The Manufacturers Of The Ten Drugs On Medicare's Price Negotiation List Have Employed A Variety Of Patent Tactics To Maintain Exclusivity And Price Controls Keeping Costs High For American Consumers

Summary: The manufacturers of the ten drugs on Medicare's price negotiation list have used a variety of patent manipulation tactics like **pay-for-delay agreements**, **evergreening**, **patent thickets**, and **product hopping** to extend their exclusivity—and thus control over the price—of these drugs for years and sometimes decades. Even though the companies hold the patents, one study found that the federal government spent a combined **$11.7 billion** on basic and applied research that led to the development of these drugs:

- **Stelara:** $6.5 billion
- **Xarelto:** $764 million
- **Imbruvica:** $566 million
- **Eliquis:** $791 million
- **Entresto:** $901 million
- **Farxiga:** $437 million
- **Enbrel:** $2.6 billion
- **Jardiance:** $433 million
- **Januvia:** $228 million

The medications on the list are taken by approximately 10 million Medicare Part D enrollees each year at an annual cost of roughly **$50 billion** to Medicare and U.S. taxpayers. These kinds of tactics keep prices high for the consumer and often lead to patients skipping doses, disproportionately affecting lower-income Black and Latin-American communities:

- 'Pay-to-delay' refers to a tactic used by pharmaceutical firms in which the company that holds a patent on a popular drug will pay competitors to not release a generic version into the market. A recent study found that these agreements can cost American consumers as much as **$36 billion** a year.

- Pharmaceutical firms also use 'evergreening' - making small, sometimes insignificant changes to their drugs to acquire new patents which extend their exclusivity and pricing control over the drug. Many patents are awarded after FDA approval and from 2005 to 2015, **80%** of the country's 100 top-selling drugs were awarded extra patents. Excessive evergreening leads to 'patent thickets' - labyrinthine knots of legal protections that generic manufacturers must navigate in order to market new, cheaper versions without infringing on the brand name's patents. These maneuvers can extend patent protections for years and even decades and some drugs have dozens - even hundreds - of patents.

- Companies also often use "product hopping" - introducing a new patent-protected medicine and moving patients to it before the original expires. In some cases, the company pulls the original brand name product from the market, forcing the consumer to pay for a higher-priced, patent-protected new drug.

An Accountable.US review of companies included in the Medicare price negotiations unveiled long histories of using these tactics to protect their patent control over those drugs as well as some of their other products:

- **Stelara:** Johnson & Johnson, the manufacturer of Stelara, has made deals to delay the entry of biosimilars until 2025. Despite a lack of an FDA-approved biosimilar for Stelara, Johnson & Johnson is getting ready for the expiration of exclusivity by building up a patent thicket.
- **Xarelto:** Xarelto is a "prime example" of a patent thicket, with Johnson & Johnson filing 49 patents for over a decade of market exclusivity. Johnson & Johnson has disclosed being involved in patent infringement lawsuits against generic manufacturers of Xarelto since 2021, with several confidential agreements reached in early 2024.
- **Imbruvica:** Manufactured by partners Johnson & Johnson and Abbvie, Imbruvica is protected by a thicket of more than 150 patents, giving the companies market exclusivity until 2036.
- **Eliquis:** Bristol Myers Squibb has applied for 48 patents for Eliquis and been **awarded 27** and has entered into patent settlements, delaying biosimilars to possibly as late as 2031.
- **Entresto:** Novartis has entered into confidential deals with other companies to delay generics of its blockbuster blood-clotting drug Entresto until **as late as 2026**.
- **Farxiga:** AZ's Farxiga is the most evergreened drug on the Medicare negotiation list, with one of its compounds enjoying patent protections **until 2040**. Overall, Farxiga is protected by 36 patents giving the company exclusivity until 2030.
- **Fiasp/NovoLog:** According to a study by the National Institutes of Health, Novo Nordisk has moved patented ingredients into new products resulting in combined patent exclusivity periods of more than **60 years** for two lines of NovoLog. Novo Nordisk created Fiasp, a drug with identical active ingredients to NovoLog which had already been on the market for 17 years.
- **Enbrel:** Enbrel, which was first awarded a patent in 1990, has been the subject of **57 patent applications**, 72% of which came after FDA approval, "with the aim of delaying competition by 39 years." A House Committee on Oversight and Reform investigation found Amgen had "'leveraged its patent and lifecycle management strategies to prevent competitors from introducing lower-priced biosimilar versions of Enbrel.'"
- **Jardiance:** Eli Lilly's and Boehringer Ingelheim's Jardiance is protected by 18 patents and will not face generic competition **until 2034** at the earliest.

Table of Contents

Background

By September 1, 2024, The Department Of Health And Human Services Will Announce The Negotiated Prices Of 10 Drugs That Totaled Over $50 Billion In Medicare Part D Spending From Just June 2022 to May 2023.

In August 2023, The Department Of Health And Human Services Announced The First 10 Drugs Subject To Negotiation, With Medicare Enrollees Paying A Staggering $3.4 Billion In Out-Of-Pocket Costs In 2022—Negotiated Prices For These Drugs Will Be Announced By September 1, 2024.

