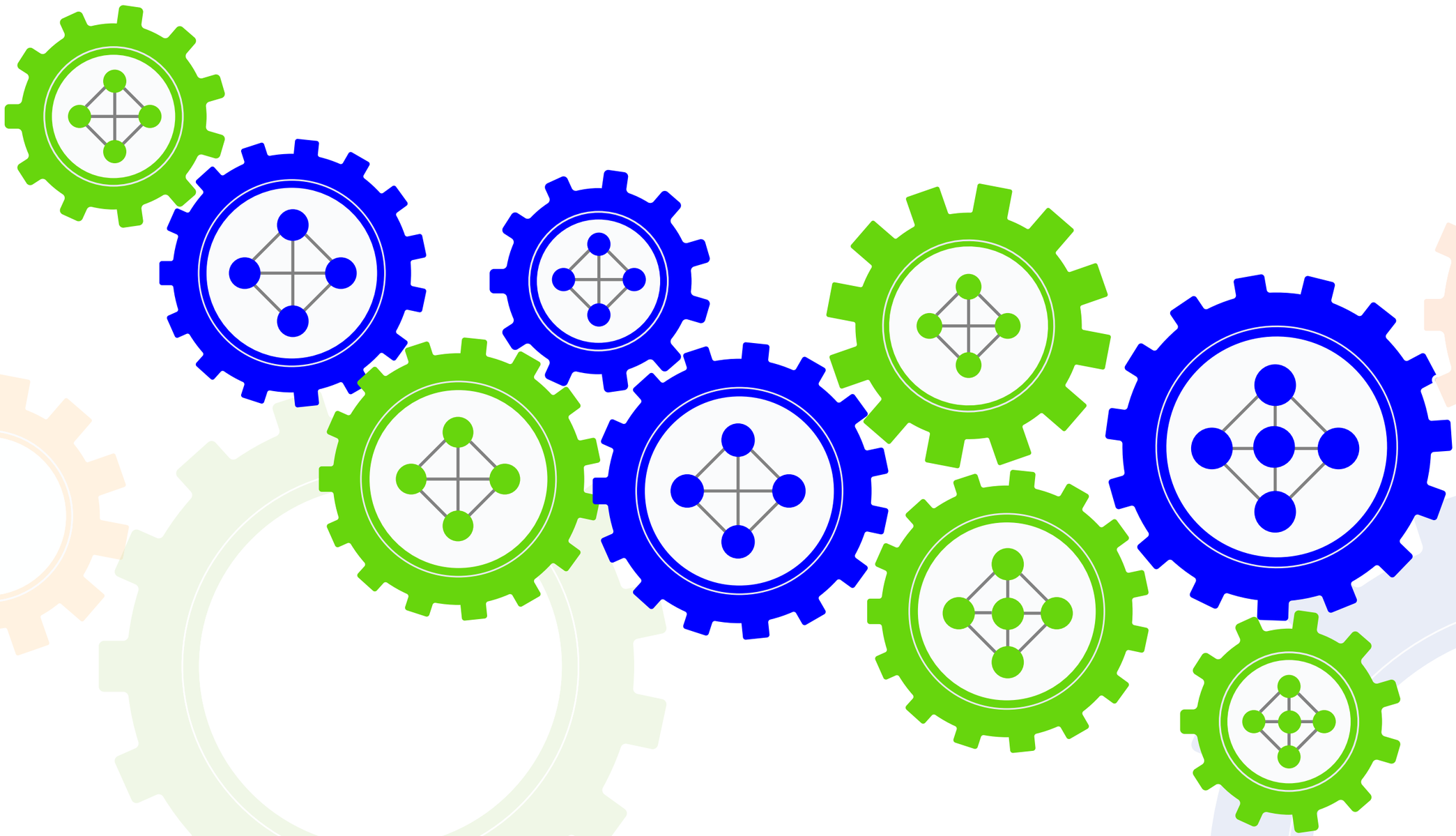
Pharmaceutical “Patent Thickets”

Separating Myth from Reality



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Introduction

When we think about prescription medicines, we often see just the final product – a small pill, a vial of liquid, or an autoinjector. What remains invisible is the complex journey of problem-solving, setbacks, and innovations that transformed a promising molecule, itself a needle in a haystack, into an effective treatment. This journey happens thanks to investment secured by patents – and not just the patent on the original active ingredient, but also on each invention that solved a problem along the way.

In recent years, pharmaceutical patents have become a flashpoint in healthcare policy debates. Critics claim – often with misleading data – that drug companies deliberately create dense "patent thickets" to block generic manufacturers and maintain high prices. They paint a picture of strategic manipulation rather than a process of genuine innovation, suggesting that limiting patents would quickly lower drug prices without consequences.

But what if this narrative fundamentally misunderstands how medicine development actually works?

This series examines four critical questions about pharmaceutical patents by contrasting popular misconceptions with evidence-based reality. Drawing on patent data, market research, and innovation studies, we demonstrate that multiple patents on a single drug product typically reflect genuine problem-solving that benefits patients rather than alleged anti-competitive behavior. The evidence reveals that generic competition has continued to arrive consistently around 13-14 years after brand drug approval.

While drug affordability is a legitimate concern, addressing it through policies that undermine innovation incentives would jeopardize the development of future treatments. The data shows that pharmaceutical companies patent less intensively than many other industries, with patents representing specific solutions to specific scientific challenges. Generic manufacturers – sophisticated market players in their own right – routinely navigate these patents to bring competition to market on a predictable and consistent timeline. The facts and data simply do not fit the critics' narrative.

At stake is not just how we regulate existing medicines, but whether we will continue to see the stream of medical breakthroughs that have transformed patient care. By separating myth from reality in pharmaceutical patent debates, we can pursue policies that balance innovation and access without sacrificing either.

Key Insights: Pharmaceutical Patents and Innovation

What people experience as a "medicine" or drug "product" is likely a bundle of inventions.

As with a car, phone, or even a golf club, a medicine represents a series of inventions, each of which may be patented, including improvements that may be added over time. Creating a medicine does not happen in a single Eureka! moment, but over a long process as scientists solve problems.

Patents protect solutions, not medicines themselves.

Each patent represents a particular invention that solves a specific scientific problem encountered during drug development – from improving absorption to enhancing stability – not strategic extensions of monopoly power. These innovations are needed to address the problems that otherwise cause 90% of drug candidates to fail.

Pharmaceutical patenting is moderate compared to other industries.

Most of the drugs (61%) currently approved for marketing no longer have any patents, a fact that reminds us that all patents expire and all generic drugs start life as patented drugs. Of those drugs with patents still in force, most have fewer than four. Leading companies in other sectors obtain ten times more patents per R&D dollar than pharmaceutical companies.

Multiple patents don't delay generic competition.

Despite critics' claims, the effective market exclusivity period has remained stable at 13-14 years for decades, regardless of patent count. Generic manufacturers routinely navigate patent landscapes, introducing competition on a predictable timeline.

Patent caps would harm innovation without helping competition.

Restricting the number of patents that can be obtained or enforced would hinder important advancements that minimize side effects and broaden treatment options, without fostering increased generic competition.

The generic industry is thriving.

Generics now fill 90% of all U.S. prescriptions (up from 13% in 1984), demonstrating that the current patent system successfully balances innovation incentives with competition and patient access.

Pharmaceutical "Patent Thickets"

Why do pharmaceutical companies seek multiple patents on one medicine? Are they just creating "patent thickets"?

