OVERPATENTED, OVERPRICED

Curbing patent abuse:
Tackling the root of the drug pricing crisis

I·MAK

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PROBLEM

The patent system is not working as intended and the public is paying the price. Astronomical prescription drug costs are straining the healthcare system and the budgets of American families and employers. Prescription drug spending has increased 60% in the last decade to over $400 billion today. The status quo is unsustainable.

CONTEXT

Primary patents on 7 out of 10 of America's top selling drugs are set to expire this decade. In theory, when these patents expire, generic or biosimilar competition should enter the market, and drug prices should come down. However, major pharmaceutical companies have significant financial incentive to delay the inevitable competition in the market once the primary patents expire. Drugmakers prepare for these looming patent expirations by filing or amassing hundreds of patents ("patent thickets"). The strategy of securing additional patents extends their monopoly power far beyond the 20 years of patent protection intended under the law for an invention. Pharmaceutical companies use this extended monopoly power in different ways, including extracting settlements in litigation from generic or biosimilar companies. These anti-competitive practices will in turn delay or block lower-cost drugs from entering the market, at substantial cost to the public.

KEY FINDINGS ON THE TEN TOP SELLING DRUGS

- On average, there are **74 granted patents on each of America's ten top selling drugs**, providing major drugmakers substantial advantage to keep generic and biosimilar competitors off the market.
- Drugmakers filed more than 140 patent applications on average per drug; on average **66% of patent applications were filed after the FDA approved the drug** to be on the market.
- Nearly one-third of Revlimid's cumulative sales in the U.S. have occurred after its primary patents expired, and **over two-thirds of Humira's U.S. sales have come after the expiration of its primary patents.**
- On average, **four times** as many patents are granted on the top ten drugs in the U.S. compared to Europe.
- Lower-cost generic and biosimilar versions of three top selling drugs - Humira, Eliquis, and Enbrel - launched in Europe an average of 7.7 years earlier than their expected U.S. entry. During this time, without generic or biosimilar competition Americans will spend an estimated **$167 Billion** on branded versions of just these three drugs. To date, these drugs still do not have generic or biosimilar competition in the U.S.

CONCLUSION

Drugmakers build anti-competitive patent thickets *because they can:* these abusive patent practices are permitted by law. We will not solve the drug pricing problem until we solve the drug patent problem, **and the time has come for patent reform.**

September 2022

Introduction

With inflation at a 40-year high, American families are clamoring for relief in their household budgets, including from the high cost of prescription drugs. There is growing bipartisan acknowledgment of and movement at the Congressional, federal agency, and Administrative levels to tackle patent abuse by drugmakers that blocks competition and keeps drug prices high. In 2021, the U.S. House Committee on Oversight and Reform's investigation[1] into the pharmaceutical industry exposed and documented manipulative patenting practices and recommended reforms to prohibit this abuse. President Biden signed an Executive Order[2] to spur competition, noting that the current patent system "unjustifiably delay(s) generic drug and biosimilar competition" to the detriment of workers, businesses, and consumers.

This report, the latest in I-MAK's *Overpatented, Overpriced* series, analyzes the ten top selling drugs in the United States and exposes the scale of the patent abuse problem and its impact on U.S. prescription drug spending. By demystifying these manipulative tactics, stakeholders can better understand how drugmakers block or delay competition, and policymakers can take evidence-based action to ensure that the system works better for the public and that every American has the opportunity to thrive.

Promoting competition and rewarding ingenuity are both core American values. The U.S. Constitution grants Congress the power to "promote the progress of science and useful arts by securing for *limited times* to authors and inventors the exclusive right to their respective writings and discoveries" (emphasis added).[3] But patenting activity today goes well beyond the time limited monopoly intended by the Constitution, and these longer monopolies too often come at an incalculable cost.[4] It is time to return the patent system to what it was always intended to be: not a vehicle for unprecedented profits, but an engine for discoveries that are truly unprecedented.

