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.

The Affordable Prescriptions for Patients Act, introduced by Senators John Cornyn (R-TX) and Richard Blumenthal (D-CT), is one such solution. This bipartisan, market-based legislation to crack down on patent thickets was unanimously passed by the U.S. Senate in July 2024 and reintroduced in the Senate in March 2025. The nonpartisan Congressional Budget Office (CBO) estimated the bill would save $1.8 billion. Senators Cornyn and Blumenthal also recently introduced the Drug Competition Enhancement Act, which would hold Big Pharma accountable for product hopping to foster greater competition in the marketplace from more affordable alternatives, like generics and biosimilars.

Below, you'll find 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 hold Big Pharma accountable.

THE COST OF BIG PHARMA'S PATENT ABUSE

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 the Journal of the American Medical Association (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."

Three-Quarters of Big Pharma's Patents on Top-Sellers Filed After FDA Approval

A May 2024 JAMA Network study examined Big Pharma's egregious patent thickets erected around the top 10 best-selling prescription drugs in the U.S. The study found the top 10 brand name drugs in terms of "US net sales revenue in 2021" had a total of 1,429 patents or pending patents. Additionally, 742 of these – or 52 percent – were issued patents, while 218 – or 15 percent – were pending patents, and 469 – or 33 percent – were abandoned patents.

Of the patents examined in the study, almost three-quarters – or 72 percent – were filed after the U.S. Food and Drug Administration (FDA) initially approved these drugs. The study found that "patent thicket density peaked 13 years after initial FDA approval, at which time these 10 drugs were protected by a median of 42 active patents – 66 percent of which were filed after FDA approval."

Among patents filed after initial FDA approval, 41 percent were for method of use claims, 27 percent were for formulation claims, 22 percent were for process or synthesis claims and 10 percent were for device claims. Fewer than 20 percent of the patent filings were for chemical composition claims. The study recommends that more "[s]crutiny of patent applications and of patents filed after FDA approval is needed to facilitate timely generic or biosimilar competition."

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 finally faced its first competition in the U.S. starting 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 FDA. The strategy helped block competition for years and generated almost $200 billion for AbbVie. In 2022, the drug brought in more money for the company, $21 billion, than all 32 teams in the NFL combined, $19 billion.

An Ongoing Case Study in Big Pharma's Patent Greed: Keytruda

At the J.P. Morgan Healthcare Conference in January 2025, Merck CEO Rob Davis said the brand name drug company "was planning to offset Keytruda's loss of exclusivity by moving up plans to file for approval and launch a subcutaneous version of Keytruda by the end of 2025."

Keytruda, which generated nearly $29 billion in revenue for the Big Pharma giant in 2024, is already patent-protected in the U.S. until 2028. To further extend monopoly pricing and undermine competition from more affordable alternatives beyond 2028, Merck first announced it would seek the new formulation and accompanying added patents in 2022.

This is just the latest example of a strategy Big Pharma companies have used repeatedly to extend their monopolies on blockbuster products – filing 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, keeping drug prices high and boosting 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

On a November 2024 earnings call with investors, Gilead Sciences' Chairman and Chief Executive Officer touted the company's patent strategy around its portfolio of HIV drugs. Gilead's anti-competitive tactics have extended monopolies for the Big Pharma giant and featured a particularly egregious product-hopping strategy that blocked patients from accessing a treatment that would have supported better health outcomes.

"Again, just to remind you, of course, the totality of our HIV business is such that we really don't have any significant patent expiry until Biktarvy in 2033," the drug company's CEO touted to investors.

Gilead has a demonstrated track record of blocking competition around its HIV portfolio, which includes several of the company's blockbuster drugs. Gilead is also notorious for having purchased government-funded research breakthroughs for pennies on the dollar, only to charge tens of thousands of dollars for these products while gaming the system to extend monopoly pricing.

In July 2023, The New York Times published an article exposing how brand name drug maker Gilead employed this 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.

Brand Name Drug Makers Increasingly Utilizing 'Use Codes' To Game Patent System And Block Competition

According to a September 2024 analysis from STAT News, brand name drug makers are increasingly utilizing an under-the-radar tactic to game the patent system that may delay the arrival of lower-cost generic medicines. The analysis points out how drug makers have increasingly been submitting more 'use codes,' "which are brief descriptions of a type of patent claim" in the FDA Orange Book. The Orange Book describes all the pharmaceutical products that have been approved by the FDA and the patents that apply to these products.

On paper, the Orange Book is meant to serve as a resource listing all the patents brand name drug manufacturers have secured for FDA approved products. However, STAT's analysis lays out how brand name drug companies are effectively gaming the Orange Book to make it more challenging for potential competitors to introduce alternative products to brand name drugs. By submitting multiple 'use codes' for their patents in the Orange Book, brand name drug makers are able to make it more "difficult for a would-be generic rival to successfully battle patent litigation."

Pharma Patents Invalidated More Than Any Other Industry For Misrepresented Or Omitted Information

According to coverage in STAT News, a 2023 JAMA Network analysis found FDA approved patents secured by Big Pharma are more frequently invalidated than any other industry sector due to drugmakers misrepresenting or omitting information during the patent application process.

The analysis found that pharmaceutical companies failed to provide accurate information to the U.S. Patent & Trademark Office (USPTO) on 34 patents previously approved by the FDA – resulting in a U.S. appeals court invalidating 15 patents relating to medicines and 10 to medical devices between 2004 and 2021.

