The Monopoly Extension Menu

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I. Executive Summary

High prescription drug prices in the United States are often explained as an unavoidable consequence of investment in biomedical progress. Yet across therapeutic areas, delayed competition more often reflects deliberate market and patenting machinations that extend monopoly power well beyond the period for the original invention.

This brief examines three high-spend Medicare drugs—Pomalyst, Darzalex, and Trelegy Ellipta—to show how different maneuvers produce the same result: delayed competition and sustained high prices. Each case study illustrates a distinct but complementary scheme. Taken together, they reveal a system in which manipulation of the market and the patent abuse operate together, reinforcing monopoly power while undermining competition. These dynamics are not anomalies. They are repeatable, predictable, and increasingly common—posing growing challenges for Medicare and for policymakers seeking to lower drug costs.

We call this system the **'Monopoly Extension Menu.'** This calculated approach allows pharmaceutical executives to choose from a variety of "monopoly entrees"—coordinated legal and regulatory maneuvers designed to maximize revenue by delaying generic entry. By utilizing these schemes, manufacturers effectively build layers of protection that extend years beyond the original invention. The following examples represent just some of the schemes currently in use:

- **The 'Patent Thicket' (Pomalyst):** Illustrates how U.S. patent litigation and settlement practices delayed generic entry for two years after Europe. In this period alone, Bristol Myers Squibb (BMS) generated roughly $5 billion in revenue while American patients paid branded prices that were at least two-times higher than those in countries with generic competition. This case offers the clearest view of how current U.S. legal frameworks—patent thickets, automatic litigation stays, and settlement incentives—produce outcomes that differ dramatically from other wealthy nations.
- **The 'Formulation Switch' (Darzalex Faspro):** Shows how product "hopping" has allowed biologic manufacturers to manipulate markets ahead of biosimilar entry by migrating patients to a different formulation that does not demonstrate superior efficacy to the existing version. Janssen's introduction of a subcutaneous (SC) version created a separately patented product insulated from intravenous (IV) biosimilar competition. Within two years from product launch, 85% of patients were shifted to the formulation with monopoly-enabled patent protection that extends more than twelve years beyond the original IV product.
- **The 'Device Lock-In' (Trelegy Ellipta):** Illustrates how drugs with staggered expiry dates for their underlying patents in combination with patented delivery devices can maintain monopoly power for a longer period. No generic exists because the combination-plus-device strategy creates regulatory and competition barriers that persist independently of underlying patent status.

Together, these three drugs account for $9.9 billion in annual Medicare spending, and rank among the highest-cost drugs in the program. Two of these—Pomalyst and Trelegy Ellipta—have been selected for the second round of Medicare price negotiation, with negotiated prices to take effect in 2027. The negotiated brand prices will likely remain far above what competitive generic markets would produce.

While the Inflation Reduction Act represents a much needed step, it still only addresses the symptoms of why we have high drug prices rather than root causes. The regulatory and patent maneuvers documented in this brief will continue, on these drugs and on the next generation, until policymakers remove the options on the Monopoly Extension Menu that keep feeding maximized profits to the pharmaceutical industry at the expense of patients and payers.

II. Introduction

For high-spend drugs in the United States, brand-name manufacturers have systematically operationalized a Monopoly Extension Menu comprising sophisticated legal and commercial maneuvers designed to shield products from competition for as long as possible. Rather than relying on new molecular breakthroughs, branded pharmaceutical companies extend their market dominance by "ordering" from a curated array of schemes to extend their monopoly: filing dense thickets of follow-on patents to block or delay the entry of competitors, migrating patients to a different formulation to reset the patent monopoly clock, and combining drugs with staggered expiration dates with patented delivery systems. The result is a system-level failure where business and legal gamesmanship extracts billions of dollars in excess spending from patients, insurers, and taxpayers long after the original invention has matured.

The Cost of the Pharmaceutical Monopoly Extension Menu

The Monopoly Extension Menu is designed to systematically extract maximum profit from the U.S. healthcare system by prioritizing patent exclusivity for as long as the current regulatory and legal frameworks allow. This approach has turned drug costs into one of the fastest-growing components of Medicare, as the branded pharmaceutical industry maximizes revenue through business and legal schemes that leave patients facing significant out-of-pocket liabilities and taxpayers bearing the burden of a program that does not curtail monopolies early enough. As a consequence, it has created a crisis unique to the United States, where patients pay the highest prices in the world, often three times as much, for longer periods of time. A key reason is because the U.S. patent and regulatory framework has several loopholes that are more easily manipulated and exploited than in other comparable jurisdictions like Europe. While the Inflation Reduction Act offers some savings against the industry's monopoly menu, its narrow scope provides relief to only 19% of the population within Medicare. This leaves the remaining 81% of Americans fully exposed to the branded prix fixe because the underlying patent abuse that enables companies to extend their monopoly power remains untouched. By treating price negotiation as the primary solution, current policy addresses only the symptoms of high costs while leaving the structural failures and procedural loopholes of the patent system completely intact.

