Patent Reform for Patients

Why should patients care about patent reform?

The short answer: **the pharmaceutical industry uses loopholes in our current patent system to keep drug prices high and increase their profits. As a result, many patients cannot access life-saving prescription drugs.** For young adult patients with chronic and rare conditions, prescription medications may cost hundreds of thousands of dollars over their lifetime. To ensure affordable access to essential medication, abuse of the patent system needs to end.

This primer introduces key terms and explains different patent abuse practices used by brand-name pharmaceutical companies. It was created for young adult patients or anyone interested in learning more about this issue. Please send any feedback or questions to **admin@generationpatient.org**!

Key terms & important background information

What is a patent?

When someone has invented something new, useful, and not obvious to others, they can file for a patent. A patent **allows someone the exclusive right to make, use, or sell their invention for a certain period** - since they have come up with a unique idea that benefits the public, they can be the only one to profit from it for a set amount of time. This system is supposed to encourage people to invest in innovations, since their ideas will be protected, they can recover any money they've invested, and can profit from their invention. After the patent expires, anyone can use the invention without needing permission.

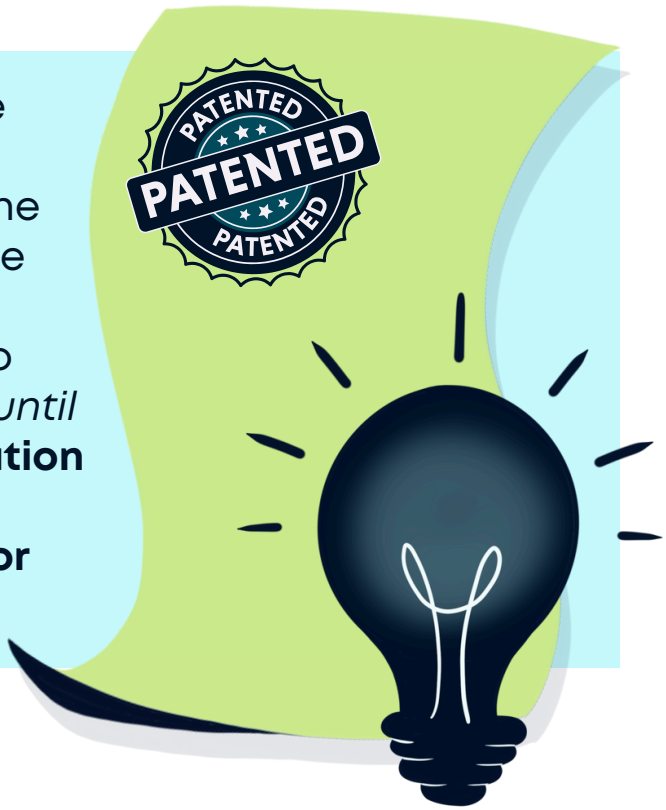
How do patents relate to prescription medications?

When a pharmaceutical company develops a new medication, they can ***patent*** any new or unique aspects of that medication such as active ingredients, medication formula, delivery mechanisms (how the medication is taken or released in the body), packaging, etc.

Once a new drug is developed, it is marketed under a patent-protected ***brand name***. These patents give the company *exclusive rights* to sell the drug for 20 years (from the patent's filing date). **During this time, no other companies can sell medications that use any part of the patented medication.**

Companies that discover, develop, or market new drugs under patent-protected names (brand names) are called "***brand-name pharmaceutical companies***," *innovators*, or *originator companies*.

In some ways, patents can incentivize the development of new medicines. Having patents for a period of time can enable the company to recoup their investment in the development of a drug. However, it also means that other companies that want to create similar medications *cannot do so until the patent expires*. **This can slow the creation of life-saving medications and block the manufacturing of cheaper alternatives for patients, such as 'generic' drugs.**



What is a generic drug?

A *generic drug* is a medication with "*bioequivalence*" to the brand-name drug. This means **it provides the same clinical benefits, dosage, form, safety, strength, route of administration, quality, performance characteristics, and intended use as the brand-name drug**. Other companies can manufacture generic versions of a drug after the brand-name patents expire.

Generic drugs are usually sold at lower prices than their brand-name counterparts, partly because the manufacturer doesn't have to recoup the same initial research/development costs as the original company. **Generic drugs are crucial for promoting competition in the pharmaceutical market**: **not only do they cost less up-front for patients, but they can help drive down drug prices overall, making life-saving medications more accessible to the public.**

More information on generic drugs:

Before a generic drug can be sold, it must be approved by regulatory authorities like the FDA (U.S. Food and Drug Administration). This involves rigorous review to ensure the generic drug meets identity, strength, purity, potency, and quality standards. Generic drugs may differ from their brand-name counterparts regarding non-active ingredients, such as fillers and coloring agents, because these do not affect the drug's therapeutic action (i.e. how it works).

