How a Drug Company Made $114 Billion by Gaming the U.S. Patent System

AbbVie for years delayed competition for its blockbuster drug Humira, at the expense of patients and taxpayers. The monopoly is about to end.

Nic Antaya for The New York Times

By Rebecca Robbins
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In 2016, a blockbuster drug called Humira was poised to become a lot less valuable.

The key patent on the best-selling anti-inflammatory medication, used to treat conditions like arthritis, was expiring at the end of the year. Regulators had blessed a rival version of the drug, and more copycats were close behind. The onset of competition seemed likely to push down the medication's $50,000-a-year list price.

Instead, the opposite happened.

Through its savvy but legal exploitation of the U.S. patent system, Humira's manufacturer, AbbVie, blocked competitors from entering the market. For the next six years, the drug's price kept rising. Today, Humira is the most lucrative franchise in pharmaceutical history.

Next week, the curtain is expected to come down on a monopoly that has generated $114 billion in revenue for AbbVie just since the end of 2016. The knockoff drug that regulators authorized more than six years ago, Amgen's Amjevita, will come to market in the United States, and as many as nine more Humira competitors will follow this year from pharmaceutical giants including Pfizer. Prices are likely to tumble.

The reason that it has taken so long to get to this point is a case study in how drug companies artificially prop up prices on their best-selling drugs.

AbbVie orchestrated the delay by building a formidable wall of intellectual property protection and suing would-be competitors before settling with them to delay their product launches until this year.

The strategy has been a gold mine for AbbVie, at the expense of patients and taxpayers.

Barb Teron plans to delay retirement because she is concerned about high out-of-pocket costs for Humira. Nic Antaya for The New York Times

Over the past 20 years, AbbVie and its former parent company increased Humira's price about 30 times, most recently by 8 percent this month. Since the end of 2016, the drug's list price has gone up 60 percent to over $80,000 a year, according to SSR Health, a research firm.

One analysis found that Medicare, which in 2020 covered the cost of Humira for 42,000 patients, spent $2.2 billion more on the drug from 2016 to 2019 than it would have if competitors had been allowed to start selling their drugs promptly. In interviews, patients said they either had to forgo treatment or were planning to delay their retirement in the face of enormous out-of-pocket costs for Humira.

AbbVie did not invent these patent-prolonging strategies; companies like Bristol Myers Squibb and AstraZeneca have deployed similar tactics to maximize profits on drugs for the treatment of cancer, anxiety and heartburn. But AbbVie's success with Humira stands out even in an industry adept at manipulating the U.S. intellectual-property regime.

“Humira is the poster child for many of the biggest concerns with the pharmaceutical industry,” said Rachel Sachs, a drug pricing expert at Washington University in St. Louis. “AbbVie and Humira showed other companies what it was possible to do.”

Following AbbVie’s footsteps, Amgen has piled up patents for its anti-inflammatory drug Enbrel, delaying a copycat version by an expected 13 years after it won regulatory approval. Merck and its partners have sought 180 patents, by one count, related to its blockbuster cancer drug Keytruda, and the company is working on a new formulation that could extend its monopoly further.

Humira has earned $208 billion globally since it was first approved in 2002 to ease the symptoms of rheumatoid arthritis. It has since been authorized to treat more autoimmune conditions, including Crohn’s disease and ulcerative colitis. Patients administer it themselves, typically every week or two, injecting it with a pen or syringe. In 2021, sales of Humira accounted for more than a third of AbbVie’s total revenue.

An AbbVie spokesman declined to comment. The company’s lawyers have previously said it is acting within the parameters of the U.S. patent system. Federal courts have upheld the legality of AbbVie’s patent strategy with Humira, though lawmakers and regulators over the years have proposed changes to the U.S. patent system to discourage such tactics.

Ms. Teron, who turns 64 in March, would have liked to retire next year but plans to delay doing so because she fears facing huge costs for Humira on Medicare. Nic Antaya for The New York Times

In 2010, the Affordable Care Act created a pathway for the approval of so-called biosimilars, which are competitors to complex biologic drugs like Humira that are made inside living cells. Unlike generic equivalents of traditional synthetic medications, biosimilars usually are not identical to their branded counterparts and cannot be swapped out by a pharmacist.

The hope was that biosimilars would drastically drive down the cost of pricey brand-name biologics. That is what has happened in Europe. But it has not worked out that way in the United States.

Patents are good for 20 years after an application is filed. Because they protect patent holders' right to profit off their inventions, they are supposed to incentivize the expensive risk-taking that sometimes yields breakthrough innovations. But drug companies have turned patents into weapons to thwart competition.

AbbVie and its affiliates have applied for 311 patents, of which 165 have been granted, related to Humira, according to the Initiative for Medicines, Access and Knowledge, which tracks drug patents. A vast majority were filed after Humira was on the market.

Some of Humira's patents covered innovations that benefited patients, like a formulation of the drug that reduced the pain from injections. But many of them simply elaborated on previous patents.