When unchallenged or invalidated, these faulty patents contribute to increasing prescription drug costs by extending periods of exclusivity, which enables Big Pharma to engage in anti-competitive and monopoly pricing – as these products face no competition. As outlined in the analysis, these anti-competitive practices have contributed to Big Pharma increasing the median brand name drug launch price from $2,115 in 2008 to $180,007 in 2021.

The analysis follows increased scrutiny of pharmaceutical patents by the U.S. Federal Trade Commission (FTC), which challenged more than 100 patents in 2023 on brand name drugs manufactured by Big Pharma giants including AbbVie, AstraZeneca and GlaxoSmithKline.

Patent Abuse on Brand Name Inhalers Produced $111 Billion for Big Pharma After Active Ingredient Patents Expired

In 2023, William B. Feldman and Aaron S. Kesselheim, physicians at Brigham and Women's Hospital and faculty members at Harvard Medical School, highlighted Big Pharma's extensive patent abuse on brand name inhalers used to treat asthma and chronic obstructive pulmonary disease in an op-ed published in The Washington Post.

The authors explained brand name manufacturers "have used the patent and regulatory system to keep generics off the market," including through tactics like patent thicketing.

"Of the $178 billion that manufacturers earned on inhalers in the United States from 2000 to 2021, about $111 billion of that total came after patents on their active ingredients had expired," according to the experts, who added, "the patent system was designed to promote innovation, not grant monopolies for small tweaks to devices containing decades-old drugs."

Big Pharma Building Patent Thickets Disconnected From Actual Innovation To Create New Monopolies On GLP-1 Weight Loss Drugs

A February 2024 analysis published in JAMA Network finds that the brand name drug makers marketing a new category of weight loss drugs, glucagon-like peptide 1 (GLP-1) receptor agonists, are increasingly utilizing device patents to build patent thickets around these products to create and elongate periods of monopoly pricing power — despite the drugs effectively being older diabetes medications repackaged for a different indication. In other words, Big Pharma isn't protecting actual innovation, but gaming the patent system to block competition, keep prices high and boost profits.

According to the analysis, the number of device patents that are unconnected to active ingredients in these GLP-1 products, garnering significant demand despite high prices, are significantly higher than other drug categories that rely on drug-device combinations, such as certain kinds of insulin and inhalers.

As the authors state in their conclusion, the "removal of these patents may substantially reduce barriers to generic entry by decreasing the number of patents that generic firms must contest ahead of [U.S. Food and Drug Administration] approval." Without this competition, "prices for GLP-1 receptor agonists will remain high for many years, reducing access for patients and raising health care costs."

VOTERS OVERWHELMINGLY SUPPORT HOLDING BIG PHARMA ACCOUNTABLE FOR PATENT ABUSE THAT KEEPS DRUG PRICES HIGH

CSRxP recently released the results of public opinion research, conducted by Fabrizio Ward, showing American voters overwhelmingly hold Big Pharma responsible for high prescription drug prices and support market-based solutions to lower prices by holding big drug companies accountable, including for gaming the U.S. patent system to block competition.

"American voters, across all party and ideological lines, rightly hold Big Pharma responsible for the high price of prescription drugs and overwhelmingly support market-based solutions to crack down on brand name drug companies' egregious pricing and anti-competitive practices," **said CSRxP executive director Lauren Aronson**. "Voters continue to reject Big Pharma's blame game and debunked innovation rhetoric, and share substantial concern with a host of pharmaceutical industry practices that contribute to high prices and saddle Americans with a worse deal on their medications, including egregious anti-competitive tactics, staggering spending on direct-to-consumer (DTC) advertising, persistent price hikes on existing products, rising launch prices for new products, offshoring of profits to avoid U.S. taxes and more. Policymakers in Washington should recognize, and act on, the overwhelming consensus across the political spectrum to hold Big Pharma accountable to lower drug prices for the American people."

"Results from the new national survey of voters just completed for the Campaign for Sustainable Rx Pricing show broad and overwhelmingly bipartisan support for policy solutions to lower the cost of prescription drugs by addressing pricing and anti-competitive practices from drug companies," **pollsters Tony Fabrizio and Bob Ward wrote in a memo on their findings**. "The electorate, including equal numbers of Trump and Harris Voters, holds intensely unfavorable views of drug companies. By wide margins, voters are very concerned about the cost of Rx drugs, hold drug companies responsible, and clearly identify drug company profits as the driver of high drug costs. Members of Congress, including Republicans, would ignore this extraordinary voter sentiment at their peril. In fact, Republicans on the Hill should be looking to the White House for guidance on this issue as Trump Voters trust the President over Republicans in Congress by a three-to-one margin to address the issue of prescription drug prices."

The survey of 1,000 registered voters, which was commissioned by CSRxP and conducted by Fabrizio Ward from February 13-16, 2025, found:

- **82 Percent**: The overwhelming majority of voters (82 percent) and Trump voters (80 percent) support reforming patent laws to prevent drug companies from abusing the system that extends their monopolies on drugs longer than intended and halts lower cost generic drugs and biosimilars from the market.

- **Nine-In-Ten**: 89 percent of all voters – and Trump voters alike – reported they were concerned with this statement: "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, including patent thickets comprised of hundreds of patents on their blockbuster drugs, effectively preventing competitors from bringing lower-cost alternatives to market."

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 a toolkit for the new Administration and 119th Congress, "brand name pharmaceutical companies use every possible tactic to game the system to extend monopolies and delay competition from more affordable generic and biosimilar medicines… These anti-competitive practices are why Americans pay significantly higher prices for brand name prescription drugs than every other country in the world."

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

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