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.

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