The Cost of Prescription Drug Patent Abuse

HOW DRUG COMPANIES ABUSE THE PATENT SYSTEM AND DEMAND INFLATED MONOPOLY PRICES IN AMERICA

U.S. PIRG Education Fund

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Written by:

Patricia Kelmar, Senior Director, Health Care Campaigns, U.S. PIRG Education Fund
Abe Scarr, Director, Illinois PIRG

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Introduction

THE U.S. SPENDS FAR MORE ON PRESCRIPTION drugs than other countries, not because we use more drugs, but because we pay higher prices. According to one 2021 study, prescription drug prices averaged 2.5 times higher in the U.S. than in 32 comparison countries.[1] U.S. prescription drug spending increased 60% over the last decade,[2] and experts estimate prescription drug spending will rise 63% between 2020 and 2030, to $917 billion annually.[3] (See Figure 1.)

High prescription drug prices harm individuals by straining household budgets, even causing some to skip doses or avoid filling their prescriptions.[4] They make it harder for employers to keep health premiums affordable. And high drug prices drive up costs for important taxpayer-funded health programs like Medicare and Medicaid.

While brand-name drugs make up only 8% of prescriptions, they account for 84% of all U.S. drug spending.[5] (See Figure 2.) Without competition from generic drugs, brand-name companies can keep their prices high for decades. One major reason is that drug companies abuse our patent system to restrict competition and maintain inflated monopoly prices for life-saving drugs.

FIGURE 1. HIGH DRUG PRICES ARE COSTING MORE EACH YEAR

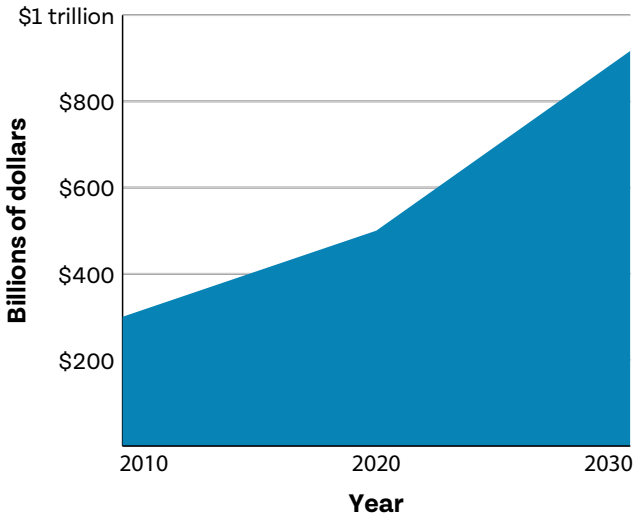
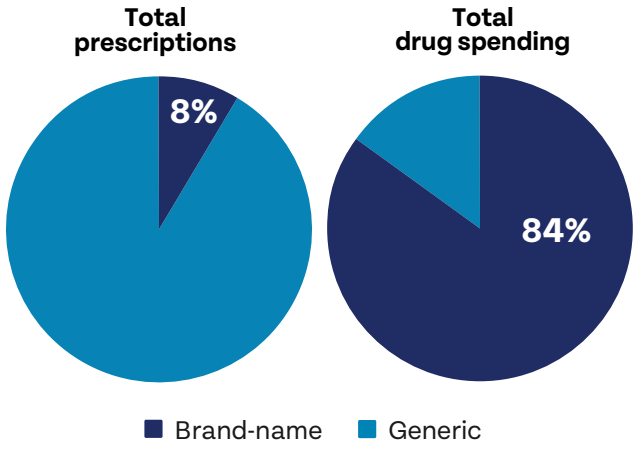


