



# Patent Reform and Pharmaceuticals: The Key to Lower Drug Prices

By Wayne T. Brough

**Identifying unnecessary impediments to a more competitive market for lifesaving drugs is vital to the drug-price debate.**

## Introduction

While there can be no doubt that the pharmaceutical industry is a significant and productive sector of the U.S. economy, it is not above criticism. For example, one report catalogues various tactics drug companies use to exploit the patent system to extend product exclusivity far beyond the 20 years stipulated by law.<sup>1</sup> This impedes new entrants into the marketplace and imposes significant burdens on consumers and patients through higher prices. Ultimately, excessive patenting may also reduce the pace of innovation, which subverts the stated goal of patent policy: to incentivize innovation such that the dispersion of knowledge increases, benefitting society as a whole.

This paper examines the market structure of the pharmaceutical sector as well as the strategic patenting practices of drug companies to identify potentially adverse impacts on competition and consumer welfare. Additionally, this study reviews legislative and regulatory changes that address concerns over the functioning of the

## Table of Contents

Introduction	1
Patents and Innovation	2
Structure of the Pharmaceutical Sector	2
Economic Forces at Work: Market Structure and Pharmaceutical Prices	5
Pharmaceutical Markets and Patent Cliffs	7
Promoting Innovation or Protecting Monopolies?	8
Evergreening	9
Patent Thickets	9
Product Hopping	10
Revisiting the Policy Framework	11
Patent Trial and Appeal Board	12
International Trade Commission	14
Conclusion	14
About the Author	15

1. Kevin T. Richards et al., “Drug Pricing and Pharmaceutical Patenting Practices,” Congressional Research Service, Feb. 11, 2020. <https://crsreports.congress.gov/product/pdf/R/R46221>.

patent system to identify policy changes that may significantly improve the system. These legislative and regulatory changes should ensure that the patent system remains true to the vital role of promoting invention and innovation while providing access to pharmaceutical products in a market where prices are not held artificially high.

## Patents and Innovation

Patents date back centuries and have been adopted by most nations as a key policy tool for promoting innovation.<sup>2</sup> The primary goal of patent policy is to provide incentives to bring new inventions and products into existence, fostering the creative process in ways that benefit society. To do so, patents create a defined period of exclusivity for inventors, allowing them an opportunity to recoup the costs of their inventions. During this period—usually 20 years in the United States—the owner of a patent can assert it against others who may infringe upon it. The owner of the patent has the sole “right to exclude others from making, using, offering for sale, or selling the invention in the United States, or importing the invention into the United States.”<sup>3</sup> Importantly, once a patent issues, it is assumed valid, which means any attempt to challenge or invalidate the patent requires meeting a higher legal standard of “clear and convincing” evidence to be successful.

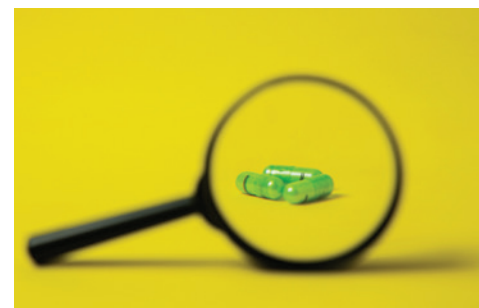
In turn, the inventor provides a description of the invention so that it becomes available to all once the period of exclusivity ends. Section 112 of the Patent Act stipulates the public disclosure the patentee must provide in order to receive a patent:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.<sup>4</sup>

This grand bargain—a period of exclusivity that ultimately yields openly accessible knowledge—is a key policy tool for facilitating invention and innovation that successfully enhances productivity and boosts economic growth. Yet, despite being straightforward procedurally, issuing patents has become problematic, especially in the last few decades. The institutional structure of the patent office, the complexity of litigation and the strategic behavior of interested parties have posed challenges to patent quality and innovation while generating an increasing number of legal disputes surrounding the validity of patents. Patent laws govern what is patentable, what standards are required to receive a patent, how that patent is defined and how invalid patents are challenged—each of which pose their own legal challenges. This is especially true in research and development (R&D)-intensive industries, such as pharmaceuticals.

## Structure of the Pharmaceutical Sector

The pharmaceutical industry requires substantial investments in R&D and faces significant regulatory compliance burdens when discovering and producing new life-saving drugs and medical products. Patent policy establishes the framework for



*Importantly, once a patent issues, it is assumed valid, which means any attempt to challenge or invalidate the patent requires meeting a higher legal standard of “clear and convincing” evidence to be successful.*

2. Wayne T. Brough, “Innovation or Monopoly? Making Patents Work,” R Street Policy Study No. 270, November 2022. <https://www.rstreet.org/2022/11/30/innovation-or-monopoly-making-patents-work>.

3. “Content and Term of Patent; Provisional Rights” 35 U.S.C., § 154, (a)(1).

4. “Specification,” 35 U.S. C. § 112.

bringing such new drugs to market. In fact, the business model for pharmaceutical companies is a direct response to patent policy. It is not surprising, therefore, that pharmaceutical companies proactively engage in legal and policy debates surrounding the patent system. Nor should it be surprising that these companies have developed strategies to maximize the rents they can extract from the patent system.

The biopharmaceutical sector in the United States has become a major contributor to U.S. gross domestic product (GDP), as it is responsible for 3.7 percent of all U.S. economic output with over 903,000 employees in 2020.<sup>5</sup> Globally, pharmaceutical sales were valued at \$1.4 trillion in 2021, with U.S. biopharmaceutical companies representing almost half of all pharmaceutical sales.<sup>6</sup> The pharmaceutical industry is perhaps the most R&D-intensive industry in the U.S. economy. One study found that, on a per-employee basis, the total R&D costs of pharmaceutical companies are more than twice as high as all other sectors.<sup>7</sup> Only the computer and electronics industry spends more, but these costs are dispersed across far more employees.<sup>8</sup>

At the same time, the costs of bringing a drug to market are also considerable, requiring investments in both R&D and the regulatory approval process. One recent estimate suggests that it costs pharmaceutical companies, on average, between \$314 million and \$2.8 billion per new drug brought to market. The median cost of R&D for a new drug was estimated to be \$1.1 billion per product.<sup>9</sup> However, it should be noted that there is some debate over this number. For example, some researchers have examined how much of the research is focused on new drugs versus extending the franchise of an existing drug, among other things.<sup>10</sup> These costs have steadily increased over time; one report found that, in 2019, drug companies spent \$83 billion on R&D—10 times what was spent per year in the 1980s.<sup>11</sup>

Patents play a key role in the constant stream of new life-saving products coming to market by allowing drug companies to recoup these significant upfront investments in R&D. The industry asserts that strong patents are critical for the development of new drugs, which can typically take 10 years to develop and bring to market, given the extent of research and time required for approval by the Food and Drug Administration (FDA).<sup>12</sup> Yet, policymakers understand that these periods of exclusivity are akin to a monopoly grant that can have adverse effects on market activity by limiting the ability of others attempting to bring new drugs to market. As a result, consumers and patients may pay significantly higher prices as competition is artificially constrained and prices remain well above the competitive level.

