Overpatented, Overpriced Special Edition

Enbrel

I·MAK Solving the drug patent problem

Revised October 2020

Introduction

In August 2018, the Initiative for Medicines, Access and Knowledge (I-MAK) released ***Overpatented, Overpriced***, a report that revealed how drugmakers have filed hundreds of patent applications – the vast majority of which are granted – on the top 12 best-selling drugs in the U.S. 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: 20 years from the time the patent application was first filed. Without the threat of competition, all but one of these medicines has drastically increased in price[2]. For the eleven other best-selling medicines, the average price increase was 80% since just 2012.

The following fact sheet on Enbrel is the third of a series of investigations into these best-selling medicines in the U.S. Enbrel, which is marketed by the biopharmaceutical corporation Amgen in the U.S., is primarily used to address and alleviate the symptoms of rheumatoid arthritis. Enbrel is also used to treat psoriatic arthritis, plaque psoriasis, ankylosing spondylitis, and moderate-to-severe juvenile idiopathic arthritis.

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

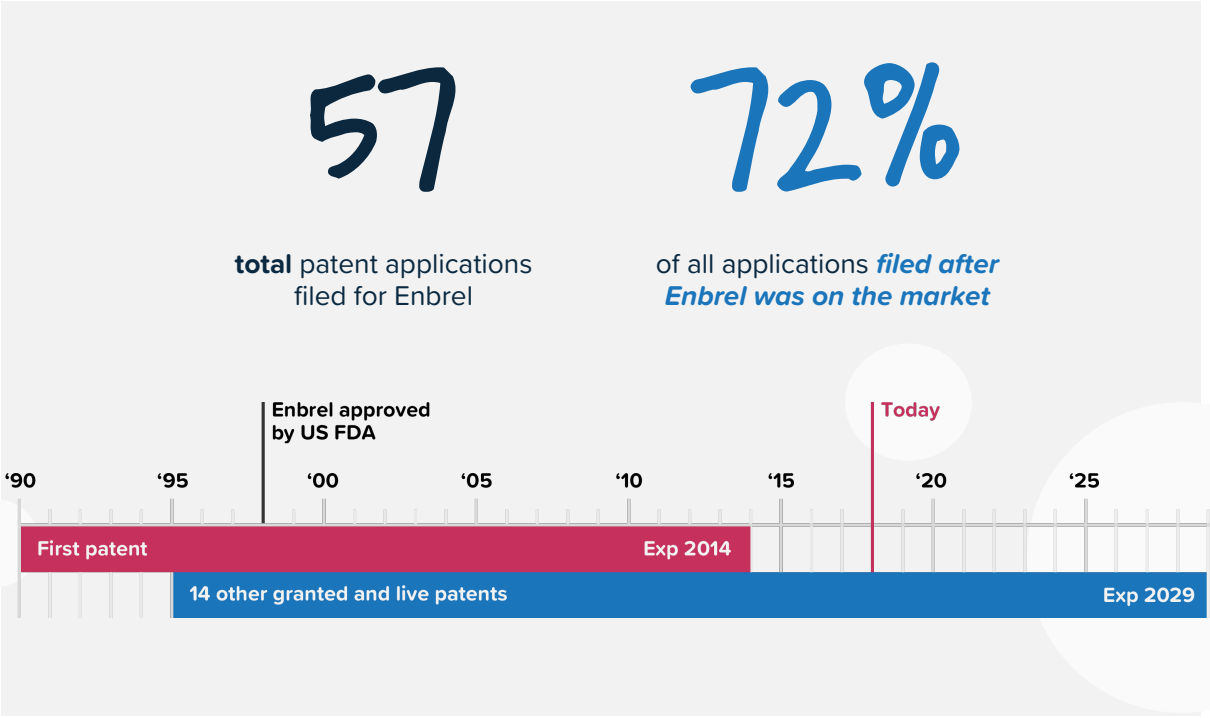
2 The one drug which experienced a price decrease was Herceptin, a drug which is likely facing competition from biosimilar product(s).

Amgen filed 72% of its total patent applications on Enbrel after US FDA approval

The primary patent on Enbrel in the U.S. was filed in 1990 and expired in 2010. However, there are at least 19 active patent applications and granted patents on Enbrel protecting its commercial exclusivity, the last of which expires in 2029.

Amgen has filed a total of 57 patent applications on Enbrel in the U.S. with the aim of delaying competition by 39 years.

