



Executive Summary¹

- Patent thicketing involves bombarding the USPTO with patent applications over time in the hopes that enough are granted to prevent generic and biosimilar² entry after the expiration of the original patents on a drug.
- Much patent thicketing is a planned strategy that starts from filing broad patents on the original discovery and then filing narrower patents on different aspects of the drug as time goes on.
- Patent thickets create a barrier to generic and biosimilar entry by making it too risky, too expensive, and too time consuming to defeat any particular thicket and expect a return on investment.
- Patent thickets delay generic and biosimilar competition. Generic competition lowers drug prices by 79% on average from the brand price before generic entry. While the price effects of biosimilar competition are still under study, early estimates put savings at between 15%-45%, with higher savings possible.
- Patent thicketing is increasingly used as a strategy to preserve monopoly pricing, with the makers of the twelve best selling drugs in the U.S. filing hundreds of patent applications to extend their monopolies far beyond the twenty years of protection intended under U.S. patent law.
- It is difficult to determine how much patent thicketing costs Americans, however a recent study found that delays in market entry of generic drugs cost Medicaid alone an excess of \$761 million over seven years. Patent litigation was the most common cause of generic entry delays.
- Solutions should be directed at two goals:
 - First, patents should be reserved as a reward for innovation, and follow-on patents sought purely to prevent competition, which tend to be of questionable validity, should be discouraged.
 - Second, to the extent possible, the date of generic and biosimilar entry should be clear and decided as early as possible.

Introduction

There are perhaps a few instances in life in which successfully balancing innovation and access require such a global effort as is the case with the COVID-19 pandemic. If anyone had been asked on January 1, 2020, whether they would experience a global shutdown of economies, shelter-in-place orders, and such a massive race towards a cure to a virus during their lifetime, it is probable that the answer would have been no. As evidenced by the abrupt interruption of daily life caused by the pandemic, the need for both innovation and access must be at the forefront of our society. Without it, there would be little hope of defeating this virus and resuming any semblance of normalcy either socially or economically in the foreseeable future.

Innovation has been needed at every step of the process of responding to the pandemic, from developing safety protocols like the amount of space needed for effective social distancing, to repurposing older drugs that prove beneficial as treatments to those suffering from the virus, to the pipeline of new vaccines that will one day prevent people from getting sick at all. This innovation often relies on policy interventions to not only orient the needs of innovation, but also directly buttress those efforts. Direct financial support in the form of grants from government and non-profit organizations is a way to support innovation, as are patent rewards that provide a limited monopoly on the right to practice the invention.

Equally important is access, people need to be able to use the disease prevention and treatment options in order to save lives and halt the progress of the disease. Sometimes access is easy, like in the case of knowledge.

¹ Special thanks to Silvia Faria for her contributions to this white paper.

² Biosimilar drugs are safe and effective substitutes for biologic drugs, analogous to generic drugs for small molecule brand name drugs. Biosimilar competition is still new but projected to save Americans \$100 billion over the next five years.



Scientists and government officials are eagerly sharing information on the best safety practices based on ongoing research into the methods of COVID-19's transmission. However, anything that is not free will limit access based on how affordable it is. An expensive drug is as inaccessible to someone who can't afford it as one that doesn't exist at all. The pandemic also shows that the issue of access can create large negative external effects. Any person that doesn't have access to a vaccine risks spreading it to others, increasing the severity of the pandemic and causing broader costs associated with an unmanaged pandemic. These negative externalities are the most extreme in a pandemic, but can also be present in other untreated medical conditions: like loss of productivity. Additionally, there are direct effects to patients like unnecessary suffering, long-term health consequences and death that come from medical conditions left untreated due to lack of access.

Access tends to be higher when drugs face competition from generics or biosimilars, driving down price and diversifying supply. For example, the drug dexamethasone that was found to reduce COVID-19 mortality is relatively inexpensive due to generic competition and has a lower risk of supply shocks due to multiple manufacturers.³ Access is at its lowest when drugs are expensive, as is often the case when there is a single supplier who can set the price of an important drug. Therefore, access often relies on whether information can be freely used or is legally walled off through an intellectual property right. Information in the public domain can be used to increase competition and diversify the supply of important drugs through generic and biosimilar entry. There is also the added benefit that this information can be used for the discovery of new drugs or vaccines that are improvements of older innovations.

Innovation policy is about selecting the best tools to both encourage innovation and promote access. An example of innovation policy is that set by the Hatch-Waxman Act and the Biologic Price Competition and Innovation Act. Among other things, these acts encourage innovation through strong exclusivities and encourage access by promoting robust competition at the end of those exclusivities. Key to these policy choices is that exclusivities come to an end, otherwise the access components are sacrificed because prices remain high. Also key to this policy is that undeserved monopolies should not be allowed to stand. Indeed, current policy rewards the first generic to defeat invalid patents with a 180-day exclusivity.⁴ Policymakers must be vigilant to prevent new strategies that can consistently renew these exclusivities and indefinitely postpone competition. To be clear, advancing the goal of access does not necessarily mean handing out one's ideas for free. Carefully applied, it is the selection of innovation policy that serves the goal stated in the Constitution, "to promote the progress of science and useful arts,"⁵ without over-rewarding patent applicants in a way that harms the public or works contrary to this goal.⁶

There are several competing theories of what exactly promotes the most innovation. One of the most well-known of these is Prospect Theory. This theory, first postulated by Edmund Kitch in 1977, attempts to equate patents with property ownership, emphasizing the notion that that a "primary point of the patent system is to encourage further commercialization and the efficient use of as yet unrealized ideas by patenting them, just as privatizing land will encourage the owner to make efficient use of it."⁷ In other words, it is only by viewing patents as an exclusive property that a patent owner will be motivated to innovate further. Kitch's theory is based on Joseph Schumpeter's idea that monopolies favor innovation through the creation of "big prizes" that can encourage investment in research and development.⁸ In contrast to that viewpoint is the Competitive Innovation theory by Ken Arrow. According to this view, "competition, not monopoly best spurs innovation because, to simplify greatly,

³ <https://www.statnews.com/2020/09/02/covid19-steroids-reduce-deaths-of-hospitalized-patients-who-analysis-confirms/>

⁴ <https://pubmed.ncbi.nlm.nih.gov/19999288/>

⁵ https://www.law.cornell.edu/wex/intellectual_property_clause

⁶ See, e.g., Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev., 1575, 1608 (2003) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=431360.