August 2023: The Department Of Health And Human Services (HHS) Announced The First 10 Drugs Set To Be Negotiated With Drug Manufacturers As Part Of The Inflation Reduction Act's Prescription Negotiation Provision. "Today, the U.S. Department of Health and Human Services (HHS), through the Centers for Medicare & Medicaid Services (CMS), announced the first 10 drugs covered under Medicare Part D selected for negotiation. The negotiations with participating drug companies will occur in 2023 and 2024, and any negotiated prices will become effective beginning in 2026." [U.S. Department of Health and Human Services, 08/29/23]

According To HHS, "Medicare Enrollees Taking The 10 Drugs Covered Under Part D Selected For Negotiation Paid A Total Of $3.4 Billion In Out-Of-Pocket Costs In 2022 For These Drugs." "Medicare enrollees taking the 10 drugs covered under Part D selected for negotiation paid a total of $3.4 billion in out-of-pocket costs in 2022 for these drugs." [U.S. Department of Health and Human Services, 08/29/23]

The Negotiated Prices For These Drugs Will Be Announced By September 1, 2024. “CMS will publish any agreed-upon negotiated prices for the selected drugs by September 1, 2024; those prices will become effective starting January 1, 2026.” [U.S. Department of Health & Human Services, 10/03/23]

The Drugs—Manufactured by Johnson & Johnson, AbbVie, Bristol Myers Squibb, Pfizer, Novartis, AstraZeneca, Novo Nordisk, Amgen, Boehringer Ingelheim, Eli Lilly, And Merck—Include Stelara, Xarelto, Imbruvica, Eliquis, Entresto, Farxiga, Fiasp/NovoLog, Enbrel, Jardiance, and Januvia, Totaling Over $50 Billion In Medicare Part D Spending From June 2022 to May 2023.

Drug[1]	Manufacturer(s)/Parent Company of Manufacturer(s)[2]	Total Part D Gross Covered Prescription Drug Costs from June 2022-May 2023[1]	Number of Medicare Part D Enrollees Who Used the Drug from June 2022-May 2023[1]
Stelara	Johnson & Johnson	$2,638,929,000	22,000
Xarelto	Johnson & Johnson	$6,031,393,000	1,337,000
Imbruvica	Johnson & Johnson; AbbVie	$2,663,560,000	20,000
Eliquis	Bristol Myers Squibb; Pfizer	$16,482,621,000	3,706,000

Entresto	Novartis	$2,884,877,000	587,000
Farxiga	AstraZeneca	$3,268,329,000	799,000
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk	$2,576,586,000	777,000
Enbrel	Amgen	$2,791,105,000	48,000
Jardiance	Boehringer Ingelheim; Eli Lilly	$7,057,707,000	1,573,000
Januvia	Merck	$4,087,081,000	869,000
	TOTALS:	**$50,482,188,000**	**9,738,000**

1. FiercePharma, 08/29/23
2. Centers for Medicare & Medicaid Services, accessed 07/17/24

From 2018 to 2022, The Average Annual Medicare Part D Spending Per Enrollee For These Drugs Increased By 59.7%, With Average Annual Out-Of-Pocket Spending Per Enrollee Increasing By 43.3% Over The Same Period.

Drug[1]	Increase In Average Annual Total Part D Spending per Enrollee from 2018 to 2022	Increase In Average Annual Out-Of-Pocket Spending per Enrollee from 2018 to 2022
Stelara	97% ($59,355 to $117,131)	190% ($709 to $2,058)
Xarelto	38% ($3,197 to $4,402)	26% ($357 to $451)
Imbruvica	51% ($85,128 to $128,548)	36% ($3,854 to $5,247)
Eliquis	43% ($3,031 to $4,342)	23% ($358 to $441)
Entresto	51% ($3,162 to $4,780)	13% ($315 to $357)
Farxiga	31% ($3,093 to $4,046)	26% ($206 to $260)
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	11% ($3,002 to $3,323)	28% decrease ($168 to $121)
Enbrel	36% ($41,500 to $56,639)	15% ($803 to $921)
Jardiance	45% ($3,063 to $4,430)	13% ($256 to $290)
Januvia	32% ($3,511 to $4,631)	12% ($240 to $270)
Overall Percentage Increase:	**59.7%**	**43.3%**

A February 2024 Study By Bentley University Found The First Ten Medications Set To Be Negotiated With Medicare Cost Taxpayers Anywhere From $227 Million To $6.7 Billion—A Combined $11.7 Billion—With 7.7 Million Medicare Enrollees Being Prescribed These Life-Saving Medications, As Americans Continue To Struggle To Afford Prescriptions, With An Estimated 18 Million Americans Forcing To Skip Dosages In 2021.

According To A February 2024 Study By Bentley University, The National Institutes Of Health Funded Anywhere From $227 Million To $6.5 Billion On The First 10 Prescription Drugs That Are Set To Be Negotiated With Medicare, Of Which 7.7 Million Enrollees Take, As Rising Costs Of Prescription Drugs Have Forced 18 Million Americans To Skip Dosages.

February 2024: A Study From The Center For Integration Of Science And Industry At Bentley University Found The First 10 Drugs Set To Be Negotiated By Medicare "Received Anywhere From $227 Million To

$6.5 Billion In Funding" From The National Institutes Of Health, With 7.7 Million Medicare Enrollees Prescribed These Medications To Treat Conditions Such As Blood Clots, Diabetes, Autoimmune Diseases And Other Disabilities And Ailments. "According to the new study out of the Center for Integration of Science and Industry at Bentley University, which was published early March, the 10 selected prescription drugs received anywhere from $227 million to $6.5 billion in funding from the government's National Institutes of Health (NIH) for crucial, foundational research. [...] These drugs, which are covered by Medicare's prescription drug benefit plan, are taken by 7.7 million enrollees, most of them elderly, to treat conditions including blood clots, heart failure, diabetes, autoimmune conditions, and chronic kidney disease. In 2022, Medicare patients spent $3.4 billion out of pocket on these medications, a number that increased by 116 percent over a four-year span." [The Lever, 02/22/24]

American Taxpayers Spent An Estimated Total of $11.7 Billion On Research For The 10 Drugs, With Their Makers Reaping $70 Billion In Profits On Them In 2022 Alone. "Now a bombshell new report reveals that Americans funded the development of all 10 drugs up for price negotiations, shelling out a total of $11.7 billion on their research. In 2022 alone, Big Pharma made $70 billion selling those same drugs — and now they want to keep their prices sky high." [The Lever, 02/22/24]

Table 3. NIH-funded PMIDs, project years of NIH funding, and NIH funding for basic or applied research prior to first approval of drugs selected for price negotiation in year one of the IRA

Brand Name (Generic name)	Approval Year	NIH-funded PMIDs[a]		Project Years		NIH Funding (millions)[b]	
		Basic	Applied	Basic	Applied	Basic	Applied
Enbrel (etanercept)	1998	2,312	1	3,077	1	$2,604.0	$2.3
NovoLog (insulin aspart)	2000	N/A[c]	1	N/A[c]	1	N/A[c]	$4.5
Januvia (sitagliptin)	2006	154	1	213	1	$227.3	$0.2
Stelara (ustekinumab)	2009	3,683	1	5,281	1	$6,467.1	$15.0
Xarelto (rivaroxaban)	2011[d]	575	16	701	16	$745.0[f]	$18.6
Eliquis (apixaban)	2012[d]	577	9	701	15		$45.6
Imbruvica (ibrutinib)	2013	195	53	369	61	$432.5	$133.5
Jardiance (empagliflozin)	2014[e]	256	6	403	16	$423.3[f]	$11.0
Farxiga (dapagliflozin)	2014[e]	252	8	403	18		$14.1
Entresto (sacubitril[g]/valsartan)	2015	383	3	689	6	$894.3	$6.8

[Institute For New Economic Thinking, 02/28/24]

A 2021 Gallup Survey Found That Adults Nationwide Are Struggling To Afford The Rising Costs Of Prescription Drugs, With 18 Million Americans Saying They Are Forced To Skip Dosages. "The rising cost of prescription drugs is a critical issue in American health care. From 2008 to 2021, the launch prices of new drugs increased by 20 percent per year, forcing 18 million Americans to skip essential dosages, according to a 2021 Gallup survey of adults nationwide." [The Lever, 02/22/24]

Having To Skip Dosages Disproportionately Affects Households Earning $48,000 Or Less A Year And Black And Hispanic Communities.

The Prices Of Prescription Drugs Disproportionately Impacts Households In Lower-Income Brackets, With 18% Of Households Earning Less Than $48,000 A Year Saying They Or A House Member Were Forced To Skip A Dose To Save Money, With More Than Five Million Medicare Beneficiaries Struggling To Afford Drug Costs. "High prices are particularly harmful for lower-income households. Of survey respondents earning less than $48,000 per year, 18 percent reported they or someone in their home had skipped a dose to save money. More than five million Medicare beneficiaries struggle to afford their prescriptions, particularly those who do not receive a low-income subsidy that lowers out-of-pocket spending." [The Lever, 02/22/24]

Meanwhile, "Black And Latino Enrollees Report Affordability Problems At 1.5 To 2 Times The Rate Of Their White Counterparts." "Additionally, Black and Latino enrollees report affordability problems at 1.5 to 2 times the rate of their white counterparts." [The Lever, 02/22/24]

U.S. Census Data Also Shows That Disability-Related Health Conditions In 2021 Predominantly Affected Black And Other Minorities The Highest. "Among adults ages 40 and older, non-Hispanic Asians reported the lowest rates of disability-related health conditions in 2021 while those in the non-Hispanic Black and Other race categories had the highest rates." [U.S. Census Bureau, 07/12/23]

31.8% Of Black Adults And 42.9% Of Multiple-Raced Americans Reported A Disability In 2021. "Black (non-Hispanic) adults (31.8%) and those reporting Other or multiple-race non-Hispanic identity (42.9%) were among those with higher rates." [U.S. Census Bureau, 07/12/23]

The Pharmaceutical Industry Uses Several Patent Abuse Tactics, Including Pay-For-Delay Deals, Evergreening, And Patent Thickets, To Delay Generic Competition For Decades, Costing Consumers Tens Of Billions A Year.

Pay-For-Delay Describes Deals Or Court Settlements In Which Pharma Firms Pay Another Company To Keep Generic Drugs Off The Market Thus Allowing Them To Maintain Patent Exclusivity And Control Product Price, Cost Americans As Much As $36 Billion A Year.

"Pay-For-Delay" Allows Brand Name Manufacturers To Pay Other Companies To Not Bring A Generic Equivalent To The Market, Thus Allowing Them To Continue Charging High Prices. "One reason for persistently high drug costs, according to many experts, is the exclusion of generic competition. Using a tactic known as 'pay for delay,' brand-name drug companies who hold the patents to blockbuster medications pay other companies to put off introducing generic equivalents. This lets them keep charging high prices." [The Atlantic, 06/15/23]

Also Referred To As "Reverse Payment Patent Settlements," These Agreements Are Often The Results Of Court Cases Or Attempts By Brand-Name Manufacturers To Avoid Litigation. "In a 'reverse payment' settlement (in the FTC's vernacular, a 'pay-for-delay' settlement), the branded-drug manufacturer settles a challenge to its patent by providing compensation to the generic challenger. In exchange, the generic manufacturer typically agrees to drop its patent challenge and enter the market as a licensee at some later time before the patent expires. The Supreme Court's *Actavis* decision established that such settlements can sometimes be anticompetitive (see our Jones Day Alert from June 2013, 'Supreme Court Holds Reverse Payment Settlements Potentially Anticompetitive—Further Guidance Awaits'). The *Actavis* court specified that such settlements are subject to antitrust's 'rule of reason' balancing test, a tally of pro versus anticompetitive

factors. ‘Large and unjustified’ settlement payments were deemed illegal. Follow-on cases after *Actavis* have all been private actions for damages—until now.” [Jones Day, April 2021, accessed 06/18/24]

Evergreening Is A Tactic Used By Pharmaceutical Companies To Potentially Extend Patents Indefinitely Through Trivial Changes To An Existing Drug’s Patent, With 80% Of The Country’s 100 Top-Selling Drugs Being Awarded Extra Patents From 2005 To 2015.

Patent “Evergreening” Is When Pharmaceutical Companies Patent Small Changes To Existing Drugs In Order To Expand Their Patent Protections, And In Theory, They Could Do This Indefinitely. “Patent evergreening is when companies take out new patents by simply changing a relatively trivial aspect of the original invention; here, pharmaceutical companies just slightly modify old drugs, and then obtain a patent on it to extend their protections. While the companies producing generic drugs are still able to produce the older version of the drug with the expired patent, brand-name prescription drugs are heavily marketed, which influences doctors’ decisions when prescribing drugs to their patients. In theory, a pharmaceutical company could continuously extend the life of their brand-name drug by making insignificant changes.” [University of Cincinnati Law Review, 12/13/22].

- **The Changes Are Often “Insubstantial” Such As Changing The Dosage Frequency And Amounts Or Slightly Altering The Formula.** “Examples of these insubstantial changes are: changing the drug to be taken once a day, instead of twice, slightly altering the formula, and changing the dosage amount of the drug.” [University of Cincinnati Law Review, 12/13/22].

Many Patents Are Filed After FDA Approval And 80% Of The Country’s 100 Top-Selling Drugs Were Awarded Extra Patents From 2005-2015 And Many Did So Multiple Times. “The research, published in a paper called ‘May Your Drug Price Be Ever Green,’ found that 74% of new drug patents in FDA records between 2005 and 2015 were awarded to existing drugs, not new medications. Of the top 100 pharma products by sales, nearly 80% won an add-on patent or other type of exclusivity extension, while nearly half did so more than once. The authors concluded that since branded drugs are winning lengthy and lucrative IP extensions, generics are taking longer to reach the market and prices around the industry continue to rise.” [FiercePharma, 11/03/17]

“Patent Thickets” Are Unnavigable Tangles Of Patents That Pharmaceutical Firms Build Up Around Their Products To Scare Off Competitors And Which Can Cost Consumers Billions Of Dollars A Year.

Patent Thickets Are “Multiple Overlapping Patents” Which Can Delay Lower Price Generics For Years—One Study Found That Among 2021’s Top Ten-Selling Prescription Medicines, 66% Of Their Active Patents Came Years After FDA Approval. “In this cross-sectional study of 1429 patents and patent applications protecting the 10 highest-revenue brand-name drugs in the US in 2021, almost three-quarters were filed after US Food and Drug (FDA) approval. [...] Brand-name drugs are sold at high prices in the US during market exclusivity periods protected by patents. Multiple overlapping patents protecting a drug are known as patent thickets and can effectively delay the emergence of price-lowering generic competition for many years. [...] Patent thicket density peaked 13 years after FDA approval, at which time these 10 drugs were protected by a median (IQR) of 42 (18-83) active patents, 66% of which were filed after FDA approval.” [Journal of the American Medical Association, 05/13/24]

- **In These Alterations To The Product, “Each Tweak Gets A New Patent.”** “Each tweak gets a new patent, which the manufacturer then adds to its official compendium of drug patents. There is no advance scrutiny of listings by regulators.” [KFF Health News, 01/31/24]

“Product Hopping” Is Used To Describe When Pharmaceutical Companies Make A New But Slightly Modified Version Of An Existing Product In Order To Transfer Patients To The New Drug Before The Patent On The Original Expires.

Patent Holding Firms Will Often Strategically Time Changes To Their Product To Harm A Generic Manufacturers’ Ability To Bring A New Drug To Market, A Tactic Called “Product Hopping.” “A second form of potentially anticompetitive conduct is ‘product hopping’. This behavior involves a brand company switching from one version of a drug to a second, often just to keep the generic off the market. [...] Sometimes, however, the change is made just to harm the generic. Brand companies sometimes know about an improvement but delay it for years until the generic is about to enter the market. Each time the brand company makes one of these changes, the generic must go back to the drawing board, reformulating its drug, obtaining approval from the FDA, confronting a new round of patent litigation, and not being able to be substituted at the pharmacy counter.” [NIH.gov, 05/19/21]

- **In “Hard Switches,” The Manufacturer Will Pull The Patented Drug Off The Market Entirely, A Move Which Is Considered Anticompetitive.** “Courts in the USA have distinguished between ‘hard switches’, viewed as anticompetitive because the brand removes the original drug from the market, and ‘soft switches’, viewed as not concerning because the original remains on the market. But this distinction should not be accorded dispositive significance, as both types of behavior could violate antitrust law. In particular, even when a brand firm leaves the original drug on the market, it can harm competition by combining a reformulation that destroys generic substitutability with an encouragement to write prescriptions for the reformulated (rather than original) product when the only reason is to impair generic entry. Because these soft switches could present competitive concern, the FTC should consider challenging this conduct.” [NIH.gov, 05/19/21]

Patent Abuses Of Negotiated Drugs

Johnson & Johnson Has Made Several Confidential Agreements To Delay Generic Competition For Its Drug, Stelara.

Johnson & Johnson (JNJ) Has Spent Unknown Sums Of Money On Pay-To-Delay Deals To Protect Their Patents On Stelara Until 2025 After The 2023 Expiration Of A Key Patent.

After A Key Patent For Stelara Expired In 2023, JNJ Made Deals To Delay The Entry Of Generics Into The Marketplace Until 2025. “A key Stelara patent expired in the United States last year, but J&J struck deals with competitors to delay the launches of their biosimilars until 2025. Amgen will be the first to launch its near-copy, Wezlana, next year. Analysts have said the delay in biosimilar launches would make Stelara a larger contributor to J&J's 2024 and 2025 sales than previously anticipated.” [Reuters, 02/15/24].

- **JNJ Also Reported In Its SEC Filings That It Made A Confidential Settlement Agreement With Biocon Biologics On Stelara.** “In November 2023, Biocon Biologics Inc. filed a Petition for Inter Partes Review (IPR) with the USPTO seeking review of U.S. Patent No. 10,961,307 related to methods of treating ulcerative colitis with ustekinumab. In February 2024, the parties entered into a confidential settlement agreement, and the IPR was terminated.” [Johnson & Johnson, SEC Form 10-Q, 05/01/24]

Despite A Lack Of An FDA-Approved Biosimilar For Stelara, Johnson & Johnson Is Getting Ready For The Expiration Of Exclusivity By Building Up A Patent Thicket, Including A Patent "Regarded As The Most Impervious To Legal Challenge."

Despite There Not Being An FDA-Approved Biosimilar For Stelara, JNJ Has Prepared For The Expiration Of Its Exclusivity Over The Drug By Building Up A Patent Thicket…"For its part, J&J executives have been preparing investors for Stelara to face biosimilar competition in 2023, but also have hinted at the possibility that it could last longer. 'It's also important to remind folks that there is not yet a [Food and Drug Administration]-approved biosimilar that's ready to be marketed out there,' CFO Joe Wolk told investors attending the J.P. Morgan Healthcare Conference in January. The case illustrates drugmakers' liberal use of intellectual property to build so-called 'patent thickets' around their top products. This practice is particularly common with biologic drugs, which, because of their complex structure and manufacturing processes, offer many more patentable opportunities than older chemical drugs." [BioPharmaDive, 03/29/23]

…Including A "'Composition Of Matter'" Patent That Is "Regarded As The Most Impervious To Legal Challenge." "In its most recent annual report, J&J disclosed that the last Stelara 'composition of matter' patent — the type of intellectual property that protects the underlying drug and is generally regarded as the most impervious to legal challenge — is due to expire in September 2023." [BioPharmaDive, 03/29/23]

Johnson & Johnson Recently Reached Several Confidential Agreements To Delay Generic Competition For Xarelto, Which Is Also A "Prime Example" Of A Patent Thicket, With The Company Applying For Nearly 50 Patents To Keep Competition At Bay For Over A Decade.

Johnson & Johnson Has Disclosed Being Involved In Patent Infringement Lawsuits Against Generic Manufacturers Of Xarelto Since 2021, With Several Confidential Agreements Reached In Early 2024.

In Its Q1 2024 SEC Filing, JNJ Reported That It Been Involved In Patent Infringement Lawsuits Against Generic Manufacturers Of Xarelto Since 2021… "Beginning in March 2021, Janssen Pharmaceuticals, Inc.; Bayer Pharma AG; Bayer AG; and Bayer Intellectual Property GmbH filed patent infringement lawsuits in United States district courts against generic manufacturers who have filed ANDAs seeking approval to market generic versions of XARELTO before expiration of certain Orange Book Listed Patents." [Johnson & Johnson, SEC Form 10-Q, 05/01/24]

… And That In January And February 2024, The Company Entered Into Several Confidential Agreements With Other Companies. "In January 2024, the Company entered into a confidential settlement agreement with Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. In February 2024, the Company entered into confidential settlement agreements with Apotex Inc. and Apotex Corp. (as to U.S. Patent No. 9,539,218), as well as Indoco Remedies Limited and FPP Holding Company LLC. In March 2024, the Company entered into confidential settlement agreements with Umedica Laboratories Pvt. Ltd." [Johnson & Johnson, SEC Form 10-Q, 05/01/24]

Xarelto Is A "Prime Example" Of A Patent Thicket; JNJ Has Applied For Nearly 50 Patents To Keep Competition At Bay For Over A Decade.

JNJ Has Applied For 49 Patents For Xarelto And Has Been Awarded 30 And Has Avoided Competition For Over A Decade. "Xarelto and Eliquis offer prime examples of this behavior. Johnson & Johnson has

applied for 49 patents on Xarelto and been granted 30; As a result, after a decade on the market, neither product has competition on the horizon." [Patients For Affordable Drugs, accessed 06/27/24]

Imbruvica, Jointly Developed And Commercialized By Subsidiaries Of Johnson & Johnson And AbbVie, Has Been Protected From Generic Competition Through Evergreening And Patent Thickets Until 2036.

Johnson & Johnson Has Used The Evergreening Tactic To Extend Patents On Imbruvica, Developed And Commercialized In Partnership With AbbVie Subsidiary Pharmacyclics.

JNJ's Cancer Drug Imbruvica Is One Of The Most Evergreened Drugs On The Medicare Negotiation List, Holding 27 Patents, Many Of Them Secondary Patents Filed Years After FDA Approval. "According to the Evergreen Drug Patent Database provided by the University of California College of the Law, most of the selected drugs listed between three to six unique patents in the *Orange Book*. Two selected drugs stand out for even higher numbers of patents: Farxiga and Imbruvica. Companies listed 36 unique patents covering Farxiga and 27 unique patents covering Imbruvica. These secondary patents extend the overall patent protection period for these drugs. [...] Second, manufacturers listed patents for each of the selected drugs in the *Orange Book* years after the product initially obtained FDA approval. Manufacturers listed new patents for each of the selected drugs at least three years after the product first obtained FDA approval. A new patent was listed for Imbruvica, for example, just a few months ago—over nine years after Imbruvica was first approved." [The Regulatory Review (Opinion), 10/16/23]

- **Imbruvica Was Jointly Developed And Commercialized by Janssen Biotech and Pharmacyclics, Subsidiaries Of Johnson & Johnson And AbbVie Respectively.** "IMBRUVICA® (ibrutinib) is a once-daily oral medication that is jointly developed and commercialized by Janssen Biotech, Inc., and Pharmacyclics LLC, an AbbVie company." [Johnson & Johnson, 02/26/24]

AbbVie Has Used A Patent Thicket Strategy To Amass Over 150 Patents On Imbruvica, Giving It Protection Until 2036.

