

Overpatented, Overpriced Special Edition

Humira



I.MAK

Solving the drug patent problem

Key findings

247 patent applications have been filed on Humira in the U.S. with the aim of delaying competition for 39 years.

In 2016 the \$3.3 billion spent on the drug by Medicare and Medicaid accounted for **31 cents of every dollar spent on Humira in the U.S.**

Total spending by Medicare and Medicaid increased 266% on Humira between 2012 and 2016, and the average spending on Humira per person more than doubled from \$16,000 to \$33,000.

89% of the total patent applications on Humira in the U.S. were filed *after* the drug was first approved and on the market.

Nearly 50% of the applications in the U.S. were filed by AbbVie from 2014 onwards – **this is more than 20 years after the initial scientific research began** and more than a decade after the product was first marketed.

AbbVie has filed over three times as many patent applications in the U.S. than at the European Patent Office. Biosimilars will enter the European market four years earlier than in the U.S. **This extended monopoly is estimated to cost American payers and taxpayers an excess of \$14.4 billion.**

AbbVie's pricing practices are protected by an aggressive evergreening patent strategy to extend the life cycle of Humira in order to deliberately delay competition. The overpatenting of Humira and other medicines **puts a strain not only America's public health care budgets, but also undermines the health and financial well-being of individuals and families throughout the country.**

Introduction

In August 2018, the Initiative for Medicines, Access and Knowledge (I-MAK) released **Overpatented, Overpriced**, a report that revealed how drugmakers file hundreds of patent applications in the U.S. – the vast majority of which are granted. Drugmakers have sought, on average, 38 years of attempted monopoly protection through patents and patent applications on these twelve best-selling medicines.¹ Patents are only supposed to protect inventions for a limited time, or for 20 years beginning from the time the patent was first filed. Without the threat of competition, all but one of the medicines has increased in price.² For the eleven other best-selling medicines, the average price increase was 80% since just 2012.

The following case study on Humira is the first of a series of in-depth investigations into these best-selling medicines. Humira, which is marketed by the drugmaker AbbVie, was the first fully human monoclonal antibody approved by the U.S. Food and Drug Administration (USFDA).

It is currently the world's best-selling drug, and the second best-selling drug of all time.³ In total, **247 patent applications have been filed on Humira in the U.S. with the aim of delaying competition for 39 years**, the most egregious example of overpatenting amongst the twelve best-selling medicines.⁴

1 <http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf>

2 The one drug which experienced a price decrease was Herceptin, a drug which is likely facing competition from biosimilar product(s).

3 <https://www.nasdaq.com/article/biggest-blockbuster-drugs-of-all-time-cm900574>