FIGURE 2. COST IMPACT OF BRAND-NAME DRUGS

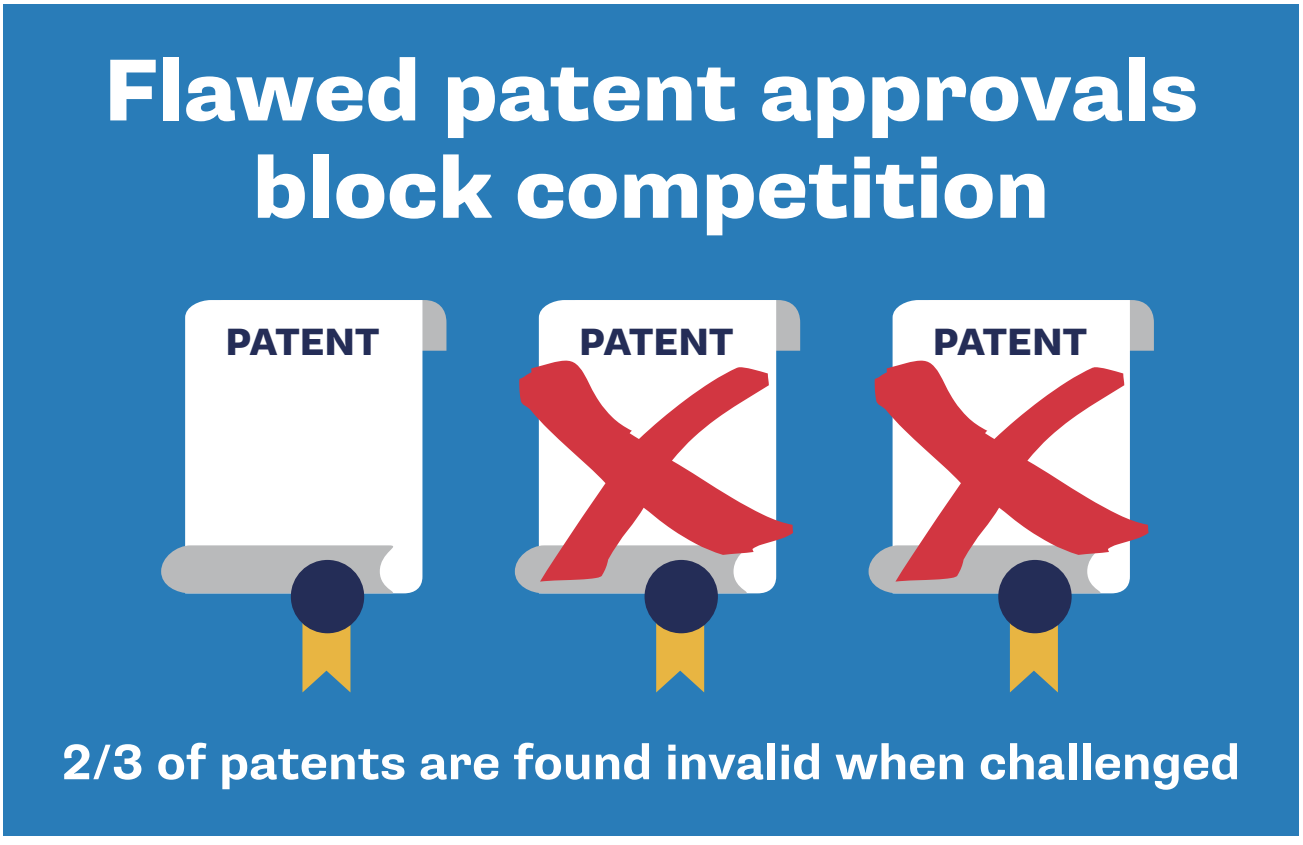


Patents 101

TO UNDERSTAND HOW DRUG COMPANIES abuse the U.S. patent system, you need to know a few basic things about the system first:

The patent system belongs to the American people and exists for our benefit. Patents give inventors a 20-year monopoly in exchange for disclosing their invention publicly.[6] The purpose of the patent system is to encourage inventors to make new inventions public and to ensure those inventions become freely available. Patents are *not* rewards for the work that went into an invention - they are incentives to make new ones. The patent monopoly is the same regardless of whether an inventor invested years and millions of dollars, or if an invention came from a flash of insight.

The U.S. patent system, which is critical to spurring innovation, has flaws that drug companies exploit. To be granted a patent, patent applicants are supposed to show their invention is new and useful, but too often applicants claim an invention that is obvious. Sometimes they don't even describe what they claim their invention does. One concern is that each year over 600,000 patent applications[7] are filed for review by 8,000 examiners[8] at the Patent Office. The sheer volume of applications puts



patent examiners under time pressure, and they end up spending an average of only 19 hours examining each application. If U.S. patent examiners had more time to review patents, they would reject more as invalid. One study found that over the course of one year, more review time would collectively speed up entry of generic competition by 17 years.[9] When challenged through lawsuits, studies have shown that more than two-thirds of secondary drug patents are invalidated.[10]

Drug companies use patent lawsuits and other expensive, time consuming tactics to block and delay generic competition. Drug companies exploit the system to get patents for minimally innovative changes to amass excessive numbers of "secondary" patents on a single drug.[11] These patents can extend a company's monopoly for years past the expiration of its primary patent, creating hurdles and increasing legal risk for potential competitors. In 2021, there were an average of 74 approved patents on each of America's ten top selling drugs.[12]

Drug companies that want to sell a generic version of a brand-name drug have to apply to the Food and Drug Administration (FDA) certifying that their generic won't infringe any existing patents.[13] They can either assert that the proposed generic is sufficiently different from the existing patents, or that those patents are invalid. When this happens, the brand-name drug company can sue the generic competitor to block or delay the approval of its version of the medicine.[14] Even if a brand name company loses a patent challenge suit, the lengthy legal process allows it to extend its monopoly for years.[15]

Patents are intended to expire so others can build on those innovations to the benefit of the public. Ending a patent monopoly enables better competition, lowers prices, and gives anyone a chance to build on earlier innovation. But when the system is abused and patents simply extend monopolies, no one wins except the profiteering patent holder.

The following examples explain some of the most common tactics drug companies use to abuse the patent system: patent thickets, pay-for-delay, product hopping, and combinations of multiple tactics.

Tactic #1: Patent thickets

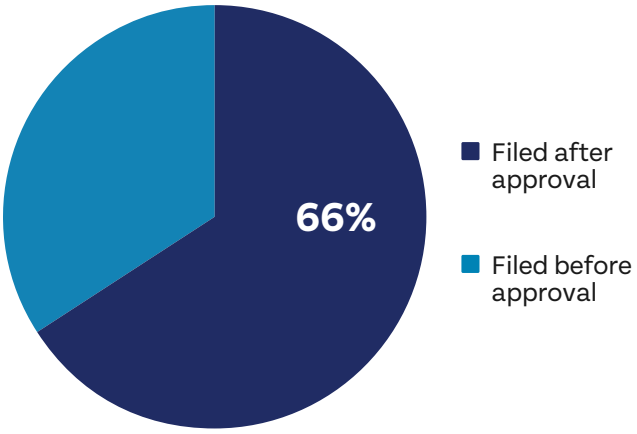
DRUG COMPANIES STRATEGICALLY APPLY for and amass dozens of approved patents on a single drug. The top 10 drugs by 2021 U.S. sales are covered by 744 approved patents, an average of 74 approved patents per drug.[16] By building up a portfolio of dozens of patents on one drug, the brand drug company creates a "patent thicket" which is extremely difficult for a competitor to break through. For a generic drug competitor to be able to sell its lower priced version of a drug to patients, it must assert - and likely prove in court - that all of the brand-name drug company's existing patents are invalid or that the generic drug does not infringe any of them. These "patent thickets" extend the drug company's monopoly by creating major hurdles for potential generic competitors, and ultimately cost patients and the public billions of dollars by delaying competition.

Primary patents typically cover a drug's active ingredient or chemical composition - the main reason it is considered a "new" drug and the innovation which makes the drug eligible for a patent allowing monopoly pricing. Secondary patents may cover any number of features of a medication that may or may not be a significant innovation. Examples include things like chemical alterations, manufacturing processes, safety practices, storage requirements, or "methods of use" - how to use the drug to treat specific conditions.

Each patent carries its own 20-year monopoly, and drug companies often file applications for these secondary patents years after the primary patent applications. This allows drug companies to prevent competition for years or even decades past the end of a drug's primary patents. Of the top 10 selling drugs, 66% of patent applications were filed after the Food and Drug Administration (FDA) approved the drug.[17] (See Figure 3.) While it's certainly possible that a drug company makes additional innovations on a drug, the high volume of secondary patents filed after initial approval indicates the tactic is a common monopoly-extending business practice.

Secondary patents create thorny thickets of legal risks for potential generic competitors. When a competing drug company applies to the FDA to sell a generic version of a drug, it must certify that its drug won't infringe any outstanding patents or that all of the outstanding patents are invalid. Brand-name drug companies can sue for patent infringement, automatically putting the potential generic drug's FDA application on hold for two and a half years.[18]

FIGURE 3. PATENT APPROVAL TIMING OF TOP 10 SELLING DRUGS



Each patent in a patent thicket provides the brand-name drug company with the opportunity to maintain its inflated monopoly pricing and to use it as leverage to negotiate deals with potential competitors. Patent trials are expensive[19] and lawsuits often end in settlement, rather than in a court judgment that could find the patents invalid. When lawsuits do reach a judgment, studies have shown that more than two thirds of drug patents are invalidated.[20]

Patent *applications* add to the thicket as well. Potential generic competitors must also consider outstanding patent applications when deciding whether or not to introduce a generic version of a drug. Each of the top 10 drugs by 2021 U.S. sales had over 140 applications, on average.[21] The cost of applying for a patent is minuscule[22] compared to the profits a drug company can make scaring off competitors.

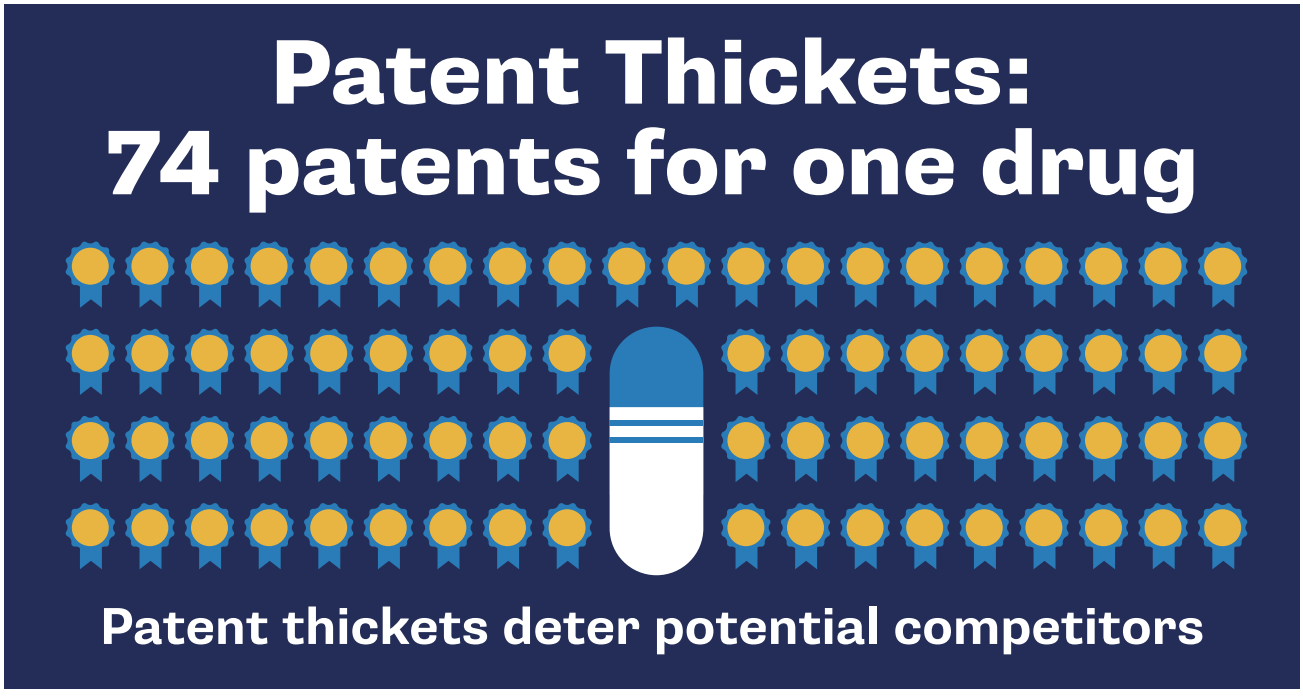
Delays in generic competition caused by patent thickets cost patients and the public billions of dollars. For just three of the top selling U.S. drugs, Americans will spend an estimated $167 billion on brand-name drugs after generic competition begins in the European Union,[23] where generic competition often starts earlier because of differences in patent law and enforcement.

For the sake of illustration, if generic competition began at the same time in the U.S. as it did in Europe and lowered prices on those drugs by 60%, Americans would instead spend $67 billion, saving $100 billion on the three drugs alone.

Patent thickets example: Revlimid

Revlimid is a drug used to treat multiple myeloma, a cancer of the blood affecting an estimated 35,000 people in the U.S.,[24] and other forms of cancer.[25] The key chemical in Revlimid is an analog of the decades old drug thalidomide,[26] famous for causing severe birth defects in the 1960s when it was marketed as an anti-nausea treatment for pregnant women.[27] Thalidomide was banned in the U.S. for decades, but researchers continued to study the drug, and drug company Celgene, now a subsidiary of Bristol-Myers Squibb,[28] won FDA approval to sell thalidomide to treat leprosy in 1998.[29] Celgene later won FDA approval to sell Revlimid, a slightly chemically altered version of thalidomide,[30] in 2005.[31]

Celgene's primary patent for the active ingredient in Revlimid was filed in 1996.[32] Despite the expiration of its primary patent in



2019, Revlimid faces only limited generic competition now, and won't face unrestricted competition until 2026.[33] Celgene has been able to enjoy inflated monopoly profits well beyond its primary patent because over the last two decades it has filed an additional 206 U.S. patent applications for Revlimid, 117 of which have been approved.[34]

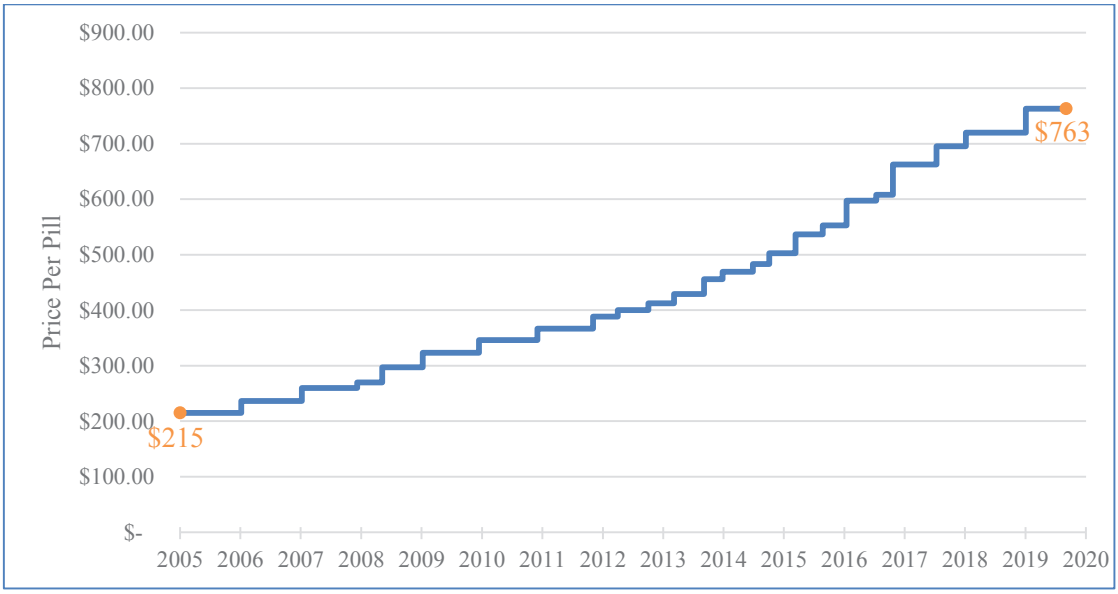
A Congressional investigation concluded that Celgene engaged in numerous anticompetitive tactics to extend its monopoly, including abusing the patent system.[35] Celgene's use of its patent thicket follows a basic pattern. First, Celgene sues a generic competitor, triggering the FDA's two-and-a-half-year hold on considering the competitor's application. Celgene then negotiates a settlement with the potential competitor, shielding its questionable patents from judicial scrutiny.

According to a complaint in pending litigation, over 15 years and at least 28 different legal actions, Celgene has settled every time, not allowing a single contested patent to face judicial scrutiny.[36] By settling, Celgene avoids judicial judgment and preserves its possibly invalid patents to delay the next potential competitor.

Generic competitors, insurers, patient groups, and experts have challenged the validity of Revlimid's patents,[37] including its primary patent.[38] Many patents identical to Revlimid's approved U.S. patents were invalidated by the European Union patent office,[39] and several of Revlimid's patents,[40] including, according to a complaint in pending litigation, its primary patent,[41] have at one point been ruled invalid by the U.S. patent office.

Through these and other tactics, Celgene has charged inflated monopoly prices for years. Celgene raised the price of Revlimid 23 times between 2005 and 2020.[42] (See Figure 4.) The price of a monthly supply of Revlimid has gone from roughly $6,000 in 2006[43] to $24,000 in 2022.[44] Experts have estimated that Celgene's extension of its Revlimid monopoly will cost Americans $45 billion.[45]

FIGURE 4. REVLIMID PRICE INCREASES



Source: Committee on Oversight and Reform, U.S. House of Representatives, *Drug Pricing Investigation Celgene and Bristol Myers Squibb—Revlimid*, September 2020, page 1.

Tactic #2: Pay-for-delay

IN A PAY-FOR-DELAY DEAL, A BRAND-NAME drug company pays off a would-be competitor to delay it from selling a generic version of the drug. Without competition, the brand-name company can continue demanding inflated monopoly prices.

Brand-name companies typically make these deals with so-called "first filers" – the first generic competitor to apply to the FDA to sell a generic version of a drug. First filers are eligible for their own period of exclusivity: the FDA will not approve another generic version of the drug until 180 days after the first filer begins *selling* its product.[46] Thus, when a brand-name drug company makes a pay-for-delay deal with a first filer, the brand-name company delays *all* generic competition.

The pay-off comes in many forms: outright payments of cash,[47] in-kind gifts of free brand-name drugs (which the generic company can then sell for pure profit), limiting competition from the brand-name company once the competitor does start selling its generic version, and allowing earlier entry into some but not all markets (for example, allowing the generic company to sell its drugs in Europe, but not in the U.S.).[48]

Both drug companies win in a pay-for-delay scheme, but patients and the public lose.

The brand-name company extends the time it can demand inflated monopoly prices. The competitor typically earns more from the pay-off than it would if it were to forgo the deal and begin selling its generic drug. Patients and government programs, on the other hand, are forced to pay inflated monopoly prices for years longer. A single generic competitor can lower prices by 30% and competition from five competitors can lower prices by nearly 85%.[49] Competing with a lower-priced generic usually triggers the original patent holder to lower its price for the brand-name drug as well.[50]

Rather than allowing competition to deliver lower prices and greater value to patients and the public, the colluding drug companies divvy up monopoly profits.

Pay-for-Delay Example: Lidoderm

Lidoderm is a topical patch used to relieve pain associated with a complication from shingles.[51] According to the Federal Trade Commission (FTC), Lidoderm became the preferred treatment for the complication,[52] generating substantial profits for its manufacturer, Endo: $948 million in 2012,[53] when it first faced potential generic competition.[54]

The active ingredient in Lidoderm - lidocaine - is not under patent. It has been used in medications for more than 50 years.[55] Rather, Endo, through its parent company, held patents specific to the delivery of lidocaine using a patch[56] — even though patches have been used to deliver medication for more than 40 years.[57]

Generic drug company Watson filed an application with the FDA in 2009 to introduce a generic version of Lidoderm.[58] In its application, Watson challenged the validity of an Endo patent set to end in 2015.[59] When Watson notified Endo of its challenge, Endo sued for patent infringement.[60]

Before that and subsequent litigation concluded, Endo and Watson made a pay-for-delay deal in which competitor Watson both agreed to abandon its patent challenge and to delay selling its generic drug by more than a year, from May 2012 to September 2013.[61] In exchange, Endo compensated Watson in the following ways valued, according to the FTC, at approximately $250 million:[62]

> First, Endo agreed not to compete with Watson by selling its own "authorized" generic version of Lidoderm for up to 7½ months.[63] Patent owners are permitted to sell authorized generic versions of their drug at any time, including during the 180-day first filer exclusivity period. They usually don't sell their own generic drug until a generic competitor arrives. The FTC estimated Endo's promise to withhold its own authorized generic would allow Watson to earn at least an additional $214 million during its first six months on the market as the sole generic producer.[64]
>
> Second, Endo agreed to give Watson free branded Lidoderm patches, valued at over $90 million, which it could sell on the monopoly-priced market. Endo also agreed to give Watson up to an additional $144 million of branded Lidoderm if the FDA did not approve Watson's generic application.[65]

According to the FTC, based on internal Watson calculations at the time of the agreement, Watson would earn at least $100 million more through the pay-for-delay deal than it would by selling its generic product upon FDA approval in 2012.[66] That $100 million is just Watson's cut of the pay-for-delay scheme. Endo got its cut as well - an additional 16 months of monopoly priced profits on Lidoderm - all of which was paid through higher prices by the American public and their public and private health plans.

Tactic #3 - Product hopping

PRODUCT HOPPING IS A TACTIC BRAND-NAME drug companies use to avert competition as a patent nears expiration and other companies are poised to sell lower priced generic versions of the drug.

In all states, and under most health plans, once a generic drug is approved by the Food and Drug Administration as equivalent to the branded drug (an "AB rating"), pharmacists may, and in some cases must, substitute the generic drug for the prescribed brand-name drug.[67] These substitution laws accelerate generic competition, saving billions of dollars each year.[68]

Product hopping works by altering the patented drug enough that generic versions with an AB rating based on the original version cannot be substituted for the new version. Brand-name drug companies then encourage or give doctors no choice but to move patients to the new version of the original medication, thereby preventing patients from automatically getting a lower priced generic substitute at the pharmacy counter.

In this way, product hopping allows a brand-name drug company to thwart meaningful competition even when a lower priced generic version of a drug is available. The drug company continues to dominate the market with inflated monopoly prices while most patients don't get the lower price and greater value of an available generic drug.

Product hopping example: Suboxone

Suboxone is a treatment for opioid addiction,[69] a major scourge in communities across the country. Importantly, when introduced, it was the only treatment approved for at-home use, which meant easier access to treatment for those struggling with opioid addiction.[70]

Several years before its drug monopoly exclusivity[71] was set to expire, executives at Suboxone manufacturer Reckitt Benckiser Group ("Reckitt) began discussing strategies to limit competition.[72] While the company engaged in a number of anticompetitive practices, the critical one was product hopping - it switched the *form* of its drug from a tablet to a thin film that dissolves under the tongue.[73] The drug itself was the same.

Reckitt knew potential competitors would introduce tablets to achieve an AB rating and benefit from state generic substitution laws.[74] Once that happened, prices for Suboxone would drop, and so would the company's profits. To delay this outcome, Reckitt needed to get doctors to switch patients from tablets to the film, which the company encouraged by aggressively marketing the film[75] and selling it for less than its tablet.[76]

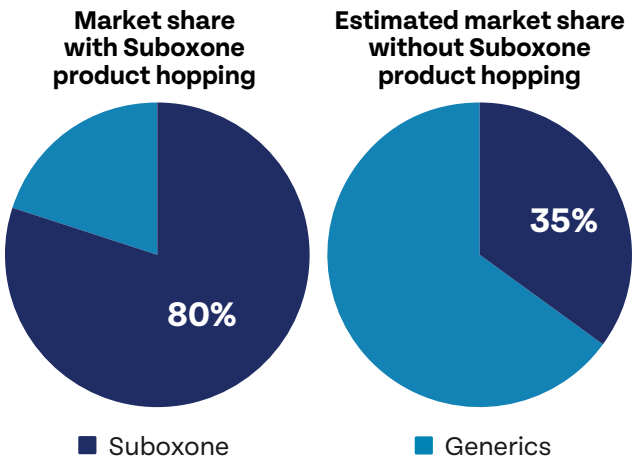
To further boost its product hopping tactic, while also creating further hurdles at the FDA for generic tablet competitors, Reckitt went a step further by inspiring fear about

its original drug packaging. Reckitt concocted a rationale that a tablet was more likely to be misused or abused by children than a film, as each film could be individually wrapped in child-proof packaging.[77] As it rolled out its film, Reckitt emphasized that the film was safer than the tablets, despite the FDA rejecting its clinical trial as poorly designed and "not useful for demonstrating any difference in the safety profile or abuse potential of these two formulations [tablet and film]."[78]

Reckitt eventually forced doctors to prescribe its film by completely removing its tablet from pharmacy shelves.[79] Because generic versions of the drug, in tablet form, could not be automatically substituted for the brand-name drug, newly available in dissolvable film form, Reckitt delayed significant competition by years,[80] even as competitors started selling generic tablet versions of the drug.

Through this and other anticompetitive practices Reckitt delayed introduction of generics, raised costs for consumers, misled doctors on safety risks, and ultimately maintained an 80% market share after generic competition began.[81] If Reckitt hadn't used the product-hopping trick, one expert estimated its market share would have been closer to 35%,[82] meaning many patients who needed the opioid treatment would have been buying the lower priced generic tablets from other companies—and enjoying substantial cost-savings. (See Figure 5.)

FIGURE 5. EFFECTS OF PRODUCT HOPPING ON MARKET SHARE



CASE STUDY: Humira, combining multiple patent abuse tactics

THIS REPORT HAS HIGHLIGHTED THREE distinct patent abuse tactics used by brand-name drug companies to extend their monopolies and drive-up drug prices for patients and the public:

- Patent thickets: amassing dozens if not hundreds of patents on a single drug to create delays and legal complications for potential competitors.
- Pay-for-delay: wherein a brand-name drug company pays a would-be competitor to delay selling its generic drug, potentially delaying *all* generic competition.
- Product hopping: slightly altering a drug to avoid easy substitution of generic versions of brand-name drugs, one of the key ways patients and the public gain access to generic drugs and their lower prices.

In practice, many drug companies employ *all of these tactics and more* to shield top-selling drugs from competition and maintain their inflated monopoly pricing.

Patent thickets lay the foundation. Patent lawsuits and the automatic delays they trigger give brand-name companies leverage to negotiate settlements with potential competitors, often in the form of pay-for delay deals. These delays also create opportunities to engage in product hopping and other tactics to further thwart competition.

There is perhaps no better example than Humira, the top selling drug in America[83] and worldwide.[84]

Humira

Humira, the brand-name of the drug adalimumab, is a treatment for rheumatoid arthritis, psoriasis, crohn's disease, and more - conditions affecting over 10 million patients in the U.S..[85] Because it is a "biological" drug,[86] Humira faces competition not from generic versions of the drug, but from so-called "biosimilar" drugs.[87]

First approved by the FDA in 2002,[88] Humira's primary patents ended seven years ago in 2016.[89] Yet, because AbbVie, the maker of Humira, has focused less on innovating new drugs but more on maintaining monopoly pricing of its profit-maker Humira, the drug did not face any biosimilar competition in the U.S. until early 2023.[90]

This business strategy has worked well for AbbVie and its shareholders, but patients, health plans and government drug programs have borne the cost of its patent abuse. Humira is a quintessential "blockbuster" drug for AbbVie. In 2021, Humira was the top selling drug in the U.S., bringing in $17.3 billion, 40% of AbbVie's total U.S. revenue that year.[91] Between 2003 and 2021, AbbVie raised the drug's price 27 times, for a total increase of 470%.[92] In 2021, a year's supply of Humira cost $77,586.[93]

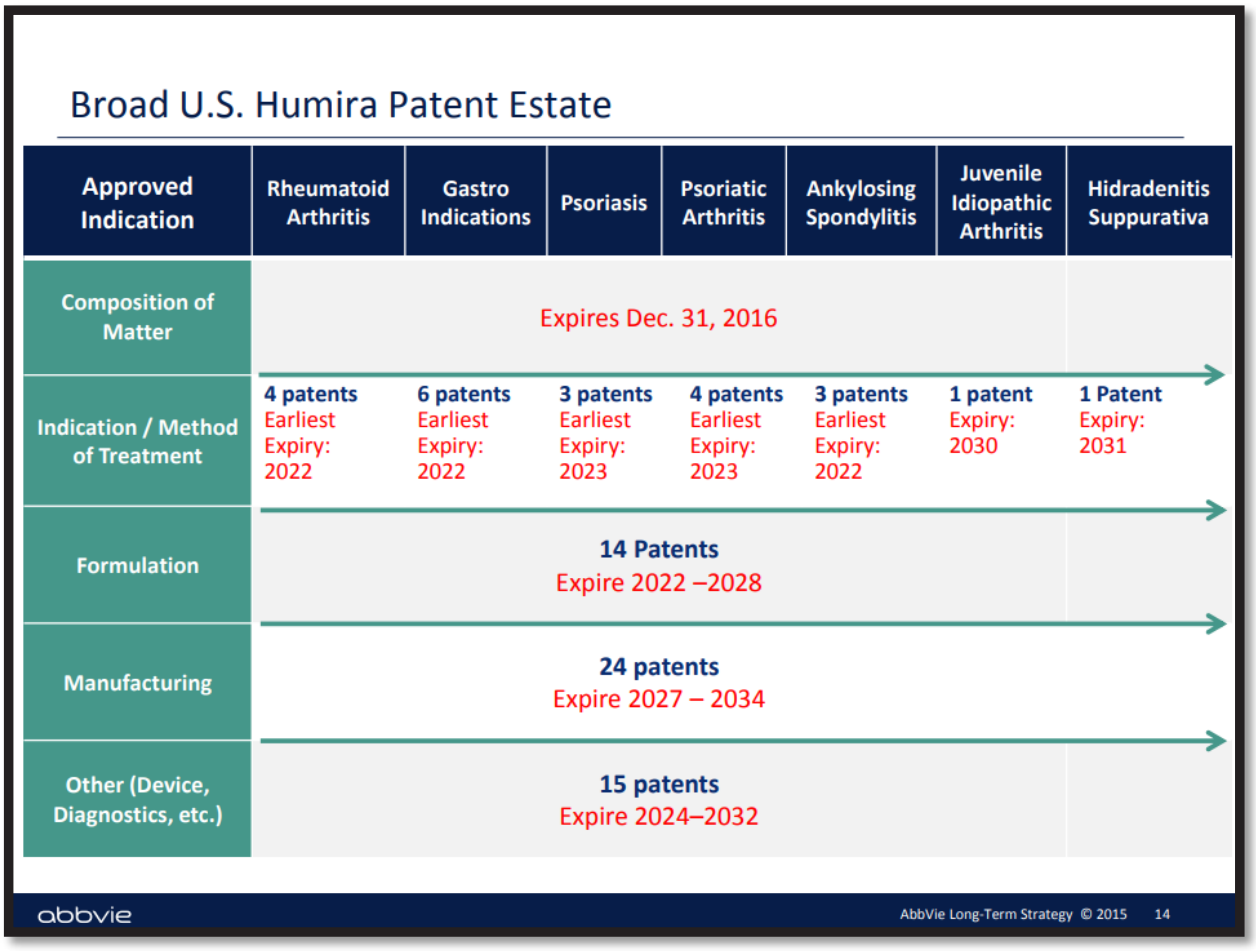
Because it has successfully kept biosimilars off of pharmacy shelves, AbbVie has collected over two-thirds of its total U.S. sales since its primary patents expired in 2016.[94] In the same time frame, the price of Humira in Europe has dropped by as much as 80% with the entry of biosimilar competitors.[95] Experts estimate that AbbVie will have earned over $100 billion from Humira sales between the end of its primary patents and the start of limited biosimilar competition in early 2023.[96] An internal company estimate obtained by a Congressional committee found that the cost of this delay to the U.S. healthcare system will be $19 billion.[97]

Patent thicket

AbbVie has built a massive patent thicket. (See Figure 6.) It has applied for 312 patents for Humira, 166 of which have been granted.[98] AbbVie submitted 94% of Humira's patent applications *after* initial FDA approval,[99] with 56 applications submitted since Humira's primary patents expired in March 2016.[100]

AbbVie used its patent thicket to block or delay all U.S. competition until early 2023. At least nine competitors may begin selling biosimilar versions of Humira by the end of 2023, all as the result of settlement agreements.[101] Finally, after a long delay, millions

FIGURE 6.



Source: Committee on Oversight and Reform, U.S. House of Representatives, *Drug Pricing Investigation: AbbVie—Humira and Imbruvica*, May 2021, page 24.

of U.S. patients may receive cost savings similar to those in Europe thanks to some competition in the drug market.

