

Overpatented, Overpriced:

How Excessive Pharmaceutical
Patenting is Extending Monopolies
and Driving up Drug Prices



Solving the drug patent problem

EXECUTIVE SUMMARY

This report analyzes the twelve best selling drugs in the United States and reveals that drugmakers file hundreds of patent applications – the vast majority of which are granted¹ – to extend their monopolies far beyond the twenty years of protection intended under U.S. patent law.

These patents are used by drugmakers for the purpose of forestalling generic² competition while continuing to increase the price of these drugs. This report found that, on average, across the top twelve grossing drugs in America:

- There are **125 patent applications filed** and 71 granted patents per drug.
- **Prices have increased by 68% since 2012**, and only one of the top twelve drugs has actually decreased in price.
- There are **38 years of attempted patent protection blocking generic competition** sought by drugmakers for each of these top grossing drugs – or nearly double the twenty year monopoly intended under U.S. patent law.
- These top grossing drugs have already been **on the U.S. market for 15 years**.
- Over half of the top twelve drugs in America have **more than 100 attempted patents per drug**.

¹ Cotropia, Christopher Anthony and Quillen, Jr., Cecil D. and Webster, Ogden H., Patent Applications and the Performance of the U.S. Patent and Trademark Office (February 26, 2013). Federal Circuit Bar Journal, Vol. 23 (2013); Richmond School of Law Intellectual Property Institute Research Paper No. 2013-01. Available at <https://ssrn.com/abstract=2225781>

² Throughout this report the term “generic” is used to indicate a non-patented version of a drug product whether it is a small molecule compound or a biologic with a biosimilar equivalent.

Findings for specific drugs revealed strikingly similar efforts by different drugmakers to abuse the patent system and leverage these patent monopolies to raise drug prices and prevent generic competition:

AbbVie, which markets the world's number one selling drug, Humira (\$18bn in global sales in 2017), is also the worst patent offender with **247 patent applications**.

One third of the drugs had **price hikes of more than 100%** since just 2012: Lyrica (163%), Enbrel (155%), Humira (144%), and Lantus (114%).

Herceptin, a cancer drug sold by Roche / Genentech, had patents first filed in 1985 and has current patent applications pending that could extend patent exclusivity until 2033, a **48-year potential monopoly span**.

Four of the top twelve drugs have **already been on the market for 20 years** and have pending patent applications seeking to extend patent life to 2033 (Herceptin, Genentech), 2030 (Rituxan, Biogen/Genentech), 2029 (Enbrel, Amgen), and 2025 (Remicade, Janssen).

Until and unless the U.S. government directly curbs this abuse of the patent system, drugmakers will continue the harmful practice of coupling over-patenting with annual price increases that undermine the U.S. healthcare system and the financial solvency of American families across the country.

INTRODUCTION

There is increasing momentum to respond to the drug pricing crisis in America. The problem is acute: lowering prescription drug prices was cited as the most critical issue by voters in a recent poll³.

One in four families report difficulty in paying for their prescriptions⁴, and a staggering nineteen million Americans or eight percent of the population are purchasing their medicines overseas due to high drug prices⁵. With overall prescription drug spending poised to nearly double in the next decade⁶, the situation is untenable, causing a growing number of Americans to call on decision-makers at the state and federal level for meaningful change.

With growing concern around drug spending, attention is beginning to focus on patent monopolies and how abuse of the patent system is a root cause of the problem. In President Trump's speech on drug pricing in May 2018, he noted that drugmakers exploit our patent laws to choke out competition;

“Our patent system will reward innovation, but it will not be used as a shield to protect unfair monopolies.”⁷

PRESIDENT TRUMP

The President's speech reflects an understanding that while the Constitution intended patents as a means to spur inventions and provide commercial exclusivity for a limited period of time, today's patent system is out of balance.

