Patent Thickets and Lost Drug Savings

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Executive Summary

In their efforts to protect profits, brand drug companies have learned to accumulate patents around lucrative products to protect monopolies. Patent thickets, as they are known, are intended to keep generic or biosimilar competition out of the market. In doing so, they impose substantial costs on consumers and the healthcare system by delaying savings that competition would bring.

Patent thickets around pharmaceuticals are particularly prevalent in the United States, where companies can file at relatively low cost for as many patents as they choose and for years after a drug is on the market. Brand companies take advantage of the patent system by adding excessive secondary patents for the simple purpose of thwarting competition. These secondary patents — which cover narrow areas such as dosing regimens — are distinct from the patents on the drug compound itself.

This paper quantifies the cost of this misuse of the US patent system for five specific brand drugs with patent thickets: Enbrel, Eylea, Humira, Imbruvica, and Opdivo. We estimate that the one-year cost from delayed competition for these products because of patent thickets ranges from $1.8 billion to $7.6 billion.

These five products are at different points in their life cycles, which means that the years of lost savings differ. Some patent thickets are already preventing competition and savings, while others soon will. In other words, these drugs illustrate the current and future cost of patent thickets in the United States. And these five certainly do not represent the universe of drugs with patent thickets. Rather, they are intended to demonstrate the magnitude of the problem.

Given that superfluous patents are key to creating patent thickets, reforms at the US Patent and Trademark Office will be necessary to curb brand manufacturers' use of this strategy. There has been executive, legislative, and regulatory interest in addressing the problem, but, while this is a promising start, tangible legislative reforms will be required to stop this long-standing anticompetitive practice.

The recently enacted Inflation Reduction Act included drug pricing provisions that could indirectly affect patent thickets, but in reality these provisions are more likely to create new uncertainties for competitors. Until the core of the problem is addressed, patent thickets will continue to block billions of dollars in savings.

ONE-YEAR COST OF PATENT THICKETS PER BRAND DRUG

Enbrel (etanercept)	EYLEA	HUMIRA (adalimumab)	imbruvica	OPDIVO (nivolumab)
$1.9 billion	$2.5 billion	$7.6 billion	$3.1 billion	$1.8 billion

Introduction

Brand drug companies are known to use a variety of tactics to block competition and maintain monopolies on profitable products (*Brill, 2019*). One such tactic is known as a patent thicket, which describes the strategy of accumulating superfluous patents around a brand drug to keep generic or biosimilar competition out of the market.

Patent thickets impose substantial costs on consumers and the healthcare system by delaying savings that generic drugs and biosimilars would bring. To quantify the cost of this misuse of the US patent system, we look at patent thickets around five specific brand drugs and estimate lost savings from delayed competition for these products. We estimate that the one-year cost of patent thickets around these drugs ranges from $1.8 billion to $7.6 billion.

Our analysis highlights only part of a large and growing problem. As brand firms are emboldened by the success of patent thickets, the strategy will become more prevalent unless policymakers intervene. While the drug pricing provisions in the recently enacted Inflation Reduction Act could indirectly affect patent thickets, they are more likely to create new uncertainties for competitors. Legislative reforms must address this anticompetitive practice directly.

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Patent Thickets

It is important to note at the outset that intellectual property protection is of the utmost importance. Patents, which last 20 years in the United States, are vital for protecting inventions and innovations for a period of time to reward productive risk-taking. In the pharmaceutical market, patents encourage brand drug firms to continue developing new products and bringing lifesaving treatments to market.

However, at the appropriate time, it is important that competitors be allowed to enter the market. Competition brings cost savings to consumers and the healthcare system and incentivizes brand firms to continue innovating. In 2021 alone, generics and biosimilars saved the US healthcare system and consumers $373 billion (*AAM, 2022*). Striking a balance between fostering competition and protecting incentives for bringing new drugs to market has long been the goal of lawmakers, beginning in 1984 with the Hatch-Waxman Act.

The issue with patent thickets — as well as the other anticompetitive tactics that brand companies have been known to employ — is that they block competition for longer than is intended by the legal and regulatory framework that promotes innovative drug development. While patent thickets have been used in other areas, they are especially common in the pharmaceutical market, particularly among biologic drugs.

Biologics are medicines made from living organisms (rather than a chemical compound),

and their complexity gives brand drug companies more opportunities for layering patents to make a thicket. Biologics are typically very expensive, and many are prescribed to tens of thousands of patients annually, creating a strong incentive for manufacturers to preserve monopoly pricing for as long as possible. For example, in Medicare Part B, 17 of the top 20 drugs by total spending in 2020 were biologics (*MedPAC, 2022*).

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HOW PATENT THICKETS ARE FORMED

Brand companies form patent thickets around drugs by adding excessive secondary patents for the simple purpose of thwarting competition. These patents — which cover narrow areas such as dosing regimens — are distinct from the patents on the drug compound itself. In a recent analysis, researchers reviewed 21 patent infringement cases involving 179 biologic patents and found that "only 6% covered the active ingredient in the biologic drug, while the vast majority covered uses or peripheral features of the drug" (*Van de Wiele et al., 2022*).

Each added secondary area represents a new patent "family" that starts an additional period of protection (20 years in the United States), even if the drug is already approved or on the market. In an analysis of the 10 top-selling drugs in the United States, I-MAK (*2022*) reports that brand companies filed two-thirds of the patent applications after Food and Drug Administration (FDA) approval of the drug.

Within each patent family, brand companies can layer multiple patents, often with similar wording, that competitors have to challenge or work around. If patent thickets were merely dense — that is, composed of many overlapping patents — generic or biosimilar firms could simply wait until patent protection ended. But because brand firms can continue creating new secondary patent families, they can preserve monopolies for decades.

PATENT THICKETS IN THE UNITED STATES

Patent thickets around pharmaceuticals are particularly prevalent in the United States compared with other countries. A recent study of patent thickets in Canada, the UK, and the United States "shows that on average nine times more patents are asserted against biosimilars in the USA than in Canada, and 12 times more patents are asserted when compared to the UK" (*Goode and Chao, 2022*). In the United States, companies can file at relatively low cost for as many patents as they choose and for years after a drug is on the market; compared with patents in other countries, US patents are costlier and more complicated to challenge (*Brill and Robinson, 2021*).

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This tactic has begun to attract attention in the United States, and several studies have looked at the impact of patent thickets. Many studies, including the analysis presented later in this paper, focus on the high brand prices and lost drug savings associated with patent thickets. But, as we have explained, patent thickets also induce companies to produce biosimilars outside the United States for fear of putting themselves at legal risk if they are perceived to be manufacturing or stockpiling biosimilars for the US market (*Brill and Robinson, 2021*).

The Biosimilars Council (*2019*) estimates that lost savings due to lack of biosimilar competition

for five biologics with patent thickets totaled $7.6 billion from 2012 to 2018. Two of these products — Enbrel and Humira — are still without biosimilar competition and are included in the analysis presented later in this paper.

Humira is one of AbbVie's blockbuster drugs, with more than $17 billion in US sales in 2021. Finally facing biosimilar competition this year, it is arguably the poster child for patent thickets. An investigation by the US House of Representatives Committee on Oversight and Reform (*2021*) into AbbVie's sales tactics found that the brand company "has obtained or applied for over 250 patents on Humira." Furthermore, "approximately 90% of AbbVie's patent applications were filed after Humira was already approved and brought to market, suggesting that they were intended to block competition and protect revenue" (*Ibid.*).

Inflation Reduction Act and Patent Thickets

In August 2022, President Joe Biden signed into law the Inflation Reduction Act (IRA), which included drug pricing provisions that have the potential to affect patent thickets. The most significant IRA provision in this context allows the Centers for Medicare & Medicaid Services (CMS) to negotiate prices for drugs that meet certain criteria. In particular, drugs that CMS selects for negotiation will be single-source (that is, lacking generic or biosimilar competition) and high-cost for Medicare.

Because this provision allows CMS to target drugs that are likely to be protected by patent thickets, one could argue that it will significantly mitigate the risk of patent thickets, but that is unlikely. The price negotiations established in the IRA only relate to Medicare Part B and Part D drugs (and Part B drugs cannot be selected for negotiation until 2028). Negotiated prices will not extend to the commercial market. Because brand companies will still be able to determine prices for their single-source products for private payers, their incentive to maintain monopolies is preserved.

In addition, the IRA introduces price negotiation gradually, with just 10 Part D drugs allowed to be negotiated in 2023, increasing every year from there. Each year, the negotiated price will not go into effect for two years. Therefore, while price negotiations will be in full effect eventually, it could be more than a decade before their impact is really felt.

Government price negotiation will do little to discourage a brand manufacturer's incentive to create patent thickets because excessive patents will remain a relatively low-cost means of extending the duration of a product's monopoly. Moreover, provisions in the IRA may actually push brand manufacturers to find ways to allow enough competition to avoid negotiations while not allowing a truly competitive market. In short, the IRA does not directly address the problem of patent thickets and may unintentionally delay competition that can lower costs for patients and payers.

A better way to address the problem of patent thickets is to get to their root. As we discuss later in this paper, a patent system that functions as intended is key to fostering drug competition, and robust competition is the best way to achieve lower drug prices.

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Analysis of Lost Savings from Patent Thickets

To illustrate the cost of patent thickets, we analyze the following five drugs whose manufacturers have employed this tactic: Enbrel, Eylea, Humira, Imbruvica, and Opdivo. Enbrel and Humira treat autoimmune diseases, Eylea is an ophthalmology product, and Imbruvica and Opdivo are oncology drugs. Enbrel, Eylea, Humira, and Opdivo are biologic drugs, and Imbruvica is a small-molecule product.

These five products certainly do not represent the universe of drugs with patent thickets. Rather, they are intended to illustrate the magnitude of the problem. Other products with mature or nascent patent thickets also block savings. And while some drugs known to have patent thickets finally are facing competition, they first imposed significant costs on consumers and the US healthcare system.

