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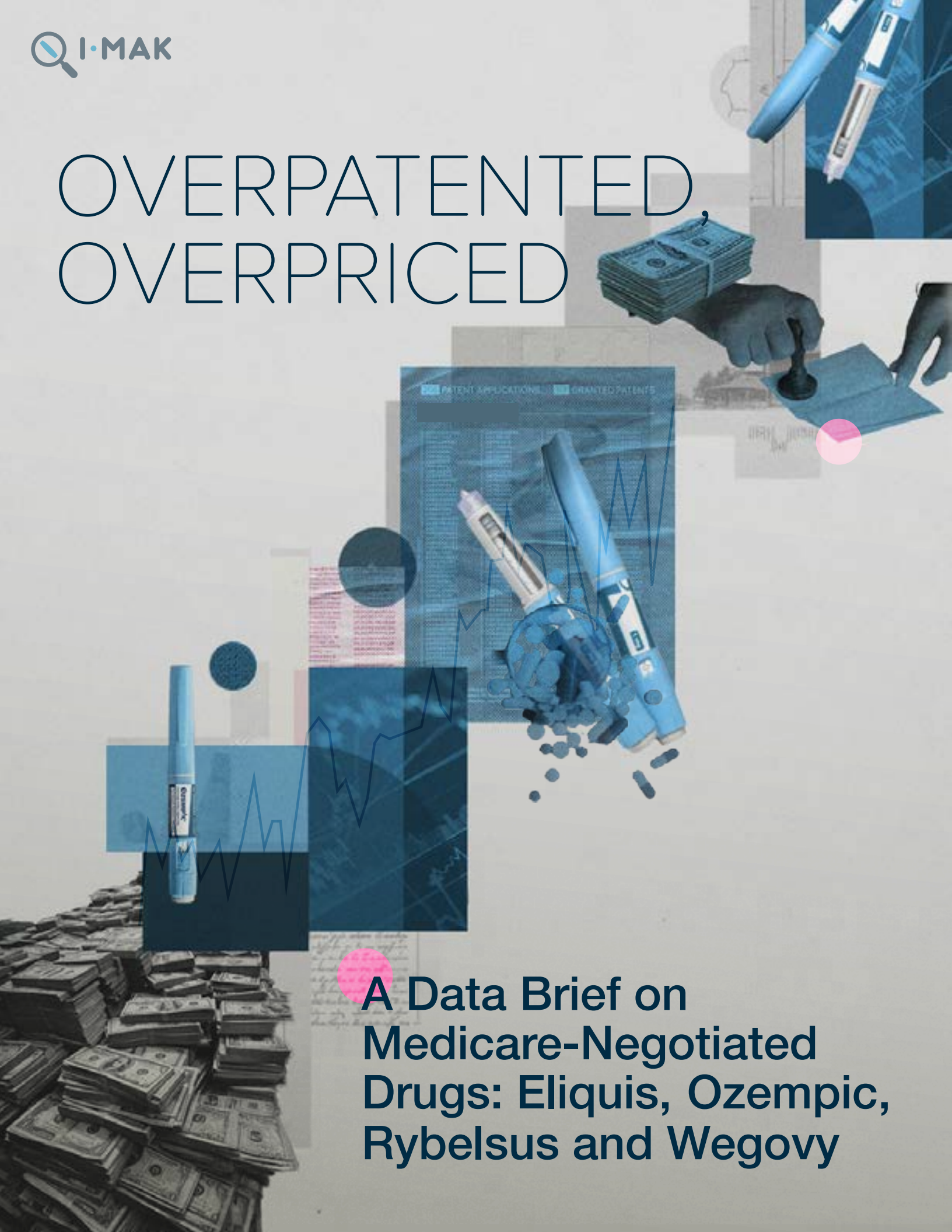
OVERPATENTED, OVERPRICED



A Data Brief on Medicare-Negotiated Drugs: Eliquis, Ozempic, Rybelsus and Wegovy

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A Data Brief on Medicare-Negotiated Drugs: Eliquis, Ozempic, Rybelsus and Wegovy

This data brief accompanies updates to I-MAK's Drug Patent Book database,[1] which now includes nine of the drug products that formed part of the first Medicare negotiation list under the Inflation Reduction Act, as well as the products Ozempic, Rybelsus, and Wegovy (semaglutide) that have been included in the list of medications selected for the second round of negotiations. In this brief, we focus on the patenting and pricing practices for the products Eliquis and Ozempic, Ryblesus, and Wegovy (semaglutide).

Introduction

This brief examines the patenting and pricing practices in the U.S. for the drug products —Eliquis and Ozempic, Rybelsus and Wegovy (semaglutide).

Across our case studies for these drugs, we observe the following trends:

1. **Patent Term Extensions:** Statutory Patent Term Adjustment (PTA) and Patent Term Extension (PTE) mechanisms delay the entry of generic medicines and add billions in additional revenue for blockbuster[2] drugs, even before accounting for any extended market monopoly as a result of follow-on patenting.[3]
2. **Follow-on Patenting and Patent Thickets:** In addition to being granted PTA and PTE, pharmaceutical companies seek numerous follow-on patents covering minor modifications of the original patented invention. These follow-on patents are used to build "patent thickets," which are then selectively used in litigation to block generic competition or extract settlements that delay the entry of generics and lengthen market monopoly.
3. **Price Disparities:** Dramatic pricing differences exist between the U.S. and other economically wealthy nations. U.S. patients often pay up to eight times more for identical medications, in part because other countries engage in more robust and often mandated pharmaceutical price negotiations that cover all patients and not just selected government programs.
4. **Delayed Generic or Biosimilar Competition:** Patients in Europe, Canada, Japan, and other similar markets benefit from earlier generic entry compared to patients in the U.S., who have to wait years longer for low-cost generic products. The earlier generic entry can be attributed to how these countries' patent systems are set up. This includes limiting the endless filing of continuation patents that are used to build large patent thickets. As a result, fewer patents would be granted and available for enforcement in litigation and the extraction of settlements.
5. **Economic Burden:** The extended market monopolies extract billions of dollars in excess spending from patients, insurers, and taxpayers—money that represents profit beyond what was intended by the original social contract of the patent system.

1 The Drug Patent Book. Accessed March 24, 2025. https://drugpatentbook.i-mak.org/.

2 A "blockbuster" drug is widely regarded to be a drug that generates annual sales of $1 billion or more for the company that sells it. See: Chen J. Blockbuster drug: What it is, how it works. Investopedia. Accessed March 24, 2025. https://www.investopedia.com/terms/b/blockbuster-drug.asp.

3 The pharmaceutical industry lobbied for Patent Term Extensions under the Hatch-Waxman Act 1984 to ensure they would be guaranteed up to 14 years of market protection from the date of a product's approval. Patent Term Extensions are a policy designed to compensate the patent holder for any loss of patent term as a result of any regulatory delays. Patent Term Adjustment is governed by the AIA Technical Corrections Act and is a separate process to Patent Term Extensions under the Hatch Waxman Act.

Medicare drug price negotiation under the Inflation Reduction Act (IRA) represents a positive step toward curbing excessive market monopolies as a result of patent abuse and pricing disparities. However, it provides only a limited solution for a certain number of drugs and patients,[4] while failing to address the root causes of patent abuse. Without comprehensive reform of the patent system and expanding drug price negotiations to the entire market, Americans that are not eligible for Medicare will continue to pay the higher prices for a longer period of time.

The following case studies provide analyses of how Bristol Myers Squibb and Pfizer (Eliquis) and Novo Nordisk (Ozempic, Rybelsus, Wegovy) have exploited the patent system, the financial consequences of these actions, and the stark contrasts in the prices of medicine and affordable access access between the U.S. and comparable international markets.

This analysis is part of I-MAK's ongoing work to maintain and expand its Drug Patent Book database, providing policymakers, researchers, and advocates with evidence-based insights into pharmaceutical patenting practices, their implications on how much Americans have to pay for their medicines, and the need for systemic patent reform.

4 The IRA authorizes Medicare to negotiate prices for only 60 drugs through 2029 (10 in 2026, 15 in 2027, 15 in 2028, and 20 in 2029), with 20 additional drugs annually thereafter. These negotiations only benefit Medicare beneficiaries—approximately 19% of the U.S. population who account for about 30% of prescription drug spending. The remaining 81% of Americans, whether insured through employers, ACA marketplace, or uninsured, receive no direct benefit from these negotiated prices.

ELIQUIS

Overview

Eliquis (apixaban), a blockbuster anticoagulant jointly marketed by Bristol Myers Squibb (BMS) and Pfizer, demonstrates how pharmaceutical companies can extend their patent protection and market monopoly in more ways than one. Through the current statutory systems of PTA and PTE, BMS and Pfizer have benefited from extending the patent term on its original compound patent, helping to delay the entry of generic versions of Eliquis.

Not satisfied with this patent term extension, BMS and Pfizer have also obtained additional follow-on patents that have further delayed the entry of generic competition, all while continuing to raise prices and bringing in billions of extra revenue.[5] Despite the FDA approving generic versions in 2019, as a result of PTE and follow-on patenting, BMS and Pfizer have prevented low cost generic versions of Eliquis entering the market until 2028 at the earliest.