Myth

Critics claim that drug companies obtain an excessive number of patents on the same medicine with little scientific justification, purely to build a dense "patent thicket" that blocks competitors. Some propose that one patent ought to be enough, others put forward reasons to question every patent beyond the first, while still others see later-filed patents as a carefully timed strategy calculated to stifle competition (Feldman, 2018; Gurgula, 2017; Goode & Chao, 2022).

Reality

Medicines aren't patented; inventions are. While some medicines might contain just a single invention, that's rarely the case in practice. Developing a medicine is a journey of several years through many scientific challenges, not a single, one-and-done "Eureka!" moment. This journey from lab to patient proceeds through a series of inventive steps, with each solution requiring further investment of resources that can't happen without the chance to obtain the security of a patent (Lietzan, 2019; Holman, 2017).

Throughout this journey, patient needs and scientific problems – not legal strategy – drive innovation. Patent attorneys don't direct research; they follow it. When scientists solve critical problems, the resulting innovations merit patent protection because they represent genuine progress. Each is a technical solution to a technical problem (Holman, 2017).

These innovations occur both before and after regulatory approval.

Some patents protect pre-approval discoveries that enable drugs to work safely and effectively for patients. Yet critics examining successful drugs see only patent counts, not these enabling innovations. The harsh reality is that approximately 90% of drug candidates fail in clinical trials, most commonly due to efficacy issues (52%) or safety concerns (24%) (Harrison, 2016; Hay, 2014). Each pre-approval patent on a successful medicine typically represents a solution to a problem that prevented failure.

Other patents protect post-approval improvements that enhance patient outcomes such as new uses, improved delivery methods, or better formulations. Critically, these later patents don't block generic versions of the original drug product once its core patents expire. This distinction matters because critics who count all patents as "blocking" competition fundamentally misunderstand or misrepresent how the system works.

For a successful drug candidate, solving problems with efficacy and safety often requires inventing solutions to problems that might have otherwise caused the drug to fail (Sun, 2022; Harrison, 2016; Hay, 2014). Patents on these solutions represent hurdles that had to be overcome in the complex journey from laboratory to patient.

This accumulation of inventions mirrors innovation in other fields. We readily understand why cars and computers contain dozens of separately patented innovations that improve over time. Most medicines are no different – they also are collections of inventions, just packaged in a less visible form.

The innovation timeline below reveals why multiple patents are both inevitable and beneficial.

Early R&D and development

A medicine's development typically begins with identifying a promising, novel compound that might eventually become a treatment. However, in its original form, it may be ineffective or even harmful inside the human body. Turning that compound into a viable treatment requires further innovation. Researchers must invent optimal formulations, delivery methods, dosing regimens, and manufacturing processes to ensure safety and efficacy. These innovations represent distinct technical solutions to scientific challenges (Sun, 2022; Lietzan & Acri, 2020; Holman, 2017).

Clinical use and further improvements

Innovation doesn't stop once clinical trials begin. Companies continue to study and improve medicines based on early patient experience and feedback in clinical trials. This innovation can improve safety and efficacy and, in some cases, solve challenges that would otherwise prevent a medicine from reaching patients. These solutions deserve protection through patents.

Post-approval innovation

Innovation continues after regulatory approval and initial market launch. Drugs are often first tested and approved for conditions where other treatments are poor or non-existent – exactly where patient need and economic justification are greatest. However, once a drug is de-risked through demonstration that it is safe and effective for one patient population, further research and innovation to bring the drug to additional patient populations makes economic, ethical, and scientific sense (Roin, 2014).

Post-approval research yields real patient benefits in several ways. Innovators may expand treatments to related patient populations – for example, testing a cancer drug proven effective for kidney tumors on other cancer types. They may also discover entirely different therapeutic applications, finding that drugs work for completely unrelated diseases. Additionally, companies develop improvements that make treatment easier and more effective for patients, such as extended-release formulations or converting lengthy infusions to simple injections.

The scale of this innovation is significant: between 2008-2018, roughly three-quarters of oncology drugs secured at least one additional FDA-approved use beyond their initial indication (Lietzan & Acri, 2020). Far from being strategic patenting gimmicks, these advances are often lifesaving – a new combination therapy or safer variant can dramatically improve outcomes (Lietzan & Acri, 2020; Holman, 2017; Roin, 2014). Without the ability to patent follow-on innovations, companies would have far less incentive to invest in finding new uses or improvements for existing drugs.

Patent quality and scope

Each patent must meet rigorous standards of novelty and genuine inventiveness. Critics often dismiss drug modifications as routine chemistry, but this oversimplifies complex innovation and the investments that are required to deliver it. If changes aren't inventive, they don't deserve patents, and they won't get them because patent offices screen patent applications for inventiveness. If they're inventive but trivial, they pose minimal barriers to generic competition (Holman, 2017). Many modifications, however, are both inventive and significant.

Consider Plavix, an important blood thinner. It was invented by researchers using methods that were themselves well known but whose outcomes were far from predictable. A generic manufacturer challenged Plavix's patents in more than one jurisdiction, claiming they were not inventive because of the familiarity of the technique used in research – ignoring the clear inventiveness of the drugs thereby created. Courts in multiple jurisdictions upheld these patents, recognizing that inventiveness lies in the results achieved, not the methods used (Holman, 2017). Scientists had to engage in substantial experimentation to achieve this rare and unexpected result.

Patient-centered improvement: From infusion to injection

One example of valuable innovation is reformulating medicines to improve how patients receive them. Many biologic drugs initially require lengthy intravenous infusions at clinics or hospitals. Companies therefore have developed subcutaneous injection versions that patients can receive in minutes in a doctor's office or at home.

These patented innovations have been dismissed as trivial or unneeded by critics. This criticism overlooks both the science and the tremendous benefits to patients.

For patients, infusion days can be physically and emotionally taxing – traveling to infusion centers, sitting uncomfortably for hours, and coping with side effects. The process disrupts work schedules and burdens caregivers.

In contrast, subcutaneous injections offer a faster, less invasive alternative. For the breast cancer drug trastuzumab, a 5-minute subcutaneous injection proved just as effective as the IV formulation – and was preferred by over 80% of patients (Pivot et al., 2017).

The simplicity gave patients greater autonomy and reduced the sense of being "tied to a treatment chair." In some instances, the subcutaneous form can reduce the reactions experienced with infusion. These innovations aren't cosmetic conveniences – they improve patients' lives in tangible, measurable ways.

These innovations also aren't trivial scientifically. Reformulating large molecules for concentrated injection presents significant technical challenges compared to IV delivery, requiring research and innovation to solve. Importantly, patents on these improvements protect the specific innovation without blocking generic versions of the original formulation, supporting both innovation and generic competition.

The bottom line

Multiple patents typically reflect cumulative innovation driven by patient needs, not abuse of the patent system. Each represents an advance in the complex process of developing and improving modern medicines. In a world of increasingly complex science and healthcare, such patents ensure that innovators can keep investing to solve problems for patients, step by step.

References

DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics, 47, 20-33. https://doi.org/10.1016/j.jhealeco.2016.01.012

Feldman, R. (2018). May your drug price be evergreen. Journal of Law and the Biosciences, 5(3), 590-647.

Goode R, Chao B. (2022). Biological patent thickets and delayed access to biosimilars, an American problem. J Law Biosci. 9(2),1-24.

Gurgula, O. (2017). Strategic Accumulation of Patents in the Pharmaceutical Industry and Patent Thickets in Complex Technologies – Two Different Concepts Sharing Similar Features. IIC – International Review of Intellectual Property and Competition Law. 48, 385–404.