→ Learn more **here**!

What are biologics and biosimilars?

Biologics

Biologics are complex, large-molecule medications made from components of living organisms. They are commonly used to treat autoimmune conditions (such as Crohn's, arthritis, and multiple sclerosis) and are often administered as injections or via IV therapy.

These drugs can also be *extremely* costly. In 2018, biologics accounted for only 0.4% of medications prescribed in the U.S., but made up 46% of the total medication costs. On average, these drugs can cost anywhere from $10,000-$30,000 **each year**.

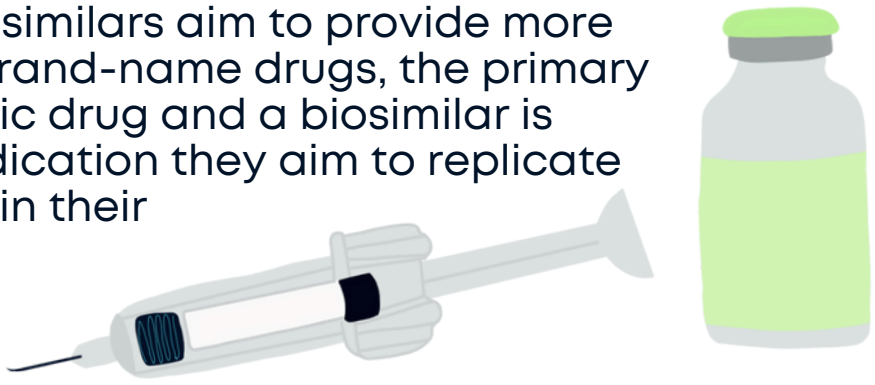
Biosimilars

Biosimilars are essentially generic versions of biologic medicines. Biosimilars are often cheaper, which helps increase patient access to these important medications. Unlike generic drugs, which are identical to their brand-name counterparts, **biosimilars are similar but not identical to their reference biologics**.

→ Learn more **here**!

So, what is the difference between a biosimilar and a generic?

While both generics and biosimilars aim to provide more affordable alternatives to brand-name drugs, the primary difference between a generic drug and a biosimilar is in the complexity of the medication they aim to replicate and the processes involved in their development and approval.



Generics

- Generic drugs are **equivalent** to brand-name drugs with respect to dosage, form, strength, route of administration, quality, performance characteristics, and intended use.
- They are made to replicate small molecule drugs, which typically have a simpler structure.
- Generics must prove **bioequivalence** to the original brand-name product, meaning they deliver the same amount of active ingredient into a patient's bloodstream in the same amount of time as the original drug.
- The manufacturing process for generics is usually straightforward and well-defined, making producing a replica of the original drug easier.

Biosimilars

- Biosimilars are highly **similar** to their reference biologic drugs. They are not identical due to the complex nature of biologics, which are large, complex molecules or mixtures of molecules made from living organisms.
- Biologics and biosimilars are more complex and variable in structure than small-molecule drugs, and their production involves living cells.
- To gain approval, biosimilars must comprehensively compare with the reference product to demonstrate **no clinically meaningful differences** in safety, purity, and potency. This process involves analytical studies, animal studies, and often clinical trials.
- The manufacturing process for biosimilars is intricate and can vary from batch to batch, so demonstrating similarity to the original biologic is more challenging than proving bioequivalence for generics.

A brief introduction to common patent abuses:

Three common ways that pharmaceutical companies abuse the patent system are **pay-for-delay**, **patent thickets**, and **product hopping**. Here, we'll explain each and how they impact patients' access to affordable medication.

What is "pay-for-delay"?

Pay-for-delay is when a **brand-name pharmaceutical company pays a potential competitor to delay selling a generic or biosimilar version of a drug**. This ensures that the brand name company does not have competition for that drug and can continue to charge high prices. **Brand-name pharmaceutical companies' use of "pay-for-delay" tactics means patients continue to pay higher prices for longer because more affordable options are not offered.** When we consider that companies like Abbvie made *$57 million per day from Humira in 2021,* paying to delay the release of generics/biosimilars for even two weeks can mean substantial profits!