*Globally, pharmaceutical sales were valued at*

**\$1.4 trillion** ◀ • • •

*in 2021, with U.S. biopharmaceutical companies representing almost half of all pharmaceutical sales.*

5. TEconomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2020 National and State Estimates," Pharmaceutical Research and Manufacturers of America, March 2022, p. 8. <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/2020-Biopharma-Jobs-ImpactsMarch-2022-Release.pdf>.
6. Matej Mikulic, "Global pharmaceutical industry - statistics & facts," Statista, Oct. 12, 2021. [https://www.statista.com/topics/1764/global-pharmaceutical-industry/#topicHeader\\_\\_wrapper](https://www.statista.com/topics/1764/global-pharmaceutical-industry/#topicHeader__wrapper).
7. Darius N. Lakdawalla, "The Economics of the Pharmaceutical Industry," *Journal of Economic Literature* 56:2 (June 2018), pp. 397-449. <https://www.aeaweb.org/articles?id=10.1257/jel.20161327>.
8. Raymond M. Wolfe, "Businesses Spent Over a Half Trillion Dollars for R&D Performance in the United States During 2020, a 9.1% Increase Over 2019," National Center for Science and Engineering Statistics, Oct. 4, 2022. <https://nces.nsf.gov/pubs/nsf22343>.
9. Oliver J. Wouters et al., "Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018," *Journal of the American Medical Association* 323:9 (March 2020), pp. 844-853. <https://pubmed.ncbi.nlm.nih.gov/32125404>.
10. Richard G. Frank and Kathleen Hannick, "5 things to understand about pharmaceutical R&D," USC-Brookings Schaeffer on Health Policy, June 2, 2022. <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2022/06/02/five-things-to-understand-about-pharmaceutical-rd>.
11. David Austin and Tamara Hayford, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, April 2021. <https://www.cbo.gov/publication/57126>.
12. Laura O'Donnell, "A New Model for Drug Development," Permira, June 22, 2022. <https://www.permira.com/about/insights/a-new-model-for-drug-development>.

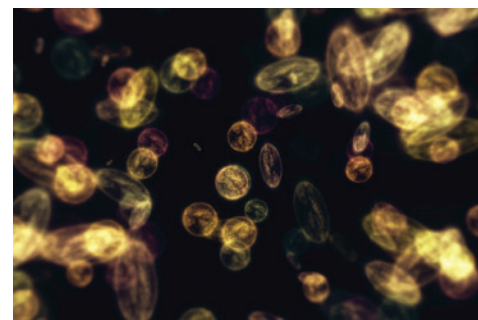
Congress enacted legislation to address concerns that patents may impede competition rather than promote innovation in the pharmaceutical industry. Rising concerns over the high cost of pharmaceuticals led to the passage of the “Drug Price Competition and Patent Term Restoration Act of 1984,” more commonly known as the Hatch-Waxman Act.<sup>13</sup> Essentially, this law aimed to inject competition into the pharmaceutical market by opening the market to generic drug manufacturers. For drugs that were coming off patent, a new abbreviated drug-approval process was set, helping to establish the generic drug industry.

In addition to reforms made to the FDA drug-approval process, the legislation also changed patent policy, including the creation of a streamlined process for patent litigation, a safe harbor that allows generics to begin research on generic substitutes prior to a patent’s expiration, and a 180-day period of exclusivity for the first generic to enter the market.<sup>14</sup> The goal of these changes was to increase competition, expedite new entry and drive down prices as patents moved toward expiration.

These policies targeted small-molecule drugs, which were the most prevalent therapies in the 1980s. Traditionally, prescription drugs have been created by chemically processing small molecules, resulting in vastly improved health care and quality of life. Yet research and technology has since advanced, leading to the introduction of biologics, which are fundamentally different than chemically derived small-molecule drugs. Advances in biotechnology led to protein-based drug therapies developed from living organisms that have been genetically modified to target various specific conditions. Biologics tend to be larger and more complex than traditional small-molecule drugs and are currently used to treat a wide array of diseases and conditions including cancer, diabetes, acquired immunodeficiency syndrome and Alzheimer’s.<sup>15</sup> Many of today’s blockbuster drugs are biologics, including Enbrel, a popular treatment for rheumatoid arthritis, and Herceptin, a treatment for breast cancer.<sup>16</sup>

While biologics have become more prevalent in recent years, they pose unique challenges for new entrants seeking to bring rival products to market as patents expire. In particular, biologics are living organisms, making it difficult to apply the FDA’s bioequivalent requirements for safety and efficacy used for small-molecule generic drugs.<sup>17</sup> In this regard, the Hatch-Waxman Act’s abbreviated new drug approval is not directly applicable to the production of biologics. At the same time, biologics are costlier to develop and more expensive to produce, making it difficult for lower-cost competitors to design similar products that could compete in the marketplace.<sup>18</sup>

Consequently, Congress returned to the issue of generic competition, this time to specifically facilitate the entrance of “biosimilars,” which are the generic versions of biologics. In 2009, Congress passed the “Biologics Price Competition and Innovation Act” (BPCIA).<sup>19</sup> Included as part of the Patient Protection and Affordable Care Act, the BPCIA created an expedited pathway for the approval of biosimilars that could be demonstrated to be “highly similar or interchangeable” with an approved biologic



*While biologics have become more prevalent in recent years, they pose unique challenges for new entrants seeking to bring rival products to market as patents expire.*

13. Pub. L. No. 98-417. <https://www.govinfo.gov/app/details/STATUTE-98/STATUTE-98-Pg1585>.

14. John R. Thomas, “The Hatch-Waxman Act: A Primer,” Congressional Research Service, Sept. 28, 2016. <https://crsreports.congress.gov/product/pdf/R/R44643>.

15. Thomas Morrow and Linda Hull Felcone, “Defining the difference: What Makes Biologics Unique,” *Biotechnology Healthcare* 1:4 (September 2004), pp. 24-29. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564302>.

