of 2024 have biosimilars," and that out of the 118 biologics expected to lose patent protection between 2025 and 2034, only 12 have biosimilars in development.[37]

What these data make clear is that contrary to the "patent thicket" myth, more patents do not mean longer timeframes before generic entry and, importantly, fewer patents do not mean that generics will enter sooner, or, in fact, at all. Indeed, factors other than patent protection contribute to, and in many instances, determine whether and when generics enter the market.

The data are not surprising. Patents have fixed 20-year terms from the filing date of the earliest-filed application in a patent family and can only be narrowly extended under very specific, limited circumstances.[38] Thus, no matter how many patents are granted from the original patent application, the expiration dates for the patent family are all generally the same. A patent restarting the 20-year clock can only be supported by a wholly new innovation that is demonstrated to be novel and nonobvious in view of all earlier patent filings. But, critically, many such later-filed patents do not block generic entry. Generic companies can simply exclude those specific features from their product or labeling. For example, generic companies may "design around" an innovator's formulation and choose to launch with their own formulation before the innovator's formulation patent expires. Likewise, generics may decide to seek

---

[34] See, A recent report from the Congressional Budget Office (CBO) entitled "Alternative Approaches to Reducing Prescription Drug Prices" examined proposals to address "patent thickets" and other strategies alleged to delay biosimilar and generic competition. "In CBO's estimation, recent proposals to accelerate generic and biosimilar entry that have been introduced in the Congress and analyzed by CBO would each reduce average drug prices in 2031 by a very small amount (0.1 percent to 1.0 percent) or by less than 0.1 percent."

[35] USPTO 2024 Patent Exclusivity Study, page 6.

[36] See, Henry Grabowski et al., *Continuing Trends in U.S. Brand-name and Generic Drug Competition*, 24 J. Med. Econ. 908, 908 (2021) available at https://pubmed.ncbi.nlm.nih.gov/34253119/; and Erika Lietzan and Kristina M. L. Acri, Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations, 33 *Fordham Intellectual Property, Media & Entertainment Law Journal* 788 (2023) available at: https://scholarship.law.missouri.edu/facpubs/1087.

[37] https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/assessing-the-biosimilar-void-in-the-us.

[38] Patent Term Adjustment (PTA) and Patent Term Extension (PTE) can be granted to an issued patent to extend the life of the patent beyond the statutory term of 20 years from the earliest filing date. PTA is granted to compensate the applicant for patent term loss due to administrative delays incurred during prosecution before the United States Patent and Trademark Office (USPTO). *See* 35 U.S.C. § 154. PTE is awarded to compensate for delays incurred in obtaining regulatory approval on a patented product or methods of manufacturing or using the product. *See* 35 U.S.C. § 156.

approval for fewer than all indications on a product label and launch while later-expiring method of treatment patents are still in force.

Indeed, in many instances, the existence of multiple patents is a result dictated by the patent laws themselves. Many follow-on patents are known as "continuation" or "divisional" patent applications, which are in the same patent "family" as the originally filed patent application. Continuation and divisional applications are procedural tools within the patent system designed to ensure clarity, fairness, and efficiency in the examination process. A continuation application, commonly used in the United States, allows an applicant to pursue additional claims derived from the same original disclosure, often when the scope of claims provided in the initial application is limited during prosecution. Divisional applications, on the other hand, are typically filed when a patent examiner determines that more than one invention has been disclosed in a single application, and the patent office procedurally requires the applicant to separate them into distinct filings. As discussed above and contrary to common misconceptions, the follow-on patents resulting from these mechanisms do not extend the patent term. While they may result in the issuance of new patents, each claim is based on the initial disclosure, and each term is calculated from the filing date of the earliest parent application in the family. Their function is not to prolong exclusivity, but to simplify the USPTO's patent examination process by ensuring that each inventive contribution is examined correctly and protected within the bounds of established legal criteria.