⁷ *Id.* at 1601

⁸ *Id.* at 1601



companies in a competitive marketplace will innovate in order to avoid losing, while monopolists can afford to be lazy.”⁹ Competition Innovation theory also argues that prospect theory is wrong because “unlike tangible property, information is a public good for which consumption is nonrivalrous.” This suggests that one person’s use of the information does not deprive others of the ability to use it.¹⁰ There have been other theories suggesting some variation of those two principles, but depending on the approach chosen, there can be significantly distinct outcomes. A pharmaceutical company will likely advocate for a Schumpeterian model, but there is significant merit to Arrow’s view that without competition, a company can become complacent.

For many industries, the best innovation policy probably lies somewhere between the policy prescriptions proposed by Kitsch and Schumpeter. This is especially apparent in the pharmaceutical industry. Drugs are expensive to discover and often easy to copy, meaning that most would-be drug innovators need a guaranteed return on their R&D expenditures before they would be willing to undertake drug discovery. However, if a drug company can gain indefinite monopolies through adding additional exclusivity periods to profitable older drugs then there is little incentive to invest in the far riskier process of discovering new ones. This white paper intends to demonstrate some of the strategies pharmaceutical companies employ, particularly the use of patent thickets, to protect their monopolies and the consequences of those strategies to society. This white paper also argues that innovation policy should greatly restrict the ability of corporations to get additional patents on discovered drugs for anticompetitive purposes.

Patent Process for Drug Approvals

The new drug pipeline is a complex process that involves identifying a potential new drug candidate, running rigorous clinical trials, developing a way to scale the medication, and finally obtaining FDA approval. Once these hurdles are overcome, the company is granted exclusivity on the production and sale of that drug as a way to reward their innovation. Given the high cost of bringing a drug to market,¹¹ it seems logical that drug companies would do everything in their power to protect that investment, including filing many patents on their pre-approval discoveries.¹²

Since drug companies are filing these patents in the beginning of the process, some of those patents will already have part of their term used up before the drug arrives in the market.¹³ Current drug policy already accounts for this by providing Patent Term Restoration of up to five years, depending on a number of factors.¹⁴ Typically, the drug company can reap the benefits of exclusivity for the remaining period after which a generic or biosimilar company can enter the market and compete with the brand name drug.¹⁵ This is a function of the design of the system, one that rewards innovation by allowing drug manufacturers to enjoy the fruits of their labor, but that encourages competition to stimulate further innovation. If drug companies were allowed absolute and expansive monopoly on their drugs, there would be little incentive for established companies to research and develop new drugs because they would be guaranteed a constant stream of revenue. This would also create excessive barriers to both access and the development of new technologies that build upon older patented

⁹ *Id.* at 1604

¹⁰ *Id.* at 1605

¹¹ See Mark Terry, *The Median Cost of Bringing a Drug to Market is \$985 million*, Biospace <https://www.biospace.com/article/median-cost-of-bringing-a-new-drug-to-market-985-million/> (citing JAMA Network study finding that estimated median capitalized research and development cost per therapeutic product was \$985 million).

¹² Robin Feldman, *May your drug price be evergreen*, *Journal of Law and the Biosciences*, Vol. 5, Issue 3, 1, 9 (2018), <https://doi.org/10.1093/jlb/lisy022>

¹³ Feldman, *supra* note 11, at 9 (noting that estimates suggest that the average remaining patent period for a new drug is twelve years).

¹⁴ <https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-patent-term-restoration-program>

¹⁵ Feldman, *supra* note 11, at 10.



technologies. Current drug policy seeks to balance exclusivity rewards for innovation with the development of a public domain of knowledge that can be used to promote access through competition and the discovery of new innovations through the use of existing knowledge. Importantly, drug policy already accounts for lost time during the FDA approval process through Patent Term Restoration and there is no justification for drug companies to take matters into their own hands through excessive patenting.

The main source of drug policy is the Hatch-Waxman Act for small molecule drugs and the Biologics Price Competition and Innovation Act (BPCIA) for biologics.¹⁶ Small molecule drugs are “relatively simple chemical compounds that can be manufactured by chemical synthesis.”¹⁷ In contrast, biologics are made through the “synthesis of certain biological molecules (primarily proteins) in microorganisms and other living cells.”¹⁸ Generics are the bioequivalent version of small molecule drugs, whereas biosimilars are the “generic” versions of biologics. The difference is that chemical compounds can be exactly replicated, but because biologics are synthesized from biological materials, they cannot be replicated in the exact same way. Therefore, an acceptably close approximation to the biologic, one that is safe for a patient to switch to, is known as a biosimilar.¹⁹