3 The Public's Views of Tax Reform and Other Domestic Issues. POLITICO-Harvard T.H. Chan School of Public Health poll of 1,016 U.S. adults. September, 2017. Available from: <https://www.hsph.harvard.edu/horp/politico-harvard-t-h-chan-school-of-public-health-polls/>

4 Kaiser Health Tracking Poll: September, 2016. The Henry J. Kaiser Family Foundation. Available from: <http://files.kff.org/attachment/Kaiser-Health-Tracking-Poll-September-2016>

5 Kaiser Health Tracking Poll: November, 2016. The Henry J. Kaiser Family Foundation. Available from: <http://files.kff.org/attachment/Kaiser-Health-Tracking-Poll-November-2016-Topline>

6 2016-2025 Projections of National Health Expenditures. Centers for Medicare and Medicaid Services, Office of the Actuary. 15 Feb 2017

7 Trump, D. (2018). Remarks by President Trump on Lowering Drug Prices [Transcript]. Retrieved from <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-lowering-drug-prices>

Patents are supposed to protect inventions for 20 years beginning from the time the patent was first filed. Today, drugmakers are filing dozens or even hundreds of patents, resulting in nearly double the length of protection, blocking competition and keeping cheaper versions of medicines off the market. This abusive practice, known as ‘evergreening’, or what drugmakers market as incremental innovation and improvements, sits at the heart of the drug price crisis in the United States.

The patent system can provide an incentive to encourage drugmakers to develop new medicines for which there is robust commercial demand, but the monopolies granted under U.S. patent law are meant to be limited in duration. Today, drugmakers have transformed the patent system in to a defensive business strategy to avoid competition in order to earn outsized profits on medicines for many years beyond what was intended.

The response to this systemic abuse has been inadequate and some measures have even further facilitated these practices over the last three decades.⁸ This report examines the extent of this abuse through an analysis of the twelve best selling drugs in the United States. It was conducted to assess whether drugmakers behind these medicines are exploiting the patent system, and how such tactics translate into delayed competition and price increases.

Abuse of the patent system causes undue economic hardship for American families and budgets of public and private payers.

⁸ A. B. Engelberg, Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness? A Political, Legislative And Legal History of U.S Law And Observations For The Future, IDEA J Law Technol 1999;39:389-428

RESULTS

The Key Metrics

A summary of the average, total, and range of values for the top 12 grossing drugs of 2017:

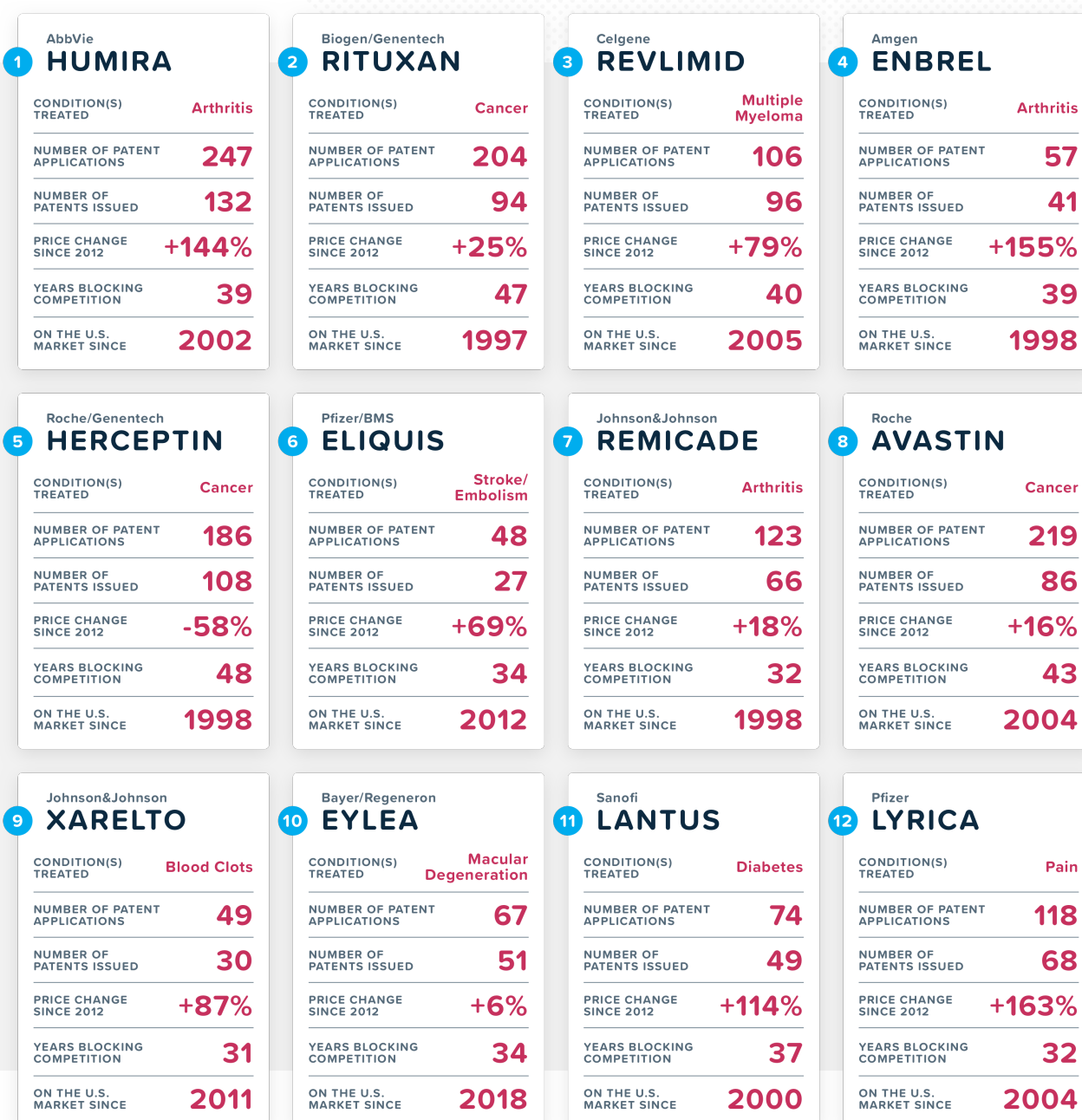
	AVG/DRUG	TOTAL	RANGE
NUMBER OF PATENT APPLICATIONS	125	1498	48–247
PATENTS ISSUED	71	848	27–132
PRICE CHANGE SINCE 2012	+68%	N/A	-58%–163%
YEARS BLOCKING COMPETITION	38	456	31–48
YEARS ON THE U.S. MARKET	15	176	6–21

- There are **125 patent applications filed** and 71 granted patents per drug.
- There are **more than 100 attempted patents per drug** on over half of the top twelve drugs in America.
- **Prices have increased by 68% since 2012**, and only one of the top twelve drugs has actually *decreased* in price.⁹
- There are **38 years of attempted patent protection blocking generic competition** sought by drugmakers for each of these top grossing drugs – or nearly double the twenty year monopoly intended under U.S. patent law.
- These top grossing drugs have already **been on the U.S. market for 15 years**.

⁹ This decrease in price for Herceptin came in a short period in mid-2017 and only after the drug had increased in price 15% over the prior five years. The price decline was attributed to a variety of factors, including increased competition from other breast cancer products, a disappointing clinical trial result with a Herceptin combination, and a forced 67% price cut on sales of the product in China.

The key metrics across all top 12 drugs:

The figure below presents data for each of the twelve drugs across the key metrics assessed, along with the drugmaker selling the product and the main conditions treated. Note that the number of patent applications and number of patents issued will continue to increase as drugmakers add applications seeking more and more patents. This could also lead to an extension of the years that related patents block competition.