> "CAPITALISM WITHOUT COMPETITION ISN'T CAPITALISM; IT'S EXPLOITATION. WITHOUT HEALTHY COMPETITION, BIG PLAYERS CAN CHANGE AND CHARGE WHATEVER THEY WANT AND TREAT YOU HOWEVER THEY WANT. AND FOR TOO MANY AMERICANS, THAT MEANS ACCEPTING A BAD DEAL."[5]
>
> **PRESIDENT BIDEN**

1 U.S. House of Representatives, Committee on Oversight and Reform, *Drug Pricing Investigation Majority Staff Report*, December 2021.

2 Joseph Biden, President of the United States, *Executive Order on Promoting Competition in the American Economy*, July 9, 2021.

3 U.S. Const. Article I, Section 8, Clause 8.

4 Supra, FN. 2. See also Dan Witters, Millions in U.S. Lost Someone Who Couldn't Afford Treatment, Gallup, November 12, 2019.

5 Joseph Biden, President of the United States, *Remarks at Signing of an Executive Order Promoting Competition in the American Economy*, July 9, 2021.

Background

Prescription drug spending on retail and non-retail drugs is poised to grow 63% from 2020 to 2030, reaching $917 billion dollars.[6] This increase is fueled by spending on patent-protected branded drugs. Branded drugs make up just 8% of prescriptions (versus 92% for generics), but account for 79% of all drug spending in the U.S.[7] In this report, we examine the drugs with the highest U.S. net sales revenue in 2021, as reported by manufacturers in the U.S. Securities and Exchange Commission (SEC) filings or earnings reports.

THE 10 TOP-SELLING DRUGS IN AMERICA BY 2021 U.S. SALES[8]

RANK	DRUG (BRAND NAME)	COMPANY	PRIMARY CONDITION TREATED
1	HUMIRA	AbbVie	Arthritis
2	KEYTRUDA	Merck	Cancer
3	REVLIMID	Bristol-Myers Squibb (Celgene)	Multiple Myeloma
4	BIKTARVY	Gilead	HIV
5	ELIQUIS	Bristol-Myers Squibb / Pfizer	Stroke / Embolism
6	STELARA	Johnson & Johnson	Psoriasis
7	EYLEA	Regeneron / Bayer	Macular Degeneration
8	TRULICITY	Eli Lilly	Diabetes
9	ENBREL	Amgen	Arthritis
10	IMBRUVICA	AbbVie / Johnson & Johnson	Cancer

6 Charles Roehrig and Ani Turner, Projections of the Non-Retail Prescription Drug Share of National Health Expenditures Report, Altarum, July 2022.

7 *The Use of Medicines in the U.S. 2022*, The IQVIA Institute, April 21, 2022.

8 List does not include COVID-19 vaccine products. For each drug, the main disease category treated is named, though many drugs may have multiple approved indications.

Findings

This report focuses on the top 10 drugs by 2021 US sales. We found that:

- On average, there are **74 granted patents on each of America's ten top selling drugs**, providing major drugmakers substantial advantage to keep generic and biosimilar competitors off the market.
- Drugmakers filed more than 140 patent applications on average per drug; **on average 66% of patent applications were filed after the FDA approved the drug** to be on the market.
- Nearly one-third of Revlimid's cumulative sales in the U.S. have occurred after its primary patents expired, and **over two-thirds of Humira's U.S. sales have come after the expiration of its primary patents**.
- On average, **four times** as many patents are granted on the top ten drugs in the U.S. compared to Europe.
- Lower-cost generic and biosimilar versions of three top selling drugs - Humira, Eliquis, and Enbrel - launched in Europe an average of 7.7 years earlier than their expected U.S. entry. During this time, without generic or biosimilar competition Americans will spend an estimated **$167 Billion** on branded versions of just these three drugs. To date, these drugs still do not have generic or biosimilar competition in the U.S.

