

MISGUIDED LEGISLATION

BRAND PATENT THICKETS

HIGH BARRIER TO ENTRY



WHITE PAPER: PART 1

FAILURE TO LAUNCH

Patent Abuse Blocks Access to
Biosimilars for America's Patients

\$7.6 Billion in Lost Savings

June 2019

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Executive Summary

As prescription drug costs continue to increase, biosimilar medicines represent hope for patients seeking access to more affordable treatment. Biosimilars are lower-priced versions of brand-name medicines used to treat debilitating and life-threatening diseases, such as Crohn's disease, ulcerative colitis, cancer and psoriatic arthritis. Patients and physicians can rely on FDA-approved biosimilar medicines just as they would the brand-name product. Widely available in the European Union and around the globe, they are an integral component of efforts to reduce the high cost of brand-name biologics and enhance patient access to lower-cost treatments.

Unfortunately, many biosimilar medicines are not available to patients even after they have successfully navigated the stringent regulatory process to obtain FDA approval. In fact, although 20 biosimilars have been approved by the FDA, only seven are currently commercially available.¹ This is a direct result of the patent schemes used by some brand-name pharmaceutical companies to maintain their lucrative product pricing monopolies beyond the period Congress deemed reasonable.

Patients, taxpayers and the overall health care system are bearing the costs of these patent schemes and delayed access to biosimilars. In this analysis, the Association for Accessible Medicines (AAM) Biosimilars Council found that delayed entry of biosimilars due to patenting has cost the U.S. health care system an astounding \$7.6 billion in lost savings since 2015.

U.S. Biosimilars Market Overview

The Biologics Price Competition and Innovation Act (BCPIA) was approved by Congress in 2010 to spur biosimilar innovation and reduce drug spending on expensive brand-name biologics.

Although the biosimilars market remains in its nascency, early experience demonstrates the promise and challenges of biosimilar medicines. For instance, currently marketed biosimilars average a 47% list price and 18% net cost discount for patients and the U.S. health care system.²

These savings mean new hope for patients. In fact, a 2017 study by the Biosimilars Council found that 1.2 million patients in the United States could gain access to biologic medicines by 2025 as the result of biosimilar competition. The report also suggests that women, lower-income and elderly individuals would particularly benefit from access to biosimilar medicines.³

1 As of June 12, 2019.

2 AAM Analysis of IQVIA Wholesale Acquisition Cost (WAC) Data, February 2019; Centers for Medicare and Medicaid Services (CMS) Average Sales Price (ASP) Pricing Files, April 2019.

3 The Biosimilars Council, Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines. (2017) Available at <https://bit.ly/2fAWtXB>.

Biosimilar manufacturers seeking to launch in the U.S. face challenges related to scientific development, regulatory approval and manufacturing and production. Beyond the rigors of obtaining FDA approval, biosimilar manufacturers increasingly encounter anticompetitive hurdles designed to delay entry. These may include the use of restricted distribution schemes, “rebate traps” and exclusionary contracting practices by brand-name pharmaceutical companies, as well as misinformation campaigns funded by the pharmaceutical industry.

However, one particularly pernicious scheme that brand-name pharmaceutical companies have deployed is the creation of patent “thickets” to delay competition and discourage manufacturers from pursuing and launching biosimilars to their products.⁴

Abuse of the Patent System Blocking Biosimilar Competition

When Congress enacted the BPCIA in 2010, it provided brand-name pharmaceutical companies with a 12-year market exclusivity period—longer than anywhere else in the world—to ensure a return on investment for research and development of new medicines.⁵ Part of the case made by the pharmaceutical industry in favor of a long period of exclusivity was the weak patent protections around this new class of medicines.⁶

Nonetheless, recent years have witnessed efforts by some brand-name pharmaceutical companies to accumulate dozens of patents near the end of the product lifecycle under the guise of “innovative” processes or development that warrant additional protections. In many cases, these late-stage patents are filed when there have been no changes made to the product manufacturing process or the underlying product itself. Under this scheme, some brand-name pharmaceutical companies prolong a brand-name biologic’s monopoly pricing and delay patient access to more affordable, FDA-approved biosimilar medicines.

These patent thickets chill competition by discouraging biosimilar competitors from entering a market because of the exorbitant cost of litigating meritless patents. A biosimilar treatment cannot come to market until this litigation has been resolved. Indeed, this is why fewer than half of the 20 FDA-approved biosimilars are available to U.S. patients.