Extending Patent Protection

BMS and Pfizer have been able to extend patent protection, and therefore their market monopoly for Eliquis, in more ways than one.

1. The compound patent, U.S. Patent No. 6,967,208 (‘208), for the active ingredient apixaban as used in the product Eliquis was filed on September 17, 2002. The original expiration date of the ‘208 patent was September 17, 2022, which was twenty years from when the patent was filed. As a result of a PTE being granted, the patent term for the ‘208 patent was extended by just over four years until November 21, 2026.[6]

2. BMS and Pfizer have been granted five follow-on patents covering minor modifications in relation to the product Eliquis and which expire after the ‘208 patent covering the original compound. The last expiry date of these follow-on patents is November 22, 2040, 14 years after the expiration of the ‘208 patent covering the original compound. Of these follow-on patents, BMS and Pfizer have so far used U.S. Patent No. 9,326,945 (‘945) in litigation to further delay generic competitors.[7] The ‘945 patent is set to expire on February 24, 2031, adding another four years of additional patent protection beyond the ‘208 patent that has already benefited from over four years of PTE. In total, between the PTE and the expiry date of the ‘945 follow-on patent, BMS and Pfizer have been able to extend their patent protection on Eliquis by over 8 years. According to a statement from BMS, the first generic versions of Eliquis will be blocked from entering until at least April 1, 2028 as a result of the ‘208 and ‘945 patents.[8] This would mean BMS and Pfizer would have gained nearly six extra years of market monopoly beyond the original expiration of September 17, 2022 for the ‘208 patent.

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5 According to Patients for Affordable Drugs, Eliquis entered the market in 2013 at a price of $250 for a monthly supply and increased to $529 by January 2022 - a 111% increase. The price has risen every year, far outpacing inflation. By 2020, Eliquis had become the fourth best-selling drug worldwide and the most costly drug for Medicare.

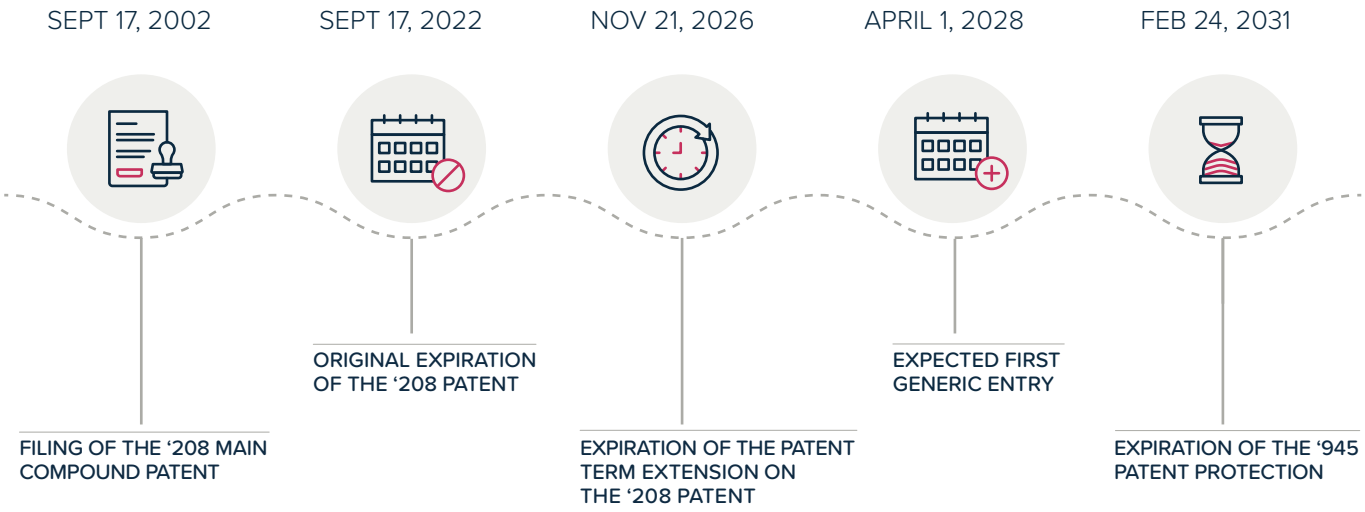
Eliquis and Xarelto Report. Patients for Affordable Drugs. April 2022. Accessed March 24, 2025. https://www.patientsforaffordabledrugs.org/wp-content/uploads/2022/04/Eliquis-and-Xarelto-report.pdf.

