the campaign for
SUSTAINABLE Rx PRICING

FACT SHEET: BIG PHARMA'S PATENT ABUSE COSTS AMERICAN PATIENTS, TAXPAYERS AND THE U.S. HEALTH CARE SYSTEM BILLIONS OF DOLLARS

Big Pharma's Anti-Competitive Tactics Are The Root Cause of Out-of-Control Prescription Drug Prices

BIG PHARMA'S PATENT ABUSE IS THE ROOT CAUSE OF OUT-OF-CONTROL PRESCRIPTION DRUG PRICES

Big Pharma has a long history of price-gouging American patients through tactics designed to game the U.S. patent system and block competition from more affordable alternatives — enabling Big Pharma to maintain monopolies over their biggest money-makers. The pharmaceutical industry's egregious abuse of the patent system is a root cause of high prescription drug prices because it enables Big Pharma to repeatedly hike prices on existing drugs and set out-of-control launch prices on new medications (knowing they can maintain monopolies longer on blockbuster products).

Egregious examples of anti-competitive tactics commonly used by Big Pharma to game the patent system include:

> **Product Hopping:** In which a pharmaceutical company makes a small tweak to an existing drug, such as a new way to administer it or a new dosage level. The drug company then patents that change just before the original patent expires, extending exclusivity, and therefore monopoly pricing, on the product.
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> **Patent Thicketing:** Where a pharmaceutical company files many, often dozens or hundreds, of patents on a single medication to extend exclusivity and block competition from more affordable options, for months, years, or even decades.

The Campaign for Sustainable Rx Pricing (CSRxP) has long encouraged policymakers to support bipartisan, market-based solutions to crack down on Big Pharma's patent abuse, including The Affordable Prescriptions for Patients Act.

Introduced by Senators John Cornyn (R-TX) and Richard Blumenthal (D-CT), The Affordable Prescriptions for Patients Act, has previously won strong support from both Republicans and Democrats — and would help end practices like patent thicketing and product-hopping that brand name drug companies use to extend unjustified monopolies and keep prices high. This bipartisan, market-based solution was unanimously passed by the U.S. Senate Committee on the Judiciary in February 2023.

Below, you'll find some more information on the cost of Big Pharma's patent abuse, examples of the industry's egregious practices and data demonstrating overwhelming support from voters for market-based solutions to rein in Big Pharma's patent abuse.

THE COST OF BIG PHARMA'S PATENT ABUSE

Big Pharma's Patent Abuse Increased Costs By More Than $40 Billion in Just One Year

In May, The American Economic Liberties Project and the Initiative for Medicines, Access & Knowledge (I-MAK) released an analysis examining the staggering cost of Big Pharma's anti-competitive practices on the U.S. health care system and American patients. The analysis found that Big Pharma's anti-competitive tactics, including patent abuse, cost U.S. consumers "an additional $40.07 billion on pharmaceuticals," in just one year, 2019.

Big Pharma's Patent Thickets On Just Five Drugs Cost Over $16 Billion In a Single Year

A January 2023 report from Matrix Global Advisors, "Patent Thickets and Lost Drug Savings," quantified the one-year cost of lost savings on five brand name drugs around which Big Pharma has built especially egregious patent thickets. The five drugs were AbbVie's autoimmune drug Humira and oncology drug Imbruvica, Regeneron's ophthalmology drug Eylea, Amgen's autoimmune drug Enbrel, and Bristol Myers Squibb's oncology drug Opdivo.

The report assesses what the savings would be for these five drugs if "a steady state of competition [existed] where generics and biosimilars have achieved price discounts and uptake currently observed in the market." Based on these calculations, the estimated one-year cost of patent thickets on each of these brand name drugs was:

- $7.6 billion for Humira
- $3.1 billion for Imbruvica
- $2.5 billion for Eylea
- $1.9 billion for Enbrel
- $1.8 billion for Opdivo

This amounts to a total of more than $16 billion.

The report calls for "tangible legislative reforms… to stop this long-standing anticompetitive practice." In particular, the report points to "the Affordable Prescriptions for Patients Act," which would "limit the number of patents a brand drug manufacturer can contest," as one important solution for lawmakers to consider.

Targeting Blockbuster Products for Patent Abuse

A May 2022 study published in JAMA Health Forum revealed how brand name drug companies target their most profitable products for reformulation to extend monopolies and prohibit generic competition from entering the market.

- The results of the study showed that "of 206 brand-name drugs approved in tablet or capsule form by the U.S. Food and Drug Administration between 1995 and 2010, approval of new formulations was four times more likely among blockbuster drugs."

- The study also found that drug makers sought to pursue new formulations, "less frequently once generic competitors entered the market."

EGREGIOUS EXAMPLES

Patent Abuse on Humira Drove More Revenue for Big Pharma Giant AbbVie Than All 32 NFL Teams Combined

While AbbVie's blockbuster autoimmune drug Humira will finally face its first competition in the U.S. in 2023, over the course of its more than 20 years on the market, AbbVie applied for more than 300 patents on the brand name medication, securing more than half of them. 94 percent of the patents filed on Humira came after the drug was initially approved by the U.S. Food and Drug Administration (FDA). The strategy helped block competition for years and generate almost $200 billion for AbbVie. Just last year, the drug brought in more money for the company, $21 billion, than all 32 teams in the NFL combined, $19 billion.

A Recent Case Study in Big Pharma's Patent Greed: Keytruda

In December 2022, Big Pharma giant Merck announced that it will seek new patents on its blockbuster cancer drug Keytruda, which last year brought in over $17 billion for the company. According to reporting from Reuters, Merck is seeking

"to patent a new formulation of its $20 billion cancer immunotherapy Keytruda that can be injected under the skin, allowing it to protect its best-selling drug from competition expected as soon as 2028."