This brief examines three high-cost drugs that illustrate how pharmaceutical companies deploy various legal maneuvers to maintain a market monopoly. These drugs are not obscure specialty products. They are among the most expensive drugs in the Medicare program, with costs that have doubled (from $5 to $10 billion) over the past four years, creating significant financial exposure for over a million beneficiaries. The question this brief addresses is: why do these drugs remain so expensive, and why has generic or biosimilar competition failed to materialize?

Table 1: Medicare Profile of Case Study Drugs (2024)[1]

	Pomalyst	Darzalex Faspro	Trelegy Ellipta
Total Spending	$2,149,966,456	$2,530,789,636	$5,294,493,957
Spending Rank within Part B or D	20	2	7
Number of Beneficiaries	14,324	26,521	1,268,937
Annual Cost per Beneficiary	$150,095	$95,426	$4,172
Medicare Part	Part D	Part B	Part D
Spending Growth (2021–2024)	35%	142%	121%
Selected for Negotiation	Yes (round 2)	No	Yes (round 2)
Manufacturer	Bristol Myers Squibb	Janssen (J&J)	GlaxoSmithKline

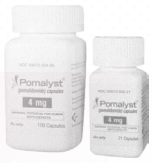
1 CMS Medicare Quarterly Part B and Part D Spending Dashboard. Available at data.cms.gov

The Monopoly Extension Menu

The answer lies in what we call the 'Monopoly Extension Menu'—a set of overlapping schemes that pharmaceutical companies deploy to exploit the U.S. patent system in order to maintain market exclusivity. Each serving on the menu involves specific regulatory and legal maneuvers to extend a drug's monopoly life. By filing dozens or hundreds of follow-on patents, companies ensure that even when one barrier falls, others remain in place to block or delay competition. The cumulative effect is a patent-enforced monopoly that can often extend years beyond the original patent for the underlying active ingredient(s) in the drug.

The Patent Thicket

Pomalyst

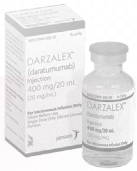


Amassing dozens of follow-on patents on minor modifications to extract settlements with delayed entry dates.

Blocks lower-cost generic alternatives in the U.S. for an additional two years, compared to Europe.

The Formulation Switch

Darzalex



Forcing a switch from IV to a newly patented SC formulation (Faspro) before IV biosimilars can launch.

Insulates ~85% of the market from biosimilar price competition.

The Device Lock-In

Trelegy Ellipta

Inhaler-Drug Co-dependency: Bundling active ingredients with staggered patent expiries in combination with patented "closed" inhaler device system that is legally non-substitutable.

Extends the monopoly period by more than seven years beyond the last expiring drug component, based on a thicket of device and method of use/formulation patents, and regulatory hurdles.

These maneuvers are not mutually exclusive; they are a coordinated effort to prioritize maintaining a market monopoly over patient access. Patent thicketing creates endless barriers that result in costly litigation and, very often, strategic settlements that block or delay real competition. Simultaneously, product hopping creates another layer of patent-protected monopoly, based usually on minor modifications to the existing drug before its patents expire. Combination products with patented devices create barriers that persist regardless of the status of individual patents covering the underlying drugs. Each layer protects revenue and profits by ensuring a market monopoly for as long as the system allows.

Viewing these machinations in isolation underestimates their cumulative effect and obscures the systemic nature of the problem. The Monopoly Extension Menu is not a collection of isolated maneuvers; it is a systematic recipe to maximize profit from the U.S. healthcare system and patients. The case studies that follow demonstrate how patents are the main ingredient that pharmaceutical companies have used to delay generic entry for Pomalyst, insulate Darzalex from biosimilar competition, and maintain a monopoly around Trelegy Ellipta. Together, these case studies make the case for why comprehensive reform of the patent system in the U.S. is needed if we are to have a pharmaceutical system that serves patients first.

III. Case Study: Pomalyst

Pomalyst
(pomalidomide)

Drug type / Medicare category	small molecule oral drug; Medicare Part D
Brand manufacturer	Bristol Myers Squibb (BMS) / Celgene
Primary Indication(s)	Multiple myeloma
FDA approval	February 2013
Annual U.S. net spending (2025)	~$2.3 billion
List price (for 30-day supply)	$21,744
Selected for Medicare negotiation?	Yes–2nd round
Medicare negotiated price (for 30-day supply)	$8,650
Generic price available in Europe (for 30-day supply)	~$1,500

Patent Thicketing and Litigation Settlements

Pomalyst is the third wave of BMS/Celgene's immunomodulatory revenue stream (thalidomide, or Thalomid, being the first and lenalidomide, or Revlimid, being the second). BMS/Celgene appear to have used the same playbook that they did with Revlimid for Pomalyst.

In 1996, Celgene began filing the primary patents covering the active ingredient of pomalidomide.[2] The primary patents expired in 2019. However, the U.S. monopoly for Pomalyst is anchored by a dense thicket of more than 100 follow-on patents that has postponed full generic competition until Q1 2026 at the earliest.[3] Celgene/BMS has used a variety of patent tricks to stave off competition. This includes a diverse thicket of patents covering methods of use, combinations with other active ingredients, crystalline forms, methods of diagnosis, methods of production, and REMS patents, among other categories of patents.