6 In addition, the ‘208 patent was granted 139 days of PTA, extending the expiry date until April 9, 2027. However,according to the U.S. Food and Drug Administration’s (FDA) Orange Book, the patent expiration for the ‘208 patent is given as November 21, 2026.

7 The claims of U.S. Patent No. 9326945 cover an inherent property already disclosed and protected in the original compound patent U.S Patent 6,967,208, namely a formulation comprising crystalline apixaban particles.

8 The Bristol-Myers Squibb-Pfizer Alliance is pleased with the decision by the U.S. Court of Appeals for the Federal Circuit upholding the Eliquis® patents. Bristol Myers Squibb - The Bristol Myers Squibb-Pfizer Alliance is pleased with the decision by the U.S. Court of Appeals for the Federal Circuit upholding the Eliquis® Patents. September 3, 2021. Accessed March 24, 2025. https://news.bms.com/news/details/2021/The-Bristol-Myers-Squibb-Pfizer-Alliance-is-pleased-with-the-decision-by-the-U.S.-Court-of-Appeals-for-the-Federal-Circuit-upholding-the-Eliquis-Patents/.

PATENT TIMELINE FOR ELIQUIS



The Cost of Extended Patent Protection and Delayed Competition

THE COST OF PATENT TERM EXTENSION

The statutory PTE granted to the '208 compound patent has significantly delayed generic competition for Eliquis. Without this extension, the patent would have expired on September 17, 2022, twenty years from its filing date. Instead, the PTE pushed expiration to November 21, 2026 - providing over four years of additional patent protection and market monopoly. During this time, Eliquis is projected to generate approximately $39.1 billion in U.S. revenue.[9] This represents an enormous windfall resulting solely from the PTE.

THE COST OF FOLLOW-ON PATENT PROTECTION

Even after the PTE for the '208 compound patent expires, BMS and Pfizer have secured additional patent protection through follow-on patents, particularly the '945 patent covering a formulation of apixaban. In the 16-month gap between the PTE-extended patent expiration on the original '208 compound patent (November 2026) and anticipated first generic entry (April 2028), Eliquis is expected to generate an estimated $11.6 billion in U.S. sales.[10] This additional revenue is extracted entirely through one single follow-on patent that covers an inherent property already disclosed and protected in the original '208 compound patent.

TOTAL FINANCIAL IMPACT OF EXTENDED MARKET MONOPOLY

These two scenarios illuminate the massive financial consequences of extended patent protection and market monopoly for a single medication. Between the patent term extension and follow-on patent protection, BMS and Pfizer are expected to collect over **$50 billion in U.S. Eliquis revenue that would otherwise have been subject to generic competition.** This sum represents the extraordinary cost borne by patients, insurers, and taxpayers due to the current patent system allowing pharmaceutical companies more than one way to extend their patent protection and market monopoly.

9 This figure was calculated based on four full years of Eliquis sales in the U.S.: 2023–2026. For 2023-2024, the actual U.S. revenue for Eliquis was used, as reported by the company in their annual filings. For 2025 and 2026, consensus estimates from Wall Street analysts were used.

10 Based on consensus revenue projections from Wall Street analysts for 2026-2028.

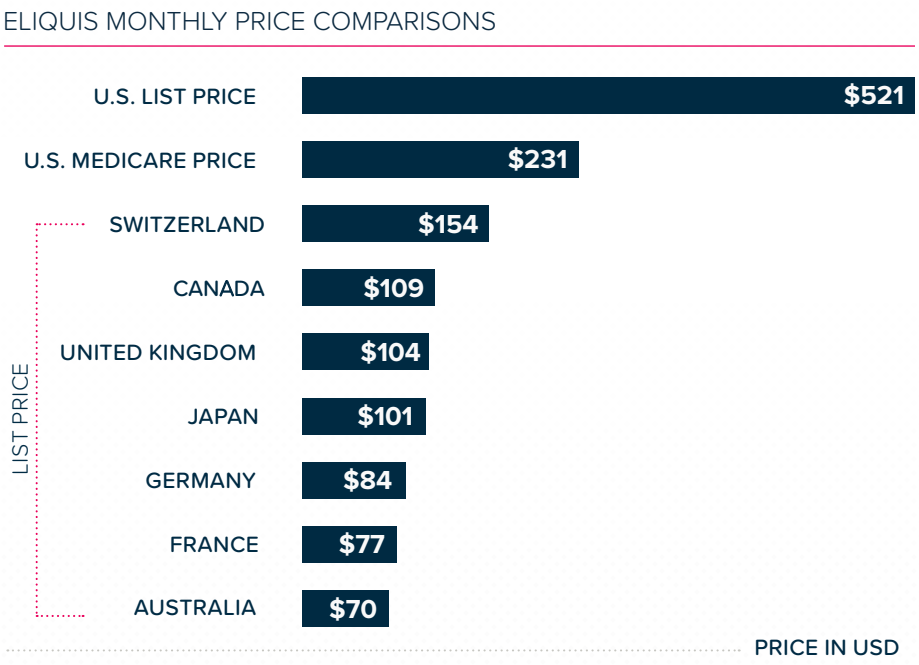
Price Disparities: U.S. vs Global Markets