Harrison, R. K. (2016). Phase II and phase III failures: 2013-2015. Nature Reviews Drug Discovery, 15(12), 817-818. https://doi.org/10.1038/nrd.2016.184

Hay, M., Thomas, D. W., Craighead, J. L., Economides, C., & Rosenthal, J. (2014). Clinical development success rates for investigational drugs. Nature Biotechnology, 32(1), 40-51. https://doi.org/10.1038/nbt.2786

Holman, C. M. (2017). In defense of secondary pharmaceutical patents: A response to the UN's guidelines for pharmaceutical patent examination. Indiana Law Review, 50(3), 759-801. https://doi.org/10.18060/4806.1153

Lietzan, E. (2019). The "evergreening" metaphor in intellectual property scholarship. Akron Law Review, 53(3), 805-871.

Lietzan, E., & Acri, K. M. L. (2020). Distorted drug patents. Washington Law Review, 95, 1317-1385.

Pivot, X., Spano, J. P., Espié, M., Cottu, P., Jouannaud, C., Pottier, V., Moreau, L., Vie, J. M., Piprot, C., Romieu, G., Serin, D., Dohollou, N., Hardy-Bessard, A. C., Bachelot, T., Jouannaud, C., Arnaud, A., Mouret-Reynier, M. A., Leheurteur, M., & Fumoleau, P. (2017). Patients' preference of trastuzumab administration (subcutaneous versus intravenous) in HER2-positive metastatic breast cancer: Results of the randomised MetaspHer study. European Journal of Cancer, 82, 230-236.

Roin, B. N. (2014). Solving the problem of new uses for existing drugs. Working Paper. http://nrs.harvard.edu/urn-3:HUL.InstRepos:11189865.

Sun, D. (2022, February 23). 90% of drugs fail clinical trials -- here's one way researchers can select better drug candidates. The Conversation. https://theconversation.com/90-of-drugs-fail-clinical-trials-heres-one-way-researchers-can-select-better-drug-candidates-175443

Pharmaceutical "Patent Thickets"

Are biopharmaceutical companies getting too many patents?

Myth

Critics allege that biopharmaceutical innovators are obtaining excessive numbers of patents as part of a strategy to thwart generic market entry. They claim that these large numbers intimidate and deter potential generic competitors from challenging patents, delaying or preventing them from entering the market. Ultimately, critics see multiple patents on drugs as a barrier to generic entry – an "overpatented, overpriced" scheme that keeps drug prices high (I-MAK, 2023).

Reality

Patent counts do not predict market exclusivity

Patent counting tells us nothing about generic competition. Studies that simply count patents (like some often-cited advocacy reports) fail to account for the reality that the mere existence of potentially related patents may have no bearing on generic entry. Analyses by researchers found no significant correlation between the number of patents on a drug and the time to generic competition (Morris & Kresh, 2024; USPTO, 2024). In practice, generic drug makers focus on the few truly blocking patents and find ways past the rest.

Despite claims of ever-greater obstacles to generic entry, the timing of generic entry has remained the same for decades. The average effective market exclusivity period, that is, the time from a drug's approval to first generic entry, remains about 13-14 years, essentially unchanged from decades past (Grabowski et al., 2021; Lietzan & Acri, 2023). This is a far cry from the decades-long monopolies alleged under theories of "evergreening" and other claimed abuses of the patent system.

In the U.S. market, 90% of all prescriptions are now filled with generics, up from 19% in 1984 (FDA, 2022; AAM, 2021). This demonstrates that robust generic market entry arrives for nearly every successful drug.

How patent counting goes wrong

The fundamental problems with patent counting become clear when we examine the questionable methodologies used in specific, prominent examples. For example, a 2018 study based on the U.C. San Francisco database counts a patent on an intravenous form of ibuprofen as extending exclusivity on this common, over-the-counter drug until 2032 (UC Law SF, 2018; Feldman, 2018). The same study counted aspirin – off patent since 1917 – as under patent until 2033, due to a patent on a combination pill. This is clearly incorrect. These common drugs have been available as over-the-counter generics for many decades, a fact encountered by consumers every day. And these aren't isolated errors; they're simply the most obvious ones.

The number of patents with some connection to a medicine also reveals far less than many believe. Not all patents are the same; one patent may have 20 distinct claims, while five related patents with a single claim might collectively cover similar scope. What matters is whether any given patent actually blocks a generic manufacturer from entering the market. Many later-filed patents (for formulations, specific uses, etc.) do not block a generic version of the original drug.

For example, a patent on an extended-release tablet doesn't stop a generic from selling an immediate-release version of the same medicine. A patent on a new therapeutic use can be "carved out" of the generic's labeling so the generic can still launch for all other uses. Patents on manufacturing processes or delivery devices can often be designed around by competitors (Freilich & Kesselheim, 2025).

The shortcomings of patent counting become even clearer when we examine the industry in broader context compared to others.

Pharmaceutical patenting is modest compared to other industries

The conversation about "excessive" pharmaceutical patenting lacks essential context. While critics focus on drug patents in isolation, cross-industry comparisons reveal a different picture. A TaylorMade golf club is protected by over 260 patents, a Fitbit fitness tracker by 528 patents, and even Philadelphia Cream Cheese is covered by seven patents (TaylorMade, 2025; Fitbit, 2024; Kraft, 2022). Yet these businesses face no accusations of creating "patent thickets."

The pharmaceutical industry's restrained approach becomes clear when examining patent intensity systematically across all industries. In the USPTO's ranking of patent-intensive industries, pharmaceuticals rank 9th, behind financial services, computer hardware, semiconductors, and software (USPTO Supp., 2022). The patent intensity score for biopharma (67.77) is roughly one-third that of computer hardware (191.35) and semiconductors (184.01).

When adjusted for research spending, pharmaceutical companies obtain approximately 0.05 patents per million R&D dollars, compared to roughly 0.5 patents per million R&D spend for other patenting companies – a tenfold difference (BIO, 2023; Shackelford, 2013). Pharma firms invest vastly more in R&D for each patent they receive. They rely on a few high-value patents to secure large investments, whereas other industries generate far more patents per investment dollar.

Moreover, few pharmaceutical companies appear among the ranks of top patent grantees. The Intellectual Property Owners Association (IPO) releases an annual list of the top 300 organizations awarded U.S. utility patents (IPO, 2024). For 2024, of those 300 companies, only 7 were pharmaceutical companies – about 2.3%. Technology companies dominated the list, with 104 companies. The combined number of patents granted to the 7 pharmaceutical companies, 3174, was about a third of the number granted to just the top patentee, Samsung, which had 9304 patents granted.

The recently announced results of a USPTO study reinforce these findings. (USPTO, 2025). Contrary to critics' allegations about pharmaceutical "patent thickets," the study found that large patent families are significantly less common in biopharma than in other industries. In one sample of large patent families analyzed for the study, only 1.3% of large patent families were found in pharmaceutical applications, while 55.5% were concentrated in electrical technologies such as computer networks and semiconductors.

The study was specifically designed to investigate concerns about pharmaceutical patent thickets, making its findings particularly noteworthy. Rather than confirming allegations of excessive pharmaceutical patenting, the USPTO data revealed that biopharma companies are actually more restrained in their patenting practices compared to other high-tech industries. These results indicate that targeting pharmaceutical innovation with the "patent thicket" narrative is fundamentally misplaced.

What the Orange Book actually shows

One way to get a clear picture of the number of patents on pharmaceuticals is to consult the U.S. FDA's "Orange Book," where drug innovators must list patents on small molecule drugs that could reasonably block generic competition. Companies have strong incentives to list relevant patents because doing so can trigger an automatic 30-month stay in generic approval if a listed patent

is challenged in court. This makes the Orange Book the authoritative source for patents that actually matter for generic entry.