When a new innovation is patented, a new and separate patent family is created. Such new innovations may be, for example, a new formulation (e.g., an extended duration of effectiveness, such as moving from a three-times per day dosing regimen to a once-a-day dosing regimen, or a different means of administration, such as moving from a capsule to liquid administration), a new use for a drug (e.g., from clinical studies demonstrating that the drug may be used to treat a new disease), or an improved version of an active drug ingredient (e.g., a chemically different drug form that, e.g., reduces undesirable side effects). Filing patents for these new inventions is not an "abuse" of the system —it is the system working as intended to encourage the development of innovations that benefit patients. Critically, these new patents cannot be directed to the original invention. To be issued by the USPTO, these new patents must claim something new and non-obvious. Thus, these new patents cannot extend the same exclusive rights as the original patents.

Patent counting studies, such as the Evergreen Drug Patent Search Database, create a metric called "latest protection end date," which represents the latest expiration of any patent or exclusivity associated with a drug application. This metric is presented as indicating when generic competition can begin; however, this inference is fundamentally flawed and overlooks the fact that many patents and exclusivities do not prevent generic approval at all. Even if they do, the "latest" date often relates to narrow improvements that generics can choose to omit from their products. It is thus not surprising that biopharmaceutical companies face generic competition on average seven years earlier than patent counting studies suggest they should.[39]

Conclusion: The evidence demonstrates that patents enable rather than prevent generic competition. The Hatch-Waxman Act has achieved extraordinary success, with generics now accounting for 90% of U.S. prescriptions compared to 13% before its passage, far exceeding the 41% generic utilization rate in other developed nations. This success derives from carefully balanced mechanisms that incentivize both innovation and timely generic entry, including abbreviated approval pathways, safe harbor provisions, and patent disclosure requirements that provide generics with a roadmap for copying. The USPTO's 2024 Drug Patent and Exclusivity Study has debunked the "patent thicket" myth by demonstrating that simply counting patents provides no meaningful assessment of the intellectual property landscape or prediction of generic entry timing. On the contrary, the study showed that the average exclusivity of an innovative drug was 11.4 years, significantly less than the 20-year patent term and far short of the "multiple decades" alleged by critics. Critically, the USPTO confirmed that follow-on patents do not "extend" earlier patents, and documented multiple instances where generics were launched successfully while later-expiring patents remained in force. This is not surprising, because generic manufacturers can "design around" specific features protected by follow-on patents. Moreover, the data reveals that factors beyond patent protection, including market size, manufacturing complexity, and commercial viability, often determine whether and when generics enter the market.

[39] https://www.uspto.gov/initiatives/fda-collaboration/drug-patent-and-exclusivity-study-available.

Myth 4: Post-Approval Innovations are Trivial and Extend Exclusivity ("Evergreening")

Myth: Pharmaceutical companies leverage trivial post-approval innovations to switch patients to more expensive branded medicines and away from lower-cost generics, thereby "evergreening" their pipeline.[40]

Facts: Post-approval innovations, also referred to as "follow-on" innovations, deliver substantial health and economic benefits by improving safety, enhancing efficacy, expanding therapeutic applications, and improving patient adherence and quality of life. These innovations represent scientific advances that undergo the same rigorous patent examination process as primary patents, providing measurable clinical value to patients and healthcare systems.

Initially, "evergreening" is not a legal term, but a political one. According to Alfred Engelberg, regarded as the legal father of the modern generic drug industry for his instrumental role in drafting and promoting the Hatch-Waxman Act, the term was deliberately adopted by the generic industry as part of a broader advocacy strategy to promote earlier market entry for generic drugs. In this sense, the term "evergreening" is intrinsically attached to the political interests of the generic industry lobby and inherently biased. Moreover, U.S. patent law prohibits evergreening via substantive doctrines that prevent obtaining multiple patents on the same invention or extending patent life by getting patents on obvious variations of a previously claimed invention.

