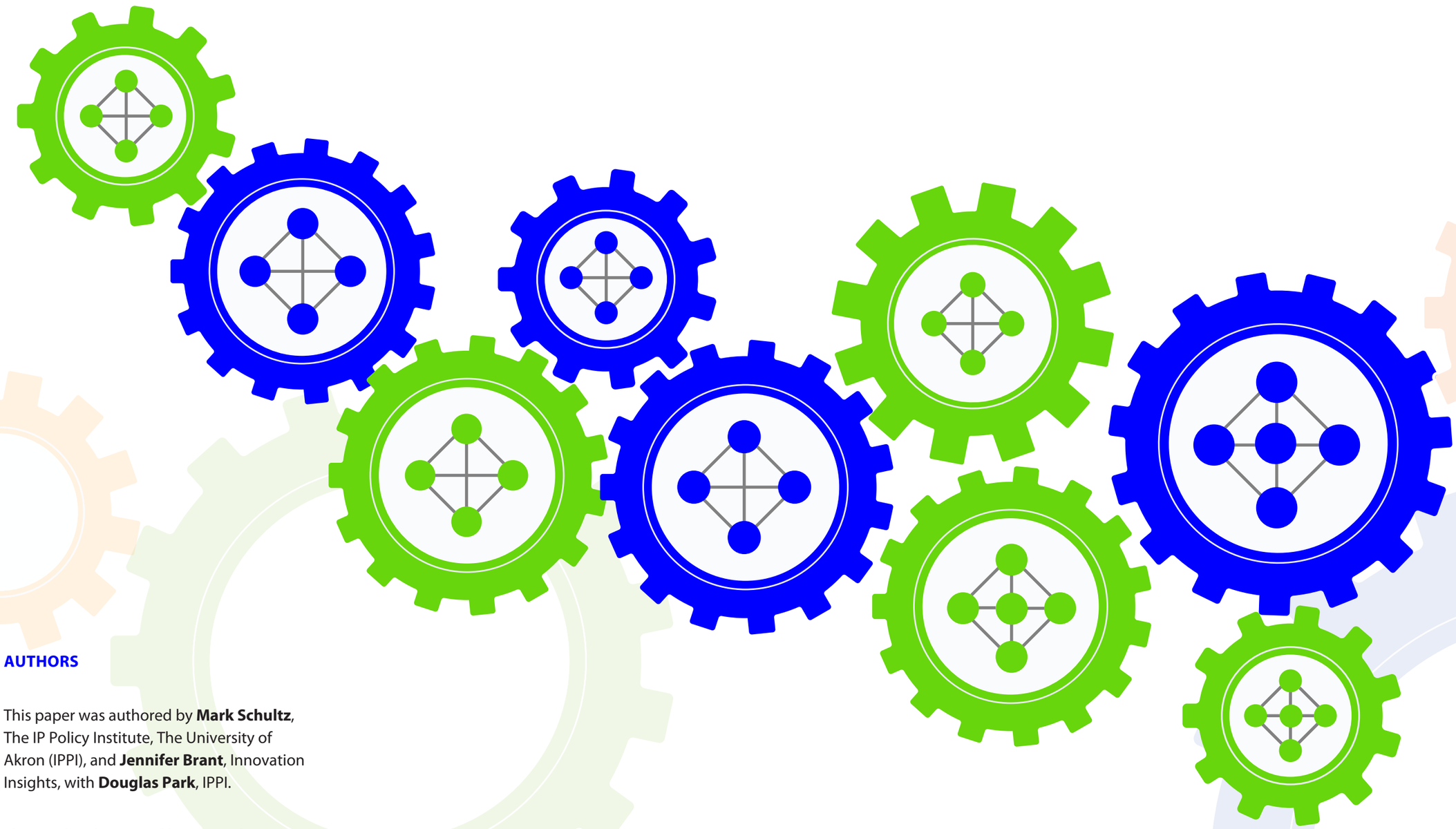
Pharmaceutical Patent "Evergreening"

Separating Myth from Reality



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Pharmaceutical Patent “Evergreening”

Key Insights

1. Beyond the patent on the original molecule, there are essentially two types of patents that cover further innovations on a pharmaceutical product: patents on innovations that occur before regulatory approval (to develop the original molecule into a safe and effective drug that can receive regulatory approval), and patents on innovations that occur after approval (to improve efficacy, user experience, patient benefits, or extend benefits to more patients).

2. Later-filed patents on improvements to existing medicines protect distinct inventions that make medicines safer, more effective, or easier to use. They can be crucial to making a compound into a workable drug, or to improving an existing medicine. These patents do not extend the original patent, and they do not block copying of the original product once its patents expire. Studies consistently find that later patents don’t delay generic entry.

3. Critics who treat every patent related to a drug as preventing entry of any generic version misinterpret how generics work. Generics copy specific approved drug products, and the effect of patents on generic entry depends only on the patents covering that specific product. Treating the initial compound patent as the only legitimate patent is like saying only the engine patent matters for a car.

4. When tested against real data, “evergreening” claims consistently fail; one study found that predictions are wrong by an average of 7 years. Despite predictions of extended monopolies, U.S. market exclusivity periods have remained stable at about 13-14 years since the 1980s.

5. Generics enter the market quickly once patents expire, benefitting from legal advantages such as abbreviated approval pathways, incentives to challenge patents, automatic substitution laws, and a patent infringement safe harbor for activities associated with regulatory approval. Today, generics now fill over 90% of U.S. prescriptions.

6. Patents expire 20 years from the filing date, save for Patent Term Adjustments (PTA) and Patent Term Extensions (PTE). These adjustments compensate for delays in patent examination and regulatory review, and they are the product of specific mathematical formulas with caps. They cannot extend patents indefinitely or repeatedly.

What is "evergreening"? Can biopharma companies use this strategy to maintain their exclusive sales beyond the original patent term of the drug?

Myth

Critics of innovative drug companies often accuse them of "evergreening" their patents. This term is more of an imprecise, pejorative metaphor than a well-defined phenomenon (Lietzan 2019), but one typical description is "where manufacturers of brand name drugs make variations to existing drugs in order to extend their patent coverage" (Commission on the Future of Health Care in Canada 2002, p. 209).

The term "extend" is used in a variety of ways in evergreening discussions, but in the popular media (and even among some scholars) it commonly leads to the assertion that biopharma companies extend the terms of their older patents by filing new patents (e.g., Dhillon, 2023; Cooper, 2023).

One critic, whose research and advocacy on pharmaceutical patents is widely relied upon in policy debates, made the claim that "once a patent is granted, companies can use frivolous tactics to extend its life – sometimes even to 40 or 50 years – and reap the spoils while locking away knowledge for a generation" (Amin, 2022).

Reality

Such claims fundamentally misunderstand and misrepresent how patent law and pharmaceutical regulation actually work. They assert a legal impossibility.

Patents cannot be extended indefinitely, and certainly not for decades. Patents have fixed terms and expire 20 years from their filing date. When a patent expires, the invention it covers becomes permanently free for anyone to copy. No later patent on an improvement to the earlier invention can change that expiration date or prevent generic companies from making the original invention.

Some critics acknowledge these legal limits but claim various business practices "effectively" extend exclusivity through market manipulation. We address these more sophisticated but equally misguided and often vague claims separately, and explain how patented improvements and solutions to problems can help patients.

Here, we explain the fundamentals of patent law and drug regulation that render many claims of evergreening simply impossible.