Competition in the U.S. may be restricted until Humira's last existing patent expires in 2037.[102] But the wait for unrestricted competition could be even longer: AbbVie has four additional patent applications pending before the U.S. patent office, potentially extending its patent thicket further into the future.[103]

Pay-for-delay

AbbVie's patent thicket allowed it to extend monopoly pricing through another tactic, pay-for-delay. A 2021 Congressional investigative report demonstrated that AbbVie's settlements with biosimilar makers could be considered pay-for-delay deals, because AbbVie used them to extend monopoly pricing in the U.S. by allowing competitors to sell their products earlier in Europe.[104] (See Figure 7.)

FIGURE 7.

AbbVie - Humira Patent Settlements				
Biosimilar Competitor	**Settlement Date**	**European License Date**	**U.S. FDA Approval**	**Originally Agreed U.S. Launch***
Amgen, Inc.	9/28/2017	10/16/2018	9/23/2016	1/31/2023
Samsung Bioepis	4/5/2018	10/16/2018	7/23/2019	6/30/2023
Mylan	7/17/2018	-	7/6/2020	7/31/2023
Novartis/Sandoz	10/11/2018	10/16/2018	10/30/2018	9/30/2023
Fresenius Kabi	10/18/2018	10/17/2018	-	9/30/2023
Momenta	11/6/2018	11/6/2018	-	11/20/2023
Pfizer	11/28/2018	11/30/2018	11/15/2019	11/20/2023
Coherus	1/25/2019	1/25/2019	-	12/15/2023
Boehringer Ingelheim	5/13/2019	-	8/25/2017	7/1/2023

*The Committee's review of these agreements shows that the Boeghringer Ingelheim settlement led to Samsung Bioepis, Mylan, Novartis/Sandoz, Fresenius Kabi, Momenta, Pfizer, and Coherus all moving their entry date to 7/1/2023 under most-favored nation clauses in their agreements.

Source: Committee on Oversight and Reform, U.S. House of Representatives, *Drug Pricing Investigation: AbbVie—Humira and Imbruvica*, May 2021, page 27.

AbbVie made multiple internal assessments that Humira would face U.S. biosimilar competition earlier than 2023, based on the strength of its position in lawsuits, settlement negotiations, or both. In 2014, AbbVie estimated it would face 3 to 5 biosimilar competitors by 2017,[105] and in 2017, after its first settlement, AbbVie estimated it would face 11 biosimilar competitors by 2022.[106]

The Congressional report wrote that AbbVie's success in delaying U.S. competition 6 years beyond its initial expectation "raises serious questions" that these settlements were not simply negotiated compromises, but rather illegal *payments* to potential competitors to agree to delay.[107]

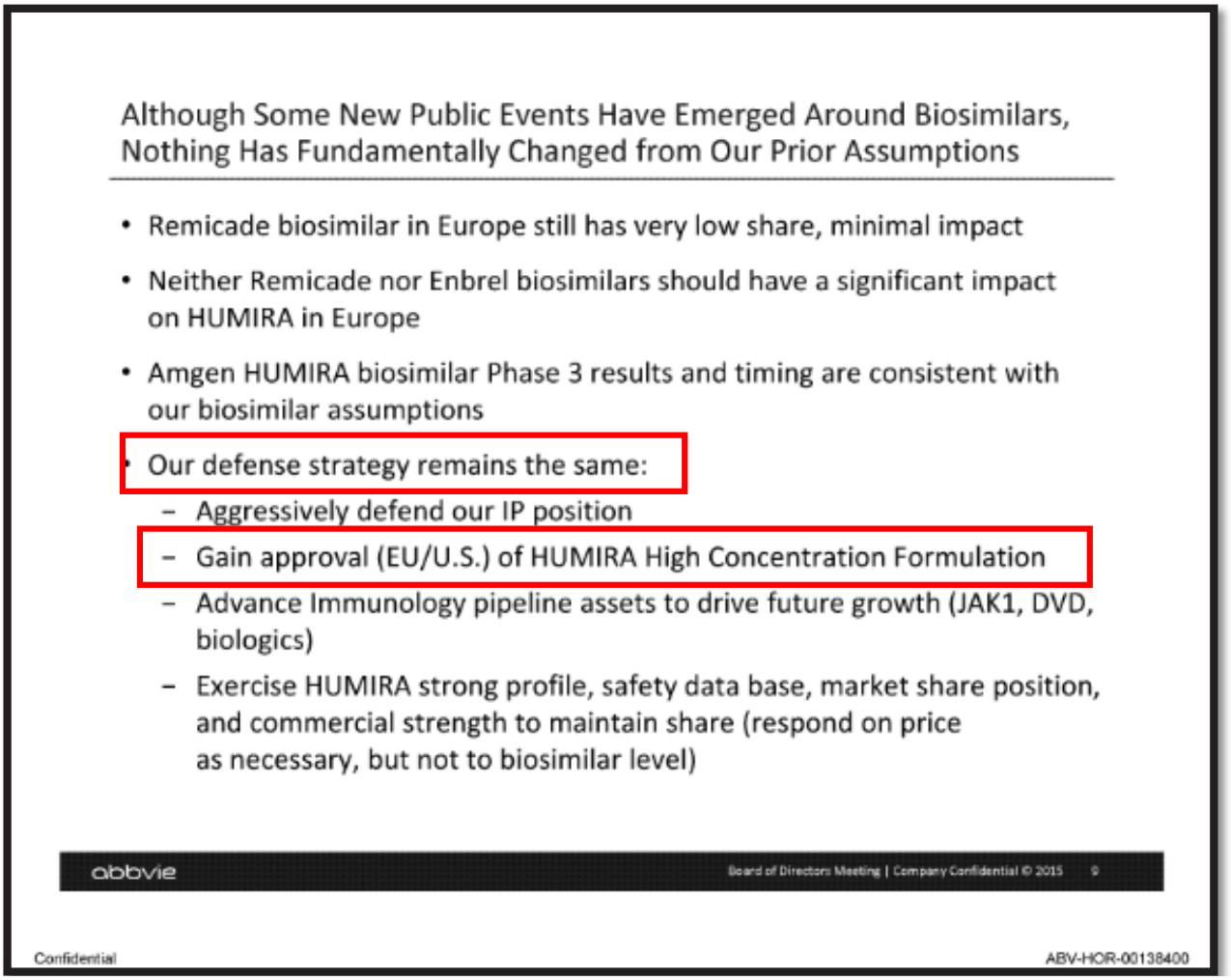
A 2013 Supreme Court decision found drug companies may violate antitrust law by offering cash payments to would-be competitors,[108] so AbbVie offered something else of value: early entry into the European market. For 6 of the 9 drug companies that settled with AbbVie to begin biosimilar sales in the U.S. in 2023, their agreement allowed them to begin sales in the European Union in 2018.[109] This competition in Europe led to AbbVie lowering the cost of Humira in that market by as much as 80%,[110] a price decrease Americans will likely not enjoy until the end of 2023 at the earliest.