COMPARING DRUG PATENTS AND SPENDING IN THE U.S. AND EUROPE[9]

DRUG	PATENTS GRANTED IN U.S. VS E.U.	FIRST GENERIC / BIOSIMILAR ENTRY		YEARS OF EARLIER GENERIC/BIOSIMILAR ENTRY IN E.U.	TOTAL REVENUES IN THE U.S. AFTER GENERIC/BIOSIMILAR ENTRY IN E.U. (BILLIONS)
		E.U. MARKET	U.S. MARKET		
HUMIRA	6.4X	10-2018	1-2023	4.3	$68
ELIQUIS	2.4X	5-2022	4-2028	5.8	$48
ENBREL	4.1X	2-2016	4-2029	13.1	$52
TOTAL	--	--	--	23.2	$167
AVERAGE	4.3X	--	--	7.7	$56

9 Dates for anticipated and actual generic and biosimilar approvals and launches in the U.S. and E.U. were researched on a drug-by-drug basis using sources such as generic drug company press releases and filings, biopharmaceutical trade press, analyst reports, and quarterly earnings updates by branded drug companies. Information current as of July 2022. Total U.S. spending for each drug was calculated for the period between the first generic/biosimilar launch in the E.U. and the anticipated launch in the U.S., beginning the quarter after E.U. entry. Consensus revenue estimates were utilized for 2022-2026 (accessed via Bloomberg LP, May 2022). For revenue projections beyond 2026, growth trends from the preceding 3 years were utilized: 0% growth in revenue was assumed for Eliquis, and 8% annual declines were assumed for both 2027 and 2028 for Enbrel.

Discussion

The term "patent thicket"[10] includes two key aspects of patenting activity: the dozens or even hundreds of patent applications that drugmakers file with the U.S. Patent and Trademark Office (USPTO), and the patents that are actually granted. The high volume of both filed patent applications and granted patents creates a complex web of both actual barriers and potential or likely barriers that generic and biosimilar competitors must avoid to stay in compliance with the law. This creates a great deal of uncertainty that deters generic and biosimilar competitors from entering the market, as well as uncertainty for Americans as to when they will have lower-cost medications.[11] Patent thickets have significant negative consequences for the country, including:

- **Harming public health**
- **Straining household budgets**
- **Overstressing the U.S. Patent and Trademark Office**
- **Creating uncertainty in the market**

A BIPARTISAN GROUP OF U.S. SENATORS NOTED RECENTLY IN A LETTER TO USPTO DIRECTOR KATHI VIDAL, "THE PATENT ACT ENVISIONS A SINGLE PATENT PER INVENTION, NOT A LARGE PORTFOLIO BASED ON ONE CREATION."[12]

Granted patents allow drugmakers to block competition. Today, drugmakers secure dozens or even hundreds[13] of patents on each of their top selling drugs, in order to expand and protect their monopoly power. The 744 granted patents[14] on America's ten top selling drugs give pharmaceutical companies substantial power in litigation and negotiations to keep lower cost generic and biosimilar alternatives off the market for longer, and out of the hands of the American public.

10 Kevin Richards, R4621, U.S. Congressional Research Service, *Drug Pricing and Pharmaceutical Patenting Practices*, February 2020. See also Jeffrey Wu & Claire W. Cheng, *Into the Woods: A Biologic Patent Thicket Analysis*, 19 Chi. -Kent J. Intell. Prop. 93 (2020) and AbbVie Inc. et al. v Boehringer Ingelheim International GMBH et al., CIVIL No. 17-1065-MSG-RL (D. Del. Sep 21, 2018) (No.209).

11 Olga Gurgula, Strategic Patenting by Pharmaceutical Companies - Should Competition Law Intervene?, International Review of Industrial Property and Copyright Law, (2020); 51(9): 1062-1085. See also Alex Brill and Christy Robinson, Patent Thickets Constrain Biosimilars Market, Bioprocess International, December 8, 2021, and Scott Gottlieb, Remarks from FDA Commissioner Scott Gottlieb, MD, as Prepared for Delivery at the Brookings Institution on the Release of the FDA's Biosimilars Action Plan. US Food and Drug Administration: Silver Spring, MD, July 18, 2018.