The Worst Offenders

The drugs that are the worst offenders in each of the three key categories analyzed:

Largest # patent applications

1 HUMIRA 247 2 AVASTIN 219 3 RITUXAN 204

Largest price hikes over 6 years

1 LYRICA +163% 2 ENBREL +155% 3 HUMIRA +144%

Most years blocking generic competition

1 HERCEPTIN 48 2 RITUXAN 47 3 AVASTIN 43

- AbbVie, which markets the world's number one selling drug, Humira (\$18bn in global sales in 2017), is also the worst patent offender with **247 patent applications**.
- One third of the drugs had **price hikes of more than 100%** just since 2012: Lyrica (163%), Enbrel (155%), Humira (144%), and Lantus (114%).
- Herceptin, a cancer drug sold by Roche / Genentech, had patents first filed in 1985 and has current patent applications pending that could extend patent exclusivity until 2033, a **48-year potential monopoly span**.
- Four of the top twelve drugs have **already been on the market for 20 years** and have pending patent applications seeking to extend patent life to 2033 (Herceptin, Genentech), 2030 (Rituxan, Biogen/Genentech), 2029 (Enbrel, Amgen), and 2025 (Remicade, Janssen).

THE COST OF OVERPATENTING:

A spotlight on Lyrica

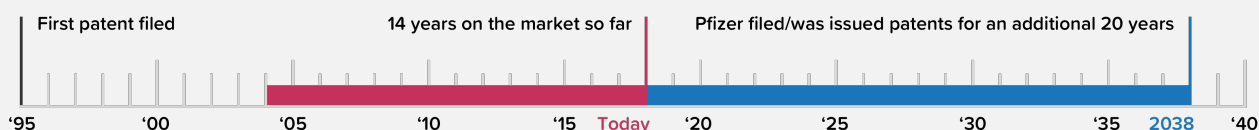
Lyrica, one of Pfizer’s top-selling drugs used to treat neuropathic pain, is a prime example of the type of over-patenting based on trivial inventions that are often used by drugmakers in order to artificially extend their commercial exclusivity while raising prices.

163% **\$216M** **\$5B+**

price increase over the last 6 years – the biggest hike of the top 12 drugs

spent on TV advertising in 2017

In global sales, with \$3b from U.S. payers



With a first patent filed in 1995, and the drug on the market for the past fourteen years, Lyrica has been a major source of revenue for Pfizer. The drug grossed over \$5 billion in global sales last year, \$3 billion of from U.S. payers, including insurance companies and Medicare and Medicaid. The commercial success of this product was driven in large part by the 163% price increases in the last six years, the most severe hike amongst the top twelve drugs. Additionally, the drug ranked as the second-highest (behind Humira) in total amount of direct-to-consumer spending in 2017 with \$216 million spent by Pfizer on television ads alone¹⁰. Lyrica was set to go off-patent at the end of 2018 and the entry of generic competition would have quickly and markedly reduce Pfizer’s revenue from

¹⁰ Bulick, Beth. "AbbVie, Pfizer Drive 2017 Pharma TV Ad Spending above 2016's Tally." FiercePharma, 12 Jan. 2018. Available at: www.fiercepharma.com/marketing/pharma-tv-ad-spending-tops-2016-tally-abbvie-and-pfizer-brands-lead

Lyrica by 70-90% in less than two years. But Pfizer had filed and was issued patents for an additional twenty year period on a controlled-release formulation of the product (Lyrica CR), meaning that patients would take a single pill instead of two or three pills daily¹¹. With these patents, Pfizer's hold on the market will remain and, if history is a guide, they will continue major repeated increases in the price of the drug.

Pfizer's patenting strategy with Lyrica illustrates how drugmakers game the patent system in order to extend the patent-protected lifespan of their key products and garner billions more in revenue beyond the twenty year period.

In July 2018, Pfizer again tried to raise the price of Lyrica, alongside approximately 100 other medicines, years after Lyrica was first put onto the market. The Administration called out Pfizer's actions and, under pressure, Pfizer reversed course. Yet ensuring generic competition by preventing patent abuse would be a far more effective and systemic solution to ensure Pfizer and other drugmakers do not continue repeated and unjustified price hikes for medicines.