16. “Top 10 blockbuster biotech drugs: next biosimilar targets?” Generics and Biosimilars Initiative Online, Feb. 12, 2009. <https://www.gabionline.net/biosimilars/news/Top-10-blockbuster-biotech-drugs-next-biosimilar-targets>.

17. Thomas, p. 16. <https://crsreports.congress.gov/product/pdf/R/R44643>.

18. “Research and Development in the Pharmaceutical Industry,” p. 22. <https://www.cbo.gov/publication/57126>.

19. Pub. L. No. 111-148, §§ 7001-7003. <https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf>.



product. This requires there be “no clinically meaningful differences between the two products in safety, purity, and potency.”<sup>20</sup> Although more complicated than demonstrating the safety and efficacy of small molecule generics, the new law did provide opportunities for quicker entry into the market for biologics.

In the wake of legislation and the ensuing regulatory reform, the generic sector of the pharmaceutical industry expanded. It has since evolved into an important and thriving component of the pharmaceutical industry. A recent report from a generic pharmaceutical trade group found that 91 percent of all prescriptions in the United States are now filled by generics and biosimilars, leading to overall savings of \$373 billion in 2021.<sup>21</sup> Additionally, researchers have found that biosimilars, on average, are priced 30 percent below their biologic alternative. While not as significant as the price reductions observed with the small-molecule generics, this decrease in price is still significant and is clearly limited by the substantially higher costs of producing more complex biosimilars.

While these savings are substantial, drug prices remain high, particularly for brand name drugs. In January 2022, there were 33 FDA-approved biologics; 21 are available in the market, whereas 10 experienced delayed market entry due to litigation over patents. Currently, there are an additional 108 biosimilars in development, and growth in this sector is expected to be robust. Sales are expected to reach \$80 billion over the next five years, and one study estimated the increasing availability of biosimilars to yield as much as \$100 billion in savings over the next five years.<sup>22</sup>



*A recent report found that 91 percent of all prescriptions in the United States are now filled by generics and biosimilars, leading to overall savings of \$373 billion in 2021.*

## **Economic Forces at Work: Market Structure and Pharmaceutical Prices**

While patent policy is a key component of drug pricing, the broader market structure of the pharmaceutical sector is also important. One study identified several factors that affect the affordability of drugs, including the “interaction of market power, health insurance, and the lack of effective incentives for controlling product price;” the design of insurance benefits; information asymmetries and unequal bargaining power between buyers and sellers; and others.<sup>23</sup> Yet patents contribute significantly to many of these factors, creating idiosyncrasies in pharmaceutical markets not seen in other markets. Health care costs are often paid by third parties, either private insurance companies or direct government transfers. Advertising in the United States can play a role unseen in other health care systems, and traditional forces of supply and demand can be muted in ways that make it difficult to see responses that would be expected in more competitive markets. These market characteristics generate a unique policy framework for the pharmaceutical sector and impact the degree of competition that is feasible in the therapeutic drug market. To the extent these broader elements shape market structure for pharmaceutical drugs, it becomes even more important to optimize patent policies to ensure that patents do not unnecessarily impede competition and new entrants.

20. U.S. Department of Health and Human Services, “Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Guidance for Industry,” Food and Drug Administration, April 2015. <https://www.fda.gov/media/82647/download>.

21. “The U.S. Generic and Biosimilars Savings Report,” Association for Accessible Medicines, September 2022, p. 8. <https://accessiblemeds.org/sites/default/files/2022-09/AAM-2022-Generic-Biosimilar-Medicines-Savings-Report.pdf>.

22. Murray Aitken et. al., “Biosimilars in the United States, 2020-24,” IQVIA Institute, October 2020, p. 2. <https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024>.

23. The National Academies of Sciences, Engineering, and Medicine, *Making Medicines Affordable: A National Imperative*, (The National Academies Press, 2018), p. 73. <https://doi.org/10.17226/24946>.

The pharmaceutical industry is unique in part due to less-well-defined market forces. Drug companies operate within a regulatory framework that includes distinct exclusivities created by both patents and the FDA's drug-approval process. The industry is divided in product segments that operate with different rules; namely, brand name pharmaceuticals and their generic rivals, for which the FDA has established specific rules for bringing a drug to market. At the same time, the demand side of the market is dominated by third-party payers—either private insurers or public payment programs—that reduce patient response to market price signals.

Moreover, prices do not necessarily transmit information that facilitates efficient transactions as they do more typical markets. In the United States there is a significant departure from price competition due to the fact that it is rare for the user or patient to pay the full cost of medications or drug therapies. Third-party payers—either private insurance companies or government programs—bear most of the costs of pharmaceutical purchases, and patients must rely on their doctors to drive their choice of medication. Similarly, restrictions on parallel trade (drug reimportation) and the role of advertising can alter market outcomes as well. Taken together, this framework insulates patients to price sensitivity, which may allow pharmaceutical companies to charge higher prices than they would in a more typical market. The lack of competition, coupled with the fact that most consumers or patients do not see the full cost of the drug, makes patients less responsive to price increases.

Insurance companies attempt to counter incentives by pharmaceutical companies to raise prices through the use of formularies, whereby prices are negotiated with suppliers and tiered according to the co-payment for which the patient is responsible. In the United States, private insurance companies and pharmacy benefits managers negotiate with drug manufacturers on the inclusion of various drugs in the formulary as well as the appropriate tier for a drug. Tier 1 includes generic drugs with the lowest co-payment by the patient. Higher tiers include non-preferred generics, brand-name drugs and specialty drugs that are priced accordingly.<sup>24</sup> Similar negotiations may begin to take place under Medicare for a limited set of pharmaceuticals, given the recent passage of the Inflation Reduction Act, which allows the federal government to negotiate some prices under Medicare Part B and Part D.<sup>25</sup>

However, this not to say that competitive forces do not exist in the pharmaceutical industry. Patent exclusivity does not preclude all competition. As an economist notes:

The high rate of entry to the pharmaceutical-biotechnology industry indicates that it is structurally competitive. The industry has transformed over the years as research has become more targeted and accessible, with smaller pharmaceutical companies robustly competing with larger established companies on specific drugs, often with the hopes a being acquired by a larger company more suited to later stages of drug development, including costly clinical trials, development and marketing.<sup>26</sup>

Despite these competitive forces at play, there are points in the lifecycle of a drug that are more conducive to strategies that extend market exclusivity rather than promote robust competition. Blockbuster drugs are key drivers of profitability, which creates strong incentives to protect and extend their exclusivity as a tool for maximizing profits.