12 *Letter from Senators Leahy, Blumenthal, et al. to USPTO Director Kathi Vidal Regarding IP Patent Thickets*, June 8, 2022.

13 The specific number of patents on each top selling drug can be viewed at https://www.i-mak.org/2021-topselling.

14 In total, there are 744 granted patents on the ten top selling drugs in America. On average, there are 74 patents on each of the ten drugs.

Patent applications also form part of patent thickets and deter competitors. Generic or biosimilar companies do not only evaluate granted patents when assessing whether to enter the market, they must also track and review patent applications to make their decision.[15] Currently there are over 140 patent applications filed on average for each of the 10 top selling drugs in America.[16] Notably, over 66% of patent applications were filed after the U.S. Food and Drug Administration (FDA) approved the drug to be on the market, indicating that drugmakers are attempting to prolong the existing exclusivity for as long as possible.

REAL WORLD IMPACT OF PATENT THICKETS

Primary patents – or the patents that cover the main active ingredient or molecule[17] – are set to expire this decade on 7 out of 10 of America's best-selling drugs.[18] When a product is a (or even *the*) key source of earnings and growth for a pharmaceutical company, there is significant financial incentive to mitigate the negative impact on the bottom line – or at least to delay the inevitable. **Excessive patenting on existing products is one key strategy drugmakers use to extend their monopolies and their revenue streams.[19]**

Generics and biosimilar companies in turn may want to enter the market for the top selling drugs, but this entails significant risk and resources because of the dense patent thickets protecting the monopolies on these products. As a result, while they are litigating the patents, generic and biosimilar companies are more likely to enter into settlements with the branded company rather than wait for a final ruling, regardless of the strength of their case.[20] In many cases, the certainty of the settlement and earlier revenues outweigh the risks of prolonged litigation.[21]

15 Baker Botts, On the Interface of Intellectual Property and Antitrust: The Case of Divisional Patent Applications in the Pharmaceutical Sector, October 19, 2021. See also Mark A. Lemley and Carl Shapiro, Probabilistic Patents, Journal of Economic Perspectives, Volume 19, Number 2, Spring 2005, pages 75-98.

16 Out of the 1431 patent applications filed on the ten top selling drugs, 30% of these applications are "abandoned", or voluntarily discontinued by the drugmaker. Even excluding abandoned applications, there are still nearly 100 patent applications filed on average per top selling drug. For a more detailed explanation of abandoned applications, see www.i-mak.org/patent-methods.

17 See, Amy Kapczynski et al, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents,* PLoS One 7(12) (2012) and Bhaven N. Sampat and Kenneth Shadlen, *Secondary pharmaceutical patenting: A global perspective*, Research Policy Vol. 46, Iss. 3, 693-707, (April 2017).

18 The primary patents on all but three of the top 10 drugs expire between 2020 and 2029. Primary patents on Humira and Revlimid already expired in 2016 and 2019 respectively. A key primary patent on Biktarvy will not expire until 2033. See Drug Patent Book Background and Methods for more information on primary patents.

19 Chie Hoon Song and Jeung-Whan Han, *Patent cliff and strategic switch: exploring strategic design possibilities in the pharmaceutical industry*, SpringerPlus 5(1):692, (May 23, 2016). and W. Murray Sprull and Michelle Cunningham, *Strategies for Extending the Life of Patents,* BioPharm International, March 2005.

20 Settlements are legal agreements on patent disputes with branded pharmaceutical companies to delay market entry or enter only under certain conditions. See Mike McCaughan, Health Policy Brief, *Patent Settlements*, Health Affairs, Prescription Drug Pricing #4, July 21, 2017. See also, Jamie Towey and Brad Albert, *Then, now and down the road: Trends in pharmaceutical patent settlements after FTC v Actavis*, Bureau of Competition, Federal Trade Commission, May 28, 2019.

