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.

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