72% of the total patent applications on Enbrel in the U.S. were filed by drugmaker Amgen after the drug was first approved and on the market in 1998.

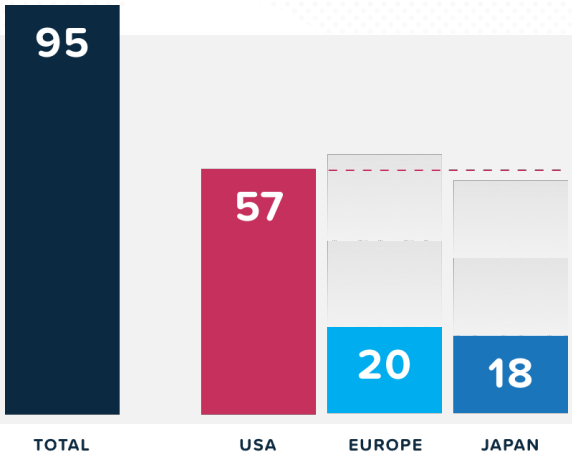


Amgen filed three times as many patent applications in the U.S. compared to Europe and Japan

Amgen has filed nearly three times as many patent applications in the U.S. than at the European Patent Office and Japan respectively.

Biosimilar versions of Enbrel launched in Europe in early 2016, and in less than two years, prices have dropped by nearly half and biosimilars have a 40% market share. By contrast, in the U.S. ongoing patent litigation prevents entry of a lower-cost competitor[3].

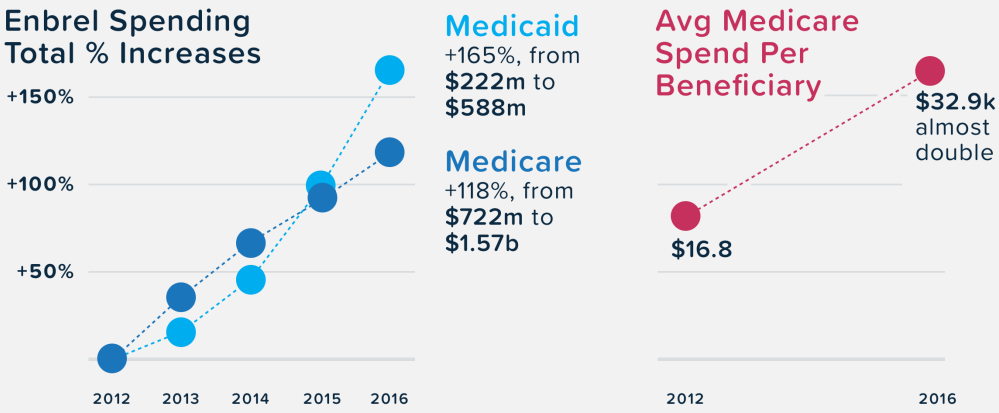
Enbrel's 57 patent applications in the U.S. more than triple those in Japan, and *almost* triple those in Europe.

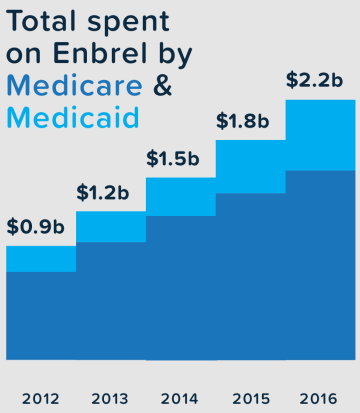


3 www.fiercepharma.com/pharma/eu-biosim-embrace-hits-roche-s-herceptin-hard-but-pain-coming-for-abbvie-j-j-and-more-report

Overpatenting of Enbrel results in financial burden on taxpayers (through Medicare and Medicaid purchases)

Total Medicare and Medicaid spending on Enbrel increased 129% between 2012 and 2016, and during that time the average annual Medicare spending on Enbrel per person nearly doubled from $16,828 to $32,891.[4]





Two decades after it entered the market, Enbrel ranks fourth worldwide for global spending on a single prescription drug, reaping nearly 8 billion dollars in 2017, or $21 million dollars per day.

How much *does* Amgen make on Enbrel?