A core assumption underlying the "evergreening" myth is that discovering an active pharmaceutical ingredient (API) alone ensures therapeutic success. However, an API rarely guarantees clinical effectiveness. A medicine's real-world performance depends on numerous factors that require sustained, expensive R&D beyond the original invention:

- Stable and scalable formulations that maintain potency throughout manufacturing, storage, and distribution;
- Safe and targeted delivery systems that optimize drug absorption and minimize side effects;
- Predictable pharmacokinetics across diverse patient populations;
- Manageable adverse effect profiles that enable patient adherence; and
- Patient-friendly administration that supports long-term treatment compliance.

[40] https://cip2.gmu.edu/2018/05/01/cpip-scholars-examine-the-flaws-in-the-term-evergreening/.

Research demonstrates that follow-on innovations provide substantial patient benefits. For example, between 2008 and 2018, 65% of oncology drugs went on to have at least one subsequent indication, in which the innovator performed clinical studies that demonstrated the drug's safety and effectiveness in treating another type of cancer after approval.[41] Post-approval research often yields the discovery of new therapeutic applications, with approximately half of post-approval indications being approved in entirely new disease areas.[42]

An example of a clinically meaningful follow-on innovation is the reformulation of Bimatoprost from 0.03% to 0.01% concentration (Lumigan), which significantly reduced side effects and improved compliance, while maintaining effectiveness.[43]

Another example is Merck's strategic development in the statin market, which exemplifies how follow-on innovation leads to genuinely new therapeutic approaches. The company developed Vytorin® (ezetimibe + simvastatin) and Liptruzet® (ezetimibe + atorvastatin)—combinations that target cholesterol through complementary mechanisms. Clinical trials demonstrated that Vytorin® reduced cardiovascular events by 6.4% compared to statin monotherapy, providing measurable patient benefits beyond those of the original compound.[44] Moreover, Vytorin® and Liptruzet® did not extend the duration of the primary patents but allowed Merck to create new market niches and maintain competitiveness vis-à-vis other innovators, such as Pfizer with Lipitor®.[45]

The term "secondary patents" often carries dismissive undertones that obscure the legitimate technical contributions these innovations represent. Follow-on innovation patents more accurately describe these protections, acknowledging the cumulative nature of

---

[41] https://itif.org/publications/2025/03/17/the-value-of-follow-on-biopharma-innovation/.
[42] https://www.healthaffairs.org/doi/10.1377/hlthaff.2024.00202.
[43] L. Jay Katz, John S. Cohen, Amy L. Batoosingh, Carlos Felix, Vincent Shu, Rhett M. Schiffman, Twelve-Month, Randomized, Controlled Trial of Bimatoprost 0.01%, 0.0125%, and 0.03% in Patients with Glaucoma or Ocular Hypertension, American Journal of Ophthalmology, Volume 149, Issue 4, 2010, Pages 661-671.e1, ISSN 0002-9394, https://doi.org/10.1016/j.ajo.2009.12.003.
[44] Cannon, C. P., Blazing, M. A., Giugliano, R. P., McCagg, A., White, J. A., Theroux, P., Darius, H., Lewis, B. S., Ophuis, T. O., Jukema, J. W., De Ferrari, G. M., Ruzyllo, W., De Lucca, P., Im, K., Bohula, E. A., Reist, C., Hagström, E., Spinar, J., Murphy, S. A., … Kastelein, J. J. P. (2015). Ezetimibe Added to Statin Therapy after Acute Coronary Syndromes. *The New England Journal of Medicine*, 372(25), 2387–2397.
[45] Kiran, S., & Kulkarni, M. (2018). Secondary patents in the pharmaceutical industry: missing the wood for the trees? *Expert Opinion on Therapeutic Patents*. https://doi.org/10.1080/13543776.2018.1424134.

biopharmaceutical R&D. According to UN Guidelines for Pharmaceutical Patent Examination,[46] these innovations encompass diverse technical advances:

- Selection Patents – Protect specific compounds or subgroups with unexpectedly superior properties, driving refinement and optimization of prior discoveries.
- Polymorphs – Represent new crystalline forms of known compounds that may enhance stability, solubility, or bioavailability, improving shelf life and patient outcomes.
- Enantiomers – Isolated therapeutically active isomers in racemic mixtures, often leading to safer or more effective treatments.
- Salts and Esters – Modify chemical properties to improve solubility, absorption, or targeting, expanding therapeutic potential.
- Compositions – Combines actives with innovative excipients or carriers to enhance efficacy, safety, or ease of administration.
- Optimized Dosage Regimens – Tailor drug exposure to maximize therapeutic effect while minimizing side effects, especially across different patient populations.
- Combinations – Create synergistic effects or simplify treatment regimens by combining multiple actives into a single therapy.
- Prodrugs – Design inactive compounds that convert into active drugs in the body, improving delivery, targeting, or tolerability.
- Metabolites – Protect active breakdown products of drugs that may themselves serve as effective and safer therapies.
- New Medical Uses – Discover novel therapeutic applications for known compounds, expanding their value and benefit to patients.

Each innovation must independently satisfy the patentability requirements of novelty, inventive step, and, in some instances, industrial applicability. Patent offices examine applications individually, routinely rejecting those lacking a genuine technical contribution.

Rather than representing abuse, follow-on innovation patents reflect a functioning and adaptive innovation system. They support cumulative progress where today's refinements incrementally built on yesterday's breakthroughs. Without protection for follow-on innovations,

[46] Correa C. M. *Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective*; United Nations Development Programme: New York, 2015.

companies would have little incentive to pursue improvements that benefit patients but require substantial additional investment.

The original patent rewards the initial molecular discovery, but translating molecules into safe, effective, and accessible therapies requires sustained innovation. Follow-on innovations often address real therapeutic needs, reducing side effects, improving adherence, expanding utility to new indications, and contributions that deserve recognition when meeting established legal criteria.

By ensuring valuable enhancements receive appropriate protection, the patent system fosters continuous investment in better healthcare solutions. If improvements were dismissed simply because they followed initial discovery, much meaningful pharmaceutical progress would be lost, particularly improvements directly benefiting patients through enhanced safety, efficacy, and accessibility.

Moreover, if follow-on innovations were truly trivial, payers and pharmacy benefit managers would have little incentive to offer reimbursement beyond previously approved medicines. The market adoption of follow-on products depends on their demonstrated value to providers and patients, not patent manipulation. This reality becomes especially apparent when examining the phenomenon critics call "product hopping," or what the industry terms "hard switches"—instances where an innovator transitions patients from an original drug formulation to an improved version.

While such product hopping occasionally occurs in pharmaceutical markets, it is not common. When it does happen, economic factors typically drive the decision. An innovator generally lacks the incentive to maintain two product versions when one is demonstrably superior, as manufacturing parallel lines creates unnecessary operational and quality control burdens. Yet this normal business practice is fundamentally constrained by robust regulatory safeguards. Unless the original drug is withdrawn due to safety or effectiveness concerns, it remains available to serve as a reference listed drug, and generic versions can still be approved and marketed following patent expiration—a process that occurs frequently. When such transitions do not occur, it is typically because the improved version demonstrates such clear clinical superiority that there exists no real market demand for generic versions of the original formulation.

Patients and providers understand this distinction intuitively. When they choose brand-name drugs over generics—something that happens for just one in every 10 prescriptions—their decisions are primarily explained by a preference for the latest, most up-to-date versions of drugs rather than by a lack of available options.[47] This represents normal market behavior where consumers select updated technology versions, similar to any other technological product that is sometimes phased out when newer and more updated versions become available.