21 See for example, Valeri Bauman, "Pharma Pay-For-Delay Deals Called 'Cost of Doing Business'" Bloomberg Law, February 10, 2020.

The Cost of Patent Thickets

When a top selling drug generates a high percentage of a company's revenue, the drugmaker will often build a patent thicket in an effort to block or delay the inevitable competition that will enter the market once primary patents expire.[22] The company has a strong incentive to protect the revenue stream by any means permitted under current law, and the drug's outsized importance to the company's bottom line leads to aggressive patenting activity. As long as these anti-competitive patenting practices remain legal, the drug pricing crisis will persist.

Three top selling drugs that are facing current or near-term loss of exclusivity are Humira, Eylea, and Revlimid. These three drugs generate an outsized percentage of their company's revenues and earnings, currently ranging from 30 to 48% of the company's drug sales in the U.S.

PATENT AND MARKET HIGHLIGHTS FOR THREE TOP SELLING DRUGS

DRUG	ANNUAL U.S. SALES (2021, $ BILLIONS)	% OF CO.'S 2021 U.S. PHARMA REVENUE	YEARS ON MARKET (FIRST FDA APPROVAL DATE)	# PATENT APPLICATIONS	% PATENT APPLICATIONS FILED AFTER FDA APPROVAL	# OF GRANTED PATENTS
HUMIRA	$17.3	40%	19.7 (12/2002)	312	94%	166
REVLIMID	$8.7	30%	16.7 (12/2005)	206	74%	117
EYLEA	$5.8	48%	10.8 (11/2011)	135	65%	92
AVERAGE	$10.6	39%	15.5	218	78%	125

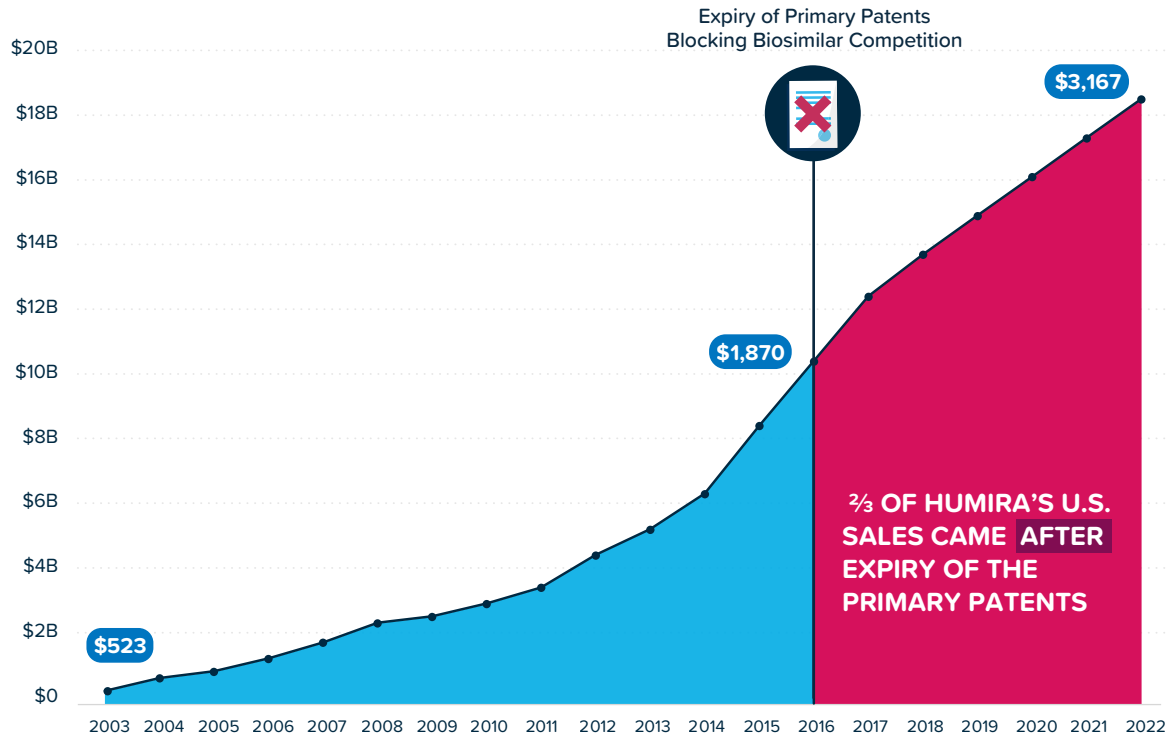
On all three drugs, there are a large number of patent applications filed after FDA approval (indicating an attempt to prolong existing exclusivity). There are also a high number of granted patents related to these drugs compared to the rest of the top ten drugs (an average of 125 patents granted on these three drugs vs. 74 patents granted on average across the top ten drugs).