This is just the latest example of a strategy Big Pharma companies have used repeatedly to extend their monopolies on blockbuster products – filing for patents for changes such as intake method or dosage that don't represent truly new innovations or improve clinical benefits for patients. This enables Big Pharma to add to patent thickets designed to block competition from more affordable alternatives, keep drug prices high and boost profits.

Dr. Shailender Bhatia, an oncologist at the Fred Hutchinson Cancer Center in Seattle said, "I don't think it's going to improve the safety or the effectiveness of the drug."

"It's the way the pharmaceutical companies now use that system — it's all about taking up as much space as possible, making it difficult for anybody to enter," Tahir Amin, co-founder of Initiative for Medicines, Access & Knowledge (I-MAK), said in Reuters coverage of the move. "Keytruda is going to be the next Humira by all accounts."

According to research from I-MAK, Merck has filed for 129 patent applications on Keytruda – more than half of which were filed after the drug's initial approval by the FDA The Big Pharma company has been granted 53 patents on this one drug. I-MAK estimates that Americans will spend at least $137 billion on Keytruda while the drug faces no competition due to its extended exclusivity that already totals more than eight years — without reflecting the added impact of the Big Pharma giant's new patent strategy.

Drug Maker's Product-Hopping Scheme Blocked Access To Safer HIV Medications

In July, The New York Times published an article exposing how brand name drug maker Gilead employed a greedy patent strategy around a pair of blockbuster HIV treatments to maximize profits while blocking access to newer versions of those treatments proven to be safer for patients.

As The Times wrote, "Gilead had devised a plan to delay the new drug's release to maximize profits, even though executives had reason to believe it might turn out to be safer for patients."

The Gilead scheme offers a particularly egregious case study in the Big Pharma practice of "product hopping," one of the pharmaceutical industry's commonly employed tactics to game the patent system. Product-hopping involves a drug manufacturer making changes to an existing product — then patenting those changes before an original product expires to extend exclusively, delay competition and keep prices high.

According to The Times, internal documents from Gilead showed executives and researchers at the company were aware that a newer version of one of their HIV drugs, Truvada, "had the potential to be less toxic to patients' kidneys and bones than the earlier iteration." However, the company purposefully delayed the development of this "less toxic" treatment so that its eventual release would coincide with the loss of patent protection around Gilead's existing HIV treatments that were already on the market. This meant Gilead delayed the development of a safer, less harmful treatment for HIV for over ten years. The company paused development on the newer version of the drug, eventually marketed as Descovy, in 2004, and didn't bring it to market until 2015 — all to maximize the length of time the Big Pharma giant could maintain a monopoly on the treatments and juice profits.

Gilead's use of this tactic around its HIV treatments is particularly egregious because instead of timing changes, like delivery method, dosage level or pill casing, to a new drug to maximize profits, the company chose to prevent patients from accessing a safer, less harmful treatment option.

VOTERS WANT CONGRESS TO HOLD BIG PHARMA ACCOUNTABLE FOR ABUSE OF THE PATENT SYSTEM

CSRxP recently released the results of a national, bipartisan survey that found American voters overwhelmingly identify Big Pharma as the culprit for out-of-control prescription drug prices and want lawmakers focused on holding brand name drug companies accountable for their egregious anti-competitive practices to lower drug prices.

The survey, jointly conducted by two industry leading pollsters, Republican Erik Iverson of Moore Information Group (MIG), and Democrat Celinda Lake of Lake Research Partners (LRP), found:

- **60 Percent:** A clear majority of American voters (58 percent) name pharmaceutical companies as most responsible for rising prescription drug prices, 40 percent more than the next most blamed entity: The U.S. government (18 percent). No other entity broke single digits. A majority of Republicans, Democrats and independent voters all identify the pharmaceutical industry as responsible.

- **More than Three-in-Four:** 78 percent of voters say they support the bipartisan Affordable Prescriptions for Patients Act, or Cornyn-Blumenthal, which is designed to help lower prescription drug prices "by preventing large pharmaceutical companies from abusing the U.S. drug patent system to keep their monopolies on brand-name drugs and block competition from lower priced drugs, like generics." This includes more than 73 percent of independents, 75 percent of Republicans and 86 percent of Democrats.

    - **88 Percent:** Nearly 90 percent of voters say they are more likely to support the solution because it focuses on holding large pharmaceutical companies accountable to lower drug prices.

    - **81 Percent:** More than four-in-five (81 percent) voters say they would be more likely to vote for a candidate for U.S. Senate or the U.S. House of Representatives who supported The Affordable Prescriptions for Patients Act (Cornyn-Blumenthal).

- **89 Percent:** Nearly 90 percent of voters find it concerning to hear "Humira is the number one selling drug in the world with $21.2 billion in sales in 2022" and that "the drug's manufacturer AbbVie filed hundreds of patents and secured 130 patents on this one drug to block competition for decades in the United States, while increasing its price. In 2022, Humira brought in more than $21 billion in revenue – more than all 32 NFL teams combined."

THE ROAD AHEAD

Big Pharma's continued abuse of the patent system to block competition and keep drug prices high demonstrates why Congress must hold Big Pharma accountable. As CSRxP executive director Lauren Aronson highlighted in an op-ed in D.C. Journal in May, "Congress cannot deliver lower prescription drug prices for patients without focusing on the root cause of high prices in the first place."

About CSRxP: The Campaign for Sustainable Rx Pricing is a broad-based coalition of physicians, nurses, hospitals, consumers, health plans, pharmacy benefit managers, pharmacists, and businesses promoting bipartisan, market-based solutions to lower drug prices. Learn more: www.csrxp.org

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