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Review Article

Intellectual Property Right in Pharmaceutical Industry

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ABSTRACT

The intersection of intellectual property rights (IPR) and the pharmaceutical industry embody a fundamental policy tension: incentivising drug innovation through temporary monopolies versus ensuring affordable access to life saving medicines. This thesis systematically examines how patents, trademarks, trade secrets, and regulatory exclusivities shape pharmaceutical firm behaviour, generic competition, and public health outcomes. The global pharmaceutical market exceeds $1.5 trillion annually, with R&D costs often surpassing $2.6 billion per new molecular entity, making robust IP protection essential for recouping investments. However, strategic patenting practices—evergreening, patent thickets, reverse payment settlements, and product hopping—have extended market exclusivity beyond legitimate bounds, delaying generic entry and sustaining high prices. The COVID 19 pandemic and high-cost cancer immunotherapies have further exposed deep inequities in access between high income and low - and middle-income countries. This analysis covers the full spectrum of pharmaceutical IP: product, process, formulation, and use patents; trademark strategies and brand persistence; trade secrets in manufacturing; data exclusivity and regulatory protections (orphan drug, pediatric, NCE exclusivities). It evaluates key legal frameworks including the Hatch Waxman Act, TRIPS Agreement, Doha Declaration, and TRIPS plus provisions in bilateral trade agreements. The central finding is that while strong IPR is necessary for pharmaceutical innovation, poorly calibrated regimes enable abuse without corresponding therapeutic benefit. A nuanced, empirically grounded approach—incorporating compulsory licensing, patent opposition mechanisms, and stricter patentability criteria (e.g., India's Section 3(d))—is required to reconcile monopoly rights with the public health imperative of affordable medicines.

INTRODUCTION

The intersection of intellectual property rights (IPR) and the pharmaceutical industry represents one of the most contested and consequential domains of modern innovation policy. At its core lies a fundamental tension: the need to incentivise the discovery of new drugs through temporary

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monopolies, balanced against the equally urgent need to ensure affordable access to life-saving medicines for global populations. This thesis undertakes a systematic examination of how IPR – particularly patents, but also trademarks, trade secrets, and regulatory exclusivities – shapes the behaviour of pharmaceutical firms, the structure of the generic drug industry, and the realisation of public health objectives. The rationale for this study is underscored by several empirical realities. First, the global pharmaceutical market, valued at over $1.5 trillion annually, is characterised by extreme research and development (R&D) costs – often exceeding $2.6 billion per successful new molecular entity – and a corresponding dependence on robust IP protection to recoup investments. Second, despite the undeniable progress in treating diseases such as HIV/AIDS, hepatitis C, and various cancers, access to innovative medicines remains highly inequitable across high-income countries (HICs) and low- and middle-income countries (LMICs). Third, the rise of strategic patenting practices – evergreening, patent thickets, and reverse payment settlements – has prompted legal and regulatory reforms worldwide, from the Hatch-Waxman Act in the United States to the TRIPS Agreement and the Doha Declaration at the international level. Understanding the nuances of pharmaceutical IPR is therefore not merely a legal or commercial exercise; it is a moral and policy imperative.

The Pharmaceutical Industry: Structure and Global Significance

The pharmaceutical industry is broadly divided into two segments: originator (or innovative) companies that discover, develop, and market new chemical or biological entities, and generic manufacturers that produce off-patent versions of established drugs. The originator sector is dominated by a handful of multinational corporations – Pfizer, Roche, Novartis, Merck, Sanofi, and AstraZeneca, among others – which invest heavily in R&D and maintain large patent portfolios. Their business model relies on a period of market exclusivity (typically 20 years from filing, effectively reduced to 8–12 years after regulatory approval) to price drugs at premium levels, thereby funding not only current projects but also high-risk early-stage research. The generic sector, by contrast, operates on thin margins and high volumes, entering the market immediately after patent expiry or successful invalidation. In recent decades, the global significance of the pharmaceutical industry has expanded dramatically, driven by aging populations in developed nations, the emergence of chronic lifestyle diseases (diabetes, hypertension) in emerging economies, and the urgent need for rapid vaccine and therapeutic development demonstrated by the COVID-19 pandemic. Beyond economic dimensions, the industry is a cornerstone of public health infrastructure; the World Health Organization (WHO) lists essential medicines – many of which are off-patent generics – as critical to functioning healthcare systems. Yet the same industry has also been the subject of intense scrutiny over pricing practices, most notably Martin Shkreli's 5,000% price hike of Daraprim and the sustained high prices of sofosbuvir (Sovaldi) for hepatitis C. Thus, understanding the industry's structure is inseparable from understanding its IP strategies.