Example:

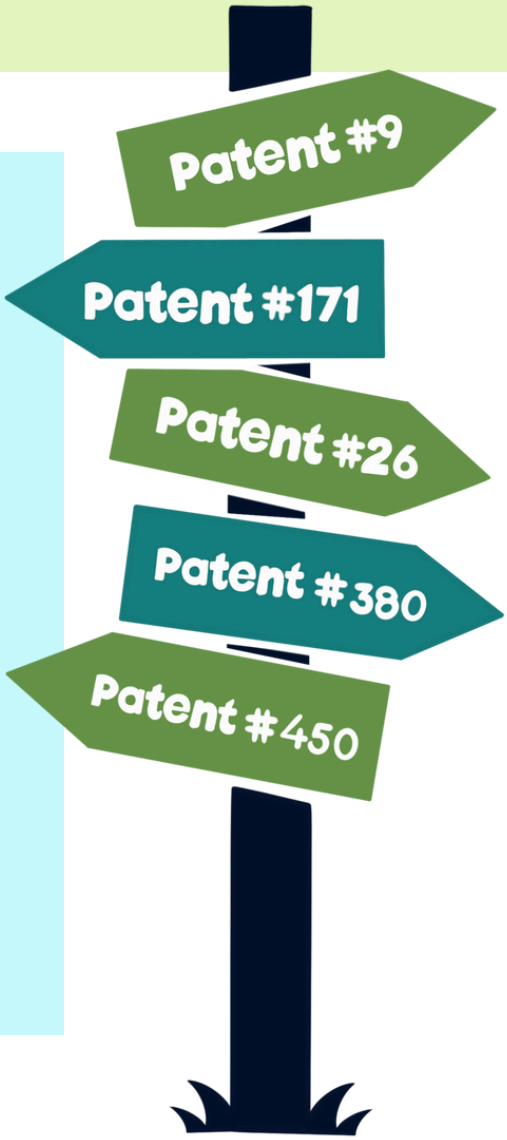
Endo Pharmaceuticals manufactured Lidoderm, a topical patch used to relieve pain associated with Shingles. In 2012, drug manufacturer Watson attempted to sell a generic version of Lidoderm at a more affordable cost. Instead of welcoming the competition, Endo Pharmaceuticals paid Watson an estimated $250 million to wait a year to enter the market. **Endo Pharmaceuticals profited $948 million without competition, while patients had to wait an extra year for a more affordable option** (U.S. PIRG).

What are patent thickets?

Drug companies create patent thickets when they **strategically apply for and accumulate dozens of patents on a single drug**. They do this by filing patents on multiple aspects of a medication: delivery mechanisms, minor changes to ingredients, or even cosmetic differences in packaging. **All the patents around a drug (a "thicket") are difficult for generic companies to work around, which delays and prevents the development of lower-cost generic competitor drugs.**

Example:

Enbrel, made by Amgen, treats rheumatoid arthritis, psoriatic arthritis, plaque psoriasis, ankylosing spondylitis, and moderate-to-severe juvenile idiopathic arthritis. According to the Initiative for Medicines, Access and Knowledge (I-MAK), **Amgen filed 57 patent applications on Enbrel, blocking generic competition for the drug for 39 years - almost double the time patents are supposed to protect innovators!** Patients need access to innovative and cost-saving approaches now, not in 39 years.



What is product hopping?

Brand-name pharmaceutical companies engage in *product hopping* when they **change a patented drug by a small amount to prevent pharmacies from substituting their brand-name drug with a lower-cost generic.**

They may encourage doctors to prescribe the "new and improved" version of their brand-name products specifically rather than an older version with a generic equivalent.

There are two types of product hopping: *hard* and *soft switches*.

- In a **'soft switch,'** a brand-name company keeps the "old" version of a drug on the market, but heavily promotes the "new" version.
- In a **'hard switch,'** the brand-name company asks the FDA to withdraw approval for their "old" product, or will discontinue/destroy inventory of the "old" product while promoting/selling the "new" version. It heavily influences patients and providers to get a "new and improved" product, rather than a lower-cost generic.

Example:

A few years before patent exclusivity on Suboxone (a treatment for opioid addiction) was set to expire, the brand-name manufacturer Reckitt changed the drug's form from a tablet to a dissolving film. Reckitt encouraged doctors to prescribe the new version, and **since Reckitt then had patent exclusivity on the "new" form, generic companies could not make a competing alternative. As a result, patients were unable to access more affordable alternatives of this life-saving drug** (U.S. PIRG).

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If you have any questions or comments about our primer, please contact us at **admin@generationpatient.org**.