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ISSUE BRIEF | Center for a Healthy America

Patent Abuses Keep Prescription Drugs Unaffordable

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TOPLINE POINTS

- ★ The cost of prescription drugs has skyrocketed over the past 10 years.
- ★ A key reason drugs are so expensive is that brand-name drug manufacturers abuse America's patent system and the Food and Drug Administration's drug approval process to artificially block generic competition and raise prices.
- ★ Policymakers can enhance competition and make prescription drugs more affordable by closing loopholes in America's patent system that allow brand-name drug manufacturers to delay competition.

America's patent system and the Food and Drug Administration's (FDA) drug approval process have promoted enormous pharmaceutical breakthroughs that have saved and improved the lives of millions of Americans. Unfortunately, both systems also contain numerous loopholes that allow drug manufacturers to block competitors from selling affordable generic versions of their drugs.

These patent abuses have significantly increased the cost of prescription drugs and made it harder for patients to access the medications they need. A plentiful supply of generic options is essential to lowering the cost of prescription drugs. Policymakers must close the loopholes in America's patent system and drug approval process and end these harmful abuses. This will ensure that families can access cutting-edge pharmaceutical innovations and affordable generic drugs.

Drugs Are Increasingly Unaffordable

The cost of prescription drugs has increased dramatically in recent years. Between 2011 and 2021, America's annual spending on prescription drugs increased from $366 billion (ASPE, 2016) to $603 billion (adjusted for inflation), a 64 percent increase (ASPE, 2022). Today, prescription drugs account for 22 percent of the cost of health insurance premiums (AHIP, 2022).

Due to the high cost of drugs, growing numbers of Americans are struggling to afford the medicine they need. Last year, one in 10 Medicare beneficiaries did not fill a physician's prescription because they could not afford to pay for it **(**Dusetzina, 2023).

Over the next several years, the cost of drugs is expected to get even worse. The Centers for Medicare and Medicaid Services estimates that the total cost of drugs in the U.S. will grow from $564 billion in 2020 to $917 billion by 2030, a 62 percent increase (Roehrig, 2022) and more than two and a half times the expected rate of inflation.

Drug Patents

Patients urgently need solutions to make medications affordable. The most proven method to lower the cost of medicine is to introduce more generics into the prescription drug market. Generic competition has saved America's patients, employers, and taxpayers $2.6 trillion over the last decade (Association for Accessible Medicines, 2022). In 2021 alone, generics reduced drug costs by $119 billion for Medicare beneficiaries and by $178 billion for commercially insured individuals.

Unfortunately, brand-name drugmakers have exploited loopholes in America's patent system to block generic companies from offering consumers affordable options. America's patent system has played an essential role in developing new medications and fostering robust generic competition. When a drug manufacturer invents a new drug, the company can apply for a product patent at the United States Patent and Trademark Office (USPTO that gives the inventor ownership of the invention for 20 years (35 U.S.C. 154, 1946). Federal law prohibits other companies and inventors from selling the same drug during this time. This gives drugmakers ample time to recoup the vast upfront research and development expenses they incurred for the drug by being the exclusive manufacturer and seller for the duration of the patent.

After 20 years, the patent expires and other companies are free to reproduce their drugs and charge consumers a lower price. Without the patenting process, inventors would have little incentive to spend enormous resources developing a drug that other companies could immediately mimic and mass produce at a low cost by free-riding off the original inventor's research and development.

America's patent system also allows drug manufacturers to add ancillary patents to a drug for specific features or updates. For example, manufacturers can obtain a method-of-treatment patent that covers the use of the drug to treat a certain disease. They can obtain a manufacturing patent

that covers the way the drug is produced. Manufacturers can also obtain a patent on the delivery device that administers the drug.

However, drug manufacturers are increasingly obtaining patents that do not advance new drugs or new innovations for existing drugs. Instead, they are obtaining patents to stymie generic competition so they can raise prices for consumers.

Ancillary Patents Abuse

For starters, drug manufacturers frequently abuse the practice of ancillary patenting. When a brand-name drugmaker invents a new drug, the drugmaker will often patent some but not all of the drug's structure in its initial product patent. As the drug's initial patent approaches its expiration date, the maker will then file new patents on its original structure to receive 20 more years of patent protection.