The Role of IPR in Pharmaceutical Innovation

Intellectual property rights serve as the primary legal mechanism through which pharmaceutical companies appropriate returns from their R&D investments. Without patent protection, a new drug could be copied immediately by generic competitors after regulatory approval, driving prices down to marginal cost and eliminating any

chance of recouping the sunk costs of discovery, preclinical testing, and phase I–III clinical trials. Empirical evidence strongly supports the proposition that the pharmaceutical sector is more dependent on patents than almost any other industry – including software, electronics, or mechanical devices. This dependency arises from the unique characteristics of drug development: high risk (only one in 5,000–10,000 screened compounds reaches market), long lead times (10–15 years from lab to pharmacy), and the ease of reverse engineering once a molecule is disclosed. Patents address this appropriability problem by granting a temporary right to exclude others from making, using, or selling the invention. In addition to patents, trade secrets protect confidential manufacturing processes and formulation know-how, while data exclusivity provisions prevent generic companies from relying on originator clinical trial data for a defined period, further delaying generic entry. Trademarks, though less central to innovation per se, play a crucial role in building brand loyalty and differentiating originator products from generic substitutes, particularly in over-the-counter (OTC) segments. The cumulative effect of these IP instruments is a legal framework that makes the high-risk, high-cost pharmaceutical enterprise economically viable. However, this same framework can be – and often is – extended well beyond its legitimate scope through strategic behaviours such as secondary patenting of minor modifications, product hopping, and abusive litigation, leading to what critics term "evergreening."

Problem Statement: Balancing Monopoly Rights and Public Health

The central problem addressed by this thesis is the persistent difficulty of reconciling the patent-based monopoly rights granted to pharmaceutical innovators with the public health imperative of affordable and timely access to medicines. On one hand, weakening IP protection risks reducing the flow of new drugs, particularly for neglected diseases (e.g., tuberculosis, malaria, emerging antimicrobial resistance) that lack profitable markets. On the other hand, overly strong or poorly calibrated IP regimes lead to extended market exclusivity that delays generic competition, sustains high prices, and places essential medicines out of reach for millions. The COVID-19 pandemic starkly illustrated this dilemma: the rapid development of mRNA vaccines by Pfizer/BioNTech and Moderna was enabled by decades of publicly funded research and robust IP expectations, yet subsequent debates over vaccine equity, technology transfer, and the proposed TRIPS waiver revealed deep fractures between the Global North and South. Similarly, the high cost of novel cancer immunotherapies (e.g., CAR-T treatments costing $500,000 or more) raises questions about whether current IP-based models can deliver sustainable access. The problem is compounded by asymmetrical bargaining power: originator companies leverage patent portfolios to block or delay generic entry, while generic manufacturers operate within legal constraints that permit only certain "early working" exemptions. Jurisdictional differences further complicate the landscape: India's Section 3(d) of the Patents Act bars patents on mere new forms of known substances unless they demonstrate enhanced efficacy, whereas the United States and Europe have historically allowed broader secondary patenting. Consequently, a one-size-fits-all policy solution is unlikely; instead, nuanced, empirically grounded analysis is required to identify where IP protection stimulates genuine innovation and where it merely extends monopolies without therapeutic benefit.

Overview of Intellectual Property Rights

Intellectual property rights are a bundle of exclusive legal rights granted to creators and inventors over their intangible creations. In the pharmaceutical context, the most relevant categories are patents, trademarks, copyright (limited application), and trade secrets. Each serves a distinct purpose, has different duration and enforceability characteristics, and interacts with regulatory approval pathways in specific ways. The international framework is governed by the WTO's TRIPS Agreement (1995), which sets minimum standards for IP protection and enforcement, including 20-year patent terms and data exclusivity obligations. However, TRIPS also contains flexibilities – such as compulsory licensing and parallel importation – that countries may use to protect public health. Subsequent bilateral and regional free trade agreements have often introduced TRIPS-plus provisions, extending exclusivity periods and restricting compulsory licensing, thereby tilting the balance further toward rightsholders. A thorough understanding of each IPR category is therefore essential.

Patents in Pharmaceuticals

Patents are the cornerstone of pharmaceutical IP strategy. A patent confers the right to exclude others from making, using, selling, or importing the claimed invention for a term of 20 years from the filing date. In exchange, the inventor must disclose the invention in sufficient detail to enable a person skilled in the art to replicate it.

Patentability Criteria – To be patentable, an invention must satisfy three criteria: novelty (not anticipated by prior art), inventive step (non-obvious to a skilled person), and industrial applicability (useful). For pharmaceuticals, the "inventive step" bar is particularly high; mere discovery of a naturally occurring substance is not patentable, but isolating and purifying it with a new use may be.

Types of Pharmaceutical Patents – Originator companies file multiple patent types around a single drug. Product patents cover the active pharmaceutical ingredient (API) itself. Process patents protect the method of manufacturing the API. Composition patents cover formulations (e.g., a specific mixture with excipients). Use patents claim new medical indications for an existing drug. Formulation patents cover specific dosage forms (tablet, capsule, injectable, transdermal patch). This layering creates what is known as a "patent thicket" – a dense web of overlapping rights that generic manufacturers must navigate, often requiring litigation to clear each barrier.

Patent Term and Extension Mechanisms- Because the 20-year patent term begins from the filing date, and clinical trials and regulatory review may take 8–12 years, the effective post-approval exclusivity can be as short as 8 years. To compensate, most jurisdictions provide patent term restoration mechanisms. In the US, the Patent Term Restoration Act (Hatch-Waxman) allows up to five additional years of exclusivity, capped at 14 years post-approval. In the EU, Supplementary Protection Certificates (SPCs) provide similar extensions. These mechanisms are critical to originator business models but are also targets of reform advocacy, as they can delay generic entry by several additional years.

Trademarks: Branding and Generic Substitution

While trademarks do not protect the drug's chemical structure or formulation, they play a crucial commercial role. A pharmaceutical trademark (brand name, e.g., "Viagra" for sildenafil, "Humira" for adalimumab) serves to

identify the originator product and build consumer trust. Generic drugs, by contrast, are sold under their International Nonproprietary Name (INN) or a generic brand. Trademark protection can be renewed indefinitely as long as the mark remains in use, meaning that brand loyalty can persist long after patent expiry – a phenomenon known as "brand persistence." In many jurisdictions, pharmacists are permitted or required to substitute a generic equivalent unless the prescriber explicitly writes "dispense as written" or "brand medically necessary." Originator companies sometimes engage in "product hopping" – reformulating a drug (e.g., from a twice-daily to once-daily version) and then discontinuing the older version, thereby forcing patients to switch to the new branded product even after the original patent expires. This practice has been challenged under antitrust law, notably in the US Federal Trade Commission's cases against Abbott Laboratories and Actavis.

Copyright and Trade Secrets in Drug Development

Copyright protection is rarely central to pharmaceutical IP disputes, as it covers original expression (e.g., drug labels, patient information leaflets, and software code) rather than the drug substance. However, trade secrets are of immense strategic value.

Protection of Clinical Trial Data (Data Exclusivity) – Before a new drug can be marketed, originator companies must generate extensive preclinical and clinical data to prove safety and efficacy. This data is protected under regulatory data exclusivity regimes, which prevent generic competitors from relying on that data for a defined period (typically 5–8 years in the US and EU, 10 years for biologics). Data exclusivity operates independently of patent protection; even if a patent is invalidated, data exclusivity can still block generic entry. This is a TRIPS-plus feature increasingly demanded by originator companies.

Trade Secrets in Manufacturing Processes – Many pharmaceutical manufacturing processes – particularly for complex biologics, polymorphic forms, and sustained-release formulations – are protected as trade secrets rather than patents. The advantage is indefinite duration (as long as secrecy is maintained). The disadvantage is that a trade secret offers no exclusionary right against independent discovery or reverse engineering. In practice, originator companies combine patents (on the API and basic uses) with trade secrets (on specific manufacturing conditions, catalysts, crystallization methods) to create layered protection.

Regulatory Exclusivities (Orphan Drug, Pediatric Exclusivity, New Chemical Entity Exclusivity)

Beyond patents and data exclusivity, several regulatory exclusivities provide additional market protection.

Orphan Drug Exclusivity – For drugs treating rare diseases (affecting fewer than 200,000 people in the US, or prevalence ≤5 in 10,000 in the EU), regulators grant 7 years (US) or 10 years (EU) of market exclusivity, plus certain tax credits and fee waivers. This has successfully stimulated development of treatments for conditions such as cystic fibrosis and Gaucher's disease, but also led to criticism when blockbuster drugs (e.g., Humira for a rare uveitis indication) received orphan benefits.

Pediatric Exclusivity – In the US, the FDA may grant an additional six months of exclusivity if the manufacturer conducts pediatric studies as requested. This applies even to drugs whose patent

has expired, effectively extending the monopoly period.

New Chemical Entity (NCE) Exclusivity – For a drug containing an active moiety never before approved, the FDA grants five years of NCE exclusivity. Generic applications cannot be submitted during this period, regardless of patent status. Together, these regulatory exclusivities form a complex, overlapping system that can delay generic entry far beyond the nominal 20-year patent term. Understanding their interactions is essential for any realistic assessment of pharmaceutical IPR's impact on competition and access.

CONCLUSION

This article has demonstrated that intellectual property rights are simultaneously indispensable for pharmaceutical innovation and a significant barrier to equitable medicine access. The pharmaceutical industry's unique characteristics extreme R&D costs, long development timelines, ease of reverse engineering, and direct impact on human health—render it more dependent on patent protection than almost any other sector. Without the prospect of temporary market exclusivity, few originator firms would undertake the high-risk, multi-billion-dollar investment required to bring a new drug from discovery to pharmacy. The empirical record confirms that robust IP protection has stimulated breakthrough therapies for HIV/AIDS, hepatitis C, various cancers, and, most recently, COVID-19 vaccines.

REFERENCES

1. Hemphill, C. S., & Sampat, B. N. (2025). Patents, innovation, and competition in pharmaceuticals: The Hatch Waxman Act after 40 years. Journal of Economic Perspectives, 39(2), 27–52.
2. Logothetis, D. (2024). Rewarding pharmaceutical innovation for being innovative: A summary of the pharmaceutical patent system and an amendment to the Patent Act to negate "evergreening" and "patent thickets." Appeal, 29, 1–24.
3. DrugPatentWatch. (2026). The defensive architecture of biopharmaceutical monopolies: A strategic analysis of the 'Patent Wall'.
4. Ahmad, H., Shabbir, I., Iqbal, I., & Akhtar, M. M. (2023). The crossroad between intellectual property and clinical trials: Balancing incentives for innovation with access to healthcare. Trends in Intellectual Property Research, 1(2), 16.
5. Li, Z., & Guo, P. (2025). Compulsory licensing of pharmaceuticals during public health crisis: A TRIPS framework analysis. Frontiers in Public Health, 13, 1630586.
6. Dunn, M., et al. (2026). TRIPS flexibilities help change policy and practice to increase access to medicines: Evidence from 2001 to 2024. BMJ Global Health, 11(1), e021481.
7. FDA. (2024). 40th anniversary of the generic drug approval pathway. U.S. Food and Drug Administration.
8. Kesselheim, A. S., & Gagne, J. J. (2024). Serial patent litigation: An emerging strategy to delay entry of generic competition. Health Affairs Scholar, 3(12), qxaf240.
9. Khurana & Khurana. (2025). Interrelation between TRIPS Agreement and compulsory licensing.
10. BananaIP Counsels. (2023). Pharmaceutical regulatory data protection in India. Intellepedia.
11. Novartis AG v. Union of India, (2013). Supreme Court of India.
12. WTO. (2001). Declaration on the TRIPS agreement and public health (Doha Declaration). World Trade O

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