

America's Intellectual Property System:

Key Things to Know

Backed by America's strong intellectual property (IP) protections, the biopharmaceutical industry has delivered more than 900 new medicines since 2000 for devastating illnesses such as cancer, heart disease, neurodegenerative conditions and rare diseases — with more than 8,000 in development today.

When you pick up a prescription, you're seeing our IP system at work. Patents incentivize the complex research behind medicine development and encourage competitors to develop innovative new treatments as well. Importantly, first-in-class medicines have a brand competitor **within 2.5 years** on average. This competition often leads to discounts and rebates which can lower the net costs of medicines by **50% or more**. Lower-cost generics and biosimilars follow, providing lower cost options to benefit patients and society over the long term.

The result of the IP system helps balance innovation and affordability. Prescription medicines remain a small and stable share of overall health care spending even as new treatments reach patients, and U.S. patients have **more medicine choices** sooner than anywhere else in the world.

77% of new medicines launched globally over the past three years launched in the United States first.

How the patent system works for patients

America's patent system grants protection only to inventions that pass the U.S. Patent and Trademark Office's (USPTO) review for patentability, meaning the invention must be useful, novel and non-obvious. Because medicines are complex products, they often incorporate multiple such inventions: the active ingredient, formulation, dosage form, delivery mechanism, use in treating a particular disease and manufacturing process, each potentially eligible for its own patent, regardless of whether it is discovered before or after U.S. Food and Drug Administration (FDA) approval.

4 patents protecting a drug on average over the past decade.

60+ patents that can cover a single golf ball.

Landmark legislation turns innovation into competition

Congress built two frameworks to ensure continued innovation doesn't come at the expense of competition.

- **The Hatch-Waxman Act**, enacted in 1984, lets generic manufacturers rely on a brand's existing clinical data for FDA approval and resolve patent disputes before a drugs launch. It also preserved incentives for innovators by restoring a limited portion of the patent term lost during the FDA review process in some cases.
 - **The Biologics Price Competition and Innovation Act (BPCIA)**, enacted in 2010, created an abbreviated approval process that encouraged the development of lower-cost alternatives to biologic medicines while maintaining incentives for the development of new innovative biologics. In striking this balance, the BPCIA has facilitated biosimilar competition and helped expand patient access to lifesaving treatments.
- **Nearly 90%** of U.S. prescriptions today are filled with generics, up from just 19% before Hatch-Waxman.
 - **67** biosimilars have been launched to compete against 18 reference brand biologics since the first biosimilar launched in 2015.

Correcting the record

Critics often misrepresent our IP system, which effectively promotes innovation, competition and lower costs. **Here are the IP facts:**

Monopolies

Myth: Exclusivities granted by patents give brand-name manufacturers “monopolies” to treat a certain disease or condition. 

Fact: No company monopolizes treatment for a disease or condition. First-in-class medicines face competition on average after 2.5 years, cutting costs by 50% or more. And once exclusivity lapses, generics and biosimilars provide lower-cost options for patients indefinitely. The true barrier to competition is middlemen, the PBMs and insurers, who exclude lower-cost alternatives from formularies. 

Thickets

Myth: Drug Companies build “patent thickets” by obtaining excessive amounts of patents on a single medicine to block lower-cost generic and biosimilar competitors. 

Fact: The term “patent thicket” for biopharmaceuticals is a made-up term by IP critics. It is not unusual for complex products like medicines to have more than one patent. Biopharmaceutical companies actually patent less than other sectors. Most of the top patent owning companies belong to the tech sector, while just **2.6% of the top 300** are in the innovative biopharmaceutical sector. Drugs for instance are associated with an average of **about four patents**. A **2024 USPTO study** also found no correlation between the number of patents on a drug and the length of exclusivity before generic entry. 

Evergreening

Myth: Companies seek additional patents on medicines after FDA approval to extend its market exclusivity and keep generics and biosimilars off the market longer. 

Fact: While post-approval R&D can lead to new patents granted on medicines, they cannot extend previous ones, and trivial tweaks cannot be patented. Each new patent on a post-approval innovation runs on its own clock without extending an original medicine's patent protection, and generic competition still arrives after **12-14 years** on average, a pattern that has been held for decades. 

Product Hopping

Myth: Drug companies make “meaningless tweaks” to existing products and market a new version just as the original medicine nears generic or biosimilar competition, steering patients to switch to the new version of the medicine. 

Fact: Post-approval research and development produces real advances for patients, including formulations that may improve adherence and reduce side effects. Protections on a new version of a medicine do not block FDA approval of generics or biosimilars of the original version. 

Skinny Labeling: A “skinny label” lets a generic drugmaker obtain FDA approval before a brand drug's other patent protected uses have expired.

Myth: Legislation is needed to address the uncertainty for generics discouraging them from pursuing skinny label generic applications. 

Fact: FDA's skinny-label process already balances generic competition with the incentive to keep researching new uses for existing medicines. Proposed legislation would undermine incentives for post-approval innovation despite the Supreme Court recently confirming in *Hikma v. Amarin* that skinny labeling remains available for generic competition. 

Serial Patent Litigation

Myth: Brand biopharmaceutical companies engage in serial patent litigation to stall competition and keep prices high. 

Fact: Industry critics making such claims focus only on roughly ten cherry-picked examples out of more than 4,000 Hatch-Waxman cases filed between 2010 and 2025. In those examples, generics overwhelmingly launched within the historical 12–14-year average, often while litigation was still ongoing. 

Terminal Disclaimers: Terminal disclaimers are longstanding routine patent tools used across industries that enable patenting of products researched and developed over time. In the case of biopharmaceutical R&D, the full scope of a medicine's associated inventions often emerges over many years. Companies may file additional patents on discoveries later in the development process that are closely related but different than an invention claimed in an earlier-filed patent, requiring the filing of a terminal disclaimer so as to not improperly extend patent term.

Myth: Biopharmaceutical companies file terminal disclaimers to obtain duplicative patents that are not innovative. These terminally disclaimed patents contribute to patent thickets and create an insurmountable hurdle to generic or biosimilar entry. 

Fact: The USPTO does not grant duplicative patents and a patent subject to a terminal disclaimer must still meet the same standards as any other: new, useful and non-obvious over what was previously known in the relevant technical field. There is no evidence that terminal disclaimers have increased litigation complexity or prolonged average market exclusivity periods. 

30-month Stays

Myth: Companies use 30-month stays as a delay tactic to keep lower-cost generics off the market. 

Fact: The 30-month stay exists under the Hatch Waxman litigation framework to resolve patent disputes before a generic launches. This helps avoid scenarios where a generic is found to infringe on an innovator's patents after it enters the market and then have to be pulled off and held liable for damages. What is often misunderstood is there is only one stay per generic application, not a new stay for every later patent. Further, the stay ends early if the generic prevails in district court. 

Across every one of these statements, the pattern is the same:

America's IP system is not a barrier to patient access. It is why U.S. patients get faster access to more new medicines than anywhere else, while nearly 90% of prescriptions are filled with lower-cost generics and biosimilars. Weakening the IP system would not lower costs at the pharmacy counter. It would undermine the incentives behind long-term investment, competition and patient access.