$7.9b P/YEAR → **$21.6m** P/DAY → **$900k** P/HOUR → **$15k** P/MINUTE

4 All historical data on Medicare and Medicaid spending sourced from CMS Drug Spending Database, available at: https://www.cms.gov/ResearchStatistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-onPrescription-Drugs/index.html

Impact on Patients and Families

Amgen's overpatenting and overpricing of Enbrel has not only affected Medicare and Medicaid, but has also had a direct impact on the health and financial well-being of Americans. The story of Bernadette Simmons, provided by Patients for Affordable Drugs (P4AD), an organization working to reduce drug prices in the U.S., illustrates the reality of excessive pricing of Enbrel:

> *"I am a 75 year old retired nurse. I worked for over 50 years providing health care and health education. I have psoriatic arthritis. I was prescribed Enbrel injections for arthritis. This injection is very expensive and I am unable to afford them on a fixed income. I was able to get a break on Enbrel from the company by special request for the time being, but it has been cost prohibitive for me – $600 for a month's supply."*
>
> **BERNADETTE SIMMONS, CHESAPEAKE, VIRGINIA**

Conclusion

The wall of patents that Amgen has established around Enbrel continues to keep biosimilar products out of the market in the U.S., while a biosimilar was launched in Europe in early 2016.

Drugmakers claim that patents are the only incentive to generate new medicines to address unmet needs. While patents should be rewarded for genuine inventions, the extent of overpatenting on critical life-saving medicines such as Enbrel raises serious questions: whether many patent applications and issued patents on these medicines are strategically filed to delay competition and if they are actually warranted, and whether there is a need to review how inventiveness is determined.

In the Annex to this report, I-MAK has included a set of policy prescriptions to address overpatenting that could be taken forward by Congress and the United States Patent and Trademark Office (USPTO). Undertaking reform must first start with hearings and public comments on pharmaceutical patenting practices and their impact on drug prices for public and private payers, and households across America.

Public participation sits at the heart of effective government regulation. The USPTO should 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 hold hearings to assess how pharmaceutical patenting practices affect federal health care programs and households. This will enable Congress to provide effective oversight of the USPTO and other federal agencies that have the authority to address the overpatenting problem.

Until the U.S. government starts to substantively address the overpatenting of medicines, American consumers and payers will continue to bear the side effects. The U.S. cannot fix the drug pricing crisis until it solves the drug patent problem.

ANNEX
Patent Policy Prescriptions

The epidemic of overpatenting

Filing hundreds of secondary and tertiary patent applications allows brand name drug manufacturers to unfairly extend monopoly protection and keep drug prices high. Some potential policy options to address the problem of overpatenting are:

- Modify the "inventiveness" standard for patents so that non-inventive and commonly practiced techniques in the pharmaceutical field cannot be patented. Raising the bar for the inventiveness standard will likely help curb non-inventive patenting, reduce litigation, and accelerate competition after the intended 20 years of protection that could drive down drug prices.
- Eliminate continuation applications at the USPTO so that a patent applicant does not have unlimited attempts to gain a patent on the same invention even when the USPTO may have made initial rejections. Drugmakers deliberately file continuation applications so they linger in the system as a deterrent for potential generic drug competitors and can eventually lead to multiple patents being granted for the same invention. Removing continuation applications would address a key anticompetitive behavior of brand name drug manufacturers.

Public participation in the patent system

Unless non-commercial actors and other interested parties are sued for patent infringement, they do not have legal standing to challenge patents in federal court. This means that the only recourse for non-commercial actors and other interested parties in the patent system lies at the USPTO.

Some potential policy options to allow for greater involvement of the public in the patent system to help improve transparency and address patent abuse are:

- Maintain and improve the existing patent challenge system, which includes the Inter Partes Review (IPR) process. This process is more efficient, cost effective, and serves as an important check in the system to reverse mistakes, improve patent quality, and save money by allowing earlier generic drug competition. The IPR process could be improved by expanding the grounds for a challenge to a patent to include the lack of written description of a patent.

- Create a pre-grant opposition system similar to the one used by the USPTO for trademarks. Such a system could permit third parties to file legal challenges based on all available grounds used during examination to determine whether a patent application is valid. Pre-grant opposition systems permit knowledgeable experts to weigh in on the merits of a new patent application while it is still under review.