The Hatch-Waxman Act facilitates the entry of generics by allowing generic companies to reference the safety and efficacy data from the brand-name company’s original drug application.²⁰ This speeds up drug approval and reduces duplicative costs. The main requirement is that the generic demonstrates bioequivalence. Once a generic is approved, state laws allow pharmacists to substitute a lower cost generic for a prescription for a brand name drug. This substitution is usually done automatically, with the generics competing solely on price. As a result, generic drug prices are on average 79% lower than the brand price before generic entry.²¹ Additionally, the Hatch-Waxman system encourages generic companies to hasten the entry of competition for drugs by rewarding the first generic to successfully challenge patents with a 180-day exclusivity.²²

On the biologics side, the process is significantly more complex and requires greater safety and efficacy testing.²³ More specifically, in the case of biologics, “the product is the process”²⁴ meaning that the reliance on living cells inherently causes variability in the system.²⁵ The law governing biosimilar production is the BPCIA, which was enacted as part of the Patient Protection and Affordable Care Act in 2010.²⁶ The BPCIA differs from the Hatch-Waxman Act in that an exclusivity of one year after commercial marketing is granted to the first biosimilar found to be interchangeable, which can be reduced if certain thresholds based on litigation are reached earlier.²⁷ This benefit is only granted to the applicant that has demonstrated that its product is both biosimilar to the reference product and can be expected to produce the same clinical result as the reference product.²⁸ The impact of biosimilar competition on drug prices is still being studied, as biosimilar competition is relatively new. An [IQVIA report](#) estimated that between 15%-45% average savings can be expected, with higher discounts possible in the future. The study projects \$100 billion in savings from biosimilar competition over the next five years using a 30%

¹⁶Feldman, *supra* note 11, at 9

¹⁷ Charles Oo, Points to Consider in Drug Development of Biologics and Small Molecules, Nuventra Pharma Sciences (2020) <https://www.nuventra.com/resources/blog/small-molecules-versus-biologics/>

¹⁸ *Id.*

¹⁹ Feldman, *supra* note 11, at 11.

²⁰ *Id.* at 10.

²¹ <https://www.fda.gov/media/133509/download>

²² Michael A. Carrier & Carl J. Minniti III, The New Antitrust Frontier, U. Ill. L. Rev. 1, 15 (2018)

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2982190.

²³ Feldman, *supra* note 11, at 10.

²⁴ Carrier, *supra* note 21, at 10 (citing James T. O’Reilly & Katherine A. Van Tassel, Food and Drug Administration).

²⁵ *Id.*

²⁶ Carrier, *supra* note 21, at 14.

²⁷ *Id.* at 15.

²⁸ *Id.* at 16.



average savings. In summary, statutes and legislation govern the drug manufacturing process in different ways with the goal of balancing incentives for innovation and competition.

Patent Thicketing

Ideas do not exist in a vacuum and, as such, they necessarily involve some input from society, either based on one's upbringing, such as a conversation with a friend or a stranger or even one's own experience. Great ideas spark innovation resulting in improvements to the status quo, which means that it is their cumulative nature that allows society to flourish.²⁹ As Carl Shapiro noted, innovation can be viewed as a huge scientific pyramid, where each inventor adds to the overall structure, allowing it to grow ever larger.³⁰ In the world of technology and pharmaceuticals, each individual innovator may stumble upon an obstacle, in the form of patents, that prevents that individual from contributing to the growth of the pyramid by requiring the manufacturer to give credit to each of the patent holders in the form of licenses. Depending on the number of patents and/or licenses created, this phenomenon can prevent the whole system from achieving its true purpose of promoting and stimulating innovation.³¹ This phenomenon has been defined as a "patent thicket." First described by Carl Shapiro, it is a "dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize a new technology."³² The term has been used in two different scenarios.³³ The first scenario occurs when multiple parties have overlapping patent rights on one product, requiring a potential manufacturer to negotiate licenses with each patent owner to bring the product to market without infringing (sometimes called the tragedy of the anticommons).³⁴ The second scenario involves a manufacturer's practice of "amassing a large number of patents relating to a single product," with the goal of blocking competitors from entering the market either by intimidating them, making it too costly, or making it excessively risky.³⁵ This second scenario is how some drug companies can successfully block generic or biosimilar entry.

The concept of patent thickets is not new. As a matter of fact, one of the first examples of a patent thicket (as described in the first scenario) dates back to the invention of the steamboat during the confederacy.³⁶ Robert Fulton is often credited with the invention of the steamboat, but historical evidence suggests that it was developed at the same time by many people.³⁷ Indeed, the confederacy's decision to leave patent policy up to each state created such a conflict over the conflicting rights in steamboat patents that it was one of the driving forces of assigning authority over patent rights to the federal government in the constitution.³⁸ A modern-day example of a patent thicket created what is known as the Smartphone Patent Wars. It is almost unimaginable to grasp that there are 250,000 active U.S. patents that are applicable to a smartphone.³⁹

²⁹ Olga Gurgula, *Strategic Accumulation of Patents in the Pharmaceutical Industry and Patent Thickets in Complex Technologies — Two Different Concepts Sharing Similar Features* (2016). IIC - International Review of Intellectual Property and Competition Law, Forthcoming, Queen Mary School of Law Legal Studies Research Paper No. 242/2016, Available at SSRN: <https://ssrn.com/abstract=2852056>.

³⁰ Shapiro, Carl, Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting (March 2001). Available at SSRN: <https://ssrn.com/abstract=273550>.

³¹ Gurgula, *supra* note 28, at 4.

³² Shapiro, *supra* note 29, at 3.

³³ Kevin T. Richards, Cong. Research Serv., R46221, Drug Pricing and Pharmaceutical Patenting Practices 27 (2020) <https://fas.org/sgp/crs/misc/R46221.pdf>.

³⁴ *Id.* at 27.