Patents Have Fixed Terms and Only Very Limited Adjustments Are Possible

Patents expire 20 years from their filing date (35 U.S.C. § 154(a)(2); TRIPS Agreement, Article 33). This is a firm legal requirement. No amount of strategic maneuvering, additional filings, or corporate tactics can change this fundamental fact. When a patent expires in 2026, it expires in 2026. A subsequent patent filing cannot change the expiration date of the patent that expires in 2026.

Patent law's novelty and non-obviousness (also called inventive step) requirements prevent "re-patenting" inventions previously patented. Novelty bars patents on anything already known or disclosed. Non-obviousness prevents patents on trivial variations that would be obvious to someone skilled in the field.

These requirements mean that once a patent expires, the patented invention is forever dedicated to the public. Neither the original invention nor obvious modifications can be patented again. This is irreversible. No subsequent patent, regulatory decision, or corporate strategy can reclaim what has entered the public domain. All are free to copy, make, use, and sell it.

In the U.S. and several other countries, two narrow statutory mechanisms can adjust patent terms, but only to compensate for government-caused delays:

Patent Term Adjustment (PTA): If a patent office takes too long to examine a patent application, the patent term may be adjusted to compensate for those specific delays. This term adjustment isn't an "extension" that companies can manipulate. Rather, it is a correction calculated by a specific formula, restoring only time lost due to patent office delays (e.g., 35 U.S.C. § 154(b)). In the U.S., it is used far more often for software and telecommunications patents than for biopharma patents, with the median PTA for all patents granted in recent decades at 108 days (Lemley & Reinecke 2024).

Patent Term Extension (PTE): Unlike innovators in most other industries, pharmaceutical companies cannot market new products until they have gone through many years of clinical trials and regulatory review. The testing and review period consumes a substantial part of the patent term. Several countries grant limited patent term extensions to compensate for these delays.

However, such extensions come with strict limits. For example, in the U.S., only one patent per drug can receive the extension. The extension calculation discounts a portion of the testing phase delay (50%). The maximum extension is 5 years, regardless of the actual regulatory delay, and the total effective post-approval term of a patent enhanced by PTE is capped at 14 years (35 U.S.C. § 156).

Without PTE, investing in drugs requiring longer clinical studies would be even more difficult. Alzheimer's drugs, for example, typically need to be tested for many years to determine whether and how well they work, which eats up a significant portion of a patent term. As things stand, PTE is only partial compensation for regulatory delays with drug products that take more research time, receiving less effective patent term on average (Lietzan & Acri 2020).

Despite these adjustments, effective market exclusivity has remained stable at 13-14 years for decades (Grabowski et al., 2021).

These patent term adjustments cannot be gamed; they are the product of specific mathematical formulas with caps. They cannot extend patents indefinitely or repeatedly, and they do not provide decades of extra patent life.

Regulatory Exclusivities: Fixed Terms with Specific Purposes

Separate from and running in parallel with patents, regulatory exclusivities provide limited periods of protection to incentivize specific research or clinical trials. Unlike patents, regulatory exclusivities do not protect an invention. Rather, for a limited time, they prevent generic companies from either (1) relying on the clinical trial data generated by the innovator company in their application to market a generic ("data exclusivity"); or (2) obtaining regulatory approval to market a generic ("market exclusivity").

Regulatory exclusivities often are implicated in evergreening allegations, so it is important to understand what they are, their purpose, and their limited and specific effects.

These exclusivities serve specific policy goals, encouraging research into new molecules, rare diseases, or pediatric uses. They cannot be extended or renewed. With the exception of a 6-month extension for testing a drug for pediatric uses, regulatory exclusivities run in parallel with any relevant patent term, rather than stacking or extending it. When they expire, they're gone forever.

The more common type of regulatory exclusivity, data exclusivity, sets a waiting period before generic companies can use the shortcut of relying on innovator safety and efficacy data to get their generic copy approved. A generic company could theoretically generate its own data by conducting its own clinical trials, though this rarely makes economic sense, as such trials can cost hundreds of millions of dollars. Instead, they wait for their chance to use the innovator's data.

> *Regulatory exclusivities are carefully defined and limited incentives provided to drug innovators. They are not conducive to evergreening and do not delay or impede generics except in constrained, predictable ways.*

Critics sometimes portray these regulatory exclusivities as evergreening tools, but it is important to note that such exclusivities:

- Generally run parallel to patent terms and typically expire before the relevant patent exclusivity period
- Are carefully defined and regulated
- Serve to accomplish policy goals set by governments
- Apply only to the specific drug product for which they are granted and not to other, related drug products (e.g., to previous uses or formulations)

In short, regulatory exclusivities are carefully defined and limited incentives provided to drug innovators. They do not result in evergreening and do not delay or impede generics except in constrained, predictable ways.

The other, less common type of regulatory exclusivity is marketing exclusivity. This type of exclusivity prevents the approval of a competing drug product for a certain period of time.

Each type of exclusivity is tied to a biopharma R&D activity that the government wants to encourage. Here are examples of regulatory exclusivities from the U.S.:

Type	Activity Encouraged	Term	Protection Provided
New Chemical Entity – New Molecule	Research, clinical testing, and regulatory filings needed to market a new small molecule drug	5 years from marketing approval (generic can begin application in year 4 if challenging patent)	**Data exclusivity:** During this period, the FDA may not accept applications that seek approval by relying on the original drug's test data (traditional generics and certain follow-on applications)
Clinical Investigation	Research, clinical testing, and regulatory filings needed to market a new use for or new formulation of previously approved drug	3 years	**Data exclusivity:** FDA may not approve a generic's application for marketing approval of the new use or formulation based on the innovator's test data regarding the new use or formulation
Orphan Drug	Development of a treatment for a rare disease	7 years	**Market exclusivity:** FDA may not approve application to market the same drug for the same rare disease or condition Does not apply to other drugs or to versions of the same drug that demonstrate clinical superiority
Reference Product Exclusivity – New Biologics	Research, clinical testing, and regulatory filings needed to market a new biologic	12 years (biosimilar can begin application in year 4)	**Market exclusivity:** FDA may not approve a biosimilar application for marketing approval
Pediatric	Conduct pediatric studies for safety, efficacy, and dosage for minors at the request of the FDA	6 months	**For small molecule drugs**: Delays final FDA approval of generic competitors by 6 months beyond the expiration of all qualifying Orange Book-listed patents and exclusivities. **For biologics:** Extends 12-year reference product exclusivity by 6 months (and any other applicable exclusivities)

How Sequential Innovation Actually Works

Beyond the patent on the original molecule, there are essentially two types of patents that cover further innovations on a pharmaceutical product:

1. Patents on innovations that occur ***before*** approval, which are innovations that develop the original molecule into a safe and effective drug that can be approved for marketing. Generics companies must wait for these patents to expire, design around, or invalidate them before they can copy the approved original drug product.

1. Patents on innovations that occur ***after*** approval, which typically improve efficacy, patient benefits, or user experience, or expand treatment to new patient groups. Generic companies do not need to wait for these patents to expire to copy the original drug product, but, rather, only the improved version.

Let's look at a few hypothetical examples regarding all these types of patents to understand how patents on drugs do and do not affect generic entry.

> *Patents cannot be extended indefinitely. They last 20 years from filing, with narrow adjustments only for government-caused delays. Later patents on improvements don't extend earlier patents or block generic entry for original inventions.*

Example 1:

- **Drug Product A1** (approved 2017): Immediate-release tablet of Active Ingredient A, taken three times daily, covered by Patent #100 on the active Ingredient A (expires 2025)

- **Drug Product A2** (approved 2023): Extended-release formulation of Active Ingredient A, once-daily dosing, covered by Patent #100 (expires 2025) *plus* Patent #101 on the new formulation (expires 2038)

When can generics enter? A generic version of Drug Product A1 launches in 2025 when Patent #100 expires.

Patent #101 is irrelevant, as it doesn't "extend" Patent #100 or block the generic version of Drug Product A1. It only protects the specific extended-release technology until 2038.

A1 and A2 are separate drug products with different exclusivities. Generic makers do not need to address Drug Product A2 or its patents if they file an application for approval to make a generic of Drug Product A1.

Why develop Drug Product A2 if generics of Drug Product A1 will be available? Extended-release formulations often provide real benefits: better patient compliance, steadier drug levels, fewer side effects. These improvements, and others like them (e.g., new routes of administration) must provide genuine value to patients to succeed in the market. Doctors won't prescribe and insurers and/or governments won't pay for marginal changes that don't benefit patients.

Won't the existence of Drug Product A2 make it harder for generics of Drug Product A1 to compete? Perhaps, if A2 works better for patients. However, the embrace of a newer version of a drug is a result of doctors and patients seeing value in the improvements that A2 offers, not a patent- or regulatory-driven result. Healthcare systems have several sophisticated gatekeepers that determine whether improved versions merit their higher cost; doctors, governments, and insurers are unlikely to prescribe a drug or approve payment if it offers insufficient benefits over a less expensive drug.

Generic makers have options to stay competitive, including developing their own non-infringing formulations or challenging Patent #101.

Example 2:

- **Drug Product B1** (approved 2017): Covered by Patent #200 on the active Ingredient B (expires 2025). In 2020, Innovator files a supplemental new drug application to add a new indication, expanding its use to a new patient population. This new indication is covered by Patent #201 on the new method of use (expires 2030).

When can generics enter? Has Innovator extended its patent on Drug Product B1 from 2025 to 2030? Just as above, generic B1 can launch in 2025 when Patent #200 expires. However, the generic's official label can only cover the original uses and not the indication covered by Patent #201, and the generic manufacturer cannot market its product for uses that are still under patent protection.

Generic makers will need to wait until 2030 to expand their labels to cover the new indication in Patent #201. Crucially, though, the new indication and its Patent #201 do not extend Patent #200 or block generic entry with regard to the original use.

Example 3:

Drug Product C1 (approved 2015). When Drug Product C1 is filed, it is covered by Patents #300 and #301.

- Patent #300: Covers active ingredient C and expires in 2025.

- Patent #301: Covers a special formulation of active ingredient C and expires in 2028. During development, Innovator discovered that active ingredient C was metabolized far too quickly to work. Patients would need to take it hourly. After further research, Innovator developed a new formulation allowing once-daily dosing.

When can generics enter? In 2025, once Patent #300 expires, a generic maker can freely make active ingredient C. However, active ingredient C alone is neither an approved drug product nor an effective treatment. Drug Product C1 was approved for sale as a complete package that includes the formulation solving the metabolization issue.

A generic maker has three options: (1) design and test its own formulation that addresses the metabolization issue while avoiding Patent #301; (2) challenge Patent #301 as invalid; or (3) wait until 2028 when Patent #301 expires.

Has Innovator "extended" its exclusivity with Patent #301? Critics claim that patenting a new formulation in this way represents gaming the system, either "extending" patents through new formulations (Dhillon, 2023; Cooper, 2023) or engaging in strategic patent filing timed to prolong exclusivity (Gurgula, 2020).

The reality:

Patent #301 protects a distinct invention that solved a metabolization problem that would likely have stopped Drug Product C1 from ever reaching clinical trials. Such failures are common; more than 90% of drug candidates do not make it through testing (Hay et al., 2014; Harrison, 2016). Patent #301 is not an extension of the earlier patent claiming the active ingredient, which cannot legally be extended.

The claim that the company would strategically delay this invention is not credible from a commercial perspective. Without the formulation that fixed the metabolization problem, there was no drug to advance into trials. Companies have every incentive to solve such problems quickly and move development forward, not hold it back.

Intentional delay would also be poor patent strategy. If the solution had been known to the applicant when the active ingredient was patented, it would have been part of Patent #300. Waiting to claim an invention only increases the likelihood of rejection.

Drug development is uncertain and failure-prone. When researchers solve real problems, they patent the solution and continue their program. Patent #301 reflects that standard process. It is not gamesmanship. This invention made a viable medicine possible.

The Bottom Line

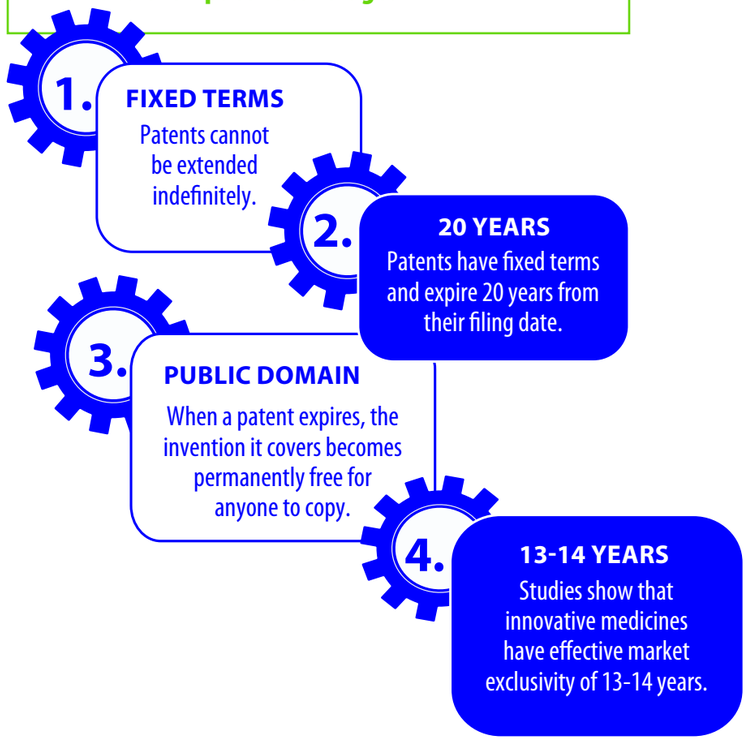
Patents cannot be extended indefinitely. They last 20 years from filing, with only very narrow and specific adjustments for delays. Later patents on drug improvements don't extend earlier patents or block generic entry of drug products using the inventions embodied in the original version of the drug.

The evergreening metaphor obscures these legal realities and misdirects policy discussions. Understanding how patents actually work – with fixed terms, strict limits, and automatic expirations – is essential for addressing legitimate concerns about drug pricing without undermining innovation incentives.

The success of this system is evident:

- Generic drugs now account for over 90% of U.S. prescriptions (FDA, 2022), up from 19% in 1984 when the Hatch-Waxman Act was enacted.
- This considerable increase in generic utilization, combined with the stable effective market exclusivity period for innovative drugs (13-14 years), demonstrates that the patent system is functioning as designed – providing limited-time innovation incentives followed by broad generic access.

According to critics, "evergreening" happens when manufacturers of brand name drugs make variations to existing drugs in order to extend their patent coverage.



No patent on an improvement to an invention can change the expiration date of an earlier patent on that invention, or prevent generic companies from making the original invention.

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Pharmaceutical Patent "Evergreening"

Do later patents block generic entry? The reality behind "evergreening" claims

Myth

Critics argue that brand-name drug companies strategically manipulate the patent system to delay generic entry and maintain high prices. They claim that innovators "evergreen" their products by timing patent filings, patenting minor tweaks, introducing reformulations, or shifting patients to new versions just as older ones face generic competition (Feldman, 2018; Carrier & Shadowen, 2016).

Some critics go further, insisting explicitly or implicitly that only the first compound patent covering the drug should "count," and that later patents on improvements such as formulations, crystalline forms, or dosing regimens are nothing more than gamesmanship (Gurgula, 2020; Frakes & Wasserman, 2025; Hong et al., 2025).

Reality

This narrative misunderstands how drug development, patents, and generic entry work in practice. Later patents cannot extend the life of earlier ones (Lietzan, 2019).

Drug development cannot be "timed" to fit a patent strategy. It is failure-prone and science-driven: more than 90% of candidates fail in clinical trials. (Hay et al., 2014; Harrison, 2016). Many drug candidates succeed only after solving stability, dosing, or tolerability problems. What critics portray as strategic layering of patents before approval is the natural result of this problem-solving.

Later patents on improvements protect distinct inventions that make medicines safer, more effective, or easier to use (Lietzan, 2019). Such improvements can be innovative enough to warrant their own patents and deliver meaningful benefits that lead patients and doctors to prefer them. However, they do not block copying of the original product once its patents expire.

Meanwhile, the generic industry is highly sophisticated. With legal advantages such as a patent infringement safe harbor for activities associated with regulatory approval, abbreviated approval pathways, incentives to challenge patents, and automatic substitution laws, generics enter the market quickly once patents expire. That is why U.S. market exclusivity periods have remained stable at about 13-14 years (Grabowski et al., 2021; USPTO, 2024) and why generics now fill over 90% of prescriptions (FDA, 2022).

This paper addresses the allegation that innovators strategically game the patent system. We examine critics' claims around patent timing, post-approval improvements, "trivial" tweaks, and patient "switching." We show why these accusations reflect misunderstandings of science, innovation, and the structure of generic competition.

Understanding What Patents Really Protect

Evergreening critiques often blur different meanings of the word drug. In everyday language, a "drug" or "medicine" is simply the pill or shot a patient takes. But that single product may embody multiple patented inventions needed to make it safe and effective. Alternatively, what patients think of as "the drug" may in fact be a different product altogether, such as an improved version (for example, an extended-release formulation) that carries new patents on the improvements, not on the earlier version.

Failing to recognize these distinctions lets critics imply that later patents extend exclusivity on a single "drug" when, in fact, they protect different inventions within a product – or even protect improvements in a separate, improved product.

Three concepts are key:

1. **The initial compound.**
   This is the molecule scientists first identify and patent, commonly called the "compound patent." Most compounds never become medicines: more than 90% fail in clinical trials (Hay et al., 2014; Harrison, 2016). A compound patent alone usually does not encompass all the innovation required to deliver a safe and effective drug.

2. **The first approved drug product.**
   To be usable as a medicine, the compound often requires other patented innovations, such as new formulations, stabilizers, dosing regimens, or delivery methods that make it safe and effective in humans. Without these innovations, each the result of significant development efforts, there would be nothing for patients to use. Patents on these solutions to problems encountered during the development process don't extend the compound patent. They protect the inventions that turn a promising molecule into a viable treatment.

3. **Later versions.**
   To improve the patient experience or reach new patient populations, companies sometimes develop new versions of the originally approved drug product, such as extended-release forms, new routes of administration, and new strengths. Each requires separate FDA approval and may have its own patents (Lietzan, 2019). These later patents don't block generics of the original product. Once patents on the original drug product expire, generics can copy it regardless of what patents exist on later versions.

Critics who treat every patent related to a drug as preventing entry of any generic version misinterpret how generics work. Generics copy specific approved drug products, and the effect of patents on generic entry depends only on the patents covering that specific product.

Compound A – A Drug Development Story

Step 1: Researchers at the Innovative Drug Company patent a promising compound, "Compound A". On its own, it isn't stable enough to use as a medicine.

Step 2: They discover a crystalline form of Compound A that is more stable and bioavailable (that is, absorbed and available at its intended site of action), and they patent it. This is the version that succeeds in clinical trials and receives FDA approval. It becomes the **first approved product**. Generics must copy this crystalline form to gain FDA approval to market their versions.

Step 3: Years later, the Innovative Drug Company develops an extended-release injection of Compound A. It patents and seeks approval for this **new product**.

What does this mean for generics?

- To copy the original approved product, generics must wait only until the patents on the compound and crystalline form expire, i.e., those patents covering the original drug product.

- The extended-release version is legally irrelevant. It is a separate product with its own patents that cannot delay generic entry of the original product.

The Bottom Line: Later patents can be crucial to making a compound into a workable drug, or they may apply only to new products. Either way, they do not "extend" the original patent.

Four "Evergreening" Claims vs. Market Reality

As Lietzan (2019) shows, evergreening is a vague metaphor often applied to later patents or new versions of a drug, to imply decades-long extensions of exclusivity that patent law does not allow. Despite the confusion, a few recurring themes dominate policy debates. Critics tend to frame four main types of "strategic" behavior as evergreening:

1. **Strategically timing patents during development** (layering patents before approval).
2. **Post-approval improvements** (new formulations or uses).
3. **"Trivial tweaks"** (e.g., salts, polymorphs, or isomers of a compound)
4. **Switching patients to new versions** (so-called "product hopping").

The following sections take each of these claims in turn and test them against the realities of drug development, patent law, and generic competition.

Claim 1: Strategic Timing of Patents

The Claim.

Critics argue that innovators strategically time their patent filings during drug development to extend exclusivity. Some suggest that only the first "key patent" or "primary patent" on the initial composition of matter should matter, and everything else is evergreening (Gurgula, 2020; Hong et al., 2025; Frakes & Wasserman, 2025). Critics consider later-filed patents on developments such as crystalline forms, salts, or formulations as strategically timed simply to delay generic entry.

The Reality.

Drug development cannot be stage-managed to fit a patent strategy. It is too uncertain, failure-prone, and science-driven. Science and unmet need drive biopharmaceutical R&D, and companies use patents to manage investments throughout the development process. Scientists are in the driver's seat, with patent attorneys along for the ride.

Moreover, the "strategic timing" critique reflects a fundamental misunderstanding of how patents on drug products work.

The "key patent" idea has no legal meaning and makes little practical sense. It treats the initial compound patent as if it covers the entire drug product when, in reality, a drug product may embody multiple patented inventions. Patents protect inventions. An approved medicine usually requires several of them. For example, scientists must create the compound itself, formulations that allow proper absorption, and/or delivery methods that achieve therapeutic levels.

Treating the initial compound patent as the only legitimate patent and everything else as a strategic ploy is like saying only the engine patent matters for a car. A functional car embodies dozens of patented inventions such as steering systems, braking systems, and safety features, with each solving specific engineering problems. The engine is critical, but without the rest, it's not a car and won't get you anywhere. Similarly, the compound is critical, but without other innovations, it is not a medicine.

The Bottom Line.

Later patents filed during development represent solutions to problems that would otherwise prevent use of the compound as a medicine. These solutions make generic entry possible by ensuring there is an approved drug product to copy.

Claim 2: Post-Approval Improvements Are a Ploy to Extend Exclusivity

The Claim.

Critics argue that once a drug is approved and successful, companies try to sustain profits by making new versions such as extended-release tablets, new delivery mechanisms, or new indications for additional patient populations. Each typically comes with new patents, which critics say artificially prolong control and "lock out" cheaper generics (I-MAK, 2025).

The Reality.

Later patents on improved versions of drug products do not block generic versions of earlier products; once patents on the original product expire, generics can launch (Lietzan, 2019).

Moreover, post-approval improvements typically respond to patient needs. Consider, for example, the recent approval of Keytruda in subcutaneous form, which means patients will no longer need hours-long intravenous infusions at infusion centers but can instead receive a quick injection in a doctor's office. This type of innovation improves the patient experience, makes treatments more accessible, and helps patients stay on necessary therapies while reducing healthcare costs.

Expanding a drug's uses to additional patient populations – finding new "indications" – can also bring real patient benefits. Roughly two-thirds of oncology drugs approved between 2008 and 2018 later gained approval for treating additional cancers (Lietzan & Acri, 2020). From a societal perspective, finding new patient populations that can benefit from drug products already proven safe and effective is far more efficient than developing entirely new compounds for every condition. Testing new uses, however, still requires expensive Phase 3 clinical trials, often costing hundreds of millions of dollars. Patents provide the incentive to take on that risk and extend benefits to new patients.

Generics, meanwhile, are not shut out of the market. If a new indication of a product is patented, they can "carve out" that indication from their labels and launch immediately for the original indication (21 C.F.R. § 314.94). It is possible to have generics of the original version in the market at the same time as branded versions that serve different patient needs.

The Bottom Line.

Post-approval improvements represent competition through innovation, not manipulation. These improvements create new options for patients and providers, while generic entry for earlier products proceeds on schedule. Limiting or devaluing patents on such improvements would not speed generic access. Rather, it would simply discourage valuable advances in formulation, delivery, and use.

Claim 3: Innovators Patent "Trivial Tweaks" to Prolong Exclusivity

The Claim.

Critics often argue that new forms of known compounds, such as different salts, polymorphs, or isomers of a small molecule, are minor variations that should not qualify for patent protection. They claim these are merely "trivial tweaks" designed to extend exclusivity without genuine innovation (Kapczynski et al., 2012; Feldman, 2018).

The Reality.

What may look like a small change on paper can represent the difference between a failed compound and a successful medicine. The act of synthesizing a salt or polymorph may appear routine, but the results frequently are not. Discovering a version that is stable, bioavailable, and safe is often difficult and unpredictable, as the absorption, solubility, and toxicity can vary dramatically between different forms. Solving these problems may transform a promising, but unusable compound into a workable therapy.

Patent law encourages this important innovation. To qualify, an invention must be new, non-obvious, and useful. If a salt or polymorph does not meet these requirements, it will not survive patent examination or litigation. But when it does, the law properly protects it.

Ritonavir illustrates the importance of post-approval innovation. After ritonavir's approval, it was discovered that the original form of the drug would spontaneously degrade when stored into a nearly insoluble new crystal form, rendering the drug ineffective. Abbott had to reformulate a new version to keep the medicine stable and viable, which the company patented (Chemburkar et al., 2000). Without that work, ritonavir would have vanished from the market, and with it an essential HIV therapy. This was not trivial tinkering but an innovation that preserved patient access.

The Bottom Line.

Labeling polymorphs, salts, and similar inventions as trivial misunderstands the science. These discoveries often determine safety, stability, and efficacy. They protect genuine inventions that either made the drug possible or improved its performance (Holman, 2017).

> ***Despite allegations of "evergreening," the U.S. generic market is one of the most robust in the world. On average, generics launch 13–14 years after brand approval, far short of the 20-year patent term. Once they arrive, they capture over 90% of prescriptions.***

Claim 4: Companies Shift Patients to New Versions to Block Generics

The Claim.

Critics argue that just before generic entry, innovators introduce a slightly modified product and encourage doctors or patients to switch to the new product. They claim this "product hopping" keeps patients on branded versions and undermines generic competition. The most cited example of this alleged phenomenon is AstraZeneca's launch of Nexium (esomeprazole) when patents on Prilosec (omeprazole) expired (Carrier & Shadowen, 2016).

The Reality.

Generics are well-positioned to enter regardless of such new product introductions, even if the old product is discontinued. Under the Hatch-Waxman framework, generic firms can begin development years before patent expiry. Thanks to a patent infringement safe harbor for activities associated with regulatory approval, generic producers can conduct bioequivalence testing well before any patents on a drug have expired (21 U.S.C. § 355(j)(2)). By the time a new version is introduced, generic versions of the original are often ready to launch.

In practice, when an innovator introduces a new version of a drug, it's typically an improvement on the original version, and the innovator continues to make the original version available on the market (a so-called "soft switch). Generic versions of the original can still launch, and usually they will capture a large market share. Scenarios in which the innovator withdraws the original branded version of a drug from the market ("hard switch") are rare and may face antitrust scrutiny.

Indeed, a closer look at the much-cited Nexium example reveals that generic versions of Prilosec (omeprazole) entered the market as soon as the relevant patents expired. Nexium's launch did nothing to obstruct the availability of generic omeprazole, and today, omeprazole is available over the counter for pennies per dose. Nexium succeeded commercially not because patents blocked competition, but because physicians prescribed it, insurers covered it, and patients took it. Market dynamics, not alleged patent extensions, explain its sales.

The Bottom Line.

Offering patients new versions of drugs does not delay generic entry of earlier versions of the drug. Generics can and do launch upon patent expiration, and they rapidly gain market share through substitution laws and insurance formularies. New versions compete alongside generics in the marketplace, providing additional choices for doctors and patients.

Generic Advantages

If evergreening claims were accurate, one would expect to find that generic drugs face an uphill battle to enter a market dominated by patented, brand-name drugs. However, despite allegations of evergreening, the U.S. generic market is one of the most robust in the world. On average, generics launch 13–14 years after brand approval, far short of the 20-year patent term (Grabowski et al., 2021; USPTO, 2024). Once they arrive, they capture over 90% of prescriptions (FDA, 2022). Several legal and structural features ease generic entry in the U.S.:

- **Generics benefit from a patent infringement safe harbor for activities associated with regulatory approval, giving them a head start on market entry.** For every other product, competitors must wait until patents expire to practice an invention for any reason. For drugs, a patent infringement safe harbor (also referred to as the "Bolar Exemption") (35 U.S.C. § 271(e)(1)) allows generic firms to start making copies for purposes of testing and preparing marketing applications years before patents expire.

- **Generics don't have to do their own clinical trials but can rely on innovator data to get approval to market their drugs.** Generic companies can file abbreviated new drug applications (ANDAs) that let them rely on innovator data to prove that their copies are safe and effective, rather than having to incur the expense of clinical trials.

- **Generics can apply for marketing approval long before innovator patents expire.** Generics may file ANDAs within just a few years after innovative drugs are launched (21 U.S.C. § 355(j)(2)) and typically years before patent expiration, allowing them to work through technical and regulatory issues with the FDA and receive tentative approval long before patent expiration. This tentative approval sets them up to receive final approval and launch on the day the relevant patents expire.

- **Generics receive rewards for invalidating innovator patents.** The first successful challenger to the patent(s) on an innovator drug receives 180 days of generic exclusivity (21 U.S.C. § 355(j)(5)(B)(iv)). Being the only generic in the market for 180 days is often worth hundreds of millions of dollars for blockbuster drugs. This creates powerful incentives for early, aggressive patent challenges (Hemphill & Sampat, 2012).

- **In most states, when generics are available, pharmacists can or must substitute them for the brand name drug.** When a prescriber writes a prescription that names the brand name an innovator uses for a drug, state substitution laws require or permit pharmacists to dispense a generic instead, unless otherwise specifically directed, ensuring rapid uptake.

Together, these measures ensure that generic entry occurs on a timely basis, and that generic uptake is swift upon entry. Generic entry happens promptly upon expiration or invalidation of relevant patents, and innovators lose most of their market share within a year (Grabowski et al., 2021).

Innovation and Competition, Not Evergreening

Later patents on drugs neither extend earlier ones nor stop generic entry. The four common evergreening claims fail when measured against drug development and generic market entry realities.

SEPARATING MYTH FROM REALITY: FOUR "EVERGREENING" CLAIMS

Myth
Innovators strategically time their patent filings during drug development to extend exclusivity.

Reality
Strategic timing arguments misunderstand science. Development is unpredictable and failure-prone. Later patents reflect solutions to problems, which make the drug viable.

Myth
Post-approval improvements are a ploy to extend exclusivity.

Reality
Post-approval improvements such as better formulations or new delivery methods expand patient access and quality of life without blocking generic entry of earlier versions of the drug.

Myth
Innovators patent "trivial tweaks" to prolong exclusivity.

Reality
So-called trivial tweaks like salts or polymorphs often determine whether a drug is safe, stable, and effective. They are real inventions, not gimmicks.

Myth
Companies shift patients to new versions to block generics

Reality
Market success of new versions of a medicine is determined by patient benefit, competition, and payor decisions. Patents for these new versions do not extend exclusivity of the original drug, generics still launch on time, and substitution laws ensure rapid uptake of generics.

The U.S. system is designed for timely entry. The Bolar exemption, early filing, abbreviated approval pathways, incentives to challenge patents, and substitution rules facilitate generic entry, and the data confirm this: generic entry occurs on average 13-14 years after a new drug is introduced, and more than 90% of all prescriptions in the United States are filled by generics. Limiting patents on improvements would not accelerate access to new drugs but would instead deter advances that improve patient outcomes.

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Does data support "evergreening" claims? Contrasting real world outcomes with critics' predictions

Myth

Evergreening critics often cite academic studies and white papers purporting to empirically show systematic, inappropriate extension of exclusivity rights in drug products. These studies typically count all patents related to a drug product, identify the latest expiration date among them, and conclude that exclusivity will last until that final patent expires, often years or even decades beyond the original compound patent (I-MAK, 2022; Feldman, 2018).

Organizations such as the Initiative for Medicines, Access & Knowledge (I-MAK) and academics using databases such as the UCSF Evergreen Drug Patent Database argue that these findings demonstrate widespread manipulation of the patent system to maintain premium pricing (I-MAK, 2022; Feldman, 2018).

These studies and their interpretations form the empirical foundation for policy proposals to restrict pharmaceutical patenting, based on the belief that limiting patents would accelerate generic entry and reduce drug prices.

Reality

The claim of "evergreening" doesn't hold up. When we look at actual market outcomes rather than patent counts, the story is consistent across decades and multiple independent studies:

- **Market exclusivity averages 13 - 14 years and has for decades.** Despite predictions of extended (even 30-40 year) monopolies, drugs consistently face generic entry in just over a dozen years. This period has remained stable since the 1980s.
- **Predictions of delay are consistently wrong.** Studies and advocacy reports routinely project many "extra" years of exclusivity, but their prophecies are almost always false, often by decades.
- **Generics are strong competitors.** Today, 90% of U.S. prescriptions are filled with generics, up from 19% since 1984. Once generics arrive, innovators typically lose about 70% of their market share within a year.

In short, critics are right that innovators continue to patent and develop improved versions of drugs after approval, but they are wrong in assuming that this extends control or market exclusivity. As Lietzan (2019) observed, the data shows continuing innovation not delayed competition. Lietzan & Acri (2023) conclude, after examining decades of evidence, that evergreening concerns are "solutions still searching for a problem."

This paper examines the empirical evidence in detail and shows why the evergreening narrative doesn't hold up when tested against the data.

Unfounded and Unproven Assumptions

Studies claiming to demonstrate "evergreening" in pharmaceutical patents make critical errors. These studies typically count all patents and other exclusivities associated with an active ingredient, identify the latest-expiring one, and assume generics or biosimilars are blocked until that date (Lietzan, 2019).

This approach assumes, rather than demonstrates, that later-filed patents delay generic entry (USPTO, 2024; Lietzan & Acri, 2023). It asserts causation without evidence, failing to examine actual dates of generic entry.

The evidence shows that these assumptions systematically overestimate exclusivity periods and mischaracterize innovation as anticompetitive "evergreening" (USPTO, 2024; Morris & Kresh 2024; Lietzan & Acri, 2023).

There are three major problems with this methodology:

1. Mistake: Treating All Patents as Equal Barriers

Not all patents associated with a drug affect generic entry. For example:

- Extended-release patents don't block immediate-release generics.
- Formulation patents do not block generics from pursuing alternative formulations.
- Method-of-use patents often can be bypassed by excluding patented uses from generic labels.

The USPTO (2024) emphasized that "not every patent listed in the Orange Book has the same scope," so treating them all as barriers systematically inflates exclusivity estimates (USPTO, 2024; Lietzan, 2019).

2. Mistake: Counting Pending or Abandoned Patent Applications

I-MAK's reports count pending or abandoned applications when projecting exclusivity (e.g., I-MAK, 2017), even though they confer no enforceable rights. As the USPTO explained in its 2024 study, "abandoned applications do not result in granted patents" and pending applications "may never become patents, and if no patent is granted, there is no enforceable right" (USPTO, 2024, p. 13). Including such filings inflates patent counts, creates a false appearance of patent "thickets," and leads to inaccurate projections of delayed generic entry.

3. Omission: Failing to Test the Core Assumption

Studies like Frakes & Wasserman (2025), Feldman (2018). and I-MAK (2017, 2018) assume that later-filed patents delay generic or biosimilar entry, but they never test whether this is true. In reality, generics or biosimilars arrive years earlier. To this point, Lietzan & Acri (2023) found that across 224 drugs, generic entry occurred on average seven years earlier than predicted by the UCSF Database on which Feldman's study was based.

The consequences of not testing assumptions can be glaring. The UCSF Database listed aspirin as protected until 2032 (despite being generic since 1917) and ibuprofen until 2032 (even though generics launched in 1985).

Feldman (2018) likewise claimed Namenda would be protected until 2029 because the innovator used "maneuvers . . . to extend its protection at least 24 years" (Feldman, 2018, p. 603), even though generic versions had already launched in 2015, three years before publication of this prediction. And I-MAK (2017) projected decades of additional exclusivity and tens of billions in "excess costs" for Revlimid and Sovaldi, but generics for those drugs entered the market in 2022.

The table provides examples that show how these kinds of predictions consistently overshoot reality, often by a decade or more, for both generics and biosimilars.

Predicted vs. Actual Entry Dates

Drug	Source of Prediction	Predicted Exclusivity End Date	Actual Generic/ Biosimilar Entry (U.S.)	Discrepancy (in Years)
Norvir (ritonavir)	Amin & Kesselheim (2012)	2028	2018	10
Revlimid (lenalidomide)	I-MAK (2017)	2028	2022	6
Sovaldi (sofosbuvir)	I-MAK (2017)	2034	2022	12
Herceptin (trastuzumab)	I-MAK (2018)	2033	2019	14
Remicade (infliximab)	I-MAK (2018)	2025	2016	9
Lyrica (pregabalin)	I-MAK (2018)	2038	2019	19
Rituxan (rituximab)	I-MAK (2018)	2030	2019	11
Namenda (memantine)	Feldman (2018)	2029	2015	14
Gleevec (imatinib)	UCSF Database (2018) (noted in Lietzan & Acri (2023))	2022	2016	6
Lunesta (eszopilone)	UCSF Database (2018) (noted in Lietzan & Acri (2023))	2016	2014	2
Actonel (risedronate sodium)	UCSF Database (2018) (noted in Lietzan & Acri (2023))	2023	1998	25
Aspirin	UCSF Database (2018) (noted here)	2032	1917	15
Ibuprofen	UCSF Database (2018) (noted here)	2032	1985	47
Humira (adalimumab)	I-MAK (2019)	2034	2023	11

These errors are not isolated outliers. Instead, they reflect systematic overestimation, undermining the credibility of evergreening claims and highlighting the need for reliable, evidence-based policymaking.

Studies That Test the Evergreening Assumption Refute It

When researchers examine real market data rather than simply counting patents, they consistently find that later patents don't delay generic entry. Three recent studies, using different methodologies, all document the same reality: market exclusivity periods for drugs are not meaningfully impacted by later-filed patents, and they remain around 13-14 years on average.

The USPTO Study: The Most Authoritative Government Analysis

In 2024, responding to Congressional requests, the U.S. Patent and Trademark Office conducted a comprehensive analysis of 25 New Drug Applications covering 13 distinct active ingredients. It found actual market exclusivity of just 3-16 years and concluded that "patent expiration dates, like the number of patents, may not be predictive of the timing of actual launch of competing products" (USPTO, 2024, p. 59). These conclusions directly contradict claims of decades-long monopolies.

Lietzan & Acri: Generics Enter 7 Years Before Critics Predict

Lietzan and Acri (2023) reviewed 224 entries from the UCSF Database against actual generic entry dates. Their most striking finding: generic drugs entered on average 7 years earlier than the database predicted.

Key points from their analysis:

- Mean actual exclusivity period: 11.3 years (median 10.8 years)
- 70% of drugs examined had fewer than 14 years of exclusivity
- 95% had generic competition before 20 years

The central reason: the flawed assumption that every listed patent blocks entry, a claim proven to be false in nearly every case examined.

Morris & Kresh: No Correlation Between Patent Numbers and Exclusivity

Morris & Kresh (2024) analyzed 130 bestselling drugs. They found an average effective patent life of 13.35 years, consistent with prior studies, and concluded that "the number of patents protecting a brand-name drug has no significant correlation with effective patent life." They concluded that "evergreening does not stop generic entry and that 'thickets'- if they even exist - appear to be rather easy to circumvent."

Four Decades of Consistent Evidence: The Market Reality

The widespread accusation that the pharmaceutical industry "evergreens" its patents turns reality on its head. Innovators in other industries expect that patents will give them close to 20 years of protection from copying in the marketplace, but pharmaceutical innovators do not. The evidence shows that they consistently receive fewer - not more - years of protection than 20.

Across time periods, methods, and researchers, the story is consistent: since the Hatch-Waxman Act in 1984, effective market exclusivity has remained stable at 13-14 years.

- **Different time periods:** Studies from the 1990s through the 2020s show the same pattern (Grabowski et al., 2016; Grabowski et al., 2021; Wang et al., 2015).
- **Different methodologies:** Despite using different datasets and analytical approaches, including auditing prior patent/exclusivity landscapes and direct measurement of actual generic entry, results converge (Lietzan & Acri, 2023; Morris & Kresh, 2024; USPTO, 2024).
- **Different researchers:** Government (USPTO, 2024; CBO, 2021) and academic researchers (Lietzan & Acri, 2020; Grabowski et al., 2021; Beall et al., 2019; Wang et al., 2015) all find the same outcome.

Why Entry is Timely: A Sophisticated Generic Industry

Generic manufacturers are highly sophisticated repeat players, and major firms like Teva and Sandoz have dedicated teams to identify entry opportunities. Generic manufacturers have many advantages under the law that smooth their path to market entry, as we explain here. As a result, generics enter the market promptly, on average within 13-14 years of drug approval – much sooner than the 20 years of exclusivity enjoyed by patent owners in other industries. Innovators typically lose about 70% of their market share within a year of generic entry (Grabowski et al., 2014), and today over 90% of prescriptions are filled with generics (FDA, 2022).

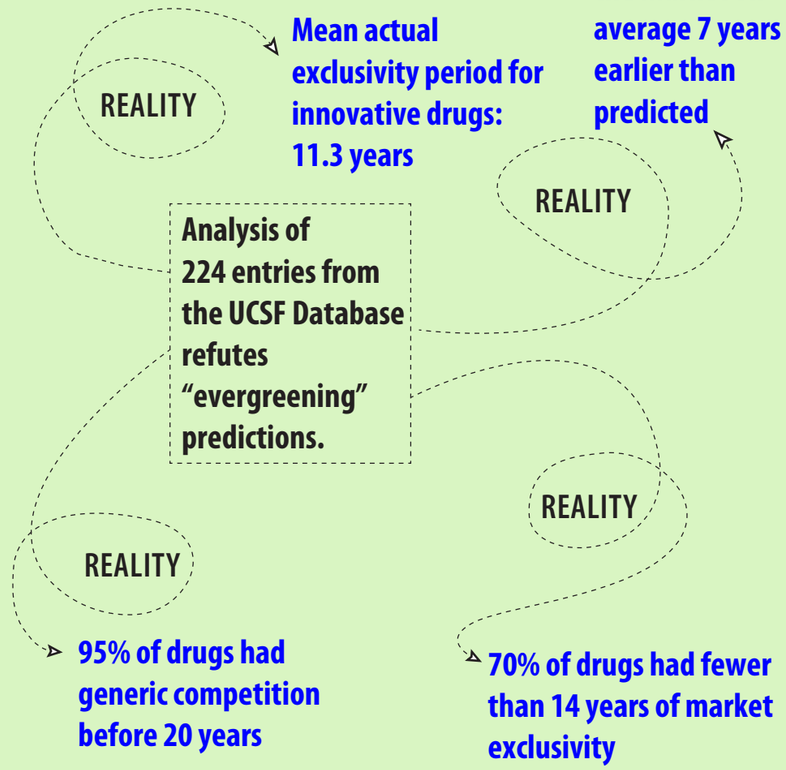
> *When tested against real data, "evergreening" claims consistently fail. Predictions are wrong by an average of seven years, and the USPTO (2024) found no correlation between patent counts and entry timing.*

Policy Implications and the Bottom Line

When tested against real data, "evergreening" claims consistently fail. Predictions are wrong by an average of seven years. The USPTO (2024) found no correlation between patent counts and entry timing. Four decades of evidence show stable market exclusivity of 13-14 years, not decades-long extensions.

The real story is robust competition: generics now account for 90% of prescriptions, up from 19% when Hatch-Waxman passed, and innovators typically lose 70% of their market share within a year of generic entry.

Evidence, not metaphor, should guide pharmaceutical policy.



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21 U.S.C. § 355(j)(5)(B)(iv) (180-day exclusivity for first generic applicant).

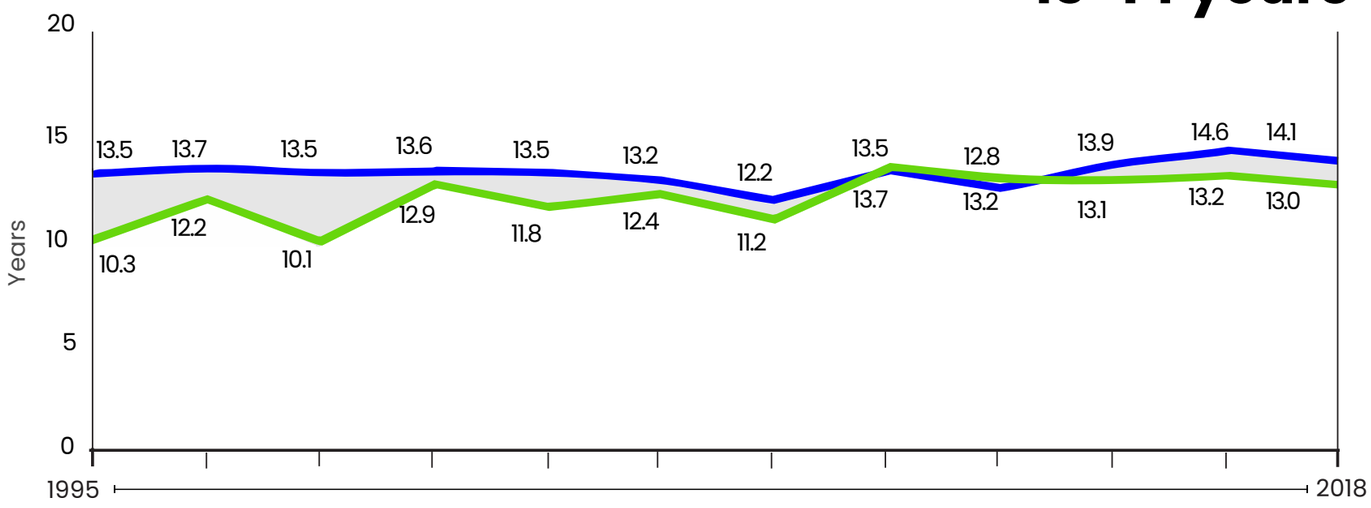
Pharmaceutical Patents "Evergreening"

Separating Myth from Reality

> *When tested against real data, "evergreening" claims consistently fail. Predictions are wrong by an average of seven years, and the USPTO (2024) found no correlation between patent counts and entry timing.*

Average Years of Pharmaceutical Market Exclusivity[1]

(Biennial by year of first generic entry 1995-2019)



AVERAGE MARKET EXCLUSIVITY
13-14 years

PATENT TERM
20 years

Lietzan and Acri (2023) reviewed 224 entries from the UCSF Evergreen Drug Patent Database against actual generic entry dates. Their most striking finding: generic drugs entered on average 7 years earlier than the database predicted.

Key points from their analysis:

11.3 years
Mean actual exclusivity period: 11.3 years (median 10.8 years)

70%
of drugs had fewer than 14 years of exclusivity

95%
had generic competition before 20 years

Multiple studies, conducted over the last 30 years, have consistently shown that exclusivity periods for new medicines have averaged 13-14 years.[2]

A 2024 United States Patent and Trademark Office (USPTO) study found that the market exclusivity period ranged from 3 to 16 years.[3]

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2. 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(3), 788–873.
3. United States Patent and Trademark Office. (2024). Drug patent and exclusivity study. United States Patent and Trademark Office.

Pharmaceutical Patents “Evergreening”

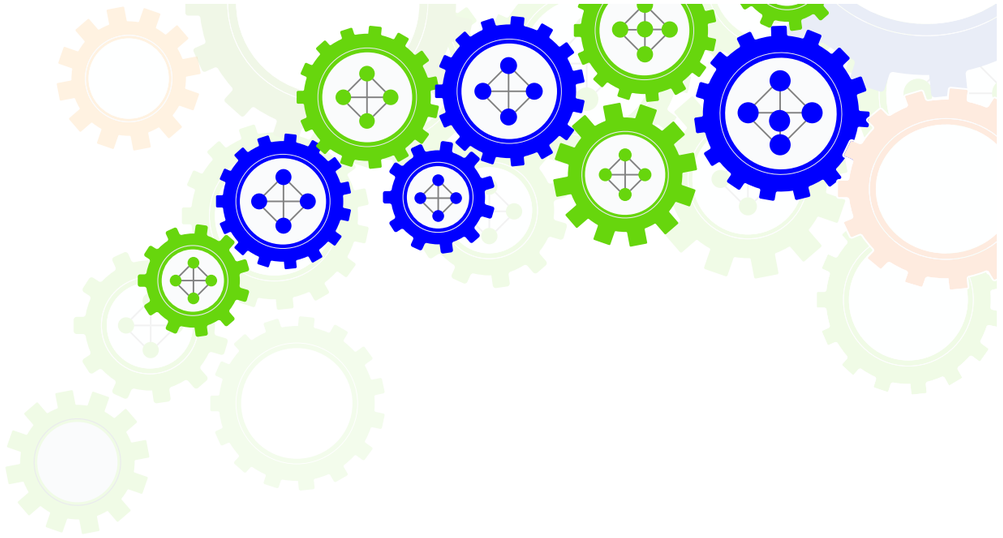
Separating Myth from Reality

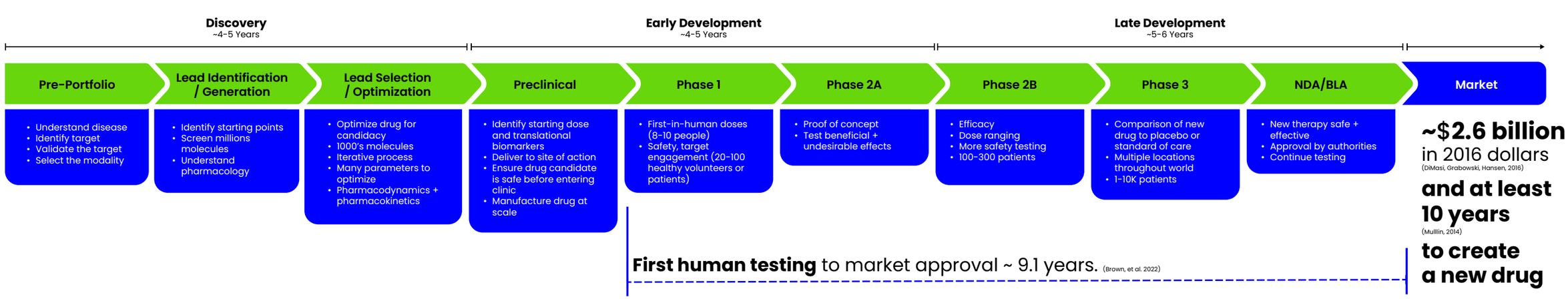
Drug Discovery and Development Overview

Less than 10% of drugs make it through clinical trials

This < 10 % success rate does not account for the numerous candidates that never make it to clinical trials

Current estimates suggest that only 7.87% of drugs that enter clinical trials successfully reach market (Mikulic, 2021)





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The NDA (New Drug Application) and BLA (Biologics License Application) are requests for approval to market a new pharmaceutical or biological product in the United States.