For example, when the drug company Genentech first developed the drug Perjeta in 2003, it filed a 20-year product patent for a part of the drug's structure called the peptide sequence (Camellia, 2003). Then, in 2009, it filed an additional product patent for another feature of the drug called its acidic profile (Reed, 2009). In another example, the drug company Merck extended the patent life on Keytruda by filing a new patent (Brower, 2022) on its initial design (Carven, 2008) and delayed competition by another six years.

Brand-name drug manufacturers frequently abuse ancillary patenting to block generic competition. A 2023 analysis found that drugmakers filed ancillary patents on their drug's original design 18 years after they first patented their drug (Goode, 2023). This strategy successfully extended their medication's patent life and delayed competition by 10 years. By delaying generic competitors, brand-name companies can charge significantly higher prices than they would be able to in a more functional marketplace.

Patent Thickets

Drug manufacturers also engage in a practice called building a "patent thicket" by utilizing duplicative patenting to block generic competitors (Goode, 2022). This occurs when brand-name drugmakers file multiple patents that use slightly different words in each patent to describe the same feature. For example, a drugmaker can file a method-of-use patent that states "a method of treating rheumatoid arthritis in a human subject, administering a total body dose of 40 mg once every 13 days." In addition, they could file a second patent that states "a method of reducing signs and symptoms in a patient with moderate to active rheumatoid arthritis, administering a total body dose of 40 mg once every 13 days" (Goode, 2022).

In most cases, federal law forbids companies from obtaining multiple patents on a single feature of a product (35 U.S.C. 103, 2011). However, the USPTO allows companies to file multiple patents on the same feature of a product if their patents meet two conditions. First, these patents must expire on the same date. Second, the company lists these patents on a legal statement the USPTO offers, known as a *terminal disclaimer* (37 C.F.R. 1.321).

The USPTO established terminal disclaimers so that companies can immediately patent the first draft of their invention (Upcounsel, 2023). As companies refine the product, they can obtain a terminal disclaimer to file new patents on the updates to the same invention.

Unfortunately, brand-name drug manufacturers abuse terminal disclaimers by using them to obtain dozens of virtually identical patents to delay generic competitors (Goode, 2022). Many patents within terminal disclaimers are of low quality and, therefore, vulnerable to litigation. However, it is extremely expensive for generic companies to litigate every patent inside a terminal disclaimer individually. On average, it costs generic drugmakers $774,000 to litigate a single patent on a brand-name drug (Goode, 2022). When a brand-name drug manufacturer files so many patents, it becomes virtually impossible for generic makers to afford to contest them.

Brand-name drug manufacturers routinely obtain duplicative patents to delay competition. A 2023 analysis in the *Journal of the American Medical Association* found that brand-name drugmakers file the vast majority of terminally disclaimed patents as their drug's 12-year exclusivity period expires (Tu, 2023). These findings strongly suggest that brand-name drug manufacturers strategically obtain terminal disclaimers to block generic competitors from entering the market.

FDA Drug Approval

The FDA also enforces regulations intended to reward drug manufacturers that bring new medications to market. The agency is tasked with regulating the entrance of brand-name and generic drugs into the market. After a brand-name manufacturer obtains a patent for a new drug, the manufacturer must apply to the FDA to sell the drug in the United States. For small-molecule medications,[1] the FDA grants the new drug a *new chemical entity* (NCE) exclusivity (21 U.S.C. 355, 1984). Under an NCE exclusivity, the agency may not approve any generic version of the drug to enter the market for five years.

If the drug is a more complex medication known as a biologic,[2] the FDA grants the drug 12 years of exclusivity without any competition (42 U.S.C. 262, 2010). Once the exclusivity expires, other companies can sell generic versions, called biosimilars.

The FDA also allows drug manufacturers to extend the exclusivity period of small-molecule drugs for three more years through another exclusivity known as a *new clinical investigation* (NCI) exclusivity (21 U.S.C. 355, 1984). Drugmakers can receive an NCI exclusivity when they change a drug's dosage form, regimen, or route of administration, or if they make other updates that does not change the drug's active ingredients.

[1] Small-molecule drugs are medications that include relatively simple chemical ingredients such as sugars, lipids, amino acids, and fatty acids. Examples of small-molecule drugs include aspirin, penicillin, Ibuprofen, and antihistamines.
[2] Biologics are produced from components of living organisms, including human, plant, and animal cells and microorganisms such as bacteria or yeast.