³⁵ *Id.*

³⁶ Lemley, Mark A., The Myth of the Sole Inventor (July 21, 2011). Stanford Public Law Working Paper No. 1856610, 110 Michigan Law Review 709 (2012), Available at SSRN: <https://ssrn.com/abstract=1856610>.

³⁷ *Id.* at 17.

³⁸ *Id.*

³⁹ *Too Many Patents*, Patent Progress, <https://www.patentprogress.org/systemic-problems/too-many-patents/>



These examples illustrate the challenges that can arise when the patent system allows its inefficiencies to prevent fair competition and innovation. How do these examples translate to the pharmaceutical world? In the context of pharmaceutical companies, “where complementary patents found in complex biopharmaceutical technologies are necessary for effective commercialization, manufacturers must negotiate individual licenses for any patented innovation they do not own.”⁴⁰ Additionally, pharmaceutical companies have been known to engage in “strategic accumulation of patents.”⁴¹ This strategy is analogous to the second scenario of patent thicketing. The practice enables pharmaceutical companies to artificially extend their monopoly by filing broad initial patents and, subsequently, filing several narrower patents on different product features of a single medical product effectively blocking the entry of any generic or biosimilar medications.⁴² A distinct pattern can be observed by analyzing the patent history of several blockbuster drugs that demonstrate a spike in patent applications related to different product features (e.g., on process, reformulations, etc) once the expiration of the core patent is approaching. A recent report analyzing the twelve best selling drugs in the United States revealed that pharmaceutical companies file hundreds of patent applications to extend their monopolies “far beyond the twenty years of protection intended under U.S. patent law.”⁴³ The concern that arises with this strategy is the correlation between the extension of these patents and the increase in drug prices across the nation.⁴⁴ More specifically, the top 12 grossing drugs of 2017 have had an average increase of 68% in prices since 2012.⁴⁵

Patent thicketing in the pharmaceutical industry involves bombarding the USPTO with patent applications over time in the hopes that enough are granted to prevent generic or biosimilar entry after the expiration of the original patents and incrementally extend the 20 year exclusivity that patents provide. These patents are often much weaker, and many have been later found to be invalid. Today, much patent thicketing is a planned strategy that starts from filing broad patents on the original discovery and then filing narrower patents on different aspects of the drug as time goes on. These patents include those that cover the compositions of matter, indications, methods of treatment, formulations, manufacturing processes, and things like the delivery devices and diagnostics. These patents are strategically drafted to prevent generic or biosimilar entry. For example, a company may patent every possible way of manufacturing a certain drug, including methods not currently used. It is difficult to design around patent claims in the pharmaceutical industry because of safety policies that require generics to be AB-rated to the drugs they reference and for biosimilars to be highly similar to the biologics they reference. As a result, while many of the patents in a thicket may be invalid, there are also valid patents that have the practical effect of barring generic and biosimilar entry even though they only cover minor aspects of a drug, its manufacturing, safety procedures, etc. This allows companies to recapture the entire value of the original drug discovery for an additional patent term with every granted patent. Therefore, it is not only erroneously granted patents that are the problem, but also patents that may functionally add no new value to patients but still block generic and biosimilar manufacturers who cannot design around these patents.

Examples

Humira (Biologic)

⁴⁰ Stu Woolman, Elliot Fishman & Michael Fisher, *Evidence of Patent Thickets in Complex Biopharmaceutical Technologies*, 53 IDEA 1, 56 (2013).

⁴¹ Gurgula, *supra* note 28, at 10.

⁴² Gurgula, *supra* note 28, at 11.

⁴³ Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving Up Drug Prices, I-Mak Report, 2 (2018) <http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf>.

⁴⁴ Christopher Rowland, Why Humira's Price Keeps Rising Despite FDA Approval of Generic Competition, Washington Post (2020) https://www.washingtonpost.com/business/economy/why-humiras-price-keeps-rising-despite-fda-approval-of-generic-competition/2020/01/07/549ed0ce-2e3a-11ea-bcb3-ac6482c4a92f_story.html (discussing recent report that Abbvie, Humira's manufacturer, increased the price of the drug in excess of 7 percent in 2020 following price hikes of 19 percent during 2017 and 2018).

⁴⁵ I-Mak Report, *supra* note 42, at 6.



Humira, the world’s number one selling drug, has been on the U.S. market since 2002. Since 2012, there has been a 144% increase in the drug’s price.⁴⁶ Additionally, at least 132 of approximately 247 patent applications have been granted for a total of 39 years blocking competition as of this writing.⁴⁷ The following table, from an AbbVie presentation, illustrates AbbVie’s patent thicketing strategy for Humira, which AbbVie refers to as a Patent Estate.

Broad U.S. Humira Patent Estate

Approved Indication	Rheumatoid Arthritis	Gastro Indications	Psoriasis	Psoriatic Arthritis	Ankylosing Spondylitis	Juvenile Idiopathic Arthritis	Hidradenitis Suppurativa
Composition of Matter	Expires Dec. 31, 2016						
Indication / Method of Treatment	4 patents Earliest Expiry: 2022	6 patents Earliest Expiry: 2022	3 patents Earliest Expiry: 2023	4 patents Earliest Expiry: 2023	3 patents Earliest Expiry: 2022	1 patent Expiry: 2030	1 Patent Expiry: 2031
Formulation	14 Patents Expire 2022 –2028						
Manufacturing	24 patents Expire 2027 – 2034						
Other (Device, Diagnostics, etc.)	15 patents Expire 2024–2032						

abbvie

AbbVie Long-Term Strategy © 2015 14

How does the Humira patent thicket work? Most of Humira’s patents were set to expire in 2016. A few years before the expiration date, AbbVie began applying for new patents on the medication.⁴⁸ This extensive patent accumulating strategy enabled AbbVie to retain monopoly on Humira in the United States for additional years. Biosimilar manufacturers challenged AbbVie’s patent thicket. However, probably due to the size of the thicket, all challenging biosimilar manufacturers eventually settled with a deal to enter the market in 2023, which is still at least decade before Humira’s final patents are due to expire.⁴⁹