*It is not to say that competitive forces do not exist in the pharmaceutical industry. Patent exclusivity does not preclude all competition.*

24. "Formulary Management," Academy of Managed Care Pharmacy, July 18, 2019. <https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/formulary-management>.

25. Juliette Cubanski et al., "Explaining the Prescription Drug Provisions in the Inflation Reduction Act," Kaiser Family Foundation, Sept. 22, 2022. <https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act>.

26. Patricia M. Danzon, "Economics of the Pharmaceutical Industry," *NBER Reporter* (Fall 2006), p. 15. <https://www.nber.org/sites/default/files/2019-08/fall062.pdf>.

This can be done through follow-on patents building off earlier versions of a drug, with secondary patents focused on dosages, delivery and other factors. While some of these patents may enhance the safety and efficacy of the drug, in other instances, they offer little therapeutic value but do extend the period of market exclusivity to the detriment of competition and patient accessibility.

These patent-extension tactics have other impacts as well. For instance, research focused on extending the exclusivity of existing drugs detracts from research efforts on more-innovative drugs that could become the next blockbuster. This raises questions about how research efforts are allocated when market exclusivity is present with respect to innovation, which is the ultimate goal of patent policy. One study found little correlation between R&D spending and the supply of new drugs but found substantial spending by large pharmaceutical companies to extend the franchise of existing drugs.<sup>27</sup> The explicit goal of patent policy is to spur invention and innovation; however, these objectives can be hindered by incentives to invest in monopoly protection of existing drug therapies rather than new lifesaving products.

As insurers and governments attempt to control drug prices through formularies and other practices, the FDA and patent market exclusivities can minimize competition and facilitate higher prices, especially in the short run. Indeed, as a pharmaceutical economics professor states: “[w]hile governments regulate market exclusivity, safety, and efficacy in the pharmaceutical industry, they also serve as a major customer,” which generates a tension that “often, but not always results in the government exercising monopsony power against the patent monopolies that it created in the first place.”<sup>28</sup>

## Pharmaceutical Markets and Patent Cliffs

Patents play a prominent role in the pharmaceutical sector, facilitating R&D by establishing the market exclusivity to recoup the necessary investments. Yet a patent-based business strategy poses unique challenges for pharmaceutical companies as well. In particular, the reliance on patents creates a phenomenon known as a “patent cliff” when brand name drugs go off patent, opening the product to competition that may significantly reduce the company’s revenue.<sup>29</sup> The economic implications of a patent cliff can be substantial, particularly when blockbuster drugs go off patent. The year 2010, in particular, ushered in a wave of patent expirations for popular, bestselling drugs. Between 2010 and 2012, drugs worth \$30 billion in sales revenue lost their market exclusivity.<sup>30</sup>

The pharmaceutical industry faces another extensive patent cliff that will play out for the remainder of this decade. During this time, 190 drugs will go off patent, with 69 of those being blockbuster drugs. The resulting sales revenues at risk total \$236 billion.<sup>31</sup> In the face of such dramatic changes, pharmaceutical companies develop strategies to address patent expirations and the threat of a patent cliff. The key focus is on replacing revenue streams lost when patents expire and there are three options to examine.

**The pharmaceutical industry faces another extensive patent cliff that will play out for the remainder of this decade.**

**PATENT CLIFF**

**190 drugs**

*will go off patent, with 69 of those being blockbuster drugs. The resulting sales revenues at risk total \$236 billion.*

27. Frank and Hannick. <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2022/06/02/five-things-to-understand-about-pharmaceutical-rd>.

28. Lakdawalla, p. 398. <https://www.aeaweb.org/articles?id=10.1257/jel.20161327>.

29. Motley Fool staff, “What Is a Patent Cliff?” The Motley Fool, July 6, 2016. <https://www.fool.com/knowledge-center/what-is-a-patent-cliff.aspx>.

30. Jack DeRuiter and Pamela L. Holston, “Drug Patent Expirations and the ‘Patent Cliff,’” *U.S. Pharmacist* 37:6 (June 20, 2012), pp. 12-20. <https://www.uspharmacist.com/article/drug-patent-expirations-and-the-patent-cliff>.

31. Gail Dutton, “Looming Patent Cliff will be Pharma’s Moment of Truth,” BioSpace, June 7, 2022 <https://www.biospace.com/article/looming-patent-cliff-will-be-pharma-s-moment-of-truth>.

First, and ideally, a company's pipeline of new therapies should have a replacement product under development that could become the next blockbuster drug. However, as noted earlier, the investment required to bring a new drug to market is substantial, with R&D costs continuing to rise as pharmaceutical products become more complex. In response to these costs, there is increasing interest in artificial intelligence (AI) applications that can enhance R&D efforts and reduce costs. While still at an early stage, the potential implementation of AI yields promise for accelerating the drug-development process while at the same time lowering the costs of research. The use of AI has already made important contributions to small-molecule drug discovery and is becoming more integral to more-complex biologic pharmaceuticals. In one case, the use of AI helped identify a potential drug candidate that would typically take up to five years in just eight months.<sup>32</sup> Not only does AI accelerate the discovery process, it can also significantly reduce the traditionally high levels of R&D in the pharmaceutical industry.

Another option available to pharmaceutical companies is acquiring smaller drug companies that are developing promising new therapies. Large pharmaceutical companies with substantial revenues have the opportunity to fill their product pipeline through such acquisitions. As in many industries, smaller startups often focus on developing products with acquisition as the end goal. Smaller firms may lack the resources to shepherd products all the way to market, but they play a key role in drug discovery research. Emerging biopharma firms (firms with less than \$200 million in R&D spending) have become a significant segment of the pharmaceutical industry, responsible for the majority of products in the late-stage pipeline, and have attracted the attention of larger, traditional pharmaceutical companies.<sup>33</sup> Costly clinical trials and limitations on manufacturing and distribution make acquisition or licensing by a larger firm an attractive option for many smaller pharmaceutical companies. Such activity has increased in recent years and may be an attractive strategy for large pharmaceutical companies to address patent cliffs.

The final strategy for addressing the potential losses of a looming patent cliff is to strategically engage in the patent process to prolong market exclusivity through litigation or regulatory and legislative strategies. The tactics employed by pharmaceutical companies throughout the lifecycle of a drug to extend exclusivity are of particular import for the purposes of this paper, as such efforts employ resources but do not necessarily promote inventiveness. Indeed, in many instances, such activities are more aptly described as rent-seeking or rent-protection, as they focus exclusively on extending supranormal profits rather than innovation. Given the substantial benefits of market exclusivity, strong incentives exist to deter new entrants, even for a short period, especially for blockbuster drugs. It is therefore important to evaluate patents and market exclusivity to ensure that the patent system is not misappropriated for the purpose of rent protection rather than innovation.