After a brand-name drug's exclusivity expires, generic drugmakers can apply to the FDA to sell generic versions of the drug. As part of their application, generic drugmakers must certify that the patents on the brand-name drug are either invalid or will not be infringed by their generic drug. If the brand-name drugmaker disagrees and sues the generic maker for patent infringement, federal law prohibits the FDA from approving the generic for 30 months (21 U.S.C. 355, 1984). Congress established this 30-month moratorium to give generic drugmakers time to resolve patent litigation before their drugs may enter the market.

These features of the FDA's drug approval process are intended to promote innovations that benefit patients. Unfortunately, drugmakers exploit the agency's approval process to strategically delay competition and raise prices.

Exclusivity Evergreening

Some drugmakers exploit the FDA's policies through the abuse of a practice known as "evergreening." As a brand-name drug's patent nears expiration, its manufacturer will strategically introduce delayed updates to the drug to obtain a three-year NCI exclusivity and delay generic entry. For example, in 1996, the drugmaker Boehringer Ingelheim released the HIV drug Viramune as an immediate release pill that delivers its entire active ingredient soon after a patient ingests it. As Viramune's patent approached expiration in 2011, Boehringer updated Viramune into an extended release pill that delivers its active ingredient over a period of several hours (CRFB, 2021). This update granted Viramune an NCI exclusivity that delayed generic competition an additional three years.

As a result of exclusivity evergreening, small-molecule drugs exist on the market without generic competition long after their initial five-year NCE exclusivity expires. Between 1995 and 2019, the average exclusivity period for small-molecule drugs was 14 years (Grabowski, 2021).

FDA Policies Encourage Patent Abuse

The FDA also enforces rules that encourage brand-name drugmakers to file frivolous patents. The agency's 30-month moratorium on approving generics under litigation gives brand-name drug manufacturers an enormous incentive to file and litigate as many patents as possible (Dickson, 2022). Many of these could be low-quality patents that the generic company could successfully litigate. Unfortunately, the FDA's 30-month moratorium empowers brand-name drug manufacturers to delay generics and keep prices high for patients.

Instead, the FDA should adopt standards for approving small-molecule drugs that are similar to its standards for approving biosimilars. The FDA does not impose any approval moratorium on biosimilars. This allows biosimilar manufacturers to offer consumers a lower-cost drug while the company fends off litigation from brand-name biologic firms. As of March 2023, 40 percent of all biosimilars that are currently available in the United States were litigating another biologic company's patents (Wong, 2023). Similarly, the FDA should permit small-molecule generic developers to sell their products while they are engaged in litigation with brand-name drug manufacturers.

Pay-For-Delay Agreements

Brand-name drug manufacturers also suppress generic competition by establishing financial arrangements with generic drug manufacturers known as pay-for-delay agreements. When a drug developer applies to the FDA to launch a generic version of a brand-name drug, the brand-name drug's manufacturer will often sue the generic manufacturer for patent infringement. The brand-name manufacturer will then offer to settle the lawsuit if the generic manufacturer signs a pay-for-delay agreement (Kaiser Permanente, 2018). Under this agreement, the brand-name manufacturer will compensate the generic drug developer to launch the generic drug at a later date.

Pay-for-delay agreements significantly slow the introduction of cost-saving generics into the marketplace. A 2010 analysis by the Federal Trade Commission (FTC) estimates that these arrangements, on average, postpone generic medications by 17 months (FTC, 2010).

Patent and Exclusivity Abuse Raises Prices

Patent abuses artificially delay competition and raise prices for families, employers, and taxpayers. Brand-name drugs can exist on the market without any competition for years or even decades. A 2021 analysis by the Institute for Medicines, Access, and Knowledge (I-MAK) of the best-selling drugs in the United States found that these drugs are covered by 74 patents on average (I-MAK, 2021). These patents provide these drugs with 40 years of protection from generic and biosimilar competition.

After blocking generic and biosimilar entry, brand-name drugmakers are free to raise prices. I-MAK's 2021 analysis found that the price of these drugs increased 44 percent between 2016 and 2021. In 2021 alone, these drugs, on average, cost Medicare and the beneficiaries who use these medications $57,000 per beneficiary. Another I-MAK analysis estimates that patent abuse will increase spending on just two medications, Revlimid and Sovaldi, by $55 billion between 2017 and 2032 (I-MAK, 2017).

Evergreening and other exclusivity abuses have also contributed to higher drug prices. A study in the *Journal of Managed Care And Specialty Pharmacy* estimates that evergreening increased patient and taxpayer spending on 50 drugs by $62 billion between 2008 and 2016 (Dickson, 2019).