Product hopping

Product hopping is a third strategy, among others, that AbbVie is using to blunt biosimilar competition and continue charging inflated monopoly prices.

AbbVie introduced a higher concentration version of Humira in July 2018.[111] While it externally claimed to be introducing the higher concentration because it is less painful for patients, AbbVie was internally explicit that the move was part of its biosimilar "defense strategy."[112] (See Figure 8.)

FIGURE 8.



Source: Committee on Oversight and Reform, U.S. House of Representatives, *Drug Pricing Investigation: AbbVie—Humira and Imbruvica*, May 2021, page 41.

AbbVie obtained FDA approval for the higher concentration version of Humira in 2015, but waited three years to begin selling it, after its competitors had invested significantly in creating biosimilar drugs that could be substituted for the original Humira concentration.[113]

AbbVie executives closely tracked the rate at which patients were transitioning to the newer higher concentration formulation, comparing it to other well known product hops.[114] An external Wall St. analyst applauded AbbVie for its strategy to move patients to the "new" version of the drug, noting it should "blunt the impact of biosimilar competition."[115] The higher concentration version of Humira is now "dominant" in the market.[116] To date, only one biosimilar competitor has achieved the "interchangeable" status[117] that will allow pharmacists to automatically replace it for Humira.[118] Because of this restriction on automatic pharmacy substitution, while numerous biosimilar competitors will be available in 2023, patients will have less, and less reliable, access to lower prices than they would if AbbVie had not engaged in product hopping.

Recommendations

PATENTS PLAY AN IMPORTANT ROLE IN spurring innovation and opening up discoveries that others can benefit from. But the monopoly-pricing granted by a patent isn't meant to last forever. Generic and biosimilar medications bring down the prices of prescription drugs by introducing competition into the health care marketplace. Recent anti-competitive actions by drug companies have blocked this competition through tactics like patent thickets, pay-for-delay, and product hopping.

Federal legislators and regulators need to put an end to patent abuse and break down the barriers that keep generic and biosimilar drugs from making it to pharmacy shelves.

Our policy recommendations:

1. **Create statutory clarity that patent thickets, product hopping and pay-for-delay deals are anticompetitive.** Federal legislation will help regulators stamp out specific anti-competitive practices and give them additional power to identify emerging tactics that block generic and biosimilar drugs from coming to market.

2. **Improve processes at the U.S. Patent and Trade Office (PTO) to prevent over-patenting and improve patent quality.** Some important PTO reforms include:

    a. Less emphasis on swift review of patent applications and more emphasis on quality review. We urge a return to the mission of the PTO to *serve the public*. It is time to shift away from an overemphasis on serving patent applicant "clients" by reviewing applications too swiftly. The public mission requires high quality examination of drug patent applications, with the collaboration of experts from the Food and Drug Administration (FDA), to prevent approvals of weak, duplicative or anti-competitive patent applications. Patent examiners should prioritize their work to avoid approving patents filed for the purpose of creating patent thickets and other abusive tactics that prevent or postpone generic competition.

    b. More stringent review of patent applications for prescription drugs already on the market. Examiners must reject patent applications that allow monopoly pricing without any clear substantial change to the medication or its efficacy. Patent applicants should clearly disclose when a new or continuation application claims aspects of or improvements to an existing drug already on the market. The agencies should flag PTO and FDA applications which correspond to substantially similar drugs, share information provided by applicants (especially regarding clinical test results and the necessity of clinical testing), and spend more time reviewing those applications for inaccuracies or outright fraudulent and

deceptive claims. Patent examiners should receive extra support from FDA experts knowledgeable with that approved drug or drug class so they can assist the patent examiner in understanding whether the new patent meets the required tests for subject matter eligibility, usefulness, nonobvious and novelty.

c. Restore and protect the utility of the Patent Trial and Appeal Board (PTAB). This arm of the PTO offers an alternative to litigating patents in the federal court system. The PTAB provides a quicker and less expensive way to challenge the validity of patents and is the only opportunity for a member of the public to challenge the patentability of a claim in an approved patent. In recent years, internal changes have narrowed the opportunities to bring challenges to the PTAB. Improving the effectiveness of the PTAB and restoring the original purpose of this alternative to litigation could result in earlier market entry of generics and biosimilar drugs.

3. **Improve collaboration between the PTO and FDA to audit, inspect and use their enforcement powers to prevent over-patenting**. The agencies should establish regular information sharing and joint training with a collaborative approach to auditing, inspections and enforcement actions. Pharmaceutical business practices and strategies regularly employ tactics that unfairly manipulate the patent and drug application systems to hinder generic competition. Therefore, we need a coordinated approach to enforcement to leverage the limited resources of each agency to ensure regulatory and statutory compliance by drug companies.

4. **Engage consumers and patients in the work of the FDA and PTO.** Many health care policy solutions are proposed, analyzed and decided with little or no consumer and patient input. Despite the complexity of patent and drug approvals, the patient and consumer voice is still an essential part of policy deliberations. When decision makers lose touch with the end-user, in this case, the patient and consumer community, policy decisions sometimes unwittingly or even in some cases purposefully put the needs and interests of the consumer last. Consumers find it difficult and time-consuming to comply with the strict formal input opportunities offered by these agencies, such as filing regulatory comments. Monitoring and reading technical applications are difficult even for highly trained chemists and patent attorneys. Other health agencies can serve as a source of ideas for how to better involve consumers in health policy considerations. The FDA and PTO should identify and consider more creative ways to solicit input from the patient/consumer community, and involve those audiences in that exploration. Then the agencies, with input from the consumers/patients, should implement an effective patient engagement model with the goal of ensuring that generic and biosimilar drug competition is restored.

These recommendations will work to bring about a measurable public benefit: more generic drug competitors will make it to market sooner and patients, insured families and our government health plans will benefit from the resulting price competition.

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