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Strategy for Remediating Intellectual Property Challenges in the Pharmaceutical Industry

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Abstract

Intellectual property (IP) management includes the processes and strategies that a company uses to protect and leverage their intellectual assets. Within the pharmaceutical industry, IP management can include strategically overseeing the creation of medical devices, software used within the manufacturing process, and patents on new drug formulations. While these practices benefit the industry in the form of incentivizing innovation, fostering economic growth, and ensuring drug safety, they can also result in several downsides. This article, through the investigation of developments in pharmaceutical IP management, aims to shed light on the current shortcomings of the industry within the research & development (R&D) of both new and current drugs whilst also providing potential solutions for healthcare executives and policymakers to address these inequities. Negative effects pertaining to the aforementioned (1) high drug prices, (2) challenges in balancing innovation with public health needs, and (3) detrimental data exclusivity will be summarized. The recommended solutions will center around (1) drug access, (2) refocusing incentivized behaviors of the patent system, and (3) the promotion of collaboration via knowledge sharing. The article will conclude by underscoring the importance of the continual refining of IP management practices as new technologies become available.

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Introduction

Pharmaceutical companies have been making drugs for centuries with companies, such as Merck, being founded as early as 1668. Within the early stages of the industry, many physicians and pharmacists viewed patenting medicines and the use of trademarks as unethical forms of monopoly (Gabriel, 2014). Unreliable enforcement and an emphasis on process patents, the protection of the manufacturing process, shaped this time period. Terms such as "patent medicine" from this era mainly referred to trademarked remedies as opposed to government-patented creations. Over time, especially into the early twentieth century, the passage of regulation in the U.S., such as the 1906 Pure Food and Drugs Act, began to erase the era of unregulated remedies (FDA, 2019). Furthermore, the industrialization of pharmaceutical production made formal IP management a crucial component of businesses within the industry. As manufacturing continued to become more complex and costly, pharmaceutical companies began to utilize patents beyond those that simply protected the final chemical compound (product patents). As a result, the specific manufacturing products used to create these substances became more heavily protected.

Today, IP management in the pharmaceutical industry includes a multitude of patents for products, process, formulation, and method-of-use. These patent components are all vital to mitigating immense R&D costs, the long-term patent management of a drug, and the overall navigation of the intricate patent landscape. For instance, IP can protect up to $2.6 billion per drug which can attract further investment and boost job creation (FTI Consulting, 2022). Additionally, it can also promote beneficial competition through the continuous creation of cutting-edge treatments. For example, immune checkpoint inhibitors such as Merck's development of *Keytruda* and Bristol Myers Squibb's development of *Opdivo* were a result of successful IP management (IFPMA, 2024). Immune checkpoint inhibitors are monoclonal antibodies that function by blocking proteins that stop the immune system from attacking cancer cells. The strong patent protections on the specific biological compounds within the substances enables companies to invest billions of dollars into R&D and clinical trials across several

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different cancer types, ultimately bringing these customized cancer treatments to market (Danlong, 2013).

Although IP management yields positive effects for both companies and consumers, there are several detrimental negative effects relating to high drug prices, challenges in balancing innovation with public health needs, and data exclusivity that arise. In examining its effects on high drug prices, it is evident that the use of patents can significantly increase a drug's sale price. When a company gains exclusive rights to produce and sell a drug for a certain period, it prevents other companies from producing alternate versions, which would decrease prices via competition. For example, in 2015, Turing Pharmaceuticals acquired the rights to the life-saving drug Deraprim (Luthra, 2018). Derapim is a medication primarily used to treat a parasitic infection called toxoplasmosis, a condition that can prove life-threatening for individuals with weakened immune systems. After the company's acquisition of the drug, Turing raised the price from $13.50 per pill to a lofty $750 per pill (Luthra, 2018). With an increase of more than 5,000%, the treatment became unaffordable for those with toxoplasmosis, many of which were HIV/AIDS patients. Some pharmaceutical companies also use strategies such as "evergreening" to raise prices. This entails making minor modifications to existing drugs and subsequently patenting said modifications. This enables companies to extend their exclusivity periods, delaying the introduction of alternative versions and keeping prices high (Gibbons et al., 2023). This tactic, along with increases in price as seen with Turing, presents operational challenges for healthcare executives regarding reputational risks and public backlash as being associated with unaffordable care damages consumer trust.