REMS Patents

Celgene has been issued 11 patents covering Risk Evaluation and Mitigation Strategies (REMS) programs, which pomalidomide is subject to, and listed 10 in the Orange Book. REMS are U.S. Food and Drug Administration (FDA) required programs used to monitor distribution of drugs with certain safety risks.

REMS programs are a regulatory safety tool and have little to do with novelty and inventiveness, which are key patentability criteria required to obtain a patent. Patents featuring REMS claims typically cover registries that determine whether, based on certain risk factors, a patient can safely be prescribed and given a drug. These registries involve routine computer systems that mostly involve filtering through databases. In addition, REMS patents should not be listed in the Orange Book as per the governing statute and Congressional statements regarding REMS. Yet, it is nearly universally accepted that such patents are filed, and often listed in the Orange Book, specifically to erect additional barriers that would delay generic competition and extract settlements.

BMS/Celgene has used various patents from its thicket to trigger waves of infringement lawsuits against generic applicants.[4] These cases were largely resolved through confidential settlements rather than court adjudications, effectively extending the drug's market monopoly through legal "innovation" rather than clinical invention. These settlement-driven delays have postponed competition by at least seven years compared to the expiration of Pomalyst's primary patents when full generic competition should have been possible. As a result, full generic competition was postponed until Q1 2026 at the earliest. However, it remains to be seen whether there will be true competition after Q1 2026, or if the generics companies will be subjected to limited volume agreements, like those made for Revlimid, which do not actually bring down costs.

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2 Multiple lawsuits allege that these primary patents were obtained fraudulently because earlier patents owned by a Dr. D'Amato and his team, not Celgene, showed that pomalidomide could be used to kill tumor cells: Compl., *La. Health Serv. & Indem. Co. v. Celgene Corp.*, No. 1:23-cv-07871 (S.D.N.Y. Sept. 5, 2023); Compl., *Cigna Grp. v. Celgene Corp.*, No. 1:25-cv-5237 (S.D.N.Y. Jun. 24, 2025).

3 U.S. Food & Drug Administration. *ANDA 213234 Tentative Approval: Pomalidomide Capsules (Dr. Reddy's Laboratories).* Washington, DC: U.S. Dept of HHS. January 2026

4 Bristol Myers Squibb. *Annual report (Form 10-K) for the fiscal year ended December 31, 2024.* Filed February 2025. Sections describing ANDA litigation and settlement agreements for pomalidomide (Pomalyst). https://www.sec.gov

Notably, these settlements also delayed competition by approximately two years compared to Europe, where multi-source generic entry was a reality in March 2024 and price reductions between 50-80% occurred.[5] During this two-year period of delayed competition, monopoly pricing continued in the United States and coincided with roughly $5 billion in U.S. net spending.[6] [7]

Medicare Negotiations vs. Generic Competition

Pomalyst represents a significant financial burden for the Medicare program, with $2.1 billion in gross spending in 2024 and a staggering $150,000 annual cost per patient. Due to the high spend, lack of generic competition, and settlement-induced delays, Pomalyst was selected for the second round of Medicare drug price negotiations.[8]

- **Negotiated Price:** The 2027 Medicare negotiated price is set at $8,650 per month, a figure achieved through federal intervention. This is in comparison to the generic versions available in European markets for approximately $1,500 per month.[9]
- **The Negotiation Paradox:** The current policy creates a "backward" dynamic where the federal government must expend significant political and administrative capital to negotiate a "fair" branded price that is still 8.5 times higher than the generic prices already available in Europe. This highlights the inefficiency of price negotiation as a substitute for structural patent reform; while a $8,650 price tag is an improvement over the current $21,000+ list price, it remains a "monopoly discount" rather than the true cost-savings provided by robust open-market generic competition.

Key Takeaways

The Pomalyst case illustrates a very popular menu item available to Pharma: using a dense patent thicket to force confidential settlements that delay generic entry long after the primary patented invention has expired.

I. **Monopoly via 'legal innovation':** The Pomalyst monopoly has not been sustained by new therapeutic inventions, but by a "thicket" of more than 100 follow-on patents. These patents—covering routine science like dosing regimens and crystalline forms—were used as legal leverage to trigger waves of multi-year litigation against generic applicants, turning the courtroom into a monopoly shield.

II. **Private Settlements Determine Market-Entry:** Confidential settlements with generic manufacturers (such as Teva and Dr. Reddy's) have functioned as the ultimate gatekeeper for the U.S. market, not the regulatory system that is supposed to safeguard the public interest. By settling Paragraph IV challenges, BMS/Celgene secured a two-year delay in competition relative to Europe where a number of follow-on patents were adjudicated and revoked – a period that coincided with approximately $5 billion in additional U.S. monopoly revenue.

III. **Medicare's Negotiation Paradox:** Pomalyst's selection for the second round of Medicare drug price negotiations highlights a fundamental policy inefficiency. While the government successfully negotiated a 2027 price of $8,650 per month, this "maximum fair price" is still nearly 6 times higher than the generic prices already available in Europe (as low as $1,500/month).[10] This dynamic underscores that price negotiation, while helpful, is a poor substitute for the massive cost-savings generated by true, open-market generic competition.