By increasing the litigation and development costs for potential biosimilar competitors, brand manufacturers may discourage potential biosimilar manufacturers from even pursuing the development

4 National Journal. “Bipartisan Legislation Targets Patent Thickets, Supports Biosimilars Uptake”. Available: <http://bit.ly/2vsQEmM>.

5 42 U.S. Code § 262.

6 Grabowski, Henry, “Data Exclusivity for Biologics: What is the Appropriate Period of Protection?” AEI, September 2009. Available at: <http://www.aei.org/publication/data-exclusivity-for-biologics-what-is-the-appropriate-period-of-protection/>

of more affordable alternatives. This is particularly true if the litigation costs are likely to exceed the potential return on investment.

Moreover, such practices run counter to congressional intent to encourage competition upon expiry of innovation incentives. As noted by Health and Human Services (HHS) Secretary Alex Azar:

“There’s a deal in our Hatch-Waxman statute. There’s a deal in the biosimilar legislation. It says you get the exclusive right to practice this molecule and this patent, up to this date, and at that point ‘katy, bar the door’ – full generic competition, full biosimilar competition. Stop the gamesmanship ... stop the evergreening.”⁷

–Health and Human Services Secretary, Alex Azar

Key Findings

Former FDA Commissioner Scott Gottlieb, M.D., highlighted the fact that delays in biosimilar commercialization costs money for patients and payers, noting that “if Americans had the opportunity to purchase successfully marketed, FDA-approved biosimilar prescription drugs, they could have saved more than \$4.5 billion in 2017.”⁸ However, these lost savings are only the tip of the proverbial iceberg resulting from patent abuse.

\$7.6B Lost savings from
2012-2018

To understand the comprehensive cost to patients and payers of the patent schemes used by some brand-name pharmaceutical companies since FDA began approving biosimilars in 2015, AAM and the Biosimilars Council calculated foregone savings for the 12 approved biosimilars that currently remain off the market as a result of patent thickets, assuming they had been marketed upon receiving FDA approval. Thus, in all cases, the brand-name biologic has already enjoyed the benefit of 12 years of market exclusivity (monopoly) that is provided under the BPCIA to ensure the originator company may recoup its investment in research and development.

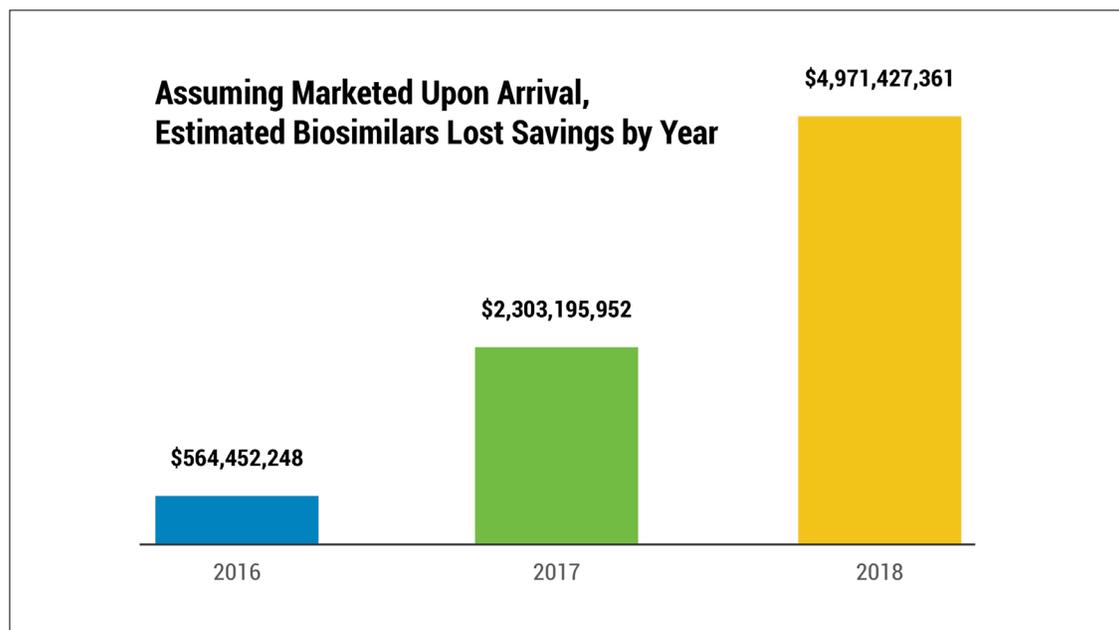
7 HHS Secretary Alex Azar, CNBC Interview, May 11, 2018. Available: <https://cnb.cx/2WcYCLA>.