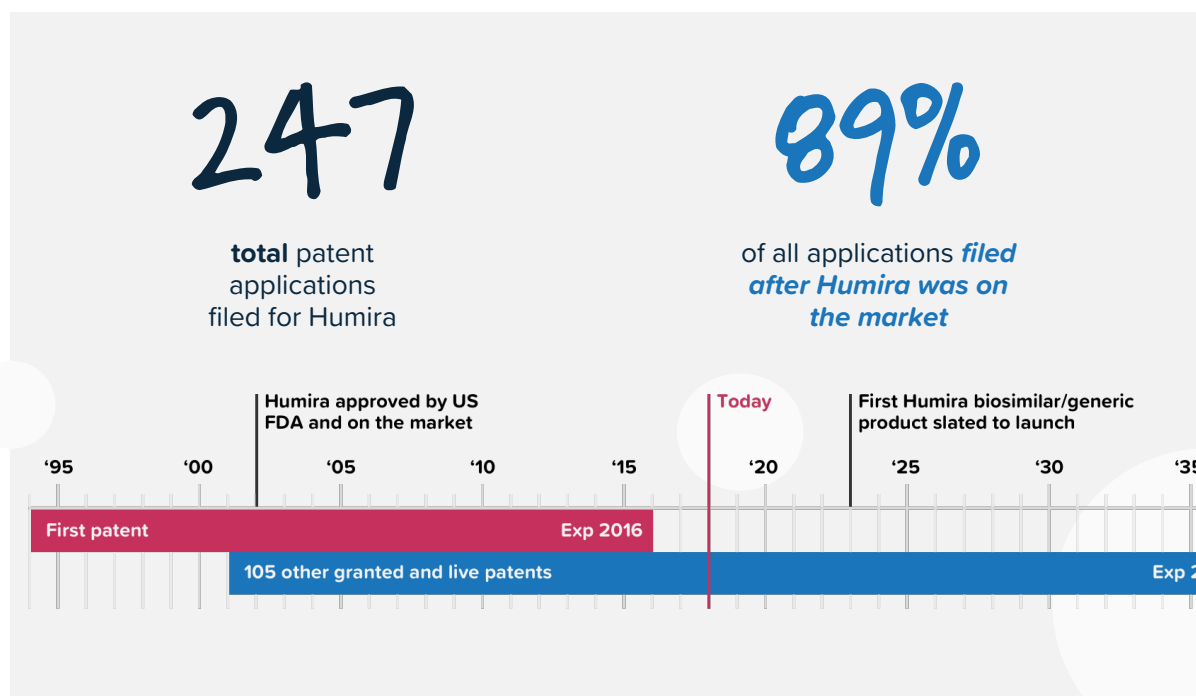
4 *Ibid.* FN 1

When did AbbVie overpatent Humira?

The development of Humira was initiated in 1993 through a collaboration including BASF, the German chemical company.⁵ The joint venture initially sought patents on Humira in 1994. BASF sold its entire pharmaceutical business to Abbott Laboratories in 2000 for \$6.9 billion.⁶ Humira was first approved by the USFDA in December 2002.⁷ In 2013, Abbott Laboratories was separated into two separate companies, creating AbbVie.

To be patentable, a claimed invention must be novel, not be obvious to a person skilled in the art, have utility, and fully describe the invention. Therefore, this begs the question: **is it credible that there are 247 different patentably-distinct inventions associated with Humira?**

For this reason, we examined how many patent applications on Humira were filed in the U.S. *following* regulatory approval at the USFDA, the first agency to grant marketing approval to the drug. We specifically focused on this time period because drugmakers often argue that patents filed *prior* to regulatory approval incentivize companies to invest in the development of a new drug and should, therefore, not be characterized as evergreening.



5 <http://www.discoverymedicine.com/Benjamin-Yang/2009/05/21/drug-profile-humira/>

6 <https://www.thepharmaletter.com/article/basf-sells-pharma-business-to-abbott-labs-for-6-9-billion-in-cash>

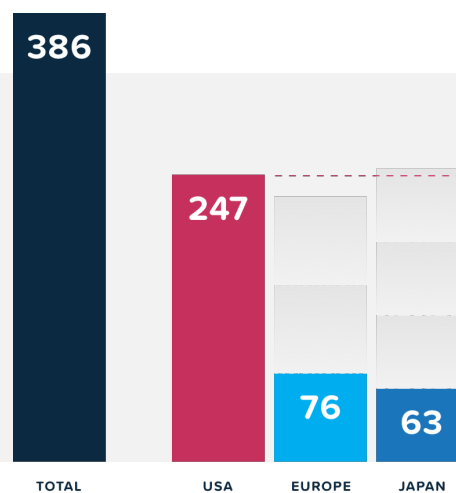
7 <https://www.medscape.com/viewarticle/447369>

Our research indicates that 89% of the total patent applications on Humira in the U.S. were filed after the drug was approved in 2002. Moreover, nearly 50% of the total applications (122 of 247) on Humira were filed by AbbVie from 2014 onwards, more than 20 years after initial scientific research began, and more than a decade after the product was being sold.

Even if we factor in all the various indications that Humira has been approved for, the last of which was for uveitis in August 2018, 122 patent applications within a period of 4 years is an astonishingly high number.⁸ **What is more concerning is that nearly all of the indications for which Humira is approved were claimed as inventions in patents dating back to between 1996–2002. Yet, even after this period, AbbVie continued to file a number of patent applications covering slight variations to treat the same indications.**

By comparison, I-MAK's research found that the total number of patent applications filed on Humira to date at the European Patent office is 76 and 63 in Japan. What is noticeable from the European Patent Office data compared to the U.S. is that a number of AbbVie's patent applications after 2002 that would have significantly extended its monopoly were either withdrawn, refused during examination, or revoked after patent challenges.

Humira's 247 patent applications in the U.S. more than triple those in Europe, and almost quadruple those in Japan.



When drugmakers file patent applications at this rate and over such a long period of time since the first inventions were claimed and the drug granted regulatory approval, it indicates a deliberate evergreening strategy⁹ to delay competition. Having built up its fortress of patent protection, AbbVie has been able to charge high prices for Humira both in the U.S. and around the world for the last fifteen years.

⁸ https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125057s399lbl.pdf

⁹ Evergreening refers to the strategy of a company obtaining multiple patents covering different features of the same product in order to extend the monopoly

period. Patent evergreening is also commonly referred to as "stockpiling", "thickets", "layering", "life-cycle management", or "line-extension".

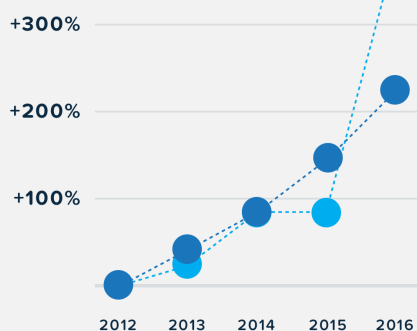
Assessing the financial burden of overpatenting on taxpayers (through Medicare and Medicaid purchases)

Humira has generated over **\$100 billion in sales for AbbVie since its launch in 2002**. Last year AbbVie reaped \$18 billion in global sales of Humira – \$12 billion of which came from U.S. payers. Humira alone is responsible for two-thirds of AbbVie’s total revenue.¹⁰

If Humira were a standalone company, it would be larger than many Fortune 500 companies, including Visa, General Mills, and Monsanto.

Funded by U.S. taxpayers, Medicare and Medicaid play an important role in ensuring that Americans have access to health care. Total spending on Humira by these agencies from 2012 to 2016 and a summary of the price increases per beneficiary are summarized below:¹¹

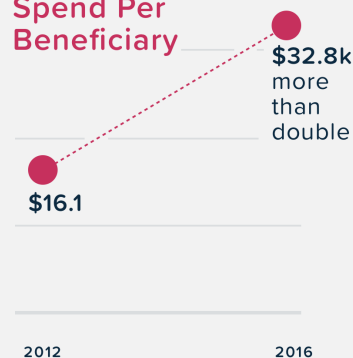
Humira Spending Total % Increases



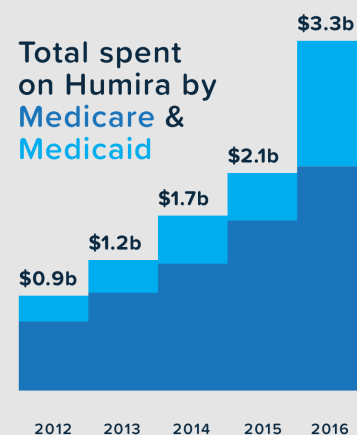
Medicaid
+377%, from \$249m to \$1.19b

Medicare
+224%, from \$657m to \$2.13b

Avg Medicare Spend Per Beneficiary



Total spent on Humira by Medicare & Medicaid



¹⁰ AbbVie 2017 Annual Report, available at: <https://investors.abbvie.com/static-files/8f8ea49f-4735-404c-be08-2f963441b74d>

¹¹ All historical data on Medicare and Medicaid spending sourced from CMS Drug Spending Database, available at: [https://www.cms.gov/Research-Statistics-Data-](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/index.html)

[and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/index.html](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/index.html)

Over a five year period from 2012 to 2016, taxpayers spent, through Medicare and Medicaid purchases, a total of \$9.2 billion on Humira. Over that period of time total spending by the two agencies increased by 266% with Medicare accounting for 71% of total spending and Medicaid 29%. In 2016, U.S. sales of Humira totaled \$10.3 billion, and 31% of that total (\$3.3 billion) came from purchases by U.S. public payers Medicare and Medicaid. Medicaid alone doubled its total annual spending on Humira in 2016 to over one billion dollars as compared to the prior year, thereby catapulting Humira to the second most costly single product for the year.

The massive public spending on Humira is due in large part to the extraordinary price increases introduced by AbbVie. Medicare reported that AbbVie has increased the price of Humira by 18% *per year* between 2012 and 2016, which puts Humira in the ‘top 5’ for highest sustained price increases during that time period for both Medicare and Medicaid. In just four years, Medicare’s average spending per person per year for Humira has more than doubled from \$16,000 in 2012 to nearly \$33,000 in 2016. This upward price trajectory has continued since 2016. Though more recent public payer data is not yet available, we found in **Overpatented, Overpriced** that the price of Humira has increased an additional 24% from 2016 to 2018.