¹¹ Sagonowsky, Eric. "With a Year Left before Generics Hit, Pfizer Nabs FDA Approval for New-and-Improved Lyrica." FiercePharma, 12 Oct. 2017. Available at www.fiercepharma.com/regulatory/pfizer-wins-lyrica-extended-release-approval-could-it-be-prepping-patient-switch-push

DISCUSSION

Our findings show that the top grossing drugs have on average 125 patent applications, which are filed with a strategic intent to extend the commercial monopolies far beyond the intended twenty years of protection.

Such filings allow drugmakers to a) increase the price of the branded drugs by an average of 68% in six years, and b) seek to stall generic competition by an average of 38 years. While these average figures are disconcerting, examples among specific drugs run even more extreme in each category. Among the top grossing and best known drugs on the market today, some of the ‘worst offenders’ include AbbVie having filed 247 patent applications for Humira, Pfizer’s 163% price hike over six years for Lyrica, and Roche’s and Genentech’s efforts to seek 48 years of patent exclusivity for Herceptin. These examples are not outliers; our analysis indicates that patent holders for the other top twelve drugs also abuse the patent system, hike the price of drugs, and delay generic competition.

Enabling drugmakers to maintain patent monopolies far beyond twenty years has significant consequences on the American healthcare system. The strategy to expand monopolies without any meaningful new science or invention exacts a heavy cost on American payers and households. Specifically, these twelve highest grossing drugs cost \$96 billion to health insurers, government payers, and consumers in 2017 alone. Since drugmakers often continue to increase the prices of medicines once or twice a year, even after the product has already been on the market for many years, revenues may continue to grow for these medicines until there is generic competition.

Generic competition, with two or more generic suppliers competing to reduce the price of a medicine, consistently lowers prescription drug prices by more than half¹². Yet policy makers have not put enough effort into accelerating generic competition, or at least ensuring that drugmakers do not extend monopolies beyond the twenty years intended under U.S. patent law. Measures must be taken to limit the power of the pharmaceutical industry to abuse the patent system and reverse the drug industry’s dramatic expansion of patent monopolies.

¹² On average it has been shown that the pricing dynamics for a variety of prescription drug products decrease by 32% in the first 12 months and by 73% in the first 24 months following generic entry. See Ernst R. Berndt and Murray L. Aitken, “Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation,” *International Journal of the Economics of Business* 18, no. 2 (2011): 177–201

METHODOLOGY

The methodology and sources used to identify the key metrics cited in the report:

List of the Top Twelve Drugs.

The top twelve grossing drugs were ranked based on global sales or revenue reported for 2017 by drugmakers in press announcements, annual reports, investor materials, and/or conference calls¹³. When considering only U.S. revenue for 2017¹⁴, the list of the top twelve drugs remains the same though the specific order differs slightly. The twelfth best-selling global product is a pneumonia vaccine that was not included in our list as our analysis was restricted to small molecule drugs and biologics that were not vaccines.

Patent Applications and Issued Patents.

Comprehensive patent landscaping was conducted to identify issued patents (both current and expired) along with patent applications (both under review and abandoned) for each of the twelve drugs.¹⁵ For all drugs, patent families were identified and each individual patent application, whether abandoned or continued, was counted as a distinct application. The Orbit Intelligence patent database from Questel¹⁶ was used as the principal patent search reference. For small molecule drugs, exact structure searches in SciFinder were used, followed by extensive searches in Orbit Intelligence using exact drug names and fragmented chemical names. For biologic drugs including monoclonal antibodies and insulin derivatives a CAS number search in SciFinder was used to identify key components of the products, followed by cross-referencing searches in the Orbit database using the drug's laboratory code names and other generally accepted names.