22 For example, documents obtained from AbbVie by U.S. House of Representatives Committee on Oversight and Reform demonstrate how McKinsey & Co. consultants advised AbbVie on patenting strategies to block biosimilar versions of Humira.

DELAYED ENTRY, INCREASED REVENUES

After delays due to litigation and settlements, Revlimid now has limited generic competition on the market but will not see unrestricted competition until 2026, and the first biosimilar for Humira is poised to enter the market in early 2023.[23] These drugs are instructive examples of how patent-related delay tactics protect the revenue and earnings for top selling products: Nearly one-third of Revlimid's cumulative sales in the U.S. have occurred after its primary patents expired in November 2019, and over two-thirds of Humira's U.S. sales have come after the March 2016 expiration of its primary patents.[24] By the time Humira faces biosimilar competition in the first quarter of 2023, it is estimated to have garnered nearly $100 billion in sales since the expiration of its primary patents.

HUMIRA U.S. SALES BEFORE AND AFTER EXPIRY OF THE PRIMARY PATENTS



$ WAC PRICE REVENUE ($BN)

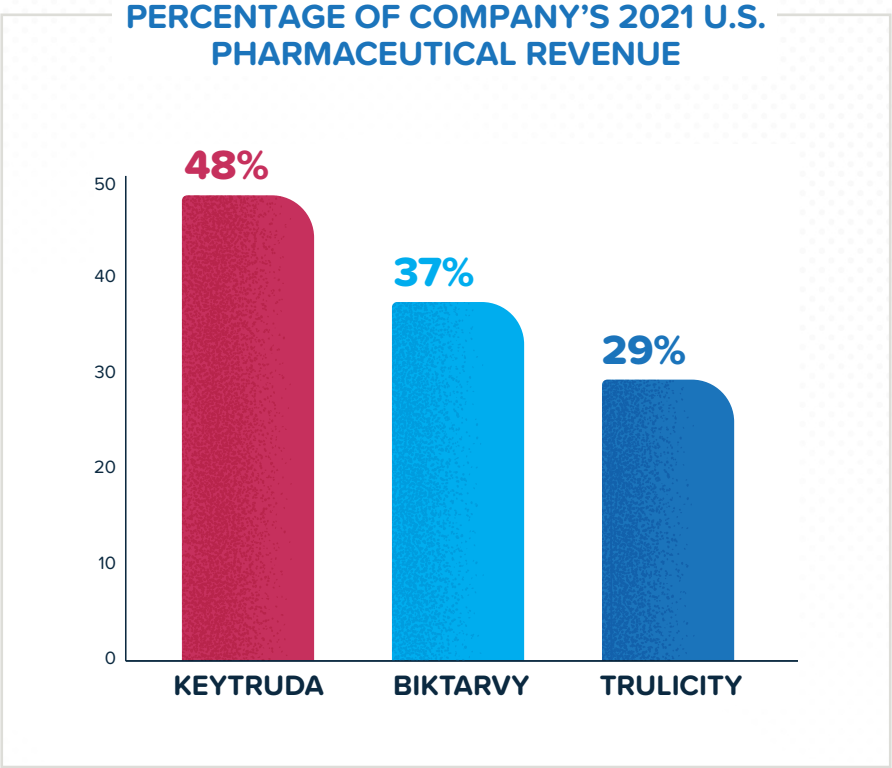
The wholesale acquisition cost (WAC) price for Humira set by AbbVie was accessed at SSR Health and reported per unit of drug for three key years: at launch in 2003, when primary patents expired in 2016, and at present in 2022. U.S. sales of Humira were extracted from annual 10K SEC filings through 2021. For 2022, consensus estimates from Wall Street analysts were used and accessed via Bloomberg LP.