Imbruvica, Manufactured By Partners JNJ & AbbVie, Is Protected By More Than 150 Patents, Giving The Companies Exclusivity Until 2036. "The company followed the same strategy for Imbruvica by obtaining or filing for over 150 additional patents to delay generic competition until 2036, the probe found. AbbVie's strategy 'is particularly abusive because it seeks to overwhelm potential competitors with the sheer number of patents on Humira regardless of whether individual patents were properly granted under U.S. law,' the committee argued." [FiercePharma, 05/18/21]

- **A 2020 Study Found That Patents Granted For Imbruvica Protect Exclusivity For 29 Years.** "Granted patents protect Imbruvica's commercial exclusivity for 29 years, from December 2006 to March 2036." [Initiative for Medicines Access and Knowledge, accessed 06/26/24]

AbbVie Has Also Tried To Game The Patent System By Product Hopping Patients To Different Dosages Of Imbruvica, A Scheme That Would Be Eliminated Under The IRA.

In 2018, AbbVie Tried Pulling A Low-Dose Version Of Imbruvica Off The Market And Altering Its Price Scale So Patients Would Have To Pay For Higher Doses But "Abandoned Its Plans After Public Outcry." "Imbruvica, a cancer drug, shows how the IRA eliminates reformulation as a means of enforcing price increases. Imbruvica was launched in 2013 as oral capsules. In 2018, tablets were introduced at the same

strengths, except for the lowest strength, which was not made available as a tablet. AbbVie, which markets Imbruvica, then announced that it would pull the lowest-strength oral capsule from the market, while pricing all strengths of the tablet formulations at the same flat amount, regardless of dose. Because low-dose capsules were the least costly option for patients on lower doses, this would have increased patients' spending because they would have had to purchase higher doses. (The company abandoned its plans following public outcry.)" [Commonwealth Fund, 12/19/23]

- **"By Requiring That A Drug's Negotiated Price Scale With The Amount Of Active Ingredient Across Its Various Versions, The IRA Makes It Impossible For Manufacturers To Introduce New Formulations That Exceed The Negotiated Price Of Existing Versions."** [Commonwealth Fund, 12/19/23]

Bristol Myers Squibb Has Used Settlements, Lawsuits, And Patent Thickets To Delay Generic Competition For Eliquis Until As Late As 2031.

Bristol Myers Squibb (BMY) Has Successfully Played The Patent Delay Game For Eliquis, Staving Off Generic Competition For The Drug Until As Late As 2031.

BMS Has Secured Control Over Blockbuster Blood-Clotting Drug Eliquis Until As Late As 2031 By Putting Up "A Wall Of Patent Infringement Lawsuits" Against Dozens Of Companies And Reaching Legal Settlements. "Generic versions of Bristol Myers Squibb and Pfizer's blockbuster Eliquis have already scored tentative FDA nods. But thanks to settlements and a key lawsuit last year, the pair have been able to fend off those cheaper rivals until at least 2026. Since first approved nearly a decade ago, the clot-fighter has become a star for Pfizer and BMS, which jointly develop and commercialize the drug that BMS discovered. Eliquis reaped $9.17 billion in sales last year, a 16% increase compared with 2019, earning a spot among 2020's top five best-selling drugs globally. The companies split profits and losses equally. But for years, the duo has been hard at work fighting back generic rivals. In 2017, for instance, BMS and Pfizer erected a wall of patent infringement lawsuits against 25 companies that had filed for FDA approval of their generics. In August of that year, the U.S. Patent and Trademark Office granted Eliquis a key composition of matter patent, extending it from February 2023 to November 2026. The anticoagulant drug has another formulation patent that doesn't expire until 2031. The pair ended up reaching legal settlements with several of those competitors, including Mylan—now Viatris—and Micro Labs, which scored tentative FDA clearance for the first two copycats in late 2019. However, not all of their rivals backed down." [Fierce Pharma, 07/21/21]

Eliquis Is Also A "Prime Example" Of Patent Thicketing, With BMS/Pfizer Keeping Biosimilars Out Of The Market Until As Late As 2026 Just Off Ongoing Litigation.

BMS/Pfizer Has Applied For 48 Patents And Been Awarded 27 For Eliquis, Delaying Biosimilars To As Late As 2026 Just Off Ongoing Litigation. "Xarelto and Eliquis offer prime examples of this behavior. [...] BMS/Pfizer has applied for 48 patents on Eliquis and has been granted 27. As a result, after a decade on the market, neither product has competition on the horizon. When a dozen Eliquis generics began the process of seeking FDA approval in 2017, BMS/Pfizer served the companies with a slew of lawsuits to delay their entry. By 2019, two generics were approved, but they could be delayed until as late as 2026 due to ongoing patent litigation." [Patients For Affordable Drugs, accessed 06/27/24]

Novartis Has Employed Pay-For-Delay Deals And Multiple Patents To Protect Entresto From Generic Competition Until 2036 While Threatening Lawsuits Against Competitors Despite There Being No Current Generic.