This was supplemented with a sequence search in the open source patent database Lens.org, and results were refined using company names and other relevant entities. Importantly, we attempted to track patents on products through their entire development and licensing history which often included multiple corporate acquisitions, co-development and sublicensing deals¹⁷.

Drug Price Changes.

To assess the change in prices for the top twelve drugs evaluated, the IQVIA National Sales Perspectives (NSP) database was utilized. The data provided monthly price summaries for each drug from June 2012 through June 2018, and total changes in monthly NSP price per drug were calculated over that six year time period. It is important to note that the NSP reports sales into the various distribution channels tracked by IQVIA. Thus, the data represent product purchases from wholesalers or manufacturers, not retail pharmacy sales to patients. As such, NSP represents sales at invoice pricing, not sales at a list price such as Wholesale Acquisition Cost (WAC) or Average Wholesale Price (AWP). Contract pricing, including discounts processed via a wholesaler chargeback transaction, are reflected in the IQVIA NSP measures of price and sales. However, rebates paid by the manufacturer (e.g. to a health plan, pharmacy benefit manager, Part D plan, Medicaid, or others) are not reflected in these data. These discounts are often referred to as "off-invoice discounts and rebates" and are not captured in the IQVIA data set.

¹³ "The Top 15 Best Selling Drugs of 2017," Genetic Engineering News; March 12, 2018 <https://www.genengnews.com/the-lists/the-top-15-best-selling-drugs-of-2017/77901068?page=1>

¹⁴ "Drumroll Please! The Top 10 Bestselling Drugs in the U.S.," Biospace; May 21, 2018 <https://www.biospace.com/article/drumroll-please-top-10-bestselling-drugs-in-the-u-s->

¹⁵ The searches conducted may not have captured all patents relating to the drugs in this study. Only published patents can be searched and there could be additional applications that may surface at a later date. Also, patents relating to a drug may not have been identified in our searches. Drugmakers and their lawyers will often use terms in a patent document to obfuscate the claimed invention in relation to a drug in order to avoid detection by competitors. Therefore, the overall number of patent applications and granted patents per drug is likely undercounted in this report.

¹⁶ Questel Inc. (2018). Orbit Intelligence Database. <https://www.questel.com/software/orbit-at-a-glance/>

¹⁷ For example, etanercept (Enbrel) was co-developed and launched by Amgen (formerly Immunex) and Wyeth (now Pfizer), following the acquisition of Wyeth (formerly American Home Products). All relevant patents from these multiple assignees have been considered.

Years Blocking Generic Competition.

To assess the span of time in which patents have been filed on each of the drugs, we identified the a) earliest filing date, and b) latest potential expiration date of all patents on each drug, according to the patent landscape analysis conducted. For all drugs, the latest expiration date was on an active patent application that was not yet an issued/granted patent. As such, the later time point represents a potential time point that could be in place if/when the patent is granted. This total span of time – from earliest filing to latest potential expiration – was calculated and used as an indication of drugmakers' intent to extend their monopoly period and thwart generic competition. It is important to note that not all patent

applications become granted patents. Only granted patents can be used to extend years of exclusivity and time blocking generic competition. But given the large number of ongoing and yet-undecided patent applications filed for each drug that could get issued, we used the latest expiration time point among these applications as the forward-looking measure of potential years blocking generic competition.

Length of Time on the U.S. Market.

To determine the length of time that each of the top twelve drugs has been on the U.S. market, the initial date of FDA approval was established, according to the FDA database of drug labels¹⁸.

¹⁸Drugs@FDA. FDA Approved Drug Products. Available at: <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>

CONCLUSION

Our analysis reveals that drugmakers file hundreds of patents to extend their monopolies far beyond the twenty years of protection intended under U.S. patent law. This abuse of the patent system by drugmakers is used to introduce repeated and extensive price hikes and block generic competition for years or decades.

Significant policy reform is needed to curb these patent abuses and restore free market competition needed to help alleviate the drug pricing crisis in America today.



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