According to a comprehensive study by Darrow & Mai (2022) of all Orange Book listings in 2022:

61.4% of drugs no longer have any patents listed, reminding us that all patents expire and the innovative sector provides the pipeline to generic competition. Every generic medicine was once a patented medicine. Without patents to secure investment in drug development, none of the generic drugs prescribed today – over 90% of all prescriptions – would exist.

Of the 39% of drugs that still had patents listed, the majority had four or fewer patents listed. The distribution was:

Number of Patents	Percentage of Patented Drugs
0 patents	61.4%
1 patent	4.2%
2 patents	9.6%
3 patents	4.7%
4 patents	3.9%
5 – 10 patents	10.9%
11 – 20 patents	4.6%
21 or more patents	0.7%

Source: Darrow & Mai (2022)

Most drugs on the market are no longer patented, and of those that are, the majority have four patents or fewer.

Biologics: More Patenting at the Frontier of Technology

While the above data focuses on small molecule drugs, biologics – a different, relatively recent class of medicines – deserve separate consideration given critics' particular focus on their larger patent portfolios. This difference isn't evidence of strategic over-patenting. Rather, it reflects the broader scope and depth of innovation required to develop these frontier technologies (Evens & Kaitin, 2015).

Biologic drugs rely on cutting-edge science and new technology at every stage of their development, as a therapy moves from laboratory discovery through clinical development to commercialization. Unlike small molecule drugs typified by chemical compounds administered via pills, biologics must be engineered in living systems, requiring advanced methods in genomics, cell culture, and biotechnology.

Eculizumab (Soliris) illustrates why biologics are becoming increasingly prominent and why they represent a revolutionary advance. Before this monoclonal antibody treatment, patients with rare blood disorders like paroxysmal nocturnal hemoglobinuria faced frequent transfusions and had a median survival of just 10-15 years. After Soliris became available, many patients achieved transfusion independence, reporting dramatically improved outcomes and greater quality of life. This transformation was possible because the drug's complex protein structure enables selective immune modulation that small molecules simply cannot achieve.

Why biologics require more innovation

Cutting-edge technology platforms: Since the first monoclonal antibodies were approved in 1986, new biologic platforms have multiplied rapidly. As of 2024, Boston Consulting Group identified 18 different types of biologic technologies across six categories: antibodies, proteins and peptides, cell therapies, gene therapies, nucleic acids, and other new modalities (Chen et al., 2024). Unlike well-established chemical synthesis methods for small molecules, these cutting-edge platforms require innovation – and patents to secure investments – from the ground up.

Manufacturing complexity: For biologics, "the process defines the product" (Vulto & Jaquez, 2017). In other words, how a biologic is made is inseparable from what it is. Unlike small molecules that enter clinical trials with largely well-established manufacturing processes, biologics often begin human testing with preliminary and evolving manufacturing methods.

Companies must innovate not just in the product itself, but in manufacturing, developing entirely new tools, purification techniques, and stability solutions. Fundamental innovations in both product design and manufacturing continue throughout development, naturally generating additional patents. These aren't peripheral add-ons. They are essential to ensuring product efficacy, quality, and regulatory approval.

Specialized delivery: Most biologics cannot be taken orally. They require sophisticated delivery systems and mechanisms for reaching cellular targets, each representing a distinct scientific advance that may warrant its own patent.

Biologics patent numbers in perspective

Critics often attribute vast patent estates to biologics, counting dozens or hundreds of patents. However, the key question is which patents matter for biosimilar entry. A comprehensive analysis of litigation under the U.S. Biologics Price Competition and Innovation Act found that an average of 17 patents had been asserted in biosimilar cases through 2024 (Wu, 2024). Considering the breadth of innovation required – from cutting-edge technology platforms to complex manufacturing processes – these numbers reflect invention in the face of genuine technological complexity rather than strategic over-patenting.

Ultimately, the challenges of developing a competing biosimilar drug are far more about science, technical capabilities, expense, and regulatory requirements than innovator patents. Biosimilars are "similar" because there is no way to make them identical to the original. The nature of the process and science make simple duplication impossible. Therefore, more research and testing are required, with a 5 to 9-year timeline and a $100 million price tag (IQVIA, 2025).

The bottom line

Evidence shows that the foundations supporting the thicket narrative are false. In fact:

- Patent numbers have little correlation with market exclusivity,
- Generics routinely navigate innovator patents and enter the market, and
- Pharmaceutical patenting is moderate compared to other industries.

Each patent represents a solution to a specific problem in developing medicines that work for patients.

Rather than focusing on arbitrary patent counts, policy discussions should consider whether the patent system is achieving its fundamental purpose: incentivizing investment in solving medical challenges. By this measure, the system is working well. Pharmaceutical innovation continues to address unmet medical needs, while generic prescriptions have grown over time, and generics have continued to enter the market within the same timeframe as they have for decades.

References

Association for Accessible Medicines (AAM). (2021). 2021 U.S. Generic & Biosimilar Medicines Savings Report. AAM.

Biotechnology Innovation Organization (BIO). (2023, February 1). Comments in Response to USPTO Request for Comments on Robust and Reliable Patent Rights. Docket PTO-P-2022-0025.

Chen, Lu, et al. (2024). New Drug Modalities Report 2024. Boston Consulting Group. https://www.bcg.com/publications/2024/new-drug-modalities-report

Darrow, J. J., & Mai, D. T. C. (2022). An Orange Book landscape: Drugs, patents, and generic competition. Food and Drug Law Journal, 77(1), 51-73.

European Patent Office & European Union Intellectual Property Office (EPO/EUIPO). (2022). IPR-intensive industries and economic performance in the European Union.

Evens, R. P., & Kaitin, K. I. (2015). The evolution of biotechnology and its impact on health care. Health Affairs, 34(2), 210-219. https://doi.org/10.1377/hlthaff.2014.1114

Feldman, R. (2018). May your drug price be evergreen. Journal of Law and the Biosciences, 5(3), 590-647.

Fitbit. (2024). Fitbit Patent List. https://support.google.com/product-documentation/answer/15146514

Food and Drug Administration (FDA). (2022). Overview: Generic Drug Program Annual Statistics. FDA.

Freilich, J. and Kesselheim, A.S. (2025). Frequency and Nature of Generic "Design Around" of Brand-Name Patents in the United States. Clin Pharmacol Ther, 118: 190-194.

Grabowski, H., Long, G., & Mortimer, R. (2021). Continuing trends in U.S. brand-name and generic drug competition. Journal of Medical Economics, 24(1), 908-917.

Initiative for Medicines, Access & Knowledge (I-MAK). (2023). Overpatented, Overpriced (Updated Report).

Intellectual Property Owners. (2025). Top 300 Organizations Granted U.S. Patents in 2024. https://ipo.org/wp-content/uploads/2025/01/2024-Top-300-Patent-Owners-List.pdf

IQVIA. (2025). Assessing the Biosimilar Void in the U.S.: Achieving Sustainable Levels of Biosimilar Competition. The IQVIA Institute. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/assessing-the-biosimilar-void-in-the-us

Kraft, Inc. (2022). Philadelphia Cream Cheese Patents. https://www.kraftheinzcompany.com/pdf/VirtualPatentMarking_Philadelphia_12.5.22.pdf

Lietzan, E., & Acri, K. M. L. (2023). Solutions still searching for a problem: A call for relevant data to support "evergreening" allegations. Fordham Intellectual Property, Media & Entertainment Law Journal, 33(4), 788-845.