MEDICARE NEGOTIATIONS: HELPFUL, BUT PERSISTENT PRICE GAPS

The cost of these extended monopoly protections falls heavily on patients and taxpayers. Medicare Part D alone spent over $16.4 billion on Eliquis between June 2022 and May 2023, covering more than 3.7 million enrollees.[11] The IRA's drug price negotiation program represents a positive step, with CMS's "maximum fair price" of $231 for a 30-day supply achieving a 56% reduction from the current list price. However, even this improved negotiated rate still significantly exceeds international list prices. The persistent gap between U.S. negotiated prices and international benchmarks underscores how extended patent protection that blocks earlier generic entry continues to inflate U.S. drug costs, even with the introduction of the IRA.

BRAND-NAME PRICE TAGS AROUND THE WORLD

Eliquis's brand-name price in the U.S. far exceeds its price in other comparable markets. Pharmaceutical companies charge what each market will bear, and in the U.S. Eliquis's price has soared 124% since its 2012 launch.[12] In 2023, a typical U.S. retail price was around $8.68 per tablet before rebates, translating to about $521 for a month's supply. Other wealthy nations pay only a fraction of that. For example, Canada's price for brand Eliquis is roughly $109 per month – about 79% lower than the U.S. price. Germany likewise paid only $84 monthly in recent comparisons, meaning the U.S. price was over 6x higher. Japan's price (around $101) and the UK's ($104) have been similarly low. Even after accounting for U.S. rebates, the estimated U.S. net price after Medicare negotiations ($231) remains far higher than the full list price in Switzerland ($154, the next-highest).[13]



11 Factsheet: Medicare Drug Price Negotiation Program. Accessed March 13, 2025. https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf.

12 Tong N. Here are 25 medicare part D drugs that have skyrocketed in price. Fierce Healthcare. August 10, 2023. Accessed March 24, 2025. https://www.fiercehealthcare.com/payers/here-are-25-medicare-part-d-drugs-have-skyrocketed-price.

13 Unit prices noted in this Commonwealth report were converted to prices for a 30-day supply on the basis of standard dosing, in accordance with the Eliquis FDA label. See: Gumas ED, Huffman P, Papanicolas I, Williams RD. High U.S. health care spending: Where is it all going? January 2024. Accessed March 24, 2025. https://www.commonwealthfund.org/publications/issue-briefs/2023/oct/high-us-health-care-spending-where-is-it-all-going.

EU, UK, AND CANADIAN GENERIC MARKETS LEAVE U.S. BEHIND

The stark contrast in market access is evident in the timing of generic approvals and launches in Canada, EU, and the UK. This highlights how the U.S. is six years behind these wealthy markets in terms of access to lower-priced generic Eliquis equivalents.

FIRST REGULATORY APPROVAL AND COMMERCIAL LAUNCH DATES FOR APIXABAN (GENERIC ELIQUIS)

REGION	FIRST REGULATORY APPROVAL	FIRST COMMERCIAL LAUNCH
EU / UK	JULY, 2020[14]	MAY, 2022[15]
CANADA	JUNE, 2022[16]	JUNE, 2022[17]
U.S.	DEC, 2019[18]	**APRIL 2028**[19]

In Canada, a healthy competitive market exists where multiple manufacturers now produce generic apixaban at dramatically lower prices. The monthly cost of generic apixaban in Canada is about $20.[20] This represents just a fraction of the U.S. Medicare-negotiated price ($231) and is substantially lower than brand-name Eliquis prices in other developed countries worldwide ($70-$154).[21]

Conclusion

The Eliquis case exemplifies how the U.S. patent system allows pharmaceutical companies more than one way to extend their patent protection and market monopoly on medicines. Through patent term extensions and follow-on patenting, BMS and Pfizer have engineered an estimated $50.7 billion in additional U.S. revenue that would otherwise face generic competition. While patients in the UK and Canada gained access to affordable generic versions in 2022, U.S. patients must wait until at least 2028. This stark disparity is reflected in the prices: all Canadian patients can access generic versions at approximately $20 monthly, while patients eligible for Medicare in the U.S. will pay $231 even after price negotiations. This case underscores the urgent need for patent law reform to prevent pharmaceutical companies having various options to extend their patent protection and maintain monopoly prices.

