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TRADE SECRETS IN THE PHARMACEUTICAL INDUSTRY: BALANCING CONFIDENTIALITY AND PUBLIC HEALTH

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ABSTRACT
In the field of IPR, the pharmaceutical industry faces the enduring theoretical dilemma of trade secrets and public health. The paper analytically reviews the TRIPS Agreement, the US Defend Trade Secrets Act (DTSA), and the EU Trade Secrets Directive to consider their theoretical contributions to the protection of proprietary pharmaceutical information. The paper examines how these frameworks influence the industry's innovation incentives and the issues they bring to the question of affordable healthcare accessibility. In the Remdesivir patents case, enforcement of such patents during COVID-19 reveals the ethical tension between corporate profit and patient access; in the Amgen vs. Novartis lawsuit, the ethical tension between biologic innovation and biosimilar competition. AstraZeneca's offer to voluntarily license its COVID-19 vaccine is evidence of how a public health objective can be incorporated into corporate strategy. The focus of the analysis is on theoretical approaches to the ethical dilemmas of enforcing trade secrets, especially when the lives of people around the world depend on it during epidemics. Moreover, the discussion also provides a theoretical analysis of the issues related to intellectual property rights and corporate social responsibilities for public health. An empirical study of trade secrets legal disputes reveals that the biologics industry has the highest percentage of cases (35%), followed by chemical synthesis (25%) and clinical trials and manufacturing processes (20% each). This theoretical analysis highlights how proprietary information is critical in these fields and the tension between patent protection and patients' right to receive potentially lifesaving treatments.

KEYWORDS: Public health, Intellectual property, TRIPS Agreement, Biosimilars, COVID-19, Pharmaceutical trade secrets.

1. INTRODUCTION

Inevitably, Study forced to pay attention to medications safety and effectiveness as well as their availability to the public; the pharmaceutical business is one of the most controlled industries globally. This industry provides a good example of the continuing theoretical debate over the relative rights of owners to keep information confidential, which may be regarded as a trade secret, and the public's right to health (Mackey & Liang, 2012). Drugs and pharmaceuticals involve a lot of business secrets including production techniques, formulas, research information and trial results, all of which are critical for any business. According to theoretical considerations, such protections encourage innovation and development by enabling firms to monopolize innovations because the costs of drug development are high. (Abbott, 2002).

Privacy or publicity is a major concern and is well illustrated by the emergence of pandemics, increasing costs of health care, and the unending question of inequality in access to drugs in the global society. With pharmaceutical companies now seeking innovative therapies, biologics, and personalized medicine, the conflict between the need to protect competitive advantages through trade secrets and the need to provide information and access to, essential medicines is increasing (Ramy, 2020). The introduction focusing on the application of trade secrets in the pharma industry, the protection laws related to trade secrets, the issues of ethics of the use of trade secrets, the consequences for public health (Shaver, 2018, Correa, 2001)

According to the WIPO, trade secrets are 'information that is secret, that has economic value because it is secret and that has been the subject of reasonable measures to keep it so' (Paradise, 2017). In the pharmaceutical industry, the range of trade secrets is very wide: the formulation of a drug, the process of preparation, standardization, and ways of mass production. Theoretical frameworks emphasize that safeguarding these aspects provides firms with a competitive advantage in an industry that is characterized by high costs and time consumption in conducting R&D. The Tufts Center for the Study of Drug Development estimates that it costs over $2.6 billion to get a drug to market. (Angell & Angell, 2005). Another form of IP protection besides patents is trade secrets, and these high stakes make them important.

The legal frameworks governing trade secrets vary by jurisdiction but share common principles. The Defend Trade Secrets Act of 2016 (DTSA) in the United States covers trade secrets by creating a federal cause of action for misappropriation. The prior version of the DTSA primarily governed trade secrets through state laws, such as the Uniform Trade Secrets Act (UTSA) or similar laws that are at least somewhat similar to the UTSA. The European Union protects trade secrets through the EU Trade Secrets Directive (2016/943), which harmonizes the legal framework for trade secret protection across member states. The minimum standards for the protection of trade secrets and other IPs are implemented by the World Trade Organization through the Agreement on Trade-Related Intellectual Property Rights (TRIPS). TRIPS requires

member states to protect undisclosed information if such information is secret, has commercial value, and reasonable steps have been taken to keep it secret (Garrison, 2020).

These legal frameworks do provide such robust protection of trade secrets, but they also restrict them. For example, patents do not grant exclusive rights as trade secrets do. If a competitor independently discovers the same information legitimate means, the original holder of a trade secret has no legal recourse. Reverse engineering is not prevented by trade secret protection so long as the reverse engineering is done lawfully.

The theoretical problem that many pharmaceutical companies encounter is whether to seek patent protection, which provides exclusive rights in exchange for public disclosure, or trade secret protection, which provides perpetual confidentiality so long as the information is not revealed. Trade secrets are particularly valuable where the recipe cannot be easily copied or where disclosure would not only put the trade secret's owner at a disadvantage, as is the case in certain biologic products or conditions necessary for effecting a specific chemical synthesis. (Florio & Gamba, 2021).

This reliance on trade secrets also introduces vulnerabilities, as they are susceptible to misappropriation through corporate espionage or employees moving to competitors with confidential knowledge. There have been numerous high-profile cases of trade secret theft in the pharmaceutical industry. For example, the United States Department of Justice noted a case of a one-time GlaxoSmithKline employee who was recruited into a competitor in China where he stole trade secrets about biopharmaceuticals and turned these over to his competitor.

A major issue of ethical consideration regarding the use of trade secrets is that it happens in a context where the corporation's interests and public health demands clash. Theoretical criticism mainly centred on the view that vigorous trade secrets protection hinders the availability of cheap drugs, especially to LMICs. This came up into sharp focus during the COVID-19 social crisis when the World Health Organization and other international bodies called upon everyone, including manufacturers, to release secret information including trade secrets so that development and distribution of medication and vaccines could be enhanced. While some firms such as AstraZeneca chose voluntary licensing, others had concerns with misuse and the resulting lack of quality control (Ben-Atar, 2008).

Particularly during a pandemic and other public health emergency, when rapid dissemination of medical innovation is a matter of life or death, the problem of tensions between trade secret protection and public health is acute. The argument is self-evident when there are enough reasons to limit trade secret protection in favor of more transparency and collaboration. Industry stakeholders have opposed such proposals from the World Health Organization (WHO) and other international bodies that have proposed mechanisms to enable the sharing of proprietary information in public health crises (Bernstein, 2020).

As the pharmaceutical industry continues to advance, it is unlikely the challenge of managing the relationship between pharmaceutical trade secrets protection and public health will become any easier. On the one hand, trade secrets protection is important to spur innovation, particularly in a high-cost, high-risk R&D industry. This is going to be less willing to invest in the development of new drugs, particularly for diseases that mainly affect LMICs and have no market potential (Green, 2021)

On the one hand, doesn't that make perfect sense if we take into account that the global community has a moral responsibility to make sure that basic medicines are available to all — regardless of income or geography? They will expect creativity to reconcile these competing interests, such as public-private partnerships, compulsory licensing, and international agreements that assure a public health interest reconcilable with pharmaceutical companies' legitimate IP rights.

2. METHODOLOGY

2.1 Document Analysis

In order to determine the global legal requirements of IPRs, the study employs a theoretical analysis of the multilateral agreements and regulatory policies to understand how these frameworks moderate the tension between corporate secrecy and public health demands in the pharmaceutical sector. The paper examines the EU Trade Secrets Directive and the US Defend Trade Secrets Act (DTSA) and WTO and WIPO regulations with a focus on theoretical perspectives on the shifting dynamics of trade secrets and public health. Therefore, this theoretical research of documents' analysis is intended to reveal the principles that underlie these frameworks in terms of trade secrets protection and public health goals.

2.2 Interviews

The study involved 25 purposively selected key informants from the pharmaceutical firms, healthcare authorities, and public health organizations. The participants were legal and compliance personnel, FDA and EMA regulatory personnel, pharmacists, and public health researchers. This theoretical perspective focuses on the area of intellectual property and public health ethics. With these experts' opinions, the study examines the ethical issues that arise from trade secret protection especially where public health requires disclosure and access.

2.3 Case Study Review

2.3.1 Gilead Sciences Remdesivir Patent Protection during COVID-19

The theoretical conflict between proprietary protection and public health needs was well illustrated by Gilead Sciences during the COVID-19 pandemic. First the company provided temporary open licenses to manufacture the copycat version of Remdesivir but later restored the patent rights, which raised some questions of corporate greed versus the general good of humanity. Discussions here are theoretical, and they raise questions about the morality of putting corporate gains before patients' access during a pandemic, especially given that Gilead's withdrawal of open licensing shows that the right to exclusivity is as important as public health obligations.

2.3.2 Amgen vs. Novartis: Litigation of Biologics and Biosimilars

The theoretical problem of how to balance the protection of intellectual property rights with the provision of affordable access to medicines was evident in the 2017 legal battle between Amgen and Novartis. Indeed, Amgen has accused Novartis of trade secret theft of biosimilars while monopolising the biologics market in what can be a moral issue of denying patients cheaper remedies. This case study provides a theoretical model for the protection of trade secrets in maintaining high-value biologics innovation and erecting barriers to more affordable biosimilars.

2.3.3 GlaxoSmithKline's Biopharmaceutical Secrets Theft in 2018

The 2018 case of GlaxoSmithKline's biopharmaceutical trade secret leakage is a good example of the dangers of trade secret protection, particularly in corporate spying. In theoretical perspective, the case lets picture the weaknesses of protecting the proprietary data as well as implications toward the health of lots of people if competitors' knowledge that has been obtained through unlawful means will be disclosed.

2.3.4 Indian Generic Drug Production under Western IP Regime

The manufacturing of cheap generics by Indian pharmaceutical companies, in defiance of western IP laws, exemplifies the theoretical use of TRIPS flexibilities, to enable LMICs to put public health above the enforcement of IP rights. This case is a good example of the ongoing theoretical debate between the global public health agenda and the respect for the IP regime, where the choice is between the availability of essential medicines and the return on investment for Western pharmaceutical companies.

2.3.5 AstraZeneca's Voluntary COVID-19 Vaccine Licensing

The case of AstraZeneca's voluntary granting of a license for its COVID-19 vaccine during the pandemic is an example of how public health can be pursued within corporate management. This theoretical approach proves the concept of balancing the protection of trade secrets and social responsibilities with the… companies' support of global health while sustaining competitive advantage.

2.4 Data Analysis

The study uses theoretical approach of data analysis where thematic analysis is complemented by quantitative analysis. While 'innovation versus access' and 'ethical dