



## Drug Policy 101: Drug Patents

Patents serve as important catalysts for innovation. But in recent years, companies – including pharmaceutical companies – have been scrutinized for leveraging the patent system far beyond what the Congress intended to maximize profits and reduce competition.

As drug prices continue rising unsustainably in the United States, patients and payers need to understand – and policy makers need to address – how pharmaceutical companies use patents to maintain monopolies and pricing power.

### The basics: Obtaining a patent

The United States Patent and Trademark Office grants patents if an invention is “new and useful” or a “new and useful improvement” on an existing invention.

“Newness” means the invention is “novel and non-obvious” – it must not have been patented before, it must not have been publicly discussed or published before, and it cannot be something that a person in that field would reasonably conceive of, even if no patent already exists.

“Usefulness” means the invention has a purpose. In their application, inventors must describe the invention with enough clarity and detail to ensure that they are in possession of the invention, and enable others to make and use the invention.

Once granted, patents exclude others from making, using, offering for sale, selling, or importing or exporting covered inventions to or from the United States for 20 years. Pharmaceutical companies may apply for extensions to the patent term to account for administrative delays with the Patent and Trademark Office or delays in the approval process with the Food and Drug Administration (up to 5 years). Drug companies also seek separate market exclusivity protections from the FDA, which may or may not run concurrently with the patent term.<sup>1</sup>

### Maximizing the commercial life of drugs

Pharmaceutical companies use several strategies to maximize patent protection as a means of extending the commercial life of their drugs.

**Evergreening.** Innovator companies engage in “evergreening” when they obtain new patents for incremental changes to an existing drug.<sup>2</sup> These types of patents can include:

- New formulations of the original compound, such as extended-release drugs

- New ways to deliver a drug – for example, a nasal spray version instead of a pill
- New uses or treatment indications
- Combinations of two or more drugs, or a drug and a device, into one product

“Evergreen” patents do not always directly block generic companies from making and selling the original drug, but innovator companies can effectively maintain market dominance by aggressively marketing new versions of existing drugs, or by tactically getting patients to switch to new versions of existing drugs before a generic is available. This is known as “product hopping.”<sup>3</sup>

**Patent thickets.** Another strategy that pharmaceutical companies employ involves creating a large, complex web of patents surrounding a drug – known as a “patent thicket” – that makes it difficult to bring generic and biosimilar drugs to market because competitors cannot design around existing patents or cannot risk infringement.

The patent thicket surrounding Abbvie’s arthritis drug, Humira, is a notable example: The original patent on Humira expired in 2016, but more than 100 other patents protect it through 2034.<sup>4</sup> The company has filed an additional 247 patents to extend patent protection even further.<sup>5</sup>

**Litigation tactics.** Pharmaceutical companies also use litigation tactics to extend the commercial life of a drug. For example, companies involved in patent disputes with generic competitors may pay the generic to stay out of the market, capitalizing on their competitors’ inability to absorb litigation costs. These companies then reap significant financial rewards, as the profits they receive from extended monopolies far exceed their payments to competitors. These controversial agreements are known as reverse payment settlements, or “pay-for-delay.” In addition, companies block competition by drawing out litigation proceedings as much as possible. Lengthy disputes between companies making biologic drugs and those making generic versions actively delay the entry of less-expensive generic drugs into the market.<sup>6</sup>

### Supporting a fair patent system

Notwithstanding these abuses, the patent system is an important driver of pharmaceutical innovation in the U.S. By granting temporary monopolies, the federal government allows innovators to recoup the high costs they incur in bringing drugs to market. In exchange, they disclose their

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inventions, which – in theory – allows generic competitors to enter the market relatively soon after patents expire. In reality, the pharmaceutical industry's aggressive tactics to maximize patent protection stifle innovation and competition.

In light of this, opportunities to create a fairer patent system, which rewards both innovation and competition, are emerging. Examples include:

**Increase scrutiny of new patents.** Patents for inventions that are not truly innovative should not be granted, but unmerited patents persist. The number of unmerited patents can be reduced if the inventiveness standard were modified and the criteria for patentability were more strictly applied. In addition, patent examinations could be improved by providing patent examiners with more time, better research resources and external, third-party expertise to review applications.<sup>7</sup>

**Challenge the validity of existing patents.** Since 2012, generic companies and third-party challengers have been able to dispute unmerited patents through a process called Inter Partes Review. Resolving IPR disputes – which are heard before a panel of specialized judges in the Patent and Trademark Office's Patent Trial and Appeals Board – tends to be faster and less costly than resolving disputes in the court system.

**Enforce antitrust law.** Although the Federal Trade Commission has successfully litigated pay-for-delay settlements, it lacks sufficient resources to monitor and take enforcement action against the pharmaceutical industry. Increasing the FTC's resources and authority to enforce antitrust law may help stem pharmaceutical companies' anti-competitive tactics. Increased oversight over "producing

hopping" can also address anticompetitive behavior. The FTC has not pursued these cases vigorously, but in 2015, New York Attorney General Eric Schneiderman successfully blocked Allergan's plan to forcibly switch patients to an extended-release version of its Alzheimer's drug, Namenda, by discontinuing the original drug before the generic became available.<sup>8</sup>

**Make patent information more transparent.** Despite government efforts to make drug patent information available, transparency issues persist. For example, companies making biologic drugs may obscure patent information by creating patent thickets or by directly withholding information from competitors. In contrast to their generic counterparts – who are able to access patent information on small molecule drugs through a public resource known as the "Orange Book" – biosimilar companies must exchange information directly with biologic companies through a highly complicated process known as the "patent dance." The patent dance is not an efficient mechanism for exchanging patent information and has contributed to delays in biosimilar market entry. To address this issue, some proposals would require public listing of patents for biologics in the "Purple Book" (the biologic equivalent to the Orange Book).

Addressing the pharmaceutical industry's misuse of the patent system is urgent given the country's difficulty absorbing high drug prices. Creating a patent system that rewards innovation and encourages competition will be an important part of the ongoing dialogue on how to address unsustainable high drug pricing.

## End Notes

1. The FDA can grant more than 10 additional types of market exclusivities. For example, companies that develop drugs for small populations ("Orphan Drugs") or conduct trials for pediatric patients can gain additional years of exclusivity. See Robin Feldman, "May Your Drug Price Be Evergreen," *Journal of Law and the Biosciences*, December 7, 2018, <https://doi.org/10.1093/jlb/lisy022>
2. It has become commonplace for pharmaceutical companies to add protections to existing drugs. Seventy-eight percent of drugs associated with new patents were for existing drugs. See Robin Feldman, "May Your Drug Price Be Evergreen," *Journal of Law and the Biosciences*, December 7, 2018, <https://doi.org/10.1093/jlb/lisy022>
3. Regulatory Affairs Professionals Society. FTC Takes Action Against Pharmaceutical 'Product Hopping' <https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2015/10/ftc-takes-action-against-pharmaceutical-product-hopping>
4. Joe Nocera, "Drug-Price Transparency Won't End the Patent Games," *Bloomberg*, October 16, 2018, <https://www.bloomberg.com/opinion/articles/2018-10-16/humira-patents-show-why-fda-s-drug-price-shaming-won-t-work>
5. Overpatented, Overpriced: Special Humira Edition," *I-Mak*, September 7, 2018, [http://www.i-mak.org/wp-content/uploads/2018/09/i-mak.humira.report.final\\_0917.pdf](http://www.i-mak.org/wp-content/uploads/2018/09/i-mak.humira.report.final_0917.pdf)
6. Cynthia Koons, "The Shield of Patents Protects the World's Best-Selling Drug," *Bloomberg*, September 7, 2017, <https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug>
7. "Patent Office Should Strengthen Search Capabilities and Better Monitor Examiners' Work," United States Government Accountability Office, June 2016, <http://www.gao.gov/assets/680/678149.pdf>
8. "A.G. Schneiderman Announces Resolution of Lawsuit That Protected Alzheimer's Patients From Anticompetitive Tactic Aimed At Maintaining Higher Drug Prices," New York Attorney General's Office press release, November 25, 2015