23 Supra, FN 1, pages 91-95.

24 The primary patents on Humira expired in 2016. U.S. Humira sales from 2016 through Q1 2022 are $87 billion, compared with total cumulative sales of $128.6 billion from 2003 through Q1 2022. The primary patents on Revlimid expired in 2019. U.S. Revlimid sales from 2019 through Q1 2022 are $19.6 billion compared with total cumulative sales of $61.4 billion from 2006 through Q1 2022.

LOOKING FORWARD

Understanding the past delays of generic and biosimilar entry may also be instructive in forecasting which products are likely to see aggressive patenting practices and other delay strategies utilized by companies in the future. **Stakeholders concerned with rising drug costs should closely watch Keytruda, Biktarvy, and Trulicity for patenting and life cycle management activity.** For example, the data on Keytruda[25] already suggests that the patent thicket will have an impact on when competition will enter after the primary patents expire in 2028. Based on experiences with other biologic drugs, a lengthy litigation period and settlements can be expected which are likely to delay lower cost versions of the drug from entering the market.[26] Similar to the drugs highlighted above, these products make up a significant portion of each company's annual revenue.



Pharmaceutical revenue derived from a single drug, as reported in 202110K SEC filings by the companies.

While these products still have between 5 to 11 years before the expiration of their primary patents, they are already their companies' largest and most important drugs. As such, the patenting activity around these products should be closely monitored until strong and effective law and policy reforms bring a halt to the damaging effects of excessive patenting.

25 Initiative for Medicines, Access & Knowledge, *Drug Patent Book*.

26 Victor I. Van de Wiele et al., The Characteristics of patents impacting availability of biosimilars, Nature Biotechnology, 40, 22-25 (2022). See also Rachel Goode and Bernard Chao, Biological Patent Thickets and Delayed Access to Biosimilars, An American Problem, Journal of Law and the Biosciences, Volume 9, Issue 2, July-December 2022.

Methods

PATENT DATA

Comprehensive patent landscaping was conducted between May and June 2022 to identify granted patents (currently active and expired) and patent applications (currently pending and abandoned) for the ten top selling drugs at both the USPTO and at the European Patent Office (EPO). For all drugs, we identified patents and their patent family members that could either be used to deter other branded competitors from upstream research and development of competing similar products (e.g., "me-too" versions of a small molecule drug or biologics that bind to the same molecular target) or which could be used downstream to block/delay generic and biosimilar entrants. Irrespective of whether a patent in a patent family was a continuation, continuation-in-part, or divisional application, and linked by a terminal disclaimer in terms of its expiry date, it was counted as a distinct patent. This is because each patent is a distinct right and could be asserted as such in any litigation. Importantly, we included patents on products through their entire development and licensing history, which often included multiple corporate acquisitions, co-development, sub-licensing deals, and litigation. Each individual patent and the main patent claims were then analyzed and coded in terms of their patent type (e.g., method of treatment, formulation, etc.), scope of protection of the subject matter covered, and to identify the primary patents on each drug based on the subject matter covered. We cross checked the primary patent data and/or expiry dates identified with patents listed in the Orange Book/Purple Book and those asserted in litigation (where applicable), statements made by companies in their SEC filings or in press releases, as well as journal articles that provided analysis of the drugs and related patent information to determine the expiry date for the primary patents on each drug.