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5 European Commission. *Pharmaceutical Sector Inquiry: Final Report.* 2009 (documenting average price reductions of ~40% at first generic entry and up to 80% with multiple generics).

6 Pomalyst U.S. net revenues totaled approximately $2.7 billion in 2024 and $2.3 billion in 2025, based on Bristol Myers Squibb earnings reports.

7 Fierce Pharma. *BMS back in court as Cigna files antitrust suit over Pomalyst monopoly.* June 25, 2025.

8 Centers for Medicare & Medicaid Services. *Medicare Drug Price Negotiation Program: Selected Drug List (Round 2).* January 17, 2025.

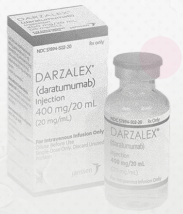
9 A Dec 2024 Italian procurement award shows pomalidomide procured at €58 per capsule, equivalent to about €1,230 per 21-capsule monthly treatment cycle. Available at: https://www.azero.veneto.it/documents/20126/4877dad7-aead-3db2-6cc4-5ebc6072d711

10 This timing also reveals an implementation gap: per a September 2024 BMS/Dr. Reddy's settlement, generic pomalidomide is expected in Q1 2026—nearly a year before the $8,650 MFP takes effect. CMS guidance addresses generic entry during negotiations or after an MFP is in effect, but not when generics reach the market before the MFP effective date. Medicare could thus be paying the higher negotiated brand price while lower-cost generics are already available.

IV. Case Study: Darzalex

Darzalex Faspro

(daratumumab and hyaluronidase-fihj)



Drug type / Medicare category	Biologic (Medicare Part B)
Brand manufacturer	Janssen (Johnson & Johnson)
Primary Indication(s)	Multiple myeloma
FDA approval	IV (2015), SC (May, 2020)
Annual U.S. net spending (2025)	~$7.0 billion
List price (for 30-day supply)[10]	$21,054
Selected for Medicare negotiation?	No
Medicare negotiated price (for 30-day supply)	N/A

The Formulation Switch

The transition of the daratumumab franchise from an intravenous (IV) to a subcutaneous (SC) formulation—marketed as Darzalex Faspro—is a primary example of a "product hop" designed to insulate a multibillion-dollar biologic from biosimilar competition. Janssen introduced the SC version in May 2020, less than four years before the initial wave of IV biosimilar challenges was anticipated.[12]

By mid-2022, Janssen reported that 85% of U.S. patients had already transitioned to the subcutaneous formulation, effectively moving the market's "standard of care" to a product with a much longer exclusivity horizon.[13] Driven by the transition, Darzalex Faspro is projected to power the franchise's U.S. revenue to $8.27 billion in 2025, representing a more than 2.5-fold increase in total U.S. sales since its full launch year in 2021.[14]

Moving the Patent Goalposts

The "Monopoly Extension Menu." for Darzalex relies on moving from a compound-focused patent strategy to one built on formulation and delivery:

- **The IV Baseline (2029):** The primary patent covering the main compound for the daratumumab antibody was originally slated to expire in 2026.[15] However, due to a successful Patent Term Extension (PTE) granted to compensate for regulatory review delays, as well as a Patent Term Adjustment (PTA) granted to compensate for delays by the USPTO, this core protection has been extended to May 22, 2029.[16] This date remains the hard "floor" for any IV biosimilar entry.[17]
- **The SC Monopoly Extension:** To protect the subcutaneous "hop," Janssen secured follow-on patents specifically covering the change of delivery method.[18] Various patents covering daratumumab + hyaluronidase formulations push patent protection to at least 2037. A device patent and a method of treatment patent add further patent protection to at least 2042, more than twelve years beyond the expiration of the original compound.[19] While these patents may not ultimately block competition until 2042, they could still play a role in litigation.

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11 Wholesale Acquisition Cost (WAC) for Darzalex Faspro (1,800 mg/15 mL) is $10,985 per single-dose vial as of early 2026. FDA-recommended 23-dose schedule per year. Source: Drugs.com Price Guide

12 *Daratumumab (DARZALEX): Cornerstone Anti-CD38 Therapy For Multiple Myeloma.* Grand View Research; September 2025. Report ID: GVR-MT-100416.

13 Johnson & Johnson. *Q2 2022 Earnings Call Transcript.* July 19, 2022. Available at J&J Investor Relations. Secondary coverage via Fierce Pharma.

14 U.S. annual net sales for the Darzalex franchise were $3.12B (2021), $4.64B (2022), $5.56B (2023), $6.59B (2024), and $8.27B (2025). Sources: Genmab 2025 Sales Report and J&J Q4 2025 Results.

15 Analysis of patents covering Darzalex Faspro. I-MAK Internal Research. February 2026; De Weers et al. (2010) *Antibodies Against CD38 for Treatment of Multiple Myeloma.* (U.S. Patent No. 7,829,673). U.S. Patent and Trademark Office.

16 Application for Extension of Patent Term (37 C.F.R. § 1. 740) for U.S. Patent No. 7,829,673.(Granted) https://downloads.regulations.gov › attachment_1

17 *Son of Darzalex hits the skids.* ApexOnco Oncology Pipeline. March 10, 2025. https://www.oncologypipeline.com/apexonco/son-darzalex-hits-skids

18 *Analysis of patents covering Darzalex Faspro.* I-MAK Internal Research. February 2026.