Morris, E. M., & Kresh, J. (2024). Pharmaceutical "Nominal Patent Life" Versus "Effective Patent Life," Revisited. Center for Intellectual Property x Innovation Policy, George Mason University.

Shackelford, B. (2013). InfoBrief: One in Five U.S. Businesses with R&D Applied for a U.S. Patent in 2008. National Center for Science Engineering and Statistics.

TaylorMade. (2025). TaylorMade Golf Patents. https://www.taylormadegolf.com/about-us/pat.html?lang=en_US

Tu, S. S., Kesselheim, A. S., Wetherbee, K., & Feldman, W. B. (2023). Changes in the Number of Continuation Patents on Drugs Approved by the FDA. JAMA, 330(5), 469-470.

United States Patent and Trademark Office (USPTO). (2022). Intellectual Property and the U.S. Economy: Third Edition.

United States Patent and Trademark Office (USPTO). (2024). Drug and Patent Exclusivity Study.

United States Patent and Trademark Office. (2025). USPTO Hour: Studying applications with large patent families, June 4, 2025, https://www.uspto.gov/about-us/events/uspto-hour-patent-initiatives-requested-congress#:~:text=Join%20us%20on%20Wednesday%2C%20June%204%2C%20from,on%20studying%20applications%20with%20large%20patent%20families. The study has not yet been published – the results were announced in a recorded webinar and slide deck made available at USPTO Hour. Key points discussed here are found in the discussion beginning at 11:30 in the recording and in the slides at pp. 6-7 comparing pharma applications with applications in USPTO Technology Centers 2400 and 2800).

United States Patent and Trademark Office (USPTO Supp.). (2022). IP-Intensive Industries in the U.S. Economy: Supplemental Materials.

University of California, San Francisco (UCSF). (2018). UCSF-UC Hastings Consortium Evergreening Database.

Vulto, A. G., & Jaquez, O. A. (2017). The process defines the product: What really matters in biosimilar design and production? Rheumatology, 56(4), iv14-iv29. https://doi.org/10.1093/rheumatology/kex278

Wu, H. & Siekman, M. (2024). Are Reference Product Sponsors Asserting More Patents in BPCIA Litigation? Goodwin's Guide to Biosimilars Litigation and Regulation in the U.S. https://www.bigmoleculewatch.com/2024/12/31/are-reference-product-sponsors-asserting-more-patents-in-bpcia-litigation/

Pharmaceutical "Patent Thickets"

Do multiple patents on drugs impede generic competition?

Myth

Critics contend that multiple patents on a drug create impenetrable "patent thickets" that block generic entry. These purported webs of later-filed patents allegedly deter or delay generic manufacturers from challenging innovator's patents and entering the market, costing patients billions in potential savings.

Reality

The marketplace tells a different story

If patent "thickets" truly blocked competition, we would expect to see extended periods of innovator exclusivity and declining generic market share. The evidence shows precisely the opposite.

The market exclusivity period of brand-name drugs has remained stable at 13-14 years for decades (Grabowski et al., 2021). This consistency directly contradicts allegations that multiple patents significantly extend market exclusivity beyond appropriate timeframes.

Meanwhile, generic drugs now account for approximately 90% of all prescriptions dispensed in the United States – up from just 13% when the Hatch-Waxman Act was enacted in 1984 (FDA, 2022; Boehm et al., 2016). This dramatic increase in generic utilization has occurred during the same period critics claim patent thickets have proliferated.

A comprehensive study examining all prescription drugs listed in the Orange Book found that only 39% had any patent protection remaining as of 2022, with most of those having four or fewer patents. Only 5.3% had more than ten patents, and fewer than 1% had twenty-one or more patents (Darrow & Mai, 2022).

Even more telling, the same study revealed that 28% of generics launched while the innovator still had unexpired patents listed in the Orange Book. This fact is evidence that not every related patent presents an absolute barrier, as critics claim.

The term "patent thicket" is not a technical description but a loaded metaphor that mischaracterizes what the evidence shows: multiple patents do not unduly complicate or delay generic competition.

Generic manufacturers are sophisticated market players

Generic pharmaceutical companies are anything but helpless victims in the patent system. They are often large, sophisticated players with litigation dockets typically larger than those of innovator companies, reflecting a business model centered on challenging patents (Lietzan & Acri, 2023; Hemphill & Lemley, 2011).

In the United States, the Hatch-Waxman Act encourages generic companies to challenge patents by awarding a valuable bounty to the first to succeed in invalidating the patents on a drug. The successful challenger gets 180 days as the exclusive generic – essentially, a chance to be part of a potential duopoly with the innovator, which can allow both to maintain higher prices. This exclusivity can be worth hundreds of millions of dollars.

Far from being deterred by large patent portfolios, leading generic manufacturers – often referred to as "first filers" – are among the most sophisticated and persistent litigants in the pharmaceutical sector. Companies such as Teva, Mylan (now Viatris), Sandoz, and Apotex have built internal legal and regulatory teams that specialize in identifying vulnerable patents, preparing filings to challenge them, and navigating complex litigation under the Hatch-Waxman Act. Patent litigation is a core business strategy for first filers, not a defensive action. They routinely initiate dozens of simultaneous lawsuits across a portfolio of brand-name drugs. They also file administrative challenges to the validity of patents using post-grant review proceedings at the U.S. Patent Trial and Appeal Board.

In contrast, innovator companies tend to defend a smaller number of products, and they generally litigate only when a specific challenge is mounted against a key asset. Once a successful brand-name drug becomes eligible for challenge – typically four years after FDA approval under Hatch-Waxman – it is not unusual for the innovator to face a flood of challenges from different generic challengers almost simultaneously (Grabowski et al., 2021). The Hatch-Waxman framework reinforces this asymmetry: the 180-day exclusivity granted to first filers (21 U.S.C. § 355(j)(5)(B)(iv)) rewards aggressive litigation, particularly by firms with specialized legal capacity. In practice, the presence of a large patent estate does not deter these challengers. Additionally, the first-filer reward remains the same regardless of how many patents are challenged.

This framework – which does not apply to patents in any other field of technology – has substantially increased challenges to small molecule drug patents. The average time from a brand drug's launch to the first generic challenge plummeted from nearly 19 years in the mid-1990s to about 6 years today. Over 80% of new drugs now face patent challenges, compared to just 9% in the 1980s (Grabowski et al., 2021). Far from waiting for alleged patent thickets to clear, generic companies are actively challenging patents earlier and more frequently than ever before. With this intense scrutiny, any potential weakness in a patent or patent portfolio is likely to be exposed.

Not all patents are created equal

A key misconception in the "patent thicket" narrative is that every patent functions to prevent generic entry. In reality, patents vary widely in scope and vulnerability, and generic companies strategically focus on those that genuinely matter.

A recent, comprehensive study by the USPTO of pharmaceutical patents found a range of 1 to 27 Orange Book-listed patents associated with each of the 25 New Drug Applications (NDAs) they examined. However, they emphasized that "not every patent listed in the Orange Book has the same scope, and therefore the impact of each listed patent on the timing of approval and launch of a generic drug product can vary" (USPTO, 2022). This statement is borne out by the results of this study: the USPTO found that generic versions for many drugs entered the market despite the fact that the drugs had patents still in force.

Generic manufacturers rarely need to invalidate every potentially relevant patent. Instead, they rely on their scientific and regulatory acumen to routinely navigate around patents through various means (Freilich & Kesselheim, 2025):

- If a patent covers a specific formulation, a generic can create a bioequivalent alternative that avoids the patented features.
- If a patent protects a particular approved use, generics can use a "skinny label" that carves out that protected indication.
- If a patent covers a specific crystalline form (polymorph), generics can develop an alternative stable form through different synthetic routes.

Research by Beall et al. (2018) found a striking difference in actual market exclusivity in relation to different types of patents. Drugs with active ingredient patents had a median actual market exclusivity of 13 years, which closely matched predictions based on patent term. However, for drugs protected only by other types of patents, the median actual market exclusivity was 8.25 years – significantly shorter than the average remaining term of these patents, due to the much narrower scope of these patents. This outcome underlines

that non-compound patents (often characterized as creating "thickets") are much less of a hindrance to generic entry than critics claim.

Later-filed patents have less impact on generic entry

Similarly, the USPTO study concluded that "continuing innovation of a marketed drug, which results in follow-on patents...rarely resulted in extended market exclusivity for the product beyond the expiration of the earlier patent(s)" (USPTO, 2024). Even for new chemical entities with additional, later-filed patents, generic versions emerged on average 13-14 years after approval – consistent with decades of historical data.

Furthermore, many later-filed patents have limited blocking power:

- "Continuation" patents reuse the same original disclosure to pursue additional or refined claims and expire on the same date as the original patent (Hickey, 2022).
- Patents on new uses can be circumvented through "skinny labels".
- Some patents include "terminal disclaimers" that tie their expiration to earlier patents (USPTO, 2024).
- And, as noted above, later-filed patents tend to be narrower in scope and cover only improvements on a drug product rather than its original formulation.

Darrow & Mai (2022) examined all prescription drugs listed in the Orange Book and found that 32% of drugs for which all patents had expired nonetheless faced no applications to approve a generic version – further evidence that factors beyond patents significantly influence the timing of generic competition.

The proof is in the marketplace

The strongest evidence against the "patent thicket" narrative comes from actual market outcomes. If patent thickets were truly blocking generic competition, we would expect to see declining generic market share and extended periods of brand exclusivity over time. The data shows the opposite.

Generic drugs now account for about 90% of all prescriptions dispensed in the United States (AAM, 2023). Meanwhile, the market exclusivity period remains steady at around 13 years (Grabowski et al., 2021).

The comprehensive Darrow & Mai study (2022) revealed that only a small share of drugs currently approved by the FDA have patents still in force; of those that do, most are associated with small numbers of patents. Only 31% had any patent at all – and most of those had four or fewer. Only about one in ten (9.6%) had more than ten patents, and fewer than 1% had twenty-one or more patents.

These findings directly contradict claims about widespread patent thickets blocking competition. Even for complex drugs with numerous patents, competition emerges – and sometimes much sooner than predicted.

The bottom line

The "patent thicket" narrative does not align with market reality. Generic manufacturers have robust legal tools, scientific expertise, and strong financial incentives to challenge patents and bring competition to market. The 13 to 14-year market exclusivity period for brand drugs has remained consistent for decades, demonstrating that multiple patents do not block generic competition or unduly extend market exclusivity for brand drugs.

The 90% generic utilization rate and steady flow of generic approvals reveal a system that successfully balances innovation incentives with robust competition. The current framework has delivered both innovative new medicines and timely access to affordable generics.

References

Association for Accessible Medicines (AAM). (2023). 2023 U.S. generic & biosimilar medicines savings report. AAM.

Beall, R. F., Darrow, J. J., & Kesselheim, A. S. (2018). A method for approximating future entry of generic drugs. Value in Health, 21(10), 1382-1389.

Boehm, G., Yao, L., Han, L., & Zheng, Q. (2016). Development of the generic drug industry in the US after the Hatch-Waxman Act of 1984. JAMA Internal Medicine, 176(6), 858-860.

Darrow, J. J., & Mai, D. T. C. (2022). An Orange Book landscape: Drugs, patents, and generic competition. Food and Drug Law Journal, 77(1), 51-73.

FDA. (2022). Overview: Generic drug program annual statistics. United States Food and Drug Administration.

Freilich, J. and Kesselheim, A.S. (2025). Frequency and Nature of Generic "Design Around" of Brand-Name Patents in the United States. Clin Pharmacol Ther, 118: 190-194.

Grabowski, H., Long, G., & Mortimer, R. (2021). Continuing trends in U.S. brand-name and generic drug competition. Journal of Medical Economics, 24(1), 908-917.

Hemphill, C. S., & Lemley, M. A. (2011). Earning exclusivity: Generic drug incentives and the Hatch-Waxman Act. Antitrust Law Journal, 77(3), 947-989.

Hemphill, C. S., & Sampat, B. N. (2012). Evergreening, patent challenges, and effective market life in pharmaceuticals. Journal of Health Economics, 31(2), 327-339.

Hickey, K. J. (2022). Terminal disclaimers of patent rights: Background and issues for Congress. Congressional Research Service.

Lietzan, E., & Acri, K. M. L. (2023). Solutions still searching for a problem: A call for relevant data to support 'evergreening' allegations. Fordham Intellectual Property, Media & Entertainment Law Journal, 33, 788-873.

Memedovich A, et al. (2025). Predicting patent challenges for small-molecule drugs: A cross-sectional study. PLoS Med 22(2): e1004540.Morris, E. M., & Kresh, J. (2024). Pharmaceutical "nominal patent life" versus "effective patent life," revisited. C-IP2 Blog, May 20, 2024.

USPTO. (2022). USPTO drug patent and exclusivity study: Report to Congress. United States Patent and Trademark Office.

Pharmaceutical "Patent Thickets"

Should policymakers limit the number of drug patents that biopharma innovators can obtain or assert?

Myth

To combat the perceived problem of patent "thickets," some legislators, academics, and advocates have called for drastic patent reform in recent years. Typically, they call for limits, or "caps", on the number of patents on a drug that an innovator can obtain or assert. Some have even suggested that patent protection for medicines should be limited to a single patent. Others have argued for increased antitrust scrutiny for later-filed patents.

Critics contend that limiting the number of patents would force companies to focus on truly new drug products – rather than patenting improvements on existing products – thus ensuring that generic copies arrive sooner. In this view, later-filed additional patents on a drug are suspect, and strong limits on these patents could be the solution to high drug prices.

Reality

Limits on the number of patents an innovator can get or assert would be a "cure" worse than any alleged problem. Such a blunt policy is misaligned with how pharmaceutical innovation works and would likely be counterproductive to increasing competition, access, and patient welfare. It would undermine the very incentives that drive companies to invest in improvements to existing therapies, without leading to faster generic launches.

Rather than promoting competition, such limits and skeptical scrutiny would likely impede the development of new medicines and of improvements to existing drugs. Some drugs would never be developed, as innovators would run out of their quota of patentable inventions before solving all the problems that cause the vast majority of drug candidates to fail. Other beneficial improvements such as expansions to new patient populations and versions of drugs that work better for patients would never occur.

Advocates of limiting patents fundamentally misunderstand pharmaceutical innovation

Medicines are not discovered in their final form. Each drug administered to a patient represents a series of inventions that solve specific scientific challenges. Patent caps artificially truncate this innovation process by declaring that only some subset of the patents on these inventions is legitimate or can be asserted in litigation. Such proposals are based on a fundamental misunderstanding of how drug development works (Lietzan, 2019; Holman, 2017).

When a company develops a promising compound into a medicine, it must solve numerous problems: How can we make this stable enough for storage? How can we formulate it to be safely absorbed, metabolized, and excreted? How can we manufacture it consistently at scale? How can we expand its use to benefit larger patient groups? Each solution represents genuine innovation worthy of protection, not strategic gaming (Morris & Kresh, 2024; Holman, 2017; USPTO, 2024).

Limiting the patents that an innovator can obtain or assert on each medicine might discourage investments in later improvements. Depending on how the policy is implemented, it could cause some drug development to end prematurely and unsuccessfully due to reaching a "limit" on enforceable patents.

Drug costs are a legitimate concern. But as the Congressional Budget Office has observed, policies that substantially reduce industry revenues would also likely reduce the number of new drugs introduced in the future (CBO, 2024). Effective policy considers the unmet needs of patients for new and improved cures rather than just the immediate pressures of healthcare budgets.

Limiting pharmaceutical patenting would discourage valuable improvements to medicines

Limiting pharmaceutical patenting would create perverse incentives that harm patients. If innovators know they can obtain or assert only a limited number of patents, they will be forced to make calculated decisions about whether to invest in additional R&D to further develop or improve a drug. If that investment cannot be protected by patents, then both the investment and the potential inventions it produces will not happen. This would thwart valuable improvements, much needed by society (Roin, 2014), that could benefit patients but might not make the cut under an arbitrary limit on patenting.

Consider improved formulations that reduce side effects, new delivery systems that enhance convenience, and additional disease indications that expand treatment options. Each requires substantial R&D and costly clinical trials – efforts that companies undertake because patents can make them financially viable. Under limits on patenting, the reality is that many improvements simply wouldn't happen (Lietzan & Acri, 2020).

A clear example is the case of Allergan's glaucoma drug Lumigan (bimatoprost). The initial version was effective but caused severe side effects (red eyes) that led many patients to discontinue treatment. Allergan scientists developed a reformulation with far fewer side effects, dramatically improving patient adherence (ITIF, 2025). This kind of follow-on innovation would be jeopardized by limits on patents.

Similarly, new uses for existing drugs often emerge years after initial approval and rely on patent protection to justify necessary trials. Approximately 65% of oncology drugs approved between 2008 and 2018 gained one or more additional FDA-approved uses in subsequent years (Patterson et al., 2024). Without adequate protection for these subsequent innovations, companies might never pursue them, leaving patients without important therapeutic options.

Patent caps address a problem that evidence shows doesn't exist

Evidence does not demonstrate that multiple patents on a drug block generic competition. Generic manufacturers routinely navigate patent landscapes to bring competition to market on a predictable timeline. Indeed, generic drugs now account for approximately 90% of all prescriptions dispensed in the United States, up from just 13% in 1984 (FDA, 2022; Boehm et al., 2016).

A comprehensive study found no significant correlation between the number of patents on a drug and the timing of generic entry (Morris & Kresh, 2024). This directly contradicts the core premise behind patent caps – that multiple patents complicate and unduly delay competition. The average effective market exclusivity period has remained steady at 13-14 years for decades (Grabowski et al., 2021; Lietzan & Acri, 2023).

The bottom line

Patent caps would be a blunt instrument that risks sacrificing valuable medical advances in an attempt to solve a barrier to generic competition (alleged patent thickets) that evidence shows doesn't exist. Virtually every major drug in use today has benefited from follow-on innovation – from insulin formulations that last longer, to HIV therapies refined into single pills, to vaccines reformulated for enhanced safety and efficacy.

Limiting the number of patents that innovators can obtain or assert would likely trade away future health benefits without any meaningful impact on competition or pricing. Policy makers should focus on ensuring that the patent system functions as intended to reward innovation and promote progress in medicine for the benefit of patients.

References

Baker, C., Laughery, S. et al. (2024). Alternative Approaches to Reducing Prescription Drug Prices. Congressional Budget Office (CBO) Report. https://www.cbo.gov/publication/58793.

Boehm, G., Yao, L., Han, L., & Zheng, Q. (2016). Development of the generic drug industry in the US after the Hatch-Waxman Act of 1984. JAMA Internal Medicine, 176(6), 858-860.

Darrow, J. J., & Mai, D. T. C. (2022). An Orange Book landscape: Drugs, patents, and generic competition. Food and Drug Law Journal, 77(1), 51-73.

FDA. (2022). Overview: Generic drug program annual statistics. United States Food and Drug Administration.

Federal Trade Commission (FTC). (2020). Authorized generic drugs: Consumer benefits at risk. FTC Report.

Grabowski, H., Long, G., & Mortimer, R. (2021). Continuing trends in U.S. brand-name and generic drug competition. Journal of Medical Economics, 24(1), 908-917.

Holman, C. M. (2017). In defense of secondary pharmaceutical patents: A response to the UN's guidelines for pharmaceutical patent examination. Indiana Law Review, 50(3), 759-801. https://doi.org/10.18060/4806.1153

Information Technology & Innovation Foundation (ITIF). (2025). The value of follow-on biopharma innovation for health outcomes and economic growth.

Lietzan, E. (2019). The "evergreening" metaphor in intellectual property scholarship. Akron Law Review, 53(3), 805-871.

Lietzan, E., & Acri, K. M. L. (2020). Distorted drug patents. Washington Law Review, 95, 1317-1385.

Lietzan, E., & Acri, K. M. L. (2023). Solutions still searching for a problem: A call for relevant data to support 'evergreening' allegations. Fordham Intellectual Property, Media & Entertainment Law Journal, 33, 788-873.

Morris, E. M., & Kresh, J. (2024, May 20). Pharmaceutical "nominal patent life" versus "effective patent life," revisited. Center for Intellectual Property x Innovation Policy. https://cip2.gmu.edu/2024/05/20/pharmaceutical-nominal-patent-life-versus-effective-patent-life-revisited/

United States Patent and Trademark Office (USPTO). (2024). Drug and Patent Exclusivity Study.