In Europe, which has not allowed these same patent thickets, a key patent expired in 2018 and biosimilars entered into the market.⁵⁰ The United Kingdom’s National Health Service, which was spending more than £400 million (\$526 million) a year on Humira prior to the expiration of the patent, hopes that it will save at least £150 million a year by 2021 by switching to biosimilars.⁵¹ AbbVie itself offered discounts of up to 80% in some European countries to maintain its sales there.⁵² In contrast, the price of Humira continued climbing in the United States as

⁴⁶ *Id.* at 7.

⁴⁷ *Id.*

⁴⁸ Richards, *supra* note 32, at 26 (noting that the Biosimilar Council alleges that AbbVie filed seventy-five patents relating to Humira in the three years before biosimilar competition was set to begin, extending nominal patent protection through 2034).

⁴⁹ <https://www.biopharmadive.com/news/abbvie-boehringer-ingenheim-settle-humira-patent-biosimilar/554729/>

⁵⁰ Peter Loftus and Danise Roland, *By Adding Patents, Drugmaker Keeps Cheaper Humira Copies out of the U.S.*, Washington Post (2018) <https://www.wsj.com/articles/biosimilar-humira-goes-on-sale-in-europe-widening-gap-with-u-s-1539687603>.

⁵¹ *Id.*

⁵² <https://www.fiercepharma.com/pharma/abbvie-offers-up-80-humira-discount-eu-tender-market-to-hold-off-biosims-report>

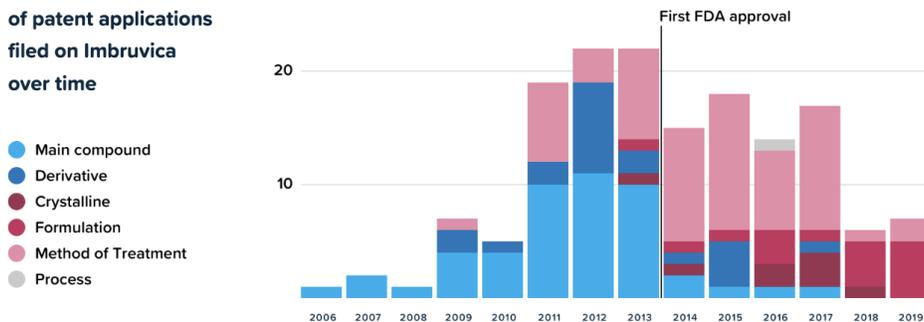


the newly approved patents effectively blocked the entry of biosimilars into the American market.⁵³ AbbVie contends that these new patents are legitimate and necessary for the company to protect investment in development costs to bring an innovative drug to market.⁵⁴ Protecting one’s investment is a legitimate strategy. However, the patent system was created to foster competition and, as mandated by the Constitution, affords only a limited period of exclusivity. When a drug manufacturer’s strategy has the intent of effectively blocking any competition while, simultaneously, increasing the price of the treatment to the consumer after the original exclusivity period has been exhausted, the legitimacy of the strategy starts to be questioned.

Imbruvica (Small Molecule)

Humira might be the classic example of patent thicketing in the pharmaceutical industry. However, it is not the only one.⁵⁵ A recent study by I-MAK investigated the patent strategy used by Imbruvica with the goal of understanding how “patent walls” are created.⁵⁶ The study found that Imbruvica has 165 patent applications of which 88 were granted.⁵⁷ Additionally, 55% of the patent applications were filed after its first FDA approval with 58% of these applications covering indications and formulations, not the active substance.⁵⁸ The following graph illustrates the shift in the types of patent applications filed over the years, especially after the first FDA approval.⁵⁹

Figure 3: The types of patent applications filed on Imbruvica over time



The analysis of the types of patent applications demonstrated that, initially, the patent applications were broad, covering over 100 potential applications for the drug.⁶⁰ After the first FDA approval, the applications became narrower focusing on the formulation and method of treatment and, subsequently, extended the exclusivity more than nine years beyond the expiration of the initial patent.⁶¹ The report questioned whether the manufacturer was aware of the different types of uses and formulations at the time the initial patent was filed, which could signal an intent to artificially extend the monopoly.⁶²

How Patent Thicketing Bolsters Other Anticompetitive Strategies

⁵³ Peter Loftus and Danise Roland, *supra* note 49.

⁵⁴ *Id.*

⁵⁵ Richards, *supra* note 32, at 29 (highlighting that Johnson & Johnson and Biogen/Genentech engage in similar practices).

⁵⁶ *Overpatented Overpriced, Imbruvica’s Patent Wall*, 1, 4, I-Mak Report <https://www.i-mak.org/imbruvica/>.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.* at 5.



Patent thicketing is only one of a variety of strategies pharmaceutical companies have used to maintain their monopoly on a profitable drug. These strategies may differ on their manner of execution, but patent thicketing provides an opportunity to make other strategies to delay generics more effective. The best example of this is called product hopping, a strategy that so commonly relies on obtaining new patents that it is often confused for patent thicketing.