14 Apixaban Accord. Accessed March 24, 2025.

15 Teva UK launches first generic version of Apixaban. Pharmacy Business. May 31, 2022. Accessed March 24, 2025. https://www.pharmacy.biz/news/teva-uk-launches-generic-version-of-apixaban/.

16 First Generic Alternative to Eliquis® Now Available in Canada. July 20, 2022. Accessed March 24, 2025. https://www.apotex.com/global/about-us/news/2022/07/20/first-generic-alternative-to-eliquis-now-available-in-canada.

17 Ibid

18 FDA approves first generics of eliquis. December 23, 2019. Accessed March 24, 2025. https://www.fda.gov/news-events/press-announcements/fda-approves-first-generics-eliquis.

19 Based on patent settlement agreements.

20 Eliquis Prices - U.S. & International. PharmacyChecker.com. Accessed March 24, 2025. https://www.pharmacychecker.com/eliquis/#prices.

21 Neumann I, Schünemann HJ, Bero L, Cooke G, Margini N, Moja L. Global access to affordable direct oral anticoagulants. National Center for Biotechnology Information. Accessed March 24, 2025. https://www.ncbi.nlm.nih.gov/.

OZEMPIC, RYBELSUS, AND WEGOVY (SEMAGLUTIDE)

Overview

Ozempic, Rybelsus and Wegovy are products based on the active ingredient and GLP-1 receptor agonist, semaglutide, as developed and marketed by Novo Nordisk. These drugs represent some of the most commercially successful pharmaceutical products in history. Initially approved for type 2 diabetes management, semaglutide has been repositioned and rebranded across three products: Ozempic (injectable, for diabetes), Rybelsus (oral tablet, for diabetes), and Wegovy (injectable, higher dose, for obesity).[22] This section examines how Novo Nordisk has utilized a statutory PTA, PTE, and the creation of a patent thicket full of follow-on patents, to extend its patent protection and potential market monopoly to delay affordable access for millions of patients. We also examine the significant pricing disparities between the U.S. and comparable international markets.

Extending Patent Protection and Delaying Competition

We have identified that Novo Nordisk has filed 320 U.S. patent applications related to its three products, Ozempic, Rybelsus, and Wegovy, which all use the same active ingredient - semaglutide. The patent thicket protecting products containing semaglutide exemplifies how pharmaceutical companies leverage patenting minor modifications with the intention of delaying competition and extending product profitability far beyond the lifecycle of the main compound. This behavior highlights how the patent system can be exploited for financial gain.

The active ingredient, semaglutide, as used in Novo Nordisk's products Ozempic, Rybelsus, and Wegovy is protected by two key compound patents, U.S. Patent Nos. 8,129,343 ('343) and 8,536,122 ('122). Aside from providing protection for the active ingredient, these patents also disclose that semaglutide can be used to treat various indications, including diabetes, obesity, and cognitive disorders, as well as in combination with other drugs. They also disclose the various potential routes of administration for using semaglutide in a product , including lingual, sublingual, oral, and parenteral.

These patents were originally filed as an international application on March, 20, 2006. As patents are provided with 20 years of protection from the date of filing once granted, these patents should technically expire on March 20, 2026. While patent '122 expires on March 20, 2026, its related patent, '343, will expire almost five years later on December 5. 2031. This extension is due to PTA and PTE.

The impact of these additional five years due to PTA and PTE is profound: Novo Nordisk is projected to earn an estimated **$166 billion from Ozempic, Rybelsus, and Wegovy as a result of this extended period of patent protection,** which spans from March 2026 to December 2031. Consequently, the U.S will not have generic equivalents of Ozempic, Rybelsus, or Wegovy until 2032 at the earliest.

Aside from being granted patents for the compound semaglutide, Novo Nordisk has filed and been granted patents covering a broad family of derivative compounds of semaglutide, which are conceived to prevent competitors from developing related drugs that could compete with Novo Nordisk's products on the market.

22 Initiative for Medicines, Access & Knowledge. "The Heavy Price of GLP-1 Drugs: How Financialization Drives Pharmaceutical Patent Abuse and Health Inequities for GLP-1 Therapies." I-MAK. 2025. p. 3.