Moreover, in regard to balancing innovation with public health needs, the manner in which IP is managed can lead to situations where profit motivated decisions overshadow public health priorities. Pharmaceutical companies have been shown to focus R&D efforts on drugs that are financially lucrative for them (Taylor, 2015). This includes chronic diseases or conditions that often affect larger, more wealthier populations. These areas offer a high return on investment

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due to the large number of patients who can afford long-treatments and therapies. As a result, diseases that affect smaller populations, most often in low income areas, receive less attention as they are seen as less profitable. For example, Pfizer invests heavily into oncology because cancer drugs are among the most profitable in the market (Constantino, 2024). The condition often requires long-term treatment, enabling patent protections to ensure high prices for years. On the other hand, antibiotic research by the company has been scaled back despite global public health needs as they are taken for shorter periods and, therefore, have far lower returns on investment (Mason, 2023). This issue matters now as it has contributed to global crises such as the COVID-19 pandemic where a focus on profits resulting in delayed medication access in poorer regions allowed the virus to continue to circulate, affecting society worldwide.

In addition to neglecting public health needs, data exclusivity within the industry also contains a few drawbacks. Data exclusivity is a form of IP protection that prevents biosimilar (drugs designed to have active properties similar to those already licensed) manufacturers from using the clinical trial data of an original drug for a certain number of years. This has the potential to delay biosimilar competition as alternative versions of a drug cannot enter the market even if patents expire if data exclusivity is still in effect. Extending the monopoly period, the practice keeps drug availability low long after patents should have enabled there to be competition and prevents access to affordable medication. This is relevant to healthcare policymakers who decide how compulsory licensing is utilized as it can override it. Compulsory licensing is a legal tool that allows an authorized party to bypass patents for public health emergencies (Van Loy, 2024). However, it does not override data exclusivity in many regions. For instance, in 2001 the country of Jordan signed a Free Trade Agreement (FTA) with the United States. As part of the agreement, Jordan enacted strict 5 year data exclusivity rules for medicines, which applied regardless of whether or not a drug was patented. As a result, regulators in Jordan were forbidden from utilizing the originator company's clinical data to approve generic drugs until after the exclusivity period has expired. With no clinical trials able to be repeated, alternate versions of the drug could not enter the market, resulting in decreased

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access and the uselessness of the compulsory licensing tools that legislators put into place (Malian, 2007).

Application of Solutions

Drug Access

Although the necessity of IP management in the pharmaceutical industry supports drug innovation, market regulation, and long-term access to medicines, its negative effects continue to persist. In order to address the aforementioned inequities, companies may adopt several solutions to responsibly combat negative effects. To ensure that high drug prices do not hinder access to essential medications, companies may reform patent practices related to “evergreening” and transparency. As mentioned prior, companies extend market exclusivity through practices such as “evergreening” by filing secondary patents on minor modifications to drugs and their usage, effectively keeping prices high. Stricter patentability standards that entail a higher required threshold for both novelty and non-obviousness, i.e. not granting patents merely for minor or strategic modifications, may decrease monopoly periods. For example, India’s section 3(d) Indian Patents Act (1970, amended 2005) states that new forms of known substances are only patentable if the applicant proves a significant clinical benefit (Sohrabji & Maloney, 2020). This The law was enacted to act as a filter for the patent process and ultimately protect access to affordable medicines. As a result, cancer, HIV/AIDS, and hepatitis drugs have priced 70-90% lower when compared to patent-protected markets (Jishnu, 2015). From a systems level perspective, this can positively contribute to higher quality of care scores and improved patient outcomes, a metric that healthcare leadership is held accountable for by regulating bodies. Additionally, in regard to patent transparency, the promotion of systems by healthcare executives such as the U.S. Food & Drug Administration’s Orange Book, a primary resource listing all patents and their transparencies, could promote accountability within the industry. Increased patent regulation and transparency in tandem with one another aids in keeping medications easy to access.

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Refocusing Incentives

Secondly, concerning challenges in balancing innovation with public health needs, the separation of R&D incentives from high drug prices can help to ensure a potential return on investment without sacrificing the needs of the public. Currently, innovation is rewarded through the creation of temporary monopolies which create high drug prices and, in turn, provide a funding source for R&D investment. This creates a structural problem where patients are paying for innovation long after R&D costs have been recovered, further resulting in a company focused on profitable diseases. Through key remediation mechanisms such as public R&D funding with access conditions, public health needs may remain a priority. Honing in on R&D funding, governments presently fund a large portion of drug research through mediums such as the National Institute of Health (NIH), public-private partnerships, and universities (Sampat, 2011). This funding is essential for the foundational work that private companies rely upon. The drugs that derive from this process are usually patented exclusively and priced at monopoly levels. As As a result, the public pays twice (taxes that fund R&D and high drug prices). One way to combatThis is for the public to receive enforceable rights whenever public money funds drug R&D. This can be accomplished through the implementation of access conditions which are legal obligations placed on recipients of public R&D funding to ensure affordability and competition (Taubman, 2004). A relevant condition can include reasonable pricing conditions where the drug is required to be sold at a fair price. Through this framework, price caps are tied to cost-effectiveness, negotiation with government payers is mandatory, and there are penalties for excessive pricing, essentially preventing unnecessary pricing when public funds have already recouped R&D investment. For healthcare executives, unnecessary R&D recoupment can lead to the cancelling of other programs as organizations must pay more to acquire a drug. Through the prevention method discussed, leadership can sustainability control budget costs while still focusing on innovation. An example of this working can be noted in the 2009 Pneumococcal Vaccine Advance Market Treatment (AMC) where companies accepted affordability conditions

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and still profited, further demonstrating that public health needs and profit can go hand in hand (Gavi, 2025).

Knowledge Collaboration

Lastly, the prevention of the shared use of clinical trial data via data exclusivity negatively impacts consumers as biosimilar competition is delayed, inevitably keeping drug prices higher for longer periods. In order to combat this effect, data reliance without disclosure can be implemented. With this process, a drug regulator would rely on existing clinical trial data to approve another product without giving the data to a competitor for commercial use. This allows data to stay confidential, keeps ownership in the hands of the original creator, avoids the repetition of clinical trials, and allows patients to get access to important medications sooner. This is crucial to remediating data exclusivity standards as clinical trials are expensive and ethically should only be repeated if absolutely necessary. Furthermore, without the need to recreate clinical trials, medicines reach the market faster and companies do not have to charge as much due to lower development costs (Sachdeva, 2024). For instance, thanks to data reliance without disclosure, a study titled *Billions in Healthcare Savings Realized Through Early Generic and Biosimilar Settlements* found that generics and biosimilars entered the market an average of 64 months ahead of original patent expiration (Jeremias, 2025). Approximately $1.1 billion in 2023 was reported to be saved thanks to the practice which resulted in the early launch of a generic multiple sclerosis medication. Benefiting healthcare leadership, the early launching of medications can differentiate organizations from competitors, potentially leading to future partnerships and investment opportunities. By allowing continual regulatory review via governments and not organizations as mentioned prior, competitors do not get a hold of the data. An analogy for the solution presented would be the following scenario: If we imagine that a teacher already knows the correct answer to a problem and a second student proves that they got an answer independently, the teacher would then use their knowledge to grade the student without giving anything away. With this system in place, both public health needs, access to medications, and beneficial medication competition can be produced.