Product Hopping is a strategy by which a brand “uses its current dominant position to switch doctors, pharmacists, and consumers to a newer version of the same (or similar drug) with later-expiring patents.”⁶³ Examples of the new version of the product include an extended release form, new dosage, or a chemical change.⁶⁴ The two main forms of product hopping are: “hard switch” or “soft switch.”⁶⁵ A hard switch occurs when the brand removes the original product from the market while a soft switch occurs where the brand leaves the original product in the market.⁶⁶

The challenge with product hopping is that by changing the formulation or other aspects of the drug, the branded drug company can prevent the generic version from entering the market. All states have enacted drug product selection (DPS) laws.⁶⁷ These laws, created to protect consumers by lowering consumer prices, allow and/or require pharmacists to fill a prescription with a generic version of the drug if available.⁶⁸ Typically, pharmacists may only substitute a small molecule generic drug for a branded drug if the drug is AB-rated by the FDA to the branded drug, meaning that it must have the same active ingredient, form, dosage, strength, and safety and efficacy profile as the branded drug.⁶⁹ When a brand name drug changes the formulation as part of its product hopping strategy, the generic version may no longer be substituted, preserving the brand name’s exclusivity for an additional period.⁷⁰ In recent years, product hopping has been challenged in courts under the antitrust laws and found, in certain circumstances, to be in violation of Section 2 of the Sherman Act.⁷¹

Product hopping borrows somewhat from the patent thicketing in that the product hops are often strategically patented not as part of an overall innovation strategy but as one which, by design, prevents competition on older drugs for which the lion's share of the up-front innovation costs have been paid. This is done by patenting the changes made to create the product hop. A successful product hop makes forecloses generic uptake on the original product, and the patents foreclose generic entry on the new product until the expiration of these new patents. However, product hopping differs from patent thicketing in that patent thicketing does not require any changes in the original drug, only that the USPTO continues to grant patents covering the original drug. Similarly, product hopping does not require patents in the hop to be successful due to the lengthy amount of time it takes for a generic or biosimilar manufacturer to develop a product that can be meet the guidelines for substitution and acquire FDA approval.

When companies engage in these practices with the intent of pushing away any competition and, simultaneously raising prices, the consequences can have devastating effects both in economic terms and in harming patients by blocking affordable access to much needed medications. Patent thicketing provides a way to make such strategies more effective and also more difficult to defeat.

⁶³ Richards, *supra* note 32, at 23.

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ *Id.* at 25.

⁶⁹ *Id.* at 22.

⁷⁰ *Id.*

⁷¹ *Id.* at 26.



Potential Solutions

As discussed above, the main consequence of creating a dense web of patents is blocking or delaying the entry of generics or biosimilars into the market. This strategy serves three main functions. First, it preserves the exclusivity of the drug by ensuring that even if a core patent expires or is invalidated, there are additional patents on the product that may be enforced to prevent a generic or biosimilar from entering the market.⁷² Second, this dense web of patents fosters an environment of uncertainty for the generic or biosimilar company regarding the timeframe for the expiration of the patent.⁷³ This concern arises primarily from potential gaps between the core patent and the secondary patents, which might result in infringement.⁷⁴ Third, this practice preserves the companies' freedom to continue exploiting their monopoly by discouraging risk-averse generic or biosimilar companies from entering the market or potentially forcing companies to wait until they have a clearer understanding of the extent of the thicket.⁷⁵

The net result is that patent thickets create a barrier to generic or biosimilar entry by making it too risky, too expensive, and too time consuming to defeat any particular thicket and expect a return on that investment. A recent study published in Health Affairs found that delays in market entry of generic drugs cost Medicaid an excess of \$761 million over seven years.⁷⁶ Additionally, patent litigation was the most common cause of generic entry delays.⁷⁷ The study concluded that policies that expedite the resolution of patent challenges are needed to ensure the timely entry of generic drugs.⁷⁸

Solutions must be explored that can effectively tackle the issue of patenting thicketing strategies and its consequences to patients and payors, including the U.S. government. These solutions should be directed at two goals. First, patents should be reserved as a reward for innovation and follow-on patents sought purely to prevent competition should be discouraged. Patent rights can be instrumental in rewarding innovation, but, when used in a manner that creates an indefinite monopoly, they become problematic and there is an incentive to file weak patent applications in the hopes that enough are granted to create a thicket even if they are later found to be invalid.

Second, the date of generic or biosimilar entry should, to the extent possible, be clear and decided as early as possible. This means policy decisions must be made on how to address follow-on innovation. Additional innovation for a drug can occur after FDA approval, and it may be good policy to reward this innovation, but not in a way that completely blocks generic or biosimilar competition indefinitely. Companies can currently use follow-on patents strategically to block any generic or biosimilar entry, even on the original drug whose exclusivities have expired. This means that follow-on innovations that would normally have little-to-no value, like a capsule instead of a pill, can recapture the value of the original invention by preventing entry. This creates the incentive to patent every way to manufacture a particular drug, or the methods to safely administer a drug. These innovations might not be worth pursuing without such a large reward and could divert resources away from more important research and development. However, policy should not be adopted that completely discourage follow-on innovations with value to patients. Rather, policies should be explored that would appropriately reward these follow-on innovations based on the value they add.

⁷² Gurgula, *supra* note 28, at 14.

⁷³ *Id.* at 15.

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ Estimating The Cost Of Delayed Generic Drug Entry To Medicaid
Chintan V. Dave, Michael S. Sinha, Reed F. Beall, and Aaron S. Kesselheim
Health Affairs 2020 39:6, 1011-1017 [Estimating The Cost Of Delayed Generic Drug Entry To Medicaid](#).

⁷⁷ *Id.*

⁷⁸ *Id.*



The current incentives to patent are simply too great for a company not to engage in a patent thicket strategy that is far removed from the incentive the Constitution intended: “to promote the progress of science and useful arts.”⁷⁹ For example, the biologic Humira makes over \$50 million in revenue every day it is protected by patents.⁸⁰ While data is still being collected on the price effects of biosimilar competition, the price of a small-molecule drug drops by about 80% on average after the entry of robust generic competition. The price of Humira has seen this same 80% price decrease in some European countries where it’s patent rights have expired.⁸¹ This means that AbbVie makes tens of millions every day it can keep biosimilar competition on Humira out of the U.S. market. This incentive justifies the expense of all of the patent abuse and other tactics AbbVie uses to keep biosimilars out of the market. Policy decisions should be made with the goal of ending these incentives to gain patent and regulatory systems for any extension of monopoly term.

We recognize that this problem is complex and the best solutions might not have been proposed yet. The following section will discuss some of existing and proposed solutions that are promising in resolving these issues:

Legislative Solutions

Strengthen IPR

Inter Partes Review (IPR) is a process created by the 2011 America Invents Act (AIA) that provides a low-cost alternative to patent litigation by using patent experts within the USPTO to review certain granted patents.⁸² The goal is to provide a more cost-effective, efficient alternative to litigation for certain types of patent disputes.⁸³ The IPR process improves the overall quality of issued and unexpired patents by providing an efficient way of testing the validity of patents and eliminating those that were erroneously granted. More specifically, the Supreme Court has recently described IPR as a way to “weed out” bad patents.⁸⁴ This is helpful in the drug context because the patents obtained to delay competition or often weaker and may be invalid.⁸⁵ Some of the advantages of IPR, aside from the lower cost, include the faster time frame for a decision and the assurance that a panel of patent expert administrative judges is reviewing the patent, as opposed to a district court judges who are generalists and may not have the same expertise.

Critics of IPR have called it a “patent death squad.” However, when looking at the actual data, it is clear that this label is hyperbolic and erroneous. In FY2019, the USPTO granted a total of 391,103 total patents.⁸⁶ In contrast, from September 16, 2012 to March 31, 2020 there were only a total of 11,307 petitions for trials by the PTAB.⁸⁷ PTAB proceedings represent a minuscule fraction of the number of patents being granted on a yearly basis. On average, there were about 1,413 petitions for trial by the PTAB per year since the AIA went into effect.⁸⁸

⁷⁹ U.S. Const. art. I, § 8.

⁸⁰ http://www.i-mak.org/wp-content/uploads/2018/09/i-mak.humira.report.final_.0917.pdf

⁸¹ <https://www.reuters.com/article/us-abbvie-results-humira/humira-biosimilars-available-at-up-to-80-percent-discount-in-europe-abbvie-idUSKCN1N71NZ>.

⁸² CAPA Patent Primer - What is Inter Partes Review <https://www.capanow.org/wp-content/uploads/2020/07/CAPA-Patent-Primer-Inter-Partes-Review.pdf>.

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ Price, W.N., Rai, A.K. How logically impossible patents block biosimilars. *Nat Biotechnol* **37**, 862–863 (2019). <https://doi.org/10.1038/s41587-019-0196-x>

⁸⁶ U.S. Patent Statistics Chart Calendar Years 1963-2019 https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (updated 04/2020).

⁸⁷ United States Patent and Trademark Office, Trial Statistics Report, 3 (2020) https://www.uspto.gov/sites/default/files/documents/trial_statistics_20200331.pdf.

⁸⁸ *Id.* at 10.



Additionally, in 2019, only 63% of petitions were instituted and, of those that were instituted, 21% were found unpatentable.⁸⁹ When looking at absolute numbers, it is evident that the IPR and PTAB process is not a patent death squad, and is actually probably underutilized. IPR only invalidates 0.3% of the drug patents and 0.12% of the total patents issued annually.⁹⁰

IPRs are important because they are an efficient alternative for the USPTO to cancel patent claims issued in error. Since the average patent application only gets about 19 hours of attention, the IPR process allows the USPTO to correct errors in issued patents.⁹¹ The IPR process should be strengthened to provide generic and biosimilar companies with a cost-effective alternative to litigation because doing so will ultimately benefit consumer welfare and will encourage pharmaceutical companies to continue innovating to create new drugs.⁹²

Affordable Prescriptions for Patients Act

This bill was introduced in June 2019 with the goal of amending the Federal Trade Commission Act to prohibit anticompetitive behaviors by drug product manufacturers.⁹³ It addresses patent thicketing and product hopping with incremental changes aimed at discouraging abuses of the drug and patent systems. The idea is to curb major drug companies' anticompetitive use of patents by encouraging competition and giving patients greater access to prescription drugs at a cheaper cost without stifling innovation or infringing on patent rights.⁹⁴ The bill instructs the FTC to police anticompetitive instances of product hopping and places a cap on the total number of patents that can be used in patent litigation to block a biosimilar competitor. This type of legislation provides a starting point to restore the balance in the system by encouraging innovation but setting clear limits to the types of strategies pharmaceutical companies can use to artificially extend their monopolies.

Biologic Patent Transparency Act

This bipartisan bill was introduced in March 2019 with the aim of ending patenting practices that make it difficult for biosimilars to enter the market by increasing transparency in the prescription drug market.⁹⁵ If this bill becomes law, it would codify the publication of FDA's Purple Book as a single, searchable list, and would require additional information (including composition patents, patents claiming methods of use, and patents claiming methods of manufacture).⁹⁶ This bill increases transparency, which in turn should reduce some of the risks faced by biosimilar companies in challenging patent thickets. It also provides new tools for researchers to identify anticompetitive uses of patent thicketing so that targeted solutions can be developed.

Increase Certainty Around the Time of Generic or Biosimilar Competition

⁸⁹ U.S. Patent Statistics Chart Calendar, *supra* note 97.