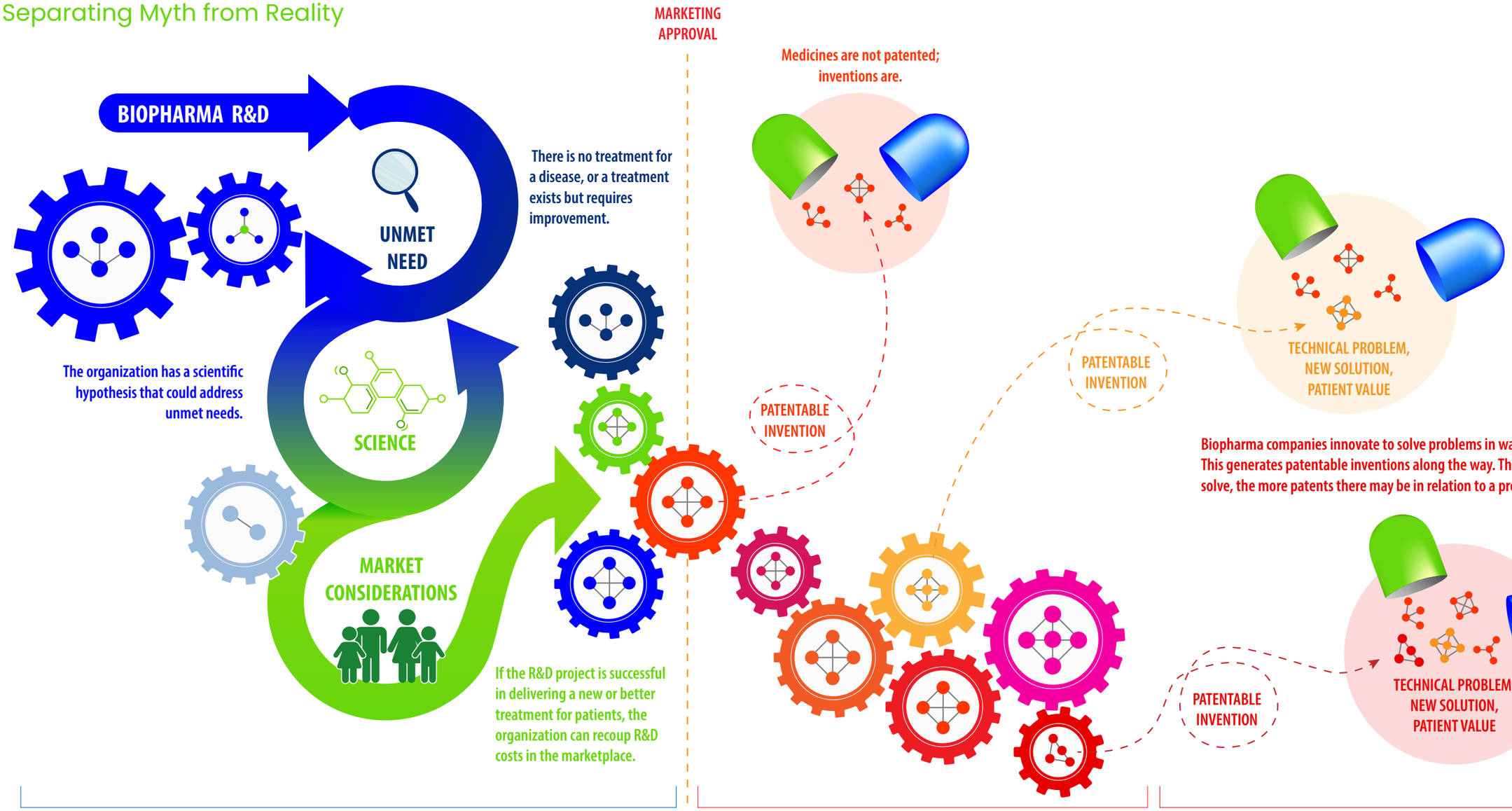
Patterson, J. A., et al. (2024). Subsequent indications in oncology drugs: Pathways, timelines, and the Inflation Reduction Act. Therapeutic Innovation & Regulatory Science.

Roin, B. N. (2014). Solving the problem of new uses for existing drugs. Harvard Journal of Law and Technology, 28(2), 1-56.

Vidal, K. (2022). USPTO initiatives to ensure the robustness and reliability of patent rights. Statement of USPTO Director Kathi Vidal, USPTO Press Release, June 2022.

Pharmaceutical "Patent Thickets"

Separating Myth from Reality



Innovative companies are not making R&D decisions based on getting patents. Decisions are made based on unmet need, science, and market considerations.

In the USPTO's ranking of patent-intensive industries, pharmaceuticals come in 9th place, behind financial services, computer hardware, semiconductors, and software.

Biopharmaceutical companies obtain approximately 0.05 patents per million R&D dollars, compared to roughly 0.5 patents per million for innovative companies in other sectors - a tenfold difference.

The patent intensity "score" for biopharma (67.77) - a measure of patents as a factor of R&D investment - is roughly one-third that of computer hardware (191.35) and semiconductors (184.01).

What people experience as a medicine or drug "product" is often a bundle of inventions.

A medicine does not appear in a single "Eureka!" moment. It emerges after a long process as scientists solve problems.

Biopharma innovators continue to invest in R&D and solve challenges even after they have identified or created the molecule. And they continue to do so even after the product is approved.

Innovation post-marketing approval delivers value for patients.

Generic entry is not impeded by multiple patents on a medicine.

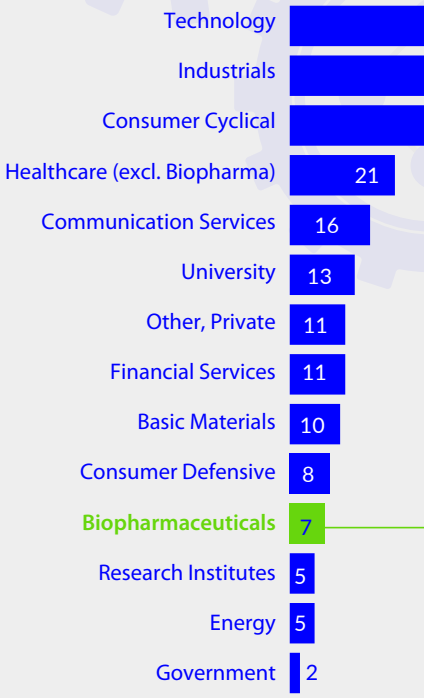
Limiting the number of patents that innovators can obtain or assert would trade away future health benefits without any meaningful impact on competition or pricing.

Policymakers should ensure that the patent system functions as intended to promote innovation and progress in medicine for the benefit of patients.

Are biopharmaceutical companies getting too many patents? No.

The top 300 organizations receiving the most US patents (2024)

Number of companies by sector



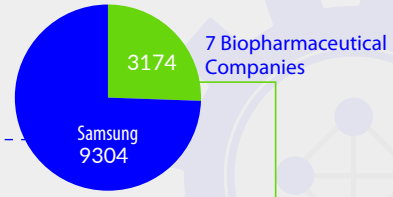
Among the top 300 patent recipients, the majority are in the high-tech sector.

Samsung was the number 1 patent recipient.

Only 7 biopharmaceutical companies (less than 3%) made the top 300 list.

FACT:

Patents granted in 2024



The 7 biopharma companies collectively received about one-third as many patents as the leading company, Samsung.[2]

FACT:

10:1

R&D intensity: Biopharmaceutical companies spent, on average, ten times more on R&D per patent received than the top patentees from other sectors.[2,3]

FACT:

Of the 39% of drugs that still have a patent, 58% have four or less patents. This is far fewer patents than on products in other sectors. [6]

TaylorMade® golf club[4]

200+

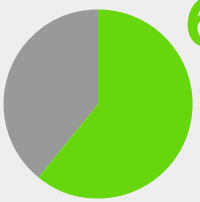
Fitbit® products[5]

528

Drugs with patents

≤4

FACT:



61 % of drugs have no patent.

90% of prescriptions in the US are filled with generics.

1. 35 U.S.C. § 102 and 35 U.S.C. § 103, https://www.uspto.gov/web/offices/pac/mpep/mpep-9015-appx-l.html#al_d1fbe1_234ed_52; USPTO Resources, MPEP. "MPEP." United States Patent and Trademark Office, www.uspto.gov/web/offices/pac/mpep/s2141.html.

2. Intellectual Property Owners Association. (2025). 2024 Top 300 Patent Owners List. Retrieved from https://ipo.org/wp-content/uploads/2025/01/2024-Top-300-Patent-Owners-List.pdf Accessed 28 July2025.

3. Sitzman, Michael, and Hans Sauer. Comments from Biotechnology Innovation Organization (BIO) in Response to the USPTO Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 1 February 2023, https://www.regulations.gov/comment/P-TO-P-2022-0025-0111. Accessed 7 November 2024.

4. TaylorMade, https://www.taylormadegolf.com/about-us/pat.html?lang=en_US. Accessed 7 November 2024.

5. Google- Fitbit products, https://support.google.com/product-documentation/answer/15146514?hl=en. Accessed 7 November 2024.

6. Darrow & Mai (2021).