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Recurring Barriers and Limitations

While reforming IP management in the pharmaceutical industry is possible to achieve with the necessary steps, there remain various legal, economic, and political barriers to its accomplishment. Firstly, IP regulations are ingrained in international agreements such as Trade-Related Aspects of Intellectual Property Rights (TRIPS) and TRIPS-plus provision. TRIPS is an international legal agreement under the World Trade Organization (WTO) and sets the minimum standards for IP protection that WTO member countries must follow which can include providing pharmaceutical patents for at least 20 years (World Trade Organization, 2025). TRIPS-plus provisions are rules that go beyond what TRIPS requires and often include data exclusivity, market exclusivity, and longer patent terms (Chen et al. 2013). Some studies predict that the use of TRIPS-plus can result in delayed generics, significant price increases, and reduced access to medicines (Chen et al., 2013). Economically, firms and investors are strongly opposed to IP reform that reduces product exclusivity as this is seen as a threat to revenue models. For instance, Abbvie's *Humira* became one of the best selling drugs in history through continuous evergreening and its reliance on over 100 patents related to *Humira* (Gibbons et al., 2023). This particular example is central to understanding persisting economic barriers as it demonstrates that exclusivity can be extended without new therapeutic breakthroughs, leading to delayed generic competition and high prices. Politically, policymakers that may influence stricter regulation face strong incentive to maintain the status quo. Among lobbyists, pharmaceutical companies are among the most powerful and influence policy through campaign donations, lobbying lawmakers and regulators, and by providing technical expertise. For example, pharmaceutical companies through groups like PhRMA consistently rank among the top lobbying spenders and play a hand in framing the narrative around reform as anti-innovation (Accountable US, 2024). PhRMA in particular has spent over $105 million in lobbying efforts against the Inflation Reduction Act, the Elijah E. Cummings Lower Drug Costs Now Act, and the Medicare Prescription Drug Price Negotiation Act of 2019 (Accountable US, 2024). Efforts to stifle reform via legal, economic, and political avenues go hand in hand in slowing change

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within the industry.

Conclusion

Given the real-world implications of the barriers mentioned, those in support of true and sustainable IP reform must reach a middle ground with the companies in question as their influence is paramount throughout all steps of the reform process. Balancing profit motivators with increased drug access, refocusing incentivized behaviors of the patent system, and the broadening of data exclusivity requires a multitude of institutional strategies as opposed to one fix. As the conversation surrounding IP reform develops, new emerging technologies can further assist in improving transparency, efficiency, access, and trust. For example, artificial intelligence (AI) can detect “evergreening” patents more effectively, lowering administrative barriers to reform (DrugPatentWatch, 2025). Major patent offices, such as the European Patent Office (EPO), are utilizing these systems to assist patent examiners in particular with the process of identifying existing formulations that are similar to new applications (EuropeanPatentOffice, 2025). Making legal research faster and more efficient enhances the reform process as it makes it harder for companies to get weak or “evergreening” patents approved. This is important in today's day and age given that another emerging technology that is assisting in industry change is blockchain, a type of distributed ledger technology. Blockchain records information in a shared, secure database across many users. Once the data is added, it is difficult to change which makes it efficient for transparency and coordination, all recurring problems in IP management. Making licensing conditions clearer, governments, researchers, and generics all have the increased ability to understand who owns what and under what conditions. One of the most tangible implementations of blockchain in the pharmaceutical industry is the MediLeger Network. Involved in this group includes but is not limited to distributors such as Pfizer, McKesson, and Cardinal Health (Gaynor et al., 2024). A pilot study on Medileger found that blockchain is feasible for tracing medications whilst simultaneously providing data privacy, an important factor to many pharmaceutical companies (Mendes, 2024). With the suggested recommendations

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for improving IP practices, new technologies, and mindfulness of barriers to overcome, the negative outcomes of the current industry can progress towards intentional remediation whilst simultaneously benefitting healthcare leadership.

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