DATA AND METHODOLOGY

Our analysis uses the total US sales for each product in 2021, as reported by the manufacturer. Humira, long the prime example of patent thickets in the United States, had more than $17 billion in US sales in 2021, and the other four products had US sales of $4 billion–$6 billion.

We assume a steady state of competition, where generics and biosimilars have achieved price discounts and uptake currently observed in the market (**see Table 1**). For Imbruvica, the small-molecule drug in our analysis, we assume that generics will be discounted 80 percent, the low end of the market average (*FDA, 2021*), and achieve the generic industry average of 90 percent market share (*FDA, 2022*).

Biosimilars have different market dynamics than generic small-molecule drugs. For the four biologics in our analysis, we use the following averages in our model. Biosimilars now capture 75 percent market share on average (*Amgen, 2022*) and have average price discounts of 50 percent (*AAM, 2022*). Unlike small-molecule generics, biosimilars have been shown to induce brand manufacturers to reduce the prices of reference products. On average, reference biologic prices fall by 25 percent following biosimilar entry (*Ibid.*).

TABLE 1. Market Share and Price Discount Assumptions

DRUG TYPE	Average Competitor Market Share	Average Competitor Price Discount	Average Reference Product Price Discount
Biologic	75%	50%	25%
Small molecule	90%	80%	0%

Sources: *AAM (2022), Amgen (2022), FDA (2021), and FDA (2022).*

RESULTS

Our analysis shows that the one-year cost of delayed competition from patent thickets is $1.9 billion for Enbrel, $2.5 billion for Eylea, $7.6 billion for Humira, $3.1 billion for Imbruvica, and $1.8 billion for Opdivo. It is important to note that these products are at different points in their life cycles, which means that the years of lost savings differ. For example, the patent thicket around Humira has come to an end, with biosimilars finally entering the market this year. The patent thicket around Enbrel (approved in 1998) is currently costing the US healthcare system $1.9 billion annually, while the patent thicket around Opdivo (approved in 2014) is expected to cost $1.8 billion annually in the future. In other words, these drugs illustrate the current and future cost of patent thickets, all on an annual, steady-state basis based on 2021 US sales.

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Policy Reforms

Given that superfluous patents are key to creating patent thickets around brand drugs, reforms at the US Patent and Trademark Office (PTO), the office responsible for issuing patents, will be necessary to curb brand manufacturers' use of this strategy. Some experts have proposed broad changes at the PTO, like increasing resources for patent examiners and setting higher patent standards (*Richards et al., 2020*), while others have recommended creating one exclusivity period for brand drugs rather than allowing manufacturers to acquire multiple patents (*Wu and Cheng, 2020*).

While legislative efforts to address patent thickets have thus far come to naught, there has been recent momentum among policymakers to address this tactic. In July 2021, President Biden issued an Executive Order directing the FDA to reach out to the PTO to coordinate in helping "ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law." The FDA and PTO have begun communicating about coordination between the agencies.

Meanwhile, lawmakers are increasingly active in their concern over patent thickets. In May 2022, Senators Bill Cassidy (R-LA) and Maggie Hassan (D-NH) wrote to the FDA administrator and the PTO director to express concern that "the lack of coordination between the [PTO] and [FDA] has allowed the pharmaceutical industry to obtain patents of questionable validity." The following month, Senators Dick Durbin (D-IL), Thom Tillis (R-NC), and Chuck Grassley (R-IA) introduced the Interagency Patent Coordination and Improvement Act (S. 4430) to facilitate collaboration between the PTO and the FDA.

Also in June, then-Senator Patrick Leahy (D-VT) and Senators John Cornyn (R-TX), Richard Blumenthal (D-CT), Susan Collins (R-ME), Amy Klobuchar (D-MN), and Mike Braun (R-IN) wrote to the PTO director requesting that the PTO "consider changes to [its] regulations and practices" to prevent patent thickets and "issue a notice of proposed rulemaking or a public request for comments."

In response to congressional attention, the PTO issued a request for comment on patent thicket–related questions in October 2022.

These efforts are a promising start to addressing this long-standing anticompetitive practice, but tangible legislative reforms will be required. For example, some legislation, including the Affordable Prescriptions for Patients Act of 2021, cosponsored by Senators Cornyn and Blumenthal, would limit the number of patents a brand drug manufacturer can contest. If policymakers do not intervene at the core of the problem, patent thickets will continue to block billions of dollars in savings.

These efforts are a promising start to addressing this long-standing anticompetitive practice, but tangible legislative reforms will be required.

Conclusion

Patent thickets are one of a range of tactics brand drug manufacturers use to block competition and maintain monopoly profits. By employing this tactic, brand manufacturers impose significant costs on consumers and the US healthcare system. By our estimate, the one-year cost of patent thickets around the five drugs in our analysis ranges from $1.8 billion to $7.6 billion. If policymakers do not put a stop to this practice, it will continue to result in billions of dollars in lost savings in the years to come.

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