## Promoting Innovation or Protecting Monopolies?

It is well documented that pharmaceutical companies are adept at using the patent system to strengthen monopoly positions by deterring entry of lower-cost generic alternatives.<sup>34</sup> Many pharmaceutical companies employ strategic behaviors that extend



*While still at an early stage, the potential implementation of AI yields promise for accelerating the drug development process while at the same time lowering the costs of research.*

32. Neil Savage, "Tapping into the drug discovery potential of AI," BiopharmaDealmakers, May 27, 2021. <https://www.nature.com/articles/d43747-021-00045-7>.

33. Murray Aitken, "Emerging Biopharma's Contribution to Innovation," IQVIA Institute, June 2022, pp.1-52. <https://www.iqvia.com/insights/the-iqvia-institute/reports/emerging-biopharma-contribution-to-innovation>.

34. "Overpatented, Overpriced, Curbing patent abuse: Tackling the root of the drug pricing crisis," I-MAK, September 2022, p. 6. <https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf>.



rents well beyond the 20 years granted by the patent. Companies deploy tactics such as evergreening, patent thickets and product hopping to create artificial barriers to potential competitors seeking to enter the market with alternative products, resulting in delayed competition and higher prices for consumers.

## Evergreening

As previously noted, market exclusivity is one of the driving economic forces within the pharmaceutical industry, and expired patents generate a sudden and dramatic change in a firm's revenues. Patent cliffs are a systemic issue that pharmaceutical companies constantly work to mitigate, either through an active pipeline of new drug therapies or strategic behaviors that protect and extend market exclusivity. It is common practice for pharmaceutical companies to continue to file patents on a product purely to extend monopoly protections. These "secondary patents" go beyond the original patent secured on a drug's active ingredient and focus on specific elements:

[...]delivery profiles, packaging, derivatives, and isomeric forms, mechanism of action, dosing regimen, and dosing range, and dosing route, different methods of treatment, combinations, screening methods, biological targets and field of use for the same old molecule.<sup>35</sup>

This tactic is known as evergreening, the sole purpose of which is to extend market exclusivity and deter the entry of lower-cost generics.<sup>36</sup> While there may be some valuable enhancements that can provide benefits beyond the original patent, follow-on patents that go beyond the therapeutic benefits of a drug are not as strong as the original patent and may, in fact, be more effectively challenged through the legal system.

When successful, evergreening has significant effects on the market for pharmaceuticals. First, the prices continue to sit at levels above a competitive market, leading to higher prices for patients as well as the deadweight loss associated with less-than-competitive markets. Second, research portfolios can shift as pharmaceutical companies divert resources away from innovative new research to explorations of potentially patent-extending attributes of existing drugs. In fact, one researcher found that between 2005 and 2015, existing drugs—not new innovative products coming to market—accounted for 78 percent of the drugs linked to new patents.<sup>37</sup>

Another study of the top-100 bestselling drugs found that 70 percent of these drugs had their market exclusivity extended at least once, and 50 percent of the drugs had two or more patent extensions.<sup>38</sup> The researchers concluded that the study "definitively shows that stifling competition is not limited to a few pharma bad apples. Rather, it is a common and pervasive problem endemic to the pharmaceutical industry."<sup>39</sup>

## Patent Thickets

A popular tactic commonly employed for the purpose of extending market exclusivity is the creation of patent thickets, a complex portfolio of patents that make it more difficult for competitors to enter the market. Both brand-name rivals and generic

**Promoting Innovation or  
Protecting Monopolies?  
Evergreening**

*One researcher found that  
between 2005 and 2015,*

**existing drugs  
accounted for**

**78%**  
**of new patents.**

35. Inderjit Singh Bansal et al., "Evergreening—A Controversial Issue in the Pharma Milieu," *Journal of Intellectual Property Rights* 14:4 (August 2009), p. 299. [https://www.researchgate.net/publication/228425922\\_Evergreening-A\\_Controversial\\_Issue\\_in\\_Pharma\\_Milieu](https://www.researchgate.net/publication/228425922_Evergreening-A_Controversial_Issue_in_Pharma_Milieu).

36. Erika Lietzan, "The 'Evergreening' Metaphor in Intellectual Property Scholarship," *Akron Law Review* 53:4 (2019), pp. 805-871. <https://scholarship.law.missouri.edu/facpubs/984>.

37. Robin Feldman, "May your drug price be evergreen," *Journal of Law and the Biosciences* 5:3 (December 2018), pp. 590-647. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750>.

38. *Ibid.*, p. 618.

39. *Ibid.*, p. 597-598.

entrants find it difficult to patent around these protective patent walls, thereby securing the market position of the original patent owner, often for years after the original patent expires. In such scenarios, the costs for patients can be substantial. A House majority staff report found that pharmaceutical companies aggressively engage in research focused on extending market exclusivity:

Collectively, the companies in the Committee’s investigation have obtained over 600 patents on the 12 drugs examined, which could potentially extend their monopoly periods to a combined total of nearly 300 years. For just six of the drugs in the Committee’s investigation, the companies were issued almost 500 patents, collectively providing more than 200 years of potential market monopolies.<sup>40</sup>

A recent research report provides more detailed examples of such thickets and their impact on patients, finding that the three top-selling drugs in the United States are all cloaked in these thickets of patents.<sup>41</sup> Top-selling Humira, for example, is covered by 166 patents, the number-two-selling Revlimid has been granted 117 patents, and third-top-selling drug Eylea has 82 patents.<sup>42</sup> Many of these patents were granted after the FDA approved the drug, suggesting that the patents prolong market exclusivity beyond the initial patent. More broadly, for the top-10, best-selling drugs, pharmaceutical companies filed an average of 140 applications per drug, with 66 percent of the patents filed after receiving FDA approval.<sup>43</sup>

Another empirical study of the pharmaceutical sector found that secondary patenting is correlated to the profitability of the drug, with more patents filed for successful drugs. In fact, such patents are an integral component of the lifecycle management of a successful pharmaceutical. The study’s analysis of patents filed after drug approval “reveals that independent secondary patents are not randomly distributed”; to the contrary, “a Firms’ propensity to obtain independent secondary patents after drug approval increases over the sales distribution.”<sup>44</sup> This increase suggestively reflects “deliberate attempts by branded firms to lengthen their monopoly for more lucrative drugs.”<sup>45</sup>

It is not surprising that bestselling drugs would be protected by a patent thicket, nor is it surprising that the most popular products attract new entrants. In fact, their popularity suggests that the availability of generic or biosimilar alternatives would also provide the greatest relief for patients locked into exclusive products. Extending monopoly power through a thicket of secondary, non-inventive patents does little to enhance innovation; the benefits accrue to the exclusive provider of the product, which, more often than not, increases expenditures on pharmaceuticals.

## Product Hopping

Product hopping is another strategy that can be used to limit entry of generic rivals. This approach involves more than just introducing protective patents. As described in one study, product hopping is a two-step process in which the manufacturer



**Promoting Innovation or  
Protecting Monopolies?**

### Patent Thickets

*For the top-10, best-selling drugs, pharmaceutical companies filed an average of 140 applications per drug, with 66 percent of the patents filed after receiving FDA approval.*

40. Committee on Oversight and Reform, “Drug Pricing Investigation: Majority Report,” U.S. House of Representatives, December 2021, p. ix. <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf>.

41. “Overpatented, Overpriced, Curbing patent abuse: Tackling the root of the drug pricing crisis.” <https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf>.

42. Ibid.

43. Ibid., p. 5.

44. Amy Kapczynski et al., “Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of ‘Secondary’ Pharmaceutical Patents,” *PLOS ONE* (Dec. 5, 2012), pp. 6-7. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0049470>.

45. Ibid.

first develops a reformulated version of a drug. For example, a pharmaceutical manufacturer can switch from a capsule to a chewable tablet, modify the chemical structure in a drug or combine two separate drugs into a single product. Whatever approach is taken, the goal is to create a new product for which there is no generic substitute.<sup>46</sup> One noteworthy example was when AstraZenca's popular anti-ulcer drug Prilosec faced patent expiration, the company switched to a new drug, Nexium, with very little chemical modification but 13 years remaining on a patent to extend market exclusivity.<sup>47</sup>

After a company produces a new version, efforts are also made to encourage those prescribing the drug to shift, or product hop, to the new formulation. The manufacturer may take the old version off the market, leaving consumers no choice but to opt for the new version. Additionally, considerable resources are spent on advertising and marketing to inform doctors that the new product is the appropriate prescription. Unlike in a competitive market, there are sufficient information asymmetries and regulatory impediments that make the product hop possible, leaving the reformulated version as the rational option. This deters generic entry, with the resultant outcome that the branded pharmaceutical company reaps a substantial economic benefit for what is, at best, a marginal enhancement to an existing drug.<sup>48</sup>

The cost of product hopping can be significant. In a study of just five popular drugs over a period of 20 years, one researcher found that eliminating generic competition imposed a cost of \$4.7 billion annually on the U.S. health care system.<sup>49</sup> The overall cost of product hopping is substantially more, given that it is a common practice for managing the lifecycle of a drug as its patent term expires.

## Revisiting the Policy Framework

The primary issue with respect to enhancing the efficacy of the market for pharmaceuticals is the fact that government forces rather than market forces dictate many aspects of the industry. Competition does take place within the market in many forms—between branded drugs and generics, between large pharmaceutical companies developing rival products, and between startups and existing companies.<sup>50</sup> Yet all this competition occurs in the shadow of a legal and regulatory framework that can dictate outcomes.

As a result, market forces are limited and may not be able to correct shortcomings that foster anticompetitive behavior, resulting in less-than-optimal outcomes for patients and consumers while hampering true innovation and invention. There are many unique attributes to the health care sector that can affect drug prices, with patents and other market exclusivities at the core of questions related to drug pricing and competition. Without addressing patents and the monopoly power they bestow, market-driven solutions cannot feasibly generate improved outcomes.

### Promoting Innovation or Protecting Monopolies?

#### Product Hopping

*In a study of just five popular drugs over a period of 20 years, one researcher found that eliminating generic competition imposed a cost of*

**\$4.7 billion annually**

*on the U.S. health care system.*

46. Michael A. Carrier and Steve D. Shadowen, "Product Hopping: A New Framework," *Notre Dame Law Review* 92:1 (November 2016), pp. 172-173. <https://scholarship.law.nd.edu/cgi/viewcontent.cgi?article=4680&context=ndlr>.

47. Alex Brill, "The Cost of Brand Drug Product Hopping," Matrix Global Advisors, Sept. 11, 2020. <https://www.affordableprescriptiondrugs.org/resources/the-cost-of-brand-product-hopping>.

48. Jorge Lemus and Olgu Ozkul, "Product Hopping and Innovation Incentives," SSRN, Sept. 30, 2019. [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3275815](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3275815).

49. Brill, p. 4. <https://www.affordableprescriptiondrugs.org/resources/the-cost-of-brand-product-hopping>.

50. Tomas J. Philipson and Carolanne Dai, "Between- vs. Within-Patent Competition," *Regulation* 26:3 (Fall 2003), pp. 42-48. <https://www.cato.org/sites/cato.org/files/serials/files/regulation/2003/10/v26n3-11.pdf>.

Examining the patent system and identifying effective reforms that will facilitate new entrants and robust competition are both critical steps toward addressing questions of drug pricing in the United States. Unlike other countries, the United States has not adopted price regulations for pharmaceuticals. Ensuring that the U.S. patent system functions properly is a viable alternative to more heavy-handed regulation or regulatory interventions into the marketplace. Properly structured, the patent system can still encourage inventiveness and spur the investments necessary for the continued innovation and creation of new, life-saving drugs.

Troubles with the patent system have not gone unnoticed. The courts, regulators and Congress have all weighed in on the role of patents more broadly.<sup>51</sup> Questions of patent eligibility have long been a source of debate, as has the issue of efficiently eliminating poor-quality or overly broad patents that should never have been granted.<sup>52</sup> Indeed, Congress intervened to address this concern when it passed the “America Invents Act” (AIA) in 2011.<sup>53</sup>

## Patent Trial and Appeal Board

Among other things, the AIA established the Patent Trial and Appeal Board (PTAB) tribunal for post-grant reviews of questionable patents. The PTAB review process provides an alternative to more-costly litigation in federal courts and, rather than a jury trial, PTAB reviews are conducted by a panel of administrative law judges with technical backgrounds. Three avenues of review were established: a post grant review to be filed within nine months of a patent’s issue; a covered business method patent review (a provision that has expired); and, most importantly, the inter partes review (IPR) process, which allows anyone to file a petition requesting that the PTAB review a patent.<sup>54</sup>

The IPR process is the most frequently used option, as it offers a lower-cost alternative to litigation in a federal court. The proceedings are also more expeditious, with the review required by statute to be completed within one year (although there is an option for a six-month extension).<sup>55</sup> This streamlined review process provides a lower-cost method for challenging the validity of questionable patents. This is of particular interest when it comes to generic entry in the face of patent thickets.