Unmerited patents listed in the Orange Book

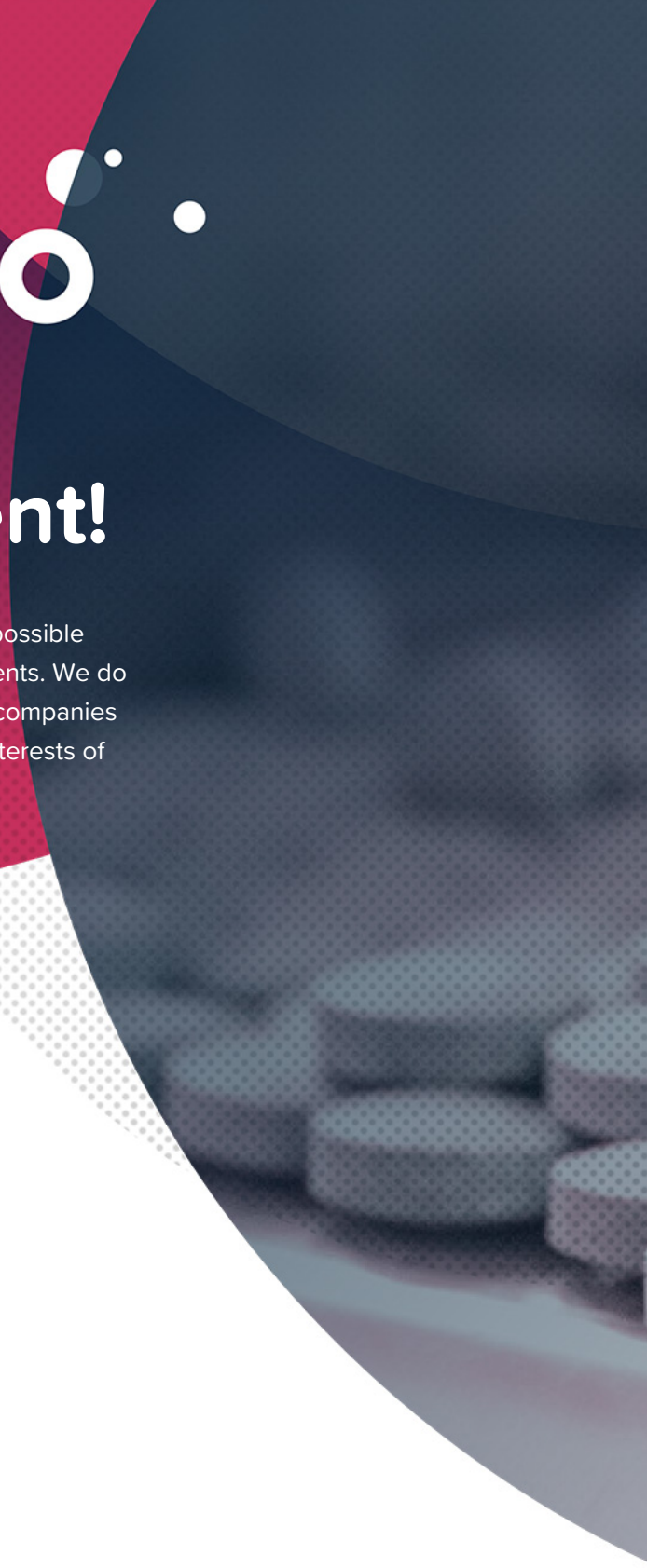
Drugmakers typically file a series of strategic sequential patents in addition to the main patents covering the active ingredient in order to delay generic entry. These secondary and tertiary patents – which can cover formulations, polymorphs, new indications, and medical devices combined with off patent active ingredients – are often found unmerited or result in settlement agreements when litigated.

Some potential policy options to improve the administration of the FDA's Orange Book, speed up generic entry, and reduce litigation are:

- Update existing legislation to allow the removal of a patent from the Orange Book if it is invalidated using the Post Grant Review (PGR) or IPR processes. Currently, the language of the law requires the decision of a federal or appellate court to remove an invalidated patent.
- Improve the quality and transparency of the Orange Book. The FDA should be given greater authority for assessing which patents can be listed on the Orange Book to ensure that only necessary patents are included and it is not used by manufacturers to strategically delay competition through litigation. For example, the FDA could require brand name drug manufacturers to provide a patent attorney opinion letter explaining why a patent should be listed in the Orange Book and the letter could be publicly displayed on the Orange Book.

Join our movement!

I-MAK seeks support from those who believe that a world is possible where all people have access to affordable lifesaving treatments. We do not accept funding from branded or generic pharmaceutical companies in order to stay independent and exclusively represent the interests of patients and consumers.



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