How much *does* AbbVie make on Humira?

\$18.4b → **\$50.4m** → **\$2.1m** → **\$35k** → **\$583**
 P/YEAR P/DAY P/HOUR P/MINUTE P/SECOND

These price increases are not due to an increased cost of manufacture or inflation. Since 2012, the historic inflation rate in the U.S. has been only 1–2% per year. **Thus, AbbVie’s average price increases on Humira are over six times greater every year than inflation.**

Impact on Patients and Families

High prices for medicines are not solely an issue of insurance reimbursements, or for the poor who cannot afford them. Overpriced medicines affect all Americans by limiting the ability of the health-care system to provide medicines for all who are in need. **AbbVie's pricing practices are protected by an aggressive evergreening patent strategy to extend the life cycle of Humira in order to deliberately delay competition. The overpatenting of Humira and other medicines puts a strain not only America's public health care budgets, but also undermines the health and financial well-being of individuals and families throughout the country.** The stories of Katherine Kaiser and Sue Lee (below), provided by Patients for Affordable Drugs (P4AD), an organization working to reduce drug prices in the U.S., are illustrations of this grim reality.

"Humira is my number one contention right now. I am on Medicare, and I am not low income. I am on disability, but my husband owns a business and my husband brings home a middle-class income. Medicare would pay 80% of my Humira bill but that still leaves my 20% which is \$1,050 per month in 2018. I cannot afford that, so I have not had any of it to help with my arthritis."

KATHLEEN KAISER, WICHITA, KANSAS

"I have plaque psoriasis and had been on Humira for over 4 years while employed. It was truly a miracle drug for me. Upon retirement (at age 75) in June 2017, I was shocked to learn that Humira would cost me close to \$10,000 per year. According to Medicare, I receive too much Social Security to qualify for assistance. I refuse to almost empty my savings to give to my drug company. I have not had an injection since 10-8-2017. Humira would drain what little savings I have left, so I have stopped taking it. There is no cure for plaque psoriasis so this will not go away. I am keeping it under control right now (less stress from not working I guess) by using topical ointment and a lot of moisturizers but just this week I got 4 new sores on left leg."

SUE LEE, CRESTWOOD, KENTUCKY

Conclusion

Competitors have employed costly litigation and time to try and overcome AbbVie's wall of patents in order to eventually enter the market in the U.S.

The first biosimilar product (barring additional, successful legal challenges from AbbVie), will enter the U.S. market in January 2023¹², with additional competitors emerging mid-year.¹³ However, according to reports, competitors (Samsung Bioepis and Amgen) will still have to pay royalties to license AbbVie's Humira patents. Typically with such license deals, the costs of these royalty payments are likely to be passed down to the consumer. As a result AbbVie will still continue to profit from its wall of defensive patents.

Since AbbVie has not been as successful in aggressively evergreening its patent protection for Humira in Europe, competitors will enter the market considerably earlier in October 2018¹⁴, which will lead to significant price reductions. Yet in the U.S., government programs, private payers, and households will have to contend with AbbVie's high prices for Humira for almost five more years. Given the difficulties and potential consequences for Americans that this unnecessary delay will cause, it is time for action to address the overpatenting of life-saving medicines.

The first step is for the U.S. Patent and Trademark Office (USPTO) to hold hearings and invite public comments on pharmaceutical patenting practices and their impact on drug prices for public and private payers, and households across America. The USPTO should also invite non-profit organizations and other experts that represent the public interest voice on the patent system to have permanent seats on the Public Patent Advisory Committee.

Congress should also hold hearings to assess how pharmaceutical patenting practices affect federal health care programs and households, while taking effective oversight of the USPTO and other federal agencies that have the authority to address the overpatenting problem.

¹² <https://www.reuters.com/article/us-abbvie-amgen-humira/abbvie-amgen-settlement-sets-humira-u-s-biosimilar-launch-for-2023-idUSKCNIC32G5>
¹³ <https://www.reuters.com/article/us-abbvie-biogen/abbvie-samsung-bioepis-in-deal-humira-biosimilar-u-s-release-in-2023-idUSKCN1HC1SP>

¹⁴ <https://pharmaphorum.com/news/humira-biosimilar-eu-sandoz-chmp/>



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