Because patents thickets are commonly built on ancillary aspects of a drug rather than the active ingredient of the original patent, they tend to be weaker patents that may be successfully challenged. They may prove to be ineligible for patenting because they are obvious or not novel. Effectively targeting these weaker patents that unnecessarily extend market exclusivity through various evergreening strategies facilitates generic entry and the lower prices of a more competitive market.<sup>56</sup> Litigation by generic drug companies against secondary patents has been successful, winning legal challenges 75 percent of the time.<sup>57</sup>

### PTAB Tribunal Established for Post-Grant Reviews of Questionable Patents

*Litigation by generic drug companies  
against secondary patents has been  
successful, winning legal challenges*

**75%**  
**of the time.**

51. Kevin J. Hickey, “Patent Law: A Primer and an Overview of Emerging Issues,” Congressional Research Service, Sept. 21, 2017. <https://crsreports.congress.gov/product/pdf/R/R44962>.

52. Sasha Moss et al., “Inter Partes Review as a Means to Improve Patent Quality,” R Street Short No. 46, September 2017. <https://www.rstreet.org/wp-content/uploads/2018/04/RSTREETSHORT46-1.pdf>.

53. Public Law No: 112-29 (Sept. 16, 2011). <https://www.congress.gov/bill/112th-congress/house-bill/1249>.

54. Janet Gongola, “The Patent Trial and Appeal Board: Who are they and what do they do?,” InventorsEye, Summer 2019. <https://www.uspto.gov/learning-and-resources/newsletter/inventors-eye/patent-trial-and-appeal-board-who-are-they-and-what#:~:text=The%20PTAB%20decides%20appeals%20from,members%20and%20administrative%20patent%20judges>.

55. Ibid.

56. C. Scott Hemphill and Bhaven N. Sampat, “Evergreening, patent challenges, and effective market life in pharmaceuticals,” *Journal of Health Economics* 31:2 (March 2012), pp. 327-339. <https://www.sciencedirect.com/science/article/abs/pii/S0167629612000057?via%3Dihub>.

57. C. Scott Hemphill and Bhaven N. Sampat, “Drug Patents at the Supreme Court,” *Science* 339:6126 (March 22, 2013), pp. 1386-1387. <https://www.science.org/doi/abs/10.1126/science.1235857>.



Courtroom victories notwithstanding, generic legal challenges can be costly and time consuming. As a result, patients may still be burdened with higher drug prices as competition is delayed. To put this in perspective, one study found that evergreened reformulations increased Medicaid payments by \$9.35 billion between 2008 and 2016.<sup>58</sup> The IPR proceedings at the PTAB provide a lower-cost and quicker alternative to address the problem of invalid secondary patents that deter entry.

Indeed, the PTAB has proved to be a popular venue for tackling the problem of patent thickets, allowing companies to challenge secondary patents that are weak or invalid. And while critics often assert that the PTAB acts to aggressively invalidate patents, the data suggests otherwise. In a recent study of IPR outcomes for pharmaceutical companies, researchers found the results in PTAB hearings to be similar to those in federal courts.<sup>59</sup> The review process established by the AIA has become an important part of the patent system, achieving results similar to other forms of adjudication in a more expedited time frame and at a lower cost.

Despite the PTAB's ability to achieve similar results with a much-reduced investment of cost and time, many continue to oppose the IPR process, pursuing regulatory or legislative changes to PTAB that would narrow its scope and limit the ability to petition for a hearing. Yet these changes go against the intent of the AIA and would leave more-costly litigation in federal district court as the only option for addressing invalid patents that have made their way into the system.

Most specifically, the previous director of the USPTO introduced administrative and policy changes to reduce access to the IPR review at PTAB. Through a mix of agency guidance and new precedential decisions, discretionary denials became a tool for refusing to institute an IPR without even reviewing the relevant merits of the case. These denials were based on the existence of parallel litigation in other venues while petitioning for PTAB review. Two cases, in particular, were made precedential, one in 2019 and one in 2020 that have become known as the NHK-Fintiv discretionary denial.<sup>60</sup> The first case made parallel litigation grounds for a discretionary denial, while the second identified a list of factors to be considered when issuing a discretionary denial for parallel litigation.<sup>61</sup>

The use of discretionary denials had a significant impact on IPR reviews at PTAB, reducing the ability to eliminate meritless cases under the guidelines established in the AIA. When the NHK decision was made precedential, there were only four discretionary denials. The number of discretionary denials peaked in the second quarter of 2021, with a total of 47 denials.<sup>62</sup> Since then, the number has dropped significantly. Some of this may be due to changes in strategic behavior by those involved in the IPR process. But, more importantly, the most recent director of the



**While critics often assert that the PTAB acts to aggressively invalidate patents, the data suggests otherwise.**

*In a recent study of IPR outcomes for pharmaceutical companies, researchers found the results in PTAB hearings were similar to those in federal courts.*

58. Sean Dickson, "Effect of Evergreened Reformulations on Medicaid Expenditures and Access from 2008 to 2016," *Journal of Managed Care and Specialty Pharmacy* 25:7 (July 2019), pp. 780-792. <https://www.jmcp.org/doi/full/10.18553/jmcp.2019.18366>.

59. Filko Prugo et al., "Insight: Orange, Purple Book Patentees Hone PTAB Survival Skills," *Bloomberg Law*, June 8, 2018, p. 3. <https://news.bloomberglaw.com/ip-law/insight-orange-purple-book-patentees-hone-ptab-survival-skills-1>.

60. Robert M. Breetz and Joshua R. Nightingale, "USPTO Releases Study On Fintiv Denials," *PTAB Litigation Blog*, August 2022. <https://www.jonesday.com/en/insights/2022/08/uspto-releases-study-on-fintiv-denials>.

61. Matthew Bultman, "Turning Away a Patent Challenge: The NHK-Fintiv Rule Explained," *Bloomberg Law*, March 3, 2021. <https://news.bloomberglaw.com/ip-law/turning-away-a-patent-challenge-the-nhk-fintiv-rule-explained>.