⁹⁰ <https://www.capanow.org/wp-content/uploads/2020/02/CAPA-IPR-Infographic-FINAL.pdf>.

⁹¹ CAPA Patent Primer, *supra* note 94.

⁹² *Id.* (discussing that IPR has saved at least \$2.31 billion in deadweight loss due to litigation).

⁹³ Affordable Prescriptions for Patients Act of 2019, S.1416, 116th Cong. (1st Sess. 2019). <https://www.congress.gov/bill/116th-congress/senate-bill/1416/text>.

⁹⁴ Cornyn, *Blumenthal Introduce Bill to Prevent Drug Companies from Abusing Patent System* (2019)

<https://www.cornyn.senate.gov/content/news/cornyn-blumenthal-introduce-bill-prevent-drug-companies-abusing-patent-system>.

⁹⁵ Allison Incerro, *Bipartisan Patent Transparency Bill Introduced in House of Representatives*, AJMC Center for Biosimilars (2019), <https://www.centerforbiosimilars.com/news/bipartisan-patent-transparency-bill-introduced-in-house-of-representatives>.

⁹⁶ *Id.*



Professor Robin Feldman, a drug policy expert at UC Hastings College of the Law, has suggested a policy called one-and-done to set a date certain for generic or biosimilar competition.⁹⁷ This policy idea is that every approved new drug should have one period of exclusivity after which generic competition must be permitted. One-and-done, as originally proposed, would have the drug originator select the exclusivity they wish to use at the time of approval and then the date in which generic entry becomes possible could be set and published by the FDA (the drug originator would presumably pick the longest exclusivity available). This policy would change current incentives, as no degree of legal maneuvering could extend a drug's monopoly once the date of competitive entry has been set. This may encourage companies to invest more in new drug pipelines and free up the resources being expended on strategies to extend the exclusivities of current blockbuster drugs. However, there are concerns that there could be unintended consequences in that follow-on innovation would go from being over-incentivized to under-incentivized. This means that companies may not invest in beneficial changes or advancements to existing medicines.

One-and-done is a useful starting point for conceptualizing drug policy that is pro-competition and difficult to game, but there are many options for increasing certainty on the date of competition and re-aligning incentives. Increasing the certainty of the date of generic and biosimilar competition is a promising potential solution. If pursued, decisions will need to be made on whether and how to account for follow-on innovation, how to best balance incentives, and how to safeguard the resulting legislation against later gamesmanship.

Antitrust

One of the proposed solutions to dealing with the patent thicketing problem is using antitrust law. Antitrust laws were developed with the goal of protecting consumers from predatory business practices by promoting vigorous competition.⁹⁸ The idea is that when pharmaceutical companies build these webs of patents, many of which are not innovative but are simply building upon a patent that already exists, they are engaging in anticompetitive practices.⁹⁹ A recent class action lawsuit against AbbVie, Humira's manufacturer, attempted to dispute the company's patent abuse by alleging anticompetitive practices under antitrust law.¹⁰⁰ The district court opinion, dismissing the suit, noted that antitrust doctrine may not be the most appropriate doctrine because it will not "revamp the FDA's biologics application process or the USPTO's drug patenting process."¹⁰¹ The court appeared to be signaling that any meaningful change to this process would need to arise from the legislative branch.¹⁰² This case is currently on appeal to the Seventh Circuit.

The availability of antitrust remedies are greatly restricted by the *Noerr-Pennington Doctrine*, which protects the right to petition the U.S. government even for anticompetitive ends.¹⁰³ This includes the right to apply for patents, except for in limited circumstances such as committing fraud on the patent office. However, there is an argument that a pattern of baseless petitions would not receive *Noerr-Pennington* protection even is some of those

⁹⁷ <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/>.

⁹⁸ FTC Guide to Antitrust Laws <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws>.

⁹⁹ Richards, *supra* note 32, at 24.

¹⁰⁰ The Drug Pricing Debate: Why Drug Innovation, Access & Affordability Matter More Than Ever During COVID-19, <https://youtu.be/hquriAm00Gs>.

¹⁰¹ Memorandum Opinion and Order, at 32, In re Humira (Adalimumab) Antitrust Litig., (2020) U.S. Dist. LEXIS 99782.

¹⁰² *Id.*

¹⁰³ <https://www.ftc.gov/sites/default/files/documents/reports/ftc-staff-report-concerning-enforcement-perspectives-noerr-pennington-doctrine/p013518enfperspectnoerr-penningtondoctrine.pdf>.



petitions result in valid patents.¹⁰⁴ This argument is currently being tested at the Seventh Circuit, and the result of that case will likely signal whether antitrust will be an available tool for curbing patent thicketing.

Conclusion

As Carl Shapiro noted, it is the cumulative effect of innovation that allows progress. Patent thicketing strategies, among others, allow pharmaceutical companies to not only block competition, but also to benefit from increasing prices on the same drugs. Rewarding innovation is essential, but not at the cost of the consumer and not when human lives are on the line. The COVID-19 pandemic has shown the need for pharmaceutical companies to continue innovating and preparing for new viruses, diseases, and scenarios. Increasing the transparency of this system, encouraging competition, and rewarding truly novel ways of utilizing drugs should be some of the goals of both the industry and any governmental regulations. Implementing some of the solutions discussed above can provide a starting point to restore the balance between competition and innovation making those goals a reality.

¹⁰⁴ See, e.g., Brief of Amicus Curiae Open Markets, available at <https://static1.squarespace.com/static/5e449c8c3ef68d752f3e70dc/t/5f85c2b9e2770d320d2b53de/1602601658675/Humira+Amicus+Brief+%28file-stamped%29.pdf>.