8 Scott Gottlieb, M.D. Remarks from FDA Commissioner Scott Gottlieb, M.D., as prepared for delivery at the Brookings Institution on the release of the FDA’s Biosimilars Action Plan. July 18, 2018. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613881.htm>.

As noted above, there are substantial gaps between the biosimilar's FDA approval date and its commercial availability. In fact, some of these biosimilar manufacturers have been FDA-approved for more than two years and are still not able to deliver their approved biosimilar to patients.

This post-approval delay in patient access continues to cost the health care system and patients alike.

As a result of the ability of companies to take advantage of the U.S. patent system in this way, **the health care system has lost \$7.6 billion in biosimilar savings since 2012**. These are savings that could have been available to patients through lower out-of-pocket costs and payer spending if biosimilars were able to come to market at the time of their approval. Much of this savings would also have accrued to all taxpayers due to federal government purchases of biologics.



Unrealized Medicare Savings: Over \$1.2 Billion Since 2015

A substantial portion of these lost savings are borne by the federal health care programs and taxpayers. The Medicare program pays a high percentage of the costs for many brand-name biologics and thereby bears a share of the unnecessary spending attributable to the lack of biosimilar availability. Based on AAM's estimates of the percentage of sales in Medicare⁹ as a share of total sales,¹⁰ Medicare has foregone more than \$1.2 billion in savings from biosimilars since 2015 as a result of patent thickets.

9 Centers for Medicare & Medicaid Services. Medicare Part D and Part B Spending Dashboard. Accessed November 2018. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/>.

10 IQVIA CORE. National Sales Perspectives (NSP). Accessed November 2018.

Tools for Navigating Patent Thickets – Settlements

As noted, the use of patent thickets to block competition is a growing challenge. The patent tracking organization I-MAK examined the top 12 brand-name drugs on the market and found that a total of 848 patents (71 per drug) shield these products from generic and biosimilar competition for an average of 38 years.

One glaring example of this challenge is AbbVie's Humira®. First approved in 2002 for treatment of a variety of diseases, Humira has improved the quality of life for millions of patients. However, annual price increases have pushed the list price to more than \$50,000 per year.¹¹ Ahead of Humira's 12-year statutory market exclusivity expiration in 2014 and the expiration of its principal patent in 2016, AbbVie filed more than 75 late-stage patents. These late-stage patents were all filed in the three years prior to when biosimilar competition was set to begin.

The patent thicket that AbbVie built around Humira allowed it to extend patent protection through 2034.¹² The FDA has approved three biosimilars to Humira, but none is currently available to patients. Biosimilar manufacturers challenged the validity of many of the patents on Humira.

However, challenging potentially non-innovative patents is an expensive endeavor without any guarantee of success. Costs to litigate are estimated to be roughly \$3 million per patent.¹³

Accordingly, a critical element of biosimilar entry is the ability for two parties to reach a **settlement agreement** providing for competition earlier than the expiration of the last patent, **rather than bear the time and expense of litigating through these thickets in court.**

The rules for such settlements were largely established by the landmark 2013 Supreme Court decision in *FTC v. Actavis*, in which agreements with "large, unjustified reverse payments" were determined to be potentially anticompetitive when combined with a market entry date beyond patent expiry. Since that decision and subsequent FTC action, the total number of patent settlement agreements has increased (there were 232 in 2016) while the number of potentially anti-competitive agreements has declined to only one.¹⁴ This has paved the way for pro-consumer patent settlement agreements and earlier entry while avoiding expensive and burdensome litigation costs.

11 Forbes. "How Abbvie's Humira Undercuts The Drug Industry Price Defense." Available: <http://bit.ly/2VyLeVO>.

12 Bloomberg. "This Shield of Patents Protects the World's Best-Selling Drug." Available: <https://bloom.bg/2GIch7F>.

13 American Bar Association. "The Cost of Doubling Up: An Economic Assessment of Duplication in PTAB Proceedings and Patent Infringement Litigation." Available: <http://bit.ly/2JIDVVV>.