62. "PTAB Parallel Litigation Study," United States Patent and Trademark Office, June 2022. [https://www.uspto.gov/sites/default/files/documents/ptab\\_parallel\\_litigation\\_study\\_exec\\_summ\\_20220621\\_.pdf](https://www.uspto.gov/sites/default/files/documents/ptab_parallel_litigation_study_exec_summ_20220621_.pdf).

USPTO has raised concerns about the use of discretionary denials, issuing interim rules on the issue and indicating the need for a possible rulemaking to address concerns with NHK-Fintiv denials due to parallel litigation.<sup>63</sup>

## International Trade Commission

One venue of parallel litigation deserves particular mention: the International Trade Commission (ITC). The patent director of the USPTO specifically mentioned that parallel litigation at the ITC should not be a reason to deny proceedings at the PTAB. This is important for several reasons. First, the ITC was established to implement trade and tariff policies and resolve unfair trade disputes; it is not an agency with the authority to address the validity of a patent. Any adjudication at the ITC assumes a patent is valid, and any infringement allows the ITC to issue an exclusion order banning the import of the product. Second, the ITC is becoming a popular venue for patent disputes, given that the ITC has the power to issue exclusionary orders that can ban a product from the market. Pharmaceutical companies have taken note, and now the ITC is being viewed as an alternative, effective venue to address disputes between branded and generic pharmaceuticals. In particular, pharmaceutical process patents, which are not part of the generic drug approval system, can be brought to the ITC for adjudication.<sup>64</sup>

Biosimilars may be even more ripe for action at the ITC. The approval process for biosimilars is different and provides more opportunities to engage the ITC to extend market exclusivity. Additionally, several biosimilars are produced overseas, making the ITC a strategic option to supplement or initiate action against a biosimilar manufacturer. The USPTO director has recognized the potential problems that are created by the ITC and has stated that ITC adjudication should not be considered a factor when the PTAB is deciding whether to discretionarily deny institution of a proceeding.<sup>65</sup>

Adjudication in alternative venues should not detract from the function of the PTAB, which was established to facilitate the swift resolution of problems derived from poor-quality patents that threaten the ability of innovators and competitors to enter the market. Efforts to avoid or minimize the role of the PTAB seek to protect market exclusivity, even in cases in which a patent may be invalid. Congress created these reviews under the AIA, and they have proved effective for addressing problematic patents. This is of import for the rivalry between branded and generic drugs; to promote market competition, PTAB proceedings should be encouraged rather than minimized.

## Conclusion

The pharmaceutical industry is a significant component of the U.S. economy, contributing to the nation's economic output and employment through the production of innovative and lifesaving products. However, many have criticized the industry's pricing policies, claiming that important drug therapies remain too expensive, often higher than similar therapies in the European Union and elsewhere.



*Efforts to avoid or minimize the role of the PTAB seek to protect market exclusivity, even in cases in which a patent may be invalid. Congress created these reviews under the AIA, and they have proved effective for addressing problematic patents.*

63. Katherine K. Vidal, "Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation," United States Patent and Trademark Office, June 21, 2022. [https://www.uspto.gov/sites/default/files/documents/interim\\_proc\\_discretionary\\_denials\\_aia\\_parallel\\_district\\_court\\_litigation\\_memo\\_20220621\\_.pdf](https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf).

64. Josh Pond and Matthew Meyer, "U.S. Spotlight: The Emerging Role of the ITC in Pharmaceutical Disputes," Stevens and Bolton, June 28, 2018. <https://www.stevens-bolton.com/site/insights/articles/the-emerging-role-of-the-its-in-pharmaceutical-disputes>.

65. David McCombs et al., "IPR tricks of the trade: Director Vidal implements changes to discretionary institution policies at PTAB," Reuters, Sept. 8, 2022. <https://www.reuters.com/legal/legalindustry/ipr-tricks-trade-director-vidal-implements-changes-discretionary-institution-2022-09-08>.

Just as concerning is the fact that patents can be strategically used to prolong market exclusivity and delay the entry of generic competitors, resulting in higher prices and fewer choices for patients. Because of the R&D intensity in the pharmaceutical industry, patents are fundamental to its existence. They drive the strategic decisions and business models underlying the industry. Even small changes to the scope or duration of patents can have substantial market impacts, particularly when examining the revenue streams generated by blockbuster drugs protected by patents. These drugs can have annual sales in excess of \$1 billion, making even a short extension a worthwhile strategy.

This is exacerbated by the regulatory framework that governs how new products are brought to market, where the lengthy drug-approval process can detract from the period of market exclusivity offered by a patent, weakening incentives to invest in the necessary R&D for additional innovation. That same regulatory framework can also limit the entry of potential competitors, mitigating the ability of competitive forces to drive down drug prices.

Policymakers have responded to political pressures over the rising costs of drugs by reforming patent policy to encourage competition and limit the ability to deploy patent strategies focused more on extending market exclusivity than on invention and innovation. This was seen first with legislation adopted to encourage generic competition in the small-molecule drug market. Additional legislation was passed to provide similar incentives to enable biosimilars to compete with the thriving new market for biologics.

Both the industry and policymakers have responded to the incentives generated by patents. Drug companies seeking to maximize revenues often engage tactically with the patent system to extend the exclusivity provided by patents by evergreening products with follow-on patents, building patent thickets around products, or encouraging product hopping to move consumers and patients to new versions of a drug before competitive rivals can enter the marketplace.

In addition, broader patent reforms have been adopted to improve patent quality and establish procedures for efficiently removing weak or overly broad patents that should not have been granted in the first place. These measures are integral to the debate over drug pricing and offer opportunities to limit gamesmanship within the patent system while still providing valuable incentives to invent and innovate.

It is important to continue evaluating patent reforms to encourage innovation while critically evaluating any new “reform” proposals that simply protect the status quo or limit the scope of earlier reforms that have proved successful in improving patent quality and avoiding unnecessary extensions of market exclusivity. The debate over drug prices remains important and ongoing; identifying unnecessary impediments to a more competitive market for lifesaving drugs is a vital element of that debate. Patents are at the core of discussions of innovation and competition and, as such, should continue to be the focus of efforts to address the challenge of rising drug prices.



*Patents are at the core of discussions of innovation and competition and, as such, should continue to be the focus of efforts to address the challenge of rising drug prices.*

## **ABOUT THE AUTHOR**

**Wayne T. Brough** is the policy director for R Street’s Technology and Innovation team. He manages product flow on technology policy issues and conducts research in competition policy and intellectual property.