19 *Ibid.*

Darzalex Faspro's delivery is enabled by rHuPH20, Halozyme's ENHANZE technology.[20] While the base patents for Halozyme's enzyme technology began to expire in 2024 in Europe and 2027 in the U.S., Janssen's specific co-formulation patents—which combine daratumumab with the enzyme— serves to prevent competitors from simply replicating the SC product even if the individual components are off-patent.[21]

The Darzalex Faspro formulation switch is not an isolated case in the world of biologic drugs. It is now a standard technique enabled by recombinant hyaluronidase technology to allow subcutaneous delivery of drugs that are otherwise delivered by intravenous infusion. Various pharmaceutical companies have been using this technology specifically to create reformulated versions of biologics approaching biosimilar competition. The pattern is now visible across multiple high-revenue biologics, as the table below shows:

Table 2: How Formulation Switching Extends Monopolies[22]

Drug (IV)	SC Version	Same Active Ingredient?	IV Patent Expiry (US)	SC Launch (US)	SC Patent Expiry (est.)	Monopoly Extension
Herceptin (trastuzumab)	Herceptin Hylecta	Yes	2019	2019	~2030	+11 years
Rituxan (rituximab)	Rituxan Hycela	Yes	2016	2017	~2034	+18 years
Darzalex (daratumumab)	Darzalex Faspro	Yes	2029	2020	~2042	+13 years
Keytruda (pembrolizumab)	Keytruda Qlex	Yes	2028	2025	~2039	+11 years
Perjeta (pertuzumab)	Phesgo*	Yes	2024	2020	~2035	+11 years

In each case, the commercial logic is identical: introduce a subcutaneous formulation with fresh patent protection before biosimilar competition can erode revenue from the IV version, then shift patients from the alternative formulation. The selling point is that the formulation provides faster administration and patient convenience even though it is the same drug and has no superior efficacy than the IV version.

The patent system in the US has evolved to conflate genuine invention of new molecules with modifications to existing drugs that the industry then promotes as innovation. The system fails to differentiate between a predictable modification that provides convenience versus an entirely new drug product that provides the clinical therapeutic effect. Consequently, the same 20-year period of patent monopoly is granted for an incremental change based on commonly practised formulation techniques, such as using a hyaluronidase enzyme, as for an entirely new molecular invention. By deliberately muddying the line between genuine invention (a high-bar) and innovation (a low-bar), the pharmaceutical industry has turned the patent system into a cover for what is fundamentally a monopoly extension buffet.

Compounding the Monopoly Extension: The Regulatory Dimension

The impact of the formulation switch is cemented by the U.S. regulatory framework under the Biologics Price Competition and Innovation Act (BPCIA). The regulatory landscape reinforces the patent monopoly extension by creating distinct silos for different formulations:

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20 Halozyme Therapeutics, Inc. *Corporate Presentation: Leader in Disruptive Drug Delivery Technologies.* December 2024

21 Halozyme Therapeutics, Inc. Form 10-K for the fiscal year ended December 31, 2023 U.S. Securities and Exchange Commission; 2024:17-18.

22 Patent expiry dates are estimates based on primary patent terms, patent term adjustments (PTA), and patent term extensions (PTE), derived from company disclosures and analyst consensus; Darzalex Faspro (2042) based on I-MAK legal analysis. Some SC formulations utilize Halozyme's ENHANZE drug delivery technology (rHuPH20), which is protected by separate formulation patents extending beyond IV patent expiry. "Monopoly Extension" calculated as difference between estimated SC patent expiry and IV patent expiry. Phesgo combines pertuzumab + trastuzumab in a fixed-dose SC formulation.

- **Separate Licensure:** Darzalex Faspro was approved through a standalone Biologics License Application (BLA) under section 351(a) of the Public Health Service Act—the pathway for entirely new biologics.[23] This makes it a distinct regulatory product from the original IV version.[24]

- **The Substitution Trap:** Under FDA rules, a biosimilar approved through the abbreviated 351(k) pathway must have the same route of administration as its reference product.[25] A biosimilar referencing IV Darzalex cannot be substituted for SC Darzalex Faspro at the pharmacy or clinic level because they are legally different products.[26]

- **State Law Barriers:** State pharmacy substitution laws compound this effect.[27] Even in states with biosimilar substitution provisions, substitution is permitted only within the same product class (e.g., an IV biosimilar for IV Darzalex).[28] A pharmacist cannot substitute an IV biosimilar when a prescription specifically identifies the SC formulation.[29]

- **Prescriber Dependency:** This means that biosimilar savings depend entirely on prescriber behavior: physicians must actively choose to prescribe the older IV formulation (with its available biosimilars) rather than the newly branded SC version.[30] By moving the majority of the market to SC, Janssen preserves branded pricing indefinitely for that dominant segment.[31]

Medicare Relevance: High Costs and Accelerated Spending

The financial impact of the Monopoly Extension Menu is most acutely felt within the Medicare program, where daratumumab has become the second-highest total spending drug in Medicare Part B. Aggregate Medicare Part B spending for Darzalex Faspro reached $2.5 billion in 2024, representing a massive escalation in program exposure where total spending has increased 2.4-fold since 2021.[32]

The introduction of the subcutaneous (SC) formulation has fundamentally shifted the economics of the treatment for the program:

- **Cost Concentration:** In 2024, Darzalex Faspro carried an average Medicare spending per beneficiary of $95,426, reinforcing its position as a primary driver of Part B expenditure.[33]
- **Market Migration:** The Medicare market has transitioned to the newer formulation even more rapidly than the general commercial market, with the SC version now accounting for the vast majority of daratumumab utilization.[34] By moving the majority of the market to SC, Janssen ensures that the vast majority of program costs are tied to the version with the longest patent tail.