14 Federal Trade Commission. "FTC Staff Issues FY 2016 Report on Branded Drug Firms' Patent Settlements with Generic Competitors." Available: <http://bit.ly/211Rwof>.

In the case of Humira, after years of litigation, the three biosimilar manufacturers that have been FDA-approved reached settlement agreements with AbbVie to begin serving the market starting in 2023. These pro-competitive agreements provide for competition 11 years earlier than might otherwise be possible, ensuring access for patients and savings for the system, and showing that post-Actavis regulation of patent settlements is working. While patent settlements do not solve the issues around anticompetitive behavior by brand-name pharmaceutical companies and their development of patent thickets, these agreements provide an important avenue for biosimilar manufacturers to bring their products to market in lieu of other solutions to patent thickets.

Unfortunately, some legislative proposals would create a de facto prohibition on patent settlements. This would merely benefit companies investing in the creation of patent thickets – forcing competitors to slog through lengthy and expensive litigation with uncertain prospects of success. Rather than encouraging earlier competition, it could further delay biosimilar entry. If the manufacturers of biosimilars to Humira were not able to settle, competition could have been delayed until 2034. This would have resulted in annual lost savings of over \$3 billion per year for 11 more years.¹⁵

Summary

This analysis demonstrates that the creation of patent thickets to delay biosimilar competition has directly contributed to billions in lost savings for the health care system. These lost savings could be used more efficiently to promote better patient care and advances in health care innovation, as well as used to lower health care costs.

Indeed, rather than supporting earlier biosimilar entry, misguided legislation to prevent patent settlements could cause further harm. Such efforts could delay important agreements allowing the launch of lower priced competition prior to patent expiry.

Instead, policymakers should take steps to ensure the viability of this market to improve access to biosimilars for America's patients.

15 This figure is based on savings projected if just three Humira biosimilars were approved but not launched in before 2034. AbbVie has reached settlements with seven total manufacturers for the U.S. market; however, four of those have not yet been FDA-approved.

Methodology

To conduct the analysis, AAM used eight FDA-approved biosimilars to examine foregone savings. The products are listed below. These products were selected due to their lack of launch despite FDA approval.

Biosimilar (Approval Year)	Reference Product	Biosimilars Per Reference Product	2016 Lost Savings	2017 Lost Savings	2018 Lost Savings
Erelzi (2016)	Enbrel	1	\$158,268,199.24	\$949,060,552.20	\$956,669,903
Amjevita (2016)	Humira	3	\$406,184,048.79	\$979,820,830.62	\$957,604,549
Cyltezo (2017)	Humira	3		\$323,340,874.10	\$957,604,549
Mvasi (2017)	Avastin	1		\$43,425,602.04	\$364,691,201
Ogivri (2017)	Herceptin	1		\$7,548,093.73	\$187,645,400
Hyrimoz (2018)	Humira	3			\$957,604,549
Herzuma (2018)	Rituxan	1			\$187,645,400
Truxima (2018)	Herceptin	2			\$140,282,097
Total Lost Savings by Year			\$564,452,248.03	\$2,303,195,952.70	\$4,971,427,361
Total Lost Savings			\$7,577,395,847		

For purposes of the analysis, AAM assumed a 30% price discount for biosimilar products relative to their reference biologic. This assumption was selected to conform with previous AAM analyses of potential biosimilar savings and aligns with European biosimilar pricing.¹⁶

Similarly, AAM assumed an uptake assumption of 40% for individual biosimilars. This uptake assumption is assumed to remain constant during the presence of two biosimilars (for example, biosimilar uptake of 40% is split between both biosimilars).

When there are assumed to be three biosimilars in the market, the total uptake assumption for all the

16 QuintilesIMS. The Impact of Biosimilar Competition in Europe. May 2017. https://www.medicinesforeurope.com/wp-content/uploads/2017/05/IMS-Biosimilar-2017_V9.pdf.

available biosimilars is assumed to be 50%.

The data on pricing were purchased by AAM from IQVIA and provide national sales and pricing information for the selected products and their reference biologics from 2012 through the present.

For purposes of determining the share of savings attributable to Medicare, AAM used the total sales figures from the CMS Medicare Parts B and D Dashboards¹⁷ from 2012 to 2017, compared to total spending available in the IQVIA dataset. As CMS only provides such numbers through 2016, AAM assumed the 2017 percentage of Medicare spending to total spending for each reference product remained constant in 2018 and 2019.

17 Ibid.



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