The methodology and resources used to build the patent landscape for each drug included the following steps: (1) identifying patents listed on the FDA Orange Book (small molecule drugs) and the Purple Book (biologic drugs); (2) where applicable and publicly available, identifying patents asserted in litigation (in the U.S and E.U) in relation to a product; and (3) conducting patent searches in Orbit Intelligence, Questel Orbit, CAS SciFinder, Lens.Org, and the Espacenet (the European Patent Office) databases using (i) keyword based search strings; (ii) inventor names; (iii) assignee/company names; (iv) compound structures (for small molecule drugs); (v) laboratory code names for a drug; and (vi) Chemical Abstracts Service (CAS) number and sequences (for biologics drugs including monoclonal antibodies). A more detailed methodology for each drug is provided at **https://www.i-mak.org/patent-methods.** Every patent identified in our landscapes in relation to the ten top selling drugs are housed in I-MAK's Drug Patent Book, available at **https://www.i-mak.org/drug-patent-book.**

MARKET DATA

Total revenues reflect sales for all indications, including any off-label indications. To assess changes in drug prices, the wholesale acquisition cost (WAC) price set by the drugmaker each year was utilized and accessed at SSR Health or IBM Micromedex RED BOOK. Spending data is conservatively based on manufacturer U.S. net revenues (actual or projected) reported in each company's annual 10K SEC filings or compiled from Bloomberg LP and does not include any rebates or discounts to payers, pharmacy benefit managers, wholesalers, or any other "middlemen." Market entry data for anticipated and actual generic and biosimilar approvals and launches in the U.S. and E.U. were researched on a drug-by-drug basis using sources such as FDA and EMA websites, company press releases, SEC filings, biopharmaceutical trade press, analyst reports, and trade association databases. Details of the analysis of projected spending on Humira, Eliquis, and Enbrel can be found in the footnote for that table. The percentage of revenue generated by each drug relative to each company's total U.S. revenues for all pharmaceutical products was calculated using 2021 net revenue figures reported in SEC filings. All market, pricing, and spending-related data is available at **https://www.i-mak.org/2021-top-selling.** All sources and methodology are available at **https://www.i-mak.org/2021-top-selling-methods.**

Conclusion

Patent abuse is not limited to a few bad actors. A growing body of evidence demonstrates that an essential part of the pharmaceutical industry's business model for top selling drugs is now built on maintaining market control by exploiting an outdated patent system. Pharmaceutical companies secure hundreds of patents to block competition **because they can: as long as abusive patent practices are permitted by law, the drug pricing crisis will persist.**

Congress, federal agencies, and the Administration need to use their power to rein in these exploitative practices that harm public health, strain household budgets, and negatively impact the American economy. There is growing bipartisan consensus that when the patent system is abused, Americans suffer. The time has come to tackle the root of the drug pricing crisis by modernizing and fortifying the patent system to truly serve the public.

ABOUT I-MAK

The Initiative for Medicines, Access, and Knowledge (or I-MAK) is a 501(c)(3) organization with a mission to build a more just and equitable medicines system. Our framework integrates deep analytical research to influence policy, education to activate change, and partnerships to drive solutions. We bring decades of private-sector expertise and an evidence based approach to this mission. Our work spans 50 countries and includes engagement with patients, drug manufacturers, patent offices, community leaders, public health professionals, policymakers, scientists, economists, and more.

I-MAK's approach to policy solution development is informed by its **Participatory Changemaking (PCM) process**, a multidimensional assessment of the patent system informed by input from stakeholders who hold or apply for patents, administer the system, and are affected by its decisions. PCM brings together individuals from different geographic, political, personal, and professional backgrounds to generate new ideas on how to modernize the patent system.

I-MAK's work on structural change in the patent system is featured regularly in the national and global press, as well as in Congressional hearings and Committee reports. In early 2021, I-MAK proposed a **10 point plan** to increase equity and competition through the patent system to inform policy solutions going forward. In 2022, I-MAK's patent system reform recommendations supported by the PCM process were **endorsed by the New York Times' Editorial Board.**