In addition to the patents protecting the compound semaglutide and its derivative forms, Novo Nordisk has built a considerable patent thicket of follow-on patents. Also known as secondary patents, these patents mainly consist of formulations, combinations with other drugs, methods of treating different indications that were already disclosed in the main compound patents, and drug delivery devices.[23]

According to our patent searches, Novo Nordisk has filed 91 patents for formulations, 41 patents covering devices to deliver the drug, and 45 patents for methods of treatment. In total, Novo Nordisk has currently been granted 49 follow-on patents. These follow-on patents provide patent protections until 2042.[24] **This is an additional ten years of patent protection beyond the main compound patent for semaglutide,** which has already benefited from an additional five year extension as a result of PTA and PTE. According to our review of Novo Nordisk's pattern of patent applications, since the filing of the main compound patents in 2006, it has been applying for patents relating to semaglutide consistently over a period of 17 years. Noticeably, Novo Nordisk increased its patenting activity in 2019, two years before Wegovy was approved.

These follow-on patents form a systematic attempt to add barriers of entry for generic competitors, with the intention of extending Novo's market monopoly for as long as possible when the main compound patent on the underlying active ingredient, semaglutide, expires.[25]

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23 On April, 30, 2024, the FTC issued a notice to Novo Nordisk identifying the improper listing of 17 of these device patents that do not contain any active ingredient on the FDA Orange Book. These improper listings can delay generic drug competition as a result of triggering automatic litigation stays, increase litigation costs that could disincentivize the development of generic drugs, and increase costs across the healthcare system. The FTC highlighted these actions as potential violations of antitrust laws and indicative of unfair methods of competition, further underscoring concerns about anti-competitive practices in the pharmaceutical industry.

Novo Nordisk - Ozempic, Saxenda, victoza warning letter. April 30, 2024. Accessed January 29, 2025. https://www.ftc.gov/system/files/ftc_gov/pdf/novo-nordisk-ozempic-saxenda-victoza-_4302024.pdf.

24 The first patent applications relating to semaglutide were filed on March 18, 1993. With the last expiring follow-on patent being in 2042, this amounts to a period of 49 years of patent protection in total.

25 In October 2024, Novo Nordisk entered a settlement with Natco Pharma and Mylan (a subsidiary of Viatris) in relation to its product Ozempic. The terms of the settlement are confidential and it remains unclear whether generic entry will happen once the main compound patent expires or later due the follow-on patents. It is also unclear whether generic entry will be subject to any restrictions imposed by Novo Nordisk, such as volume limited distribution over a period of time.

Kansteiner F. Amid GLP-1 craze, Novo and Mylan Ink Patent Settlement in ozempic case. Fierce Pharma. October 7, 2024. Accessed March 24, 2025. https://www.fiercepharma.com/pharma/novos-patent-litigation-settlement-mylan-could-pave-way-cheaper-ozempic-generics.

Litigation between Novo, Mylan and Viatris and Sun Pharmaceutical Industries with respect to the patents protecting Wegovy is still ongoing. Novo Nordisk Inc and Novo Nordisk A/S v Viatris Inc and Mylan Pharmaceuticals, 1:23-cv-00101 and Novo Nordisk Inc and Novo Nordisk A/S v Sun Pharmaceutical Industries Ltd and Sun Pharmaceutical Industries, Inc, 1:23-cv-01459.

GLOBAL PRICING DISPARITIES

Semaglutide based products demonstrate significant pricing disparities between the U.S. and comparable countries, with U.S. patients paying substantially more for the same medications.

INTERNATIONAL PRICE COMPARISON FOR SEMAGLUTIDE PRODUCTS (MONTHLY COST IN $USD)

	OZEMPIC	RYBELSUS	WEGOVY	MOUNJARO
U.S.	**$936**	**$936**	**$1,349**	**$1,023**
JAPAN	$169	$69	-	$319
CANADA	$147	$158	-	-
SWITZERLAND	$144	$147	-	-
GERMANY	$103	-	$328	-
NETHERLANDS	$103	$203	$296	$444
SWEDEN	$96	$103	-	-
UNITED KINGDOM	$93	-	-	-
AUSTRALIA	$87	-	-	-
FRANCE	$83	-	-	-

Source: Peterson-KFF Health System Tracker

PRICE DIFFERENTIALS AND IMPLICATIONS

- U.S. prices for semaglutide products average 3-8 times higher than comparable economically wealthy nations.
- Even after deep discounts (up to 50%), U.S. patients still pay substantially more.
- The price differential is most pronounced for Ozempic, where U.S. patients pay 8 times more than European counterparts.
- Price variations across markets reflect company pricing strategies rather than manufacturing costs or R&D investments.