Novartis, Maker Of Entresto, Has Employed Several Patent Extension Strategies, Including Pay-For-Delay Deals, To Protect Entresto From Generic Competition.

Entresto Is A Blockbuster Heart Failure Drug Taken By 11 Million People Worldwide And Which Brings In Billions Each Year Novartis Has Expanded The Number Of Patients And Uses For The Drug. "Launched in the U.S. in 2015, Entresto has become a blockbuster for Novartis, earning $1.4 billion globally during the first quarter. While adoption of the treatment was slow initially, Novartis invested heavily in sales and marketing and later won broader labeling that dramatically expanded the number of patients eligible for the drug. More than 11 million people now take Entresto worldwide, the company estimates." [BioPharmaDive, 07/10/23]

Novartis Is Fighting In Court Over Several Patents Protecting Entresto And It Has Previously Made Deals With Other Companies To Launch Generics "At An Agreed-Upon, Confidential Date." "Currently, Novartis is planning for 'loss of exclusivity' in the U.S. in 2025, when the patent just invalidated is set to expire. Four other patents, with expiration dates between 2023 and 2026, also protect Entresto. Novartis is fighting the challenges of those in court as well. The pharma previously entered into settlements with 'several' generic companies that will allow those firms to launch copycat versions of Entresto at an agreed-upon, confidential date." [BioPharmaDive, 07/10/23]

In Its SEC Filings, Novartis Disclosed That It Had Been In A Legal Battle For Years Over Allegations Its Reverse Payment Scheme For Its Drug Exforge Violated Antitrust Laws. "Since 2018, Novartis companies as well as other pharmaceutical companies were sued by various direct and indirect purchasers of *Exforge* in multiple US individual and putative class action complaints. They claimed that Novartis made a reverse payment in the form of an agreement not to launch an authorized generic, alleging violations of federal antitrust law and state antitrust, consumer protection and common laws, and sought damages as well as injunctive relief." [Novartis AG, SEC Form 20-F, [01/31/24]

- **Novartis Paid $245 Million To Resolve The Cases And Finished Making Payments In 2023.** "In 2022, Novartis agreed to pay USD 245 million to resolve these cases, and this resolution was completed in 2023." [Novartis AG, SEC Form 20-F, [01/31/24]

Novartis' Entresto Also Has Multiple Patents, Giving The Company Exclusivity Until 2036.

Entresto Is Protected By 16 Patents, 10 Of Which Are Active, With Generic Competition Not Expected Until 2036. "Entresto is a drug owned by Novartis Pharmaceuticals Corp. It is protected by 16 US drug patents filed from 2015 to 2021. Out of these, 10 drug patents are active and 6 have expired. Based on its patents and exclusivities, its generic launch date is estimated to be May 09, 2036." [Pharsight, accessed 06/27/24]

A U.S. District Court Invalidated One Of Entresto's Patents In 2023 And While No Generics Currently Exist For The Drug, Novartis Has Threatened To Sue Any Potential Competitors.

Novartis Is In A Court Battle After A U.S. District Court Made A Ruling That Invalidated One Of Entresto's Patents. "Novartis plans to appeal a U.S. district court ruling that invalidated a key patent protecting the Swiss pharmaceutical company's top-selling medicine, the heart drug Entresto." [BioPharmaDive, 07/10/23]

- **There Are Currently No Generics Available For Entresto But Novartis Announced It Would Sue Any Company That Attempts To Bring One To Market.** "The U.S. District Court for the District of Delaware struck down the patent, which is set to expire in 2025 and covers combinations of the two active pharmaceutical ingredients contained in Entresto. The decision, which Novartis disclosed Friday,

could open the door to generic versions of the heart failure treatment, although none are currently approved in the U.S. In a statement, Novartis said any generic drugmaker that launches an Entresto copy while its appeal is pending would do so 'at risk' of litigation." [BioPharmaDive, 07/10/23]

AstraZeneca's Farxiga Is Protected Behind A Wall Of 36 Patents, Giving The Company Exclusivity Until 2030.

AstraZeneca Is One Of The Worst Abusers Of Evergreening, Filing Dozens Of Patents For Farxiga, And Has Extended Patent Exclusivity For Its Drugs By Nearly A Century.

According To Data From The University of California San Francisco School of Law, AstraZeneca Was One Of The Worst Abusers Of Evergreening From 2005 To 2018, Extending Its Patent Protections By A Combined 90-Plus Years. "The searchable database is the first of its kind to comprehensively track the patent protections filed by pharmaceutical companies. Using patent data from 2005-2018 on brand-name drugs listed in the Federal Drug Administration's *Orange Book*, the database reveals the extent of the evergreening strategy used by pharma to prolong patents, often for trivial reasons, and delay the entry of competition, especially generics. The strategy helps drug companies maintain market share and contributes to high drug prices. AstraZeneca led the field in filing for patent protections — and the monopoly profits that go with them — with six drugs that rank among the top 20 drugs for the number of protections received. These protections combined to extend AstraZeneca's market control by more than 90 years for drugs that treat prevalent diseases, such as diabetes and gastroesophageal reflux disease (GERD)." [University of California San Francisco School of Law, 09/24/20]

AZ's Farxiga Is The Most Evergreened Drug On The Medicare Negotiation List, With One Of Its Compounds Enjoying Patent Protections Until 2040. "According to the Evergreen Drug Patent Database provided by the University of California College of the Law, most of the selected drugs listed between three to six unique patents in the *Orange Book*. Two selected drugs stand out for even higher numbers of patents: Farxiga and Imbruvica. Companies listed 36 unique patents covering Farxiga and 27 unique patents covering Imbruvica.These secondary patents extend the overall patent protection period for these drugs. For example, the patent on the compound used in Farxiga - dapagliflozin - expires on October 4, 2025. Another listed patent on a method of treating heart disease with dapagliflozin does not expire until 14 years and five months later, on March 9, 2040." [The Regulatory Review (Opinion), 10/16/23]

Farxiga Is Behind A Thicket Of 36 Patents, Buying It Exclusivity Until 2030.

Farxiga Is Protected By 36 Patents Giving The Company Exclusivity Until 2030. "Farxiga is used to treat adults with heart failure and type 2 diabetes — conditions that put patients at heightened risk of adverse outcomes from COVID-19. [...] The drug's price has been hiked two times this year, increasing to more than $500 for a month's supply. The drug is also guarded by a thicket of 36 patents, which will protect the drug from competition until 2030." [Patients For Affordable Drugs, accessed 06/27/24]

Novo Nordisk Has Extended Patents On Two Lines Of Its NovoLog Insulin By Over 30 Years Each And Created Fiasp, A New And Nearly Identical Version Of NovoLog After It Had Been On The Market For 17 Years.

Novo Nordisk Has Extended Its Novolog Patents By More Than 30 Years Each.

According To A Study By The National Institutes Of Health, Novo Nordisk Has Moved Patented Ingredients Into New Products Resulting In Combined Patent Exclusivity Periods Of More Than 60

Years For Two Lines Of NovoLog. "Manufacturers frequently moved the same active ingredients to new products with different volumes, concentrations, and modes of delivery, all covered under the same NDA (Fig 3). When considering the median time of protection from the approval of the first brand-name drug in a given insulin line to the last-to-expire regulatory exclusivity or patent for all products in the insulin line, the median duration of protection was 17.6 years (IQR 3.0 to 24.6) (Fig 3). The insulin lines with the longest periods of expected protection from the first product approved to last-to-expire patent was Lantus (32.9 years), followed by Novolog (32.3 years) and Novolog 70/30 (30.9 years)." [NIH.gov, 11/16/23]

Novo Nordisk Created A New And Nearly Identical Version Of NovoLog After It Had Been On The Market For 17 Years.

Novo Nordisk Created Fiasp, A Drug With Identical Active Ingredients To NovoLog Which Had Already Been On The Market For 17 Years. "Two formulations of aspart, a rapid-acting insulin, illustrate how the IRA's requirements contend with product hopping. Novolog, the original formulation, was on the market for 17 years. Then, Fiasp was approved under a new application. Fiasp and Novolog are marketed by the same company, Novo Nordisk. Fiasp contains the same active ingredient in the same strength as Novolog, but includes two additional inactive ingredients to hasten its absorption. It has not been demonstrated that this faster action improves long-term management of diabetes. Clinical trials compared Fiasp with Novolog; both are indicated for the same types of patients. Treating Fiasp and Novolog as different drugs because they have different FDA applications would create a loophole. If only Novolog and not Fiasp had a negotiated price, Novo Nordisk could offer Part D plans rebates to promote higher-priced versions of Fiasp at significant cost to Medicare and beneficiaries." [Commonwealth Fund, 12/19/23]

- **In February 2018, Novo Nordisk Announced The Public Availability Of Fiasp In The United States.** "Novo Nordisk today announced the availability of two new diabetes medications, Ozempic® (semaglutide) injection 0.5 mg or 1 mg and Fiasp® (insulin aspart injection) 100 Units/mL at pharmacies across the United States." [Novo Nordisk via PR Newswire, 02/05/18]

Amgen Has Used Dozens of Patents To Delay Generic Competition Of Enbrel By Nearly 40 Years—With 72% of Patents Coming After The Drug's Initial FDA Approval.

Enbrel Manufacturer, Enbrel, Has Loaded Up Patents On The Drug—Delaying Competition By Nearly 40 Years—With 72% of Patents Coming After The Drug's Initial FDA Approval.

Enbrel, Which Was First Awarded A Patent In 1990, Has Been The Subject Of 57 Patent Applications, 72% Of Which Came After FDA Approval, "With The Aim Of Delaying Competition By 39 Years." "The primary patent on Enbrel in the U.S. was filed in 1990 and expired in 2010. However, there are at least 19 active patent applications and granted patents on Enbrel protecting its commercial exclusivity, the last of which expires in 2029. Amgen has filed a total of 57 patent applications on Enbrel in the U.S. with the aim of delaying competition by 39 years. 72% of the total patent applications on Enbrel in the U.S. were filed by drugmaker Amgen after the drug was first approved and on the market in 1998." [Initiative for Medicines Access and Knowledge, 06/26/24]

- **The House Committee on Oversight and Reform Found Amgen Had "'Leveraged Its Patent And LifeCycle Management Strategies To Prevent Competitors From Introducing Lower-Priced Biosimilar Versions Of Enbrel.'"** "Another House Committee on Oversight and Reform investigation into Amgen's biologic Enbrel, used to treat rheumatoid arthritis, concluded that 'Amgen has leveraged its patent and lifecycle management strategies to prevent competitors from introducing lower-priced biosimilar versions of Enbrel.'" [Congressional Research Service, 01/30/24]

Jardiance Is Protected By 18 Patents And Will Not Face Generic Competition For Another Ten Years.

Eli Lilly's And Boehringer Ingelheim's Jardiance Is Protected By 18 Patents And Will Not Face Generic Competition Until 2034 At The Earliest

Jardiance Has 18 Patents And Will Not Face Generic Competition Until 2034 At The Earliest. "Jardiance is a drug owned by Boehringer Ingelheim Pharmaceuticals Inc. It is protected by 18 US drug patents filed from 2014 to 2023 out of which none have expired yet. Based on its patents and exclusivities, its generic launch date is estimated to be Dec 11, 2034." [Pharsight, accessed 06/27/24]