Curbing exclusivity evergreening would bolster competition and make drugs more affordable. A 2021 analysis by the Committee For a Responsible Federal Budget (CRFB) estimated that preventing brand-name drugs from obtaining excessive NCI exclusivity extensions would save $20 billion over 10 years (CRFB, 2021).

Limiting patent abuse would also make prescription drugs significantly more affordable. Without duplicative patents in patent thickets and ancillary patent abuse, generic companies could launch faster and offer patients significantly less expensive medications. A 2018 literature review found

that generic drugs cost six to 66 percent less than brand-name drugs within five years of a brand-name drug's patents expiring (Vondeling, 2018). Another 2014 study of cancer drugs found that the average price of physician-administered drugs falls 38 to 48 percent, and the price of oral drugs falls 25 percent after the brand-name drug's patents expire (Conti, 2014).

Curbing pay-for-delay agreements would also deliver crucial savings to patients. A 2021 analysis of these financial arrangements estimates that they raise the cost of prescription drugs for the Medicare program by up to $13.5 billion every year. For the nation as a whole, pay-for-delay increases the cost of prescription drugs by up to $37 billion annually, including $2.9 billion in higher out-of-pocket costs (Feldman, 2022). Eliminating this anticompetitive practice would significantly lower premiums, coinsurance, and copays for families.

Policy Recommendations:

Modernizing America's patent system and drug approval process would bring affordable drugs to the market faster, enhance health care access, and improve outcomes for patients. Policymakers should implement the following reforms to ensure that patients can purchase low-cost generics without unnecessary delays:

Curtail Patent Thickets: Policymakers should prohibit brand-name drugmakers from engaging in duplicative patenting by asserting more than one patent within a terminal disclaimer in a lawsuit. If the court system determined the patent was invalid, then all the patents in the terminal disclaimer would be invalidated. The bipartisan To Address Patent Thickets Act (2024) would enact this important solution. The USPTO should also consider implementing this reform through the formal notice and comment process.

Curb Ancillary Patent Abuse: Policymakers can curb ancillary patenting abuse by requiring brand-name drugmakers to disclose analytical and clinical information about their drug's design and features to the USPTO. This would empower the USPTO with the right information to determine if brand-name manufacturers wanted to patent a legitimate change to their drug or simply to add a new patent onto their drug's original structure. The bipartisan Medication Affordability and Patent Integrity Act (2023) would enact this commonsense solution. In addition, the FDA could disclose analytical and clinical information about brand-name drugs directly to the USPTO when companies disclose this information to the FDA.

Eliminate Evergreening: Policymakers can combat exclusivity evergreening by prohibiting brand-name drugmakers from receiving an NCI exclusivity extension within three years of their drug's patent expiration (CRFB, 2021). This would encourage drugmakers to introduce improvements to their drugs more quickly and discourage drugmakers from waiting to update their drugs to delay generic competition.

Repeal the FDA's 30-month Moratorium: Policymakers should repeal the FDA's 30-month moratorium on approving generic drugs when a brand-name manufacturer initiates litigation. The bipartisan REMEDY Act (2019) in the 116th Congress proposed prohibiting the agency from enforcing the 30-month stay for most types of drug patents.

Curtail Pay-For-Delay Agreements: Policymakers should prohibit drug developers from establishing pay-for-delay arrangements with their competitors. The Lower Costs, More Cures Act (2021) in the 117th Congress would ban brand-name drug manufacturers from financially rewarding other drug manufacturers to forgo launching generic and biosimilar versions of their products.

Strengthen Anti-Trust Enforcement: Policymakers should direct the FTC, USPTO, and FDA to identify additional anticompetitive practices drug manufacturers implement to curtail generic and biosimilar competition. These agencies should also introduce guidance and regulations to curtail such anticompetitive practices.

Conclusion

Patents and the FDA's drug approval process are essential to fostering a dynamic pharmaceutical industry that develops new lifesaving and life-improving medications. At the same time, it is also essential that patents and exclusivity periods expire so that pharmaceutical companies can develop affordable generic versions of brand-name drugs.

Unfortunately, the abuse of America's patent system and drug approval process allow brand-name drug companies to delay competition for decades and raise prices for patients, taxpayers, and employers. Policymakers should close these loopholes so that families can access cutting-edge pharmaceutical breakthroughs as well as affordable generic and biosimilar drugs.

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