MEDICARE DRUG PRICE NEGOTIATIONS FOR OZEMPIC, RYBELSUS AND WEGOVY (SEMAGLUTIDE)

The U.S. spending on all GLP-1 products currently on the market, including Ozempic, Rybelsus and Wegovy, was over $34 billion in 2024. Medicare Part D total gross spending on the three semaglutide products surpassed $14.4 billion in the most recent year.[26]

26 Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027. Accessed March 24, 2025. https://www.cms.gov/files/document/fact-sheet-medicare-drug-price-negotiation-program-ipay-2027-and-manufacturer-effectuation-mfp-2026.pdf.

In January 2025, CMS announced the selection of all semaglutide products (Ozempic, Wegovy, and Rybelsus) for the second round of Medicare drug price negotiations under the IRA.[27] Being treated as a single negotiation unit due to their shared active ingredient, these drugs will face negotiated prices beginning January 2027. This marks the first inclusion of a weight loss medication (Wegovy) in the negotiation process, despite current Medicare coverage limitations for obesity treatments.

Projected Savings and Limitations of Medicare Negotiations

The Medicare negotiations for the semaglutide-based products Ozempic, Rybelsus and Wegovy could yield substantial benefits:

- By law, the negotiated prices must range from at least 25% to 60% off the regular list prices. With the recent $14.4 billion in annual gross spending, that amounts to a savings of $3.6 to $8.6 billion annually.
- With a negotiated 50% discount, for instance, the cumulative savings between 2027-2031 could reach $36 billion. This estimate conservatively assumes that the approved uses and number of patients seeking treatment with the semaglutide products remain at current levels.[28]
- Beneficiary out-of-pocket costs could decrease by approximately $300-400 per month.[29]

Despite the savings from Medicare negotiations, significant limitations remain:

1. **Timing Gap:** Benefits only begin in 2027, leaving several years of unchallenged pricing
2. **Extended Patent Protection and Market Monopoly:** Extended patent protection and the thicket of follow-on patents around semaglutide have resulted in settlements in relation to Ozempic, and are also likely to be the result of patent litigation in relation to Wegovy. The terms of any agreed settlements are not made available publicly and could further delay generic entry and extend Novo Nordisk's market monopoly.
3. **Narrow Impact:** Any benefits are limited to Medicare beneficiaries only.
4. **Structural Issues Remain:** The negotiations address symptoms rather than the underlying systemic problems of the patent system that enable extended market monopolies.

Conclusion

The case study of the products Ozempic, Rybelsus and Wegovy (semaglutide) illustrates how pharmaceutical companies have a variety of routes available to them under the current patent system to extend patent protection and, therefore, their market monopoly.

The resulting pricing disparities between the U.S. and international markets highlight the consequences of these practices for American patients and health systems. While Ozempic, Rybelsus and Wegovy (semaglutide) can offer benefits to patients, their current pricing and extended market market monopoly power due to the extended patent protection raise significant concerns about sustainable healthcare costs.

The inclusion of semaglutide based products in Medicare price negotiations represents a step toward addressing excessive pricing, but falls short of resolving the fundamental systemic issues of the patent system that companies exploit at the expense of patients. The negotiations may provide temporary relief for Medicare beneficiaries starting in 2027, but they do not prevent extended patent protection and the development of patent thickets, or address the substantial gaps in access for non-Medicare populations.

27 Centers for Medicare & Medicaid Services. "CMS Announces Second Round of Medicare Drug Price Negotiation." January 11, 2025.

28 Almost certainly, the approved uses for semaglutide will further expand and a much greater share of the Medicare population will seek to access these products. For reference, in 2024, about 2.2 million Medicare patients received semaglutide products, equal to just 4% of the 53 million Medicare Part D enrollees.The prevalence of obesity alone is estimated to be 34% in the Medicare population, corresponding to an additional 16 million Medicare beneficiaries that would qualify for semaglutide products.

29 Commonwealth Fund. "The Impact of the Inflation Reduction Act's Drug Price Negotiations on Medicare Beneficiaries." February 2025.

About I-MAK

The Initiative for Medicines, Access and Knowledge (I-MAK) is a 501(c)(3) organization with a mission to build a more just and equitable medicines system. Our framework integrates comprehensive analytical research to inform policy, education to activate change, and partnerships to drive solutions. We bring decades of private-sector expertise and experience in the field of intellectual property as well as the pharmaceutical sector. Our work spans internationally and we collaborate with patients, drug manufacturers, patent offices, community leaders, public health professionals, policymakers, scientists, economists, and more across the globe. I-MAK's work on structural change in the patent system is featured regularly in the national and global press, as our data is cited in Congressional hearings and Committee reports. I-MAK is committed to evidence-based research and education that will benefit American families and help lower drug prices. Therefore, we have never taken funding from the pharmaceutical industry, whether branded or generic.