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.

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