For example, an early Humira patent, which expired in 2016, claimed that the drug could treat a condition known as ankylosing spondylitis, a type of arthritis that causes inflammation in the joints, among other diseases. In 2014, AbbVie applied for another patent for a method of treating ankylosing spondylitis with a specific dosing of 40 milligrams of Humira. The application was approved, adding 11 years of patent protection beyond 2016.

The patent strategy for Humira was designed to "make it more difficult for a biosimilar to follow behind," Bill Chase, an AbbVie executive, said at a conference in 2014.

AbbVie has been aggressive about suing rivals that have tried to introduce biosimilar versions of Humira. In 2016, with Amgen's copycat product on the verge of winning regulatory approval, AbbVie sued Amgen, alleging that it was violating 10 of its patents. Amgen argued that most of AbbVie's patents were invalid, but the two sides reached a settlement in which Amgen agreed not to begin selling its drug until 2023.

Over the next five years, AbbVie reached similar settlements with nine other manufacturers seeking to launch their own versions of Humira. All of them agreed to delay their market entry until 2023.

Sue Lee stopped taking Humira because of its price. She now relies on free samples of a different drug. Jessica Ebelhar for The New York Times

Some Medicare patients have been suffering as a result.

Sue Lee, 80, of Crestwood, Ky., had been taking Humira for years to prevent painful sores caused by a chronic skin condition known as psoriasis. Her employer's insurance plan had helped keep her annual payments to $60. Then she retired. Under Medicare rules, she would have to pay about $8,000 a year, which she could not afford.

"I cried a long time," she said.

For months, Ms. Lee stopped taking any medication. The sores "came back with a vengeance," she said. She joined a clinical trial to temporarily get access to another medication. Now she is relying on free samples of another drug provided by her doctor. She doesn't know what she'll do if that supply runs out.

Barb Teron, a book buyer in Brook Park, Ohio, plans to delay her retirement because she is worried about Humira's cost. Ms. Teron, who takes Humira for Crohn's disease and colitis, has never had to pay more than $5 for a refill of the drug because her employer's insurance plan picks up most of the tab. The cost, according to a pharmacy app on Ms. Teron's phone, was $88,766 in the past year.

Ms. Teron, who turns 64 in March, would have liked to retire next year, but that would have meant relying on Medicare. She fears that her out-of-pocket costs will spiral higher. "When I look at that $88,000 charge for a year, there's no way," Ms. Teron said.

AbbVie executives have acknowledged that Medicare patients often pay much more than privately insured people, but they said the blame lay with Medicare. In 2021 testimony to a congressional committee investigating drug prices, AbbVie's chief executive, Richard Gonzalez, said the average Medicare patient had to pay $5,800 out of pocket annually. (AbbVie declined to provide updated figures.) He said AbbVie provided the drug for virtually nothing to nearly 40 percent of Medicare patients.

The drug's high price is also taxing employers.

Soon after she started taking Humira, Melissa Andersen, an occupational therapist from Camdenton, Mo., got a call from a human resources representative at her company. The company directly covers its employees' health claims, rather than paying premiums to an insurer. Her Humira was costing the company well over $70,000 a year — more than Ms. Andersen's salary.

The H.R. employee asked if Ms. Andersen would be willing to obtain the drug in an unconventional way to save money. She said yes.

As soon as March, her company plans to fly Ms. Andersen, 48, to the Bahamas, so that a doctor can prescribe her a four-month supply of Humira that she can pick up at a pharmacy there. Humira is much cheaper in the Bahamas, where the industry has less influence than in it does in Washington and the government proactively controls drug pricing.

Even as patients switch to less expensive versions of the drug, Humira's manufacturer, AbbVie, will make money off royalties from rivals. Nic Antaya for The New York Times

It is not yet clear how much the knockoff products will cost and how quickly patients will switch over to them. Billions of dollars in drug spending will ride on the answers to those questions.

“We price our products according to the value they deliver,” said Jessica Akopyan, a spokeswoman for Amgen, whose biosimilar product comes to market on Tuesday. She added that the company would “employ flexible pricing approaches to ensure patient access.”

Even now, as AbbVie prepares for competitors to erode its Humira sales in the United States, the company will have a new way to make more money from the drug. Under the terms of the legal settlements it reached with rival manufacturers from 2017 to 2022, AbbVie will earn royalties from the knockoff products that it delayed.

The exact sizes of the royalties are confidential, but analysts have estimated that they could be 10 percent of net sales. That could translate to tens of millions of dollars annually for AbbVie.

In the longer run, though, AbbVie’s success with Humira may boomerang on the drug industry.

Last year, the company’s tactics became a rallying cry for federal lawmakers as they successfully pushed for Medicare to have greater control over the price of widely used drugs that, like Humira, have been on the market for many years but still lack competition.

Rebecca Robbins is a business reporter covering the pharmaceutical industry. She joined The Times in 2020 and has been reporting on health and medicine since 2015. More about Rebecca Robbins

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