Patents make it economically viable to develop and bring innovative new drugs to market. They also help keep drug prices lower for both the new innovative medicines and their eventual generic counterparts. Rather than facilitating anti-competitive "product hopping," follow-on innovations represent legitimate technological advancement that creates value for patients while maintaining robust generic competition for original formulations upon patent expiry. This dynamic—where innovation drives market transition while regulatory safeguards preserve generic competition—demonstrates that the patent system continues to function as intended.

Conclusion: The characterization of post-approval innovations as trivial "evergreening" tactics is contradicted by clinical evidence, patent law doctrine, and market realities. Fundamentally, substantive patent law prohibits the underlying concept. Instead, later-expiring patents are most commonly directed to post-approval innovations that deliver substantial, measurable health benefits. These follow-on innovations must independently satisfy the same rigorous patentability requirements as initial patents, demonstrating novelty and non-obviousness. They cannot and do not extend the term of original patents. Their market adoption demonstrates the clinical significance of these innovations: payers and pharmacy benefit managers would have no incentive to reimburse improved versions of a medicine if they lacked genuine therapeutic value. And when innovators transition patients from original to improved medicines, sometimes characterized pejoratively as "product hopping", regulatory safeguards ensure that the original drug remains available as a reference listed drug, permitting generic approval and market entry upon patent expiration. The reality that patients and providers choose brand-name drugs for only one in ten prescriptions reflects informed preference for clinically superior options, not manipulation or lack of generic availability. Follow-on innovation represents the patent system functioning as intended: providing economic incentives for the

[47] https://c4ip.org/fact-check-patents-are-not-to-blame-for-high-drug-prices/.

sustained, expensive research required to translate initial molecular discoveries into safe, effective, and patient-friendly therapies. Without patent protection for these genuine improvements, companies would lack the incentive to pursue innovations that reduce side effects, improve adherence, and expand therapeutic applications, all of which directly benefit patients. Dismissing these contributions as "trivial" or "evergreening" fundamentally mischaracterizes significant scientific progress and risks undermining the incentives that drive continuous pharmaceutical advancement.

Why These Myths Are Harmful

These narratives have flourished in an ecosystem where repeated citation, often without scrutiny, turns mischaracterizations into accepted conventional wisdom. The complexity of pharmaceutical patent law and the drug approval process make it highly challenging for journalists, general policymakers, and the public to distinguish between suspect claims and fact-based reporting.

When laws are based on false premises, they risk harming innovation and failing to address the underlying issues that drive drug pricing. Recent legislative efforts, such as the ETHIC Act (S. 2276) and the Affordable Prescriptions for Patients Act (S. 1041), target “patent thickets” and “product hopping” by using narratives that rigorous empirical studies have debunked. Industry-specific patent reforms set a dangerous precedent: when policy targets a single sector, especially with technology-specific interventions, it risks undermining balanced competition and deterring innovation and progress.

The pharmaceutical industry, unlike others, must rely on robust intellectual property protection to justify the investment of more than $2 billion and the long odds of success for each new drug candidate. Weakening these safeguards based on falsehoods undermines the primary economic engine that powers the translation of scientific breakthroughs into real therapies.

Additionally, the spread of these myths erodes public support for intellectual property rights, tainting legitimate patent practices as “abusive” and impeding open, rational debate on healthcare reform. The U.S. leadership in global pharmaceutical innovation is a direct result of its strong, science-driven patent framework, which could be jeopardized by policy based on inaccuracies.

Misinformation about pharmaceutical patents did not arise spontaneously. It was deliberately constructed, often by advocacy groups with a particular agenda, and perpetuated by repetition in the media and legislative debate. The persistence of these myths is not merely an academic concern; it has real-world implications for American patients and the future of medical innovation. As the U.S. considers reforms to its healthcare and intellectual property laws, it is more crucial than ever that policy be grounded in sound data and an accurate understanding of how patent systems function. Ensuring that legislation is based on facts, not flawed narratives, is crucial to preserving the incentives that drive medical breakthroughs and maintain America's leadership in global biopharmaceutical research and development.