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23 U.S. Food & Drug Administration. *FDA Approves Darzalex Faspro for Multiple Myeloma.* May 1, 2020.

24 A Systematic Review of U.S. Biosimilar Approvals. PMC. August 2023. PMC10398206

25 U.S. Food & Drug Administration. *Key Terms & Concepts: Biosimilars.* FDA. August 2024

26 Alston & Bird. *What Is the Regulatory Pathway for Biological Products?* January 20, 2026

27 *State Substitution Practices for Biological Drugs.* National Association of Chain Drug Stores (NACDS). July 2021.

28 *US biosimilar market entry challenges and facilitating factors final report.* Assistant Secretary for Planning and Evaluation (ASPE). August 18, 2025.

29 Federal Trade Commission. *Bringing Down the Cost of Biologics: Challenges to Biosimilar Competition.* Washington, DC: FTC; 2024

30 *Soaring off the Patent Cliff: Preparing for the Next Wave of Oncology Biosimilars.* Pharmacy Times. December 17, 2025

31 *J&J 10-K details key drugs, MedTech and risks.* Stock Titan. February 11, 2026

32 Centers for Medicare & Medicaid Services. *Medicare Drug Spending Dashboard: Daratumumab (2021-2024).* Updated February 12, 2026. Accessed February 12, 2026. https://data.cms.gov/

33 *Ibid.*

34 Lal LS, et al. *Medicare spending and use of subcutaneous biologic formulations with hyaluronidase.* PMC. June 14, 2025. PMC12166118.

- **Beneficiary Liability:** As Darzalex Faspro is primarily billed under Medicare Part B, traditional Medicare beneficiaries without supplemental insurance are responsible for a 20% coinsurance.[35] This can translate into significant annual out-of-pocket liabilities, creating a substantial financial burden for patients with multiple myeloma.[36]

Key Takeaways

The Darzalex case illustrates the second layer of the Monopoly Extension Menu: using a formulation switch to create a new monopoly before the old one erodes.

I. **Formulation Switching as a Monopoly Extension:** The transition to the subcutaneous formulation functions as a massive monopoly extension rather than a simple update. While the core daratumumab antibody patent is set to expire in May 2029—even after accounting for a maximum Patent Term Extension (PTE)—the newer SC formulation patents extend the franchise's monopoly until at least 2037, or potentially 2042 when the latest patents expire. This strategy effectively builds a seven to twelve-year bridge of potential additional patent-enforced profits beyond the life of the original invention.

II. **Regulatory Silos Block Competition:** Because biosimilars must match the route of administration of their reference product, the shift to subcutaneous delivery creates a "market silo." Even robust biosimilar competition for the IV formulation provides no relief for the 85% of patients who have been transitioned to the SC version, as they are legally non-substitutable under the BPCIA and state pharmacy laws.

III. **The "Ghost Market" Trap:** By the time IV biosimilars arrive in 2029, they will compete for a vanishingly small fraction of the market. Janssen's strategy ensures that the vast majority of revenue remains shielded within the patented SC formulation, leaving competitors to fight over a "ghost market" of the remaining IV patients.

IV. **Enormous Stakes for Medicare:** This monopoly extension playbook has turned Darzalex Faspro into the second-highest spend drug in Medicare Part B, with total spending increasing more than 2.4x since 2021 and an average cost of more than $95,000 per beneficiary. Darzalex has not been selected for the first three rounds of Medicare drug price negotiation, ensuring that the program remains locked into branded pricing for the foreseeable future.

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35 *Addressing high prices of drugs covered under Medicare Part B.* MedPAC. February 28, 2023.

36 *US biosimilar market entry challenges and facilitating factors final report.* Assistant Secretary for Planning and Evaluation (ASPE). August 18, 2025

V. Case Study: Trelegy Ellipta

Trelegy Ellipta

(fluticasone furoate / umeclidinium / vilanterol)

Drug type / Medicare category	Inhaled combo (Medicare Part D)
Brand manufacturer	GlaxoSmithKline
Primary Indication(s)	COPD maintenance; asthma
FDA approval	Sept 2017
Annual U.S. net spending (2025)	~$2.5 billion
List price (for 30-day supply)	$654
Selected for Medicare negotiation?	Yes–2nd round
Medicare negotiated price (for 30-day supply)	$175

The Combination and Device Patent Evergreening Scheme

Trelegy Ellipta exemplifies patent evergreening through device patenting and combining of drugs. It provides GSK with a way to extend its monopoly by bundling three distinct drug classes—a corticosteroid, a muscarinic antagonist, and a beta-agonist—into one product. Even though the primary patents for two of the individual active ingredients have now expired, the combination remains insulated from generic competition. Moreover, the FDA requires a generic inhaler to be functionally identical to the branded device for pharmacy-level substitution.[37] But Trelegy Ellipta is covered by an array of inhaler device patents. To further fortify its monopoly, GSK also has patents covering various formulations of the three drugs as well as methods of using the drug combination to treat various lung diseases.

- **Component Expiration vs. Product Life:** The individual components of Trelegy have staggered primary patent expiration dates: fluticasone furoate (2021) and vilanterol (2025) [38] are already off-patent, while umeclidinium bromide is set to expire in December 2027.[39] This strategic layering ensures that even as individual ingredients lose protection, the entire triple-combination remains protected as a single-unit product. GSK has also filed numerous patents covering formulations of the 3-drug combination, a number of which cover methods of using the drug combination to treat lung diseases, which extend protection until at least 2034. GSK obtained the method of use patents despite the fact that the component parts are known to treat these lung diseases. Even though U.S. patent law dictates that a patent is obvious if a person of skill in the art would have been motivated to combine known aspects, patents on combinations like Trelegy Ellipta are granted all the time. Consequently, generic applicants will have to clear as much as of this patent thicket through litigation before a single dose can reach the market.[40] During that litigation, patients will be denied more affordable versions while GSK will reap the profits of its evergreening scheme.
- **The Device Moat:** The Ellipta inhaler itself is protected by a separate layer of device patents that function as additional fortification of GSK's monopoly.[41] Device-specific patents, such as U.S. Patent No. 9,327,088, provide patent protection until at least 2032.[42] To qualify as a substitutable generic, a manufacturer must prove their device matches the "patient interface" of the Ellipta inhaler, including identical inhalation mechanics and dose-counting displays.[43]

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37 U.S. Food & Drug Administration. *Draft Guidance on Fluticasone Furoate; Umeclidinium; Vilanterol Trifenatate.* May 2022.

38 Owing to a nearly 3 year Patent Term Extension.

39 U.S. Food & Drug Administration. *Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).* Umeclidinium Bromide Patent Expiry: December 18, 2027 (also owing to a nearly 3 year Patent Term Extension).

40 Celegence. *Navigating Regulatory Challenges for Generic Inhalation Drug Products: A Strategic Approach.* March 27, 2025.

41 Drugs.com. *Generic Trelegy Ellipta Availability & Release Date: Related Patents and Device Expirations.* Updated January 8, 2026.

42 Anderson GJ, et al. (2016). *Drug dispenser* (U.S. Patent No. 9,327,088). U.S. Patent and Trademark Office.

43 Team Consulting. Key inhaler development regulatory guidelines for the generics market. March 6, 2024.

This FDA requirement makes it exceedingly difficult to "design around" any device patents which make them highly effective barriers to generic and biosimilar entry. Yet, mechanical patents, including device patents, represent some of the most easily invalidated types of patents when they actually get adjudicated, often being distilled down to a combination of predictable and routine mechanical functions. Despite this glaring abuse of inhaler device patents being well documented, neither the FDA nor the PTO have done anything to curb these abuses of the patent system.[44] [45]

"Junk" Patent Listings and Regulatory Scrutiny

The Federal Trade Commission (FTC) has, over the last several years, intensified its crackdown on what it terms "junk listings"— improper patent filings in the FDA Orange Book that claim device components rather than the drug itself.[46] In April 2024, the FTC issued a formal warning letter to GSK specifically identifying patents for Trelegy Ellipta, such as U.S. Patent No. 8,161,968, as being improperly listed.[47] The FTC's criticism is unsparing, alleging that these manufacturers use "sham" listings to trigger automatic 30-month stays of FDA approval for generic competitors, a tactic that illegally delays competition and forces Americans to pay "sky-high prices" for essential medicines.[48] By leveraging these procedural delays rather than genuine invention, manufacturers like GSK successfully block cheaper alternatives from entering the market. This practice is characterized by the FTC as an unfair method of competition that harms the entire healthcare system.[49]

Medicare: Massive Spend and Negotiated Relief

Trelegy Ellipta has become the seventh highest expenditure for the Medicare Part D program, reaching $5.3 billion in gross spending for 2024.[50] Total spending on the drug has grown more than 3.5x since 2020.[51]

- **Negotiation Status:** Trelegy was selected for the second round of Medicare drug price negotiations with negotiated prices that begin in 2027
- **2027 Price:** The negotiated 30-day price is set at $175, representing a 73% discount from the 2024 list price of $654.[52]
- **The Substitution Gap:** While negotiation provides price relief, it does not resolve the structural lack of competition. In Europe, "generic" inhalers can often be approved by showing in vitro equivalence, whereas U.S. rules require costly clinical trials, often deterring entry even after patents expire.[53]

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44 Feldman WB, Rome BN, Kesselheim AS. *Patenting strategies on inhaler delivery devices.* Journal of Law, Medicine & Ethics. 2023;51(1):54-63.

45 Kesselheim AS, Avorn J, Sarpatwari A. *Product hopping in the drug industry — lessons from albuterol.* New England Journal of Medicine. 2016;374:507-509.

46 Federal Trade Commission. *FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings.* Press Release. April 30, 2024.

47 Federal Trade Commission. *Warning Letter to GlaxoSmithKline Intellectual Property Development Limited regarding Trelegy Ellipta.* April 30, 2024.

48 Khan LM. *Statement on Challenging Junk Patent Filings to Timely Access Affordable Medicines.* Federal Trade Commission. April 30, 2024.

49 *FTC Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book.* FTC Policy Statement. September 14, 2023.

50 Centers for Medicare & Medicaid Services. Fact Sheet: Medicare Drug Price Negotiation Program Negotiated Prices for Initial Price Applicability Year 2027.

51 *Analysis of CMS Medicare Part D Spending Trends: Trelegy Ellipta (2019-2024).* I-MAK Internal Research. February 2026.

52 *CMS sets 2027 Medicare prices for Wegovy, Trelegy and 13 other drugs.* BioPharma Dive. November 26, 2025.

53 *ICOpre® Briefing Document (April 2021 update).* Iconovo. April 2021.

Key Takeaways

The Trelegy case illustrates another option on the Monopoly Extension Menu: using combination products and patented devices to create monopoly power that persists even when individual components face generic pressure.

I. **Combination Evergreening:** By bundling three ingredients into a fixed-dose combination, GSK creates a monopoly that cannot be substituted with available generic components at the pharmacy. The combination product itself becomes the source of a monopoly, independent of the patent status of its individual parts.

II. **Device Patents for Fortification:** Patented delivery devices like the Ellipta inhaler add a separate layer of monopoly protection. A generic competitor must replicate not just the triple-drug mixture but also the specific mechanics of the device, facing a separate patent thicket that extends the monopoly horizon to at least 2032.

III. **Unfair Competition:** The FTC's designation of Trelegy's device patents as "junk listings" highlights the systemic use of improper filings to secure procedural stays that delay or block cheaper alternatives. This strategy exploits regulatory loopholes to maintain "sky-high prices" for essential medicines without providing any new clinical invention.

IV. **Medicare Impact:** Despite a negotiated price of $175/month for 2027, Trelegy remains a multi-billion dollar liability for Medicare Part D. Without structural reform to address device-led exclusivity and regulatory barriers, the drug will remain a branded monopoly until generic entry, currently estimated for late 2030.

VI. Conclusion & Policy Implications

The three drugs examined in this brief—Pomalyst, Darzalex, and Trelegy Ellipta—illustrate the Monopoly Extension Menu that feeds the profit maximizing interests of pharmaceutical companies under the current patent and regulatory systems. Together, they represent $9.9 billion in gross Medicare spending in 2024, with costs that have doubled since 2021.[54] And these three drugs cost U.S. patients and payers a combined net total of $11.8 billion in spending in 2025.[55] In each case, extended monopoly is a function of business and legal 'innovation', not the invention of novel therapeutic treatments.

The Inflation Reduction Act's drug price negotiation program is a necessary and important step to help curb high drug prices. For the drugs selected and the beneficiaries covered, negotiated prices will help reduce some of the costs. But IRA negotiation alone does not get to the root of the problem, especially for the 81% of Americans who are not covered by Medicare and entitled to the benefits of negotiated prices. Price negotiation is a symptom-level intervention applied to a system-level problem. Without systemic reform, the Monopoly Extension Menu will continue to be served, on these drugs and on the next generation of high-cost therapies.

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54 2024 total spending on Pomalyst ($2.1bn), Darzalex Faspro ($2.5bn), and Trelegy Ellipta ($5.3bn). Spending growth calculated by I-MAK based on CMS Medicare Part B and Part D Drug Spending Dashboard data, 2020–2024. Centers for Medicare & Medicaid Services, "Medicare Drug Spending Dashboard," data.cms.gov.

55 2025 U.S. net revenues from company annual reports: Trelegy Ellipta ~$2.5B (GSK); Pomalyst ~$2.3B (BMS); Darzalex Faspro ~$7.0B estimated (J&J; 85% of $8.3B franchise).

Taking the Monopoly Extension Menu off the Table

To prevent the continued extraction of billions in excess costs from the U.S. healthcare system and patients, policymakers must move beyond negotiating prices and take away the ability of pharmaceutical companies to dine out on the Monopoly Extension Menu. Only by addressing the structural failures in the patent and regulatory systems can we ensure that patients are not left footing a bill they can't afford.

To achieve this, policymakers need to act on the following:

- Raise patentability standards to prevent patent thickets and patent evergreening that provide the platform for all the business and legal maneuvers described in this brief. This includes eliminating the ability of companies to patent REMS related subject matter.
- Address 'The Formulation Switch' by amending federal and state laws to permit therapeutic substitution across different delivery routes, preventing manufacturers from segmenting markets into exclusive silos.
- Provide the FDA with clear authority to remove "junk listings" from the Orange Book. Harmonize generic entry to align U.S. regulatory requirements for "complex generics" (like inhalers) with international standards, allowing for in vitro bioequivalence testing to ensure that a proprietary device does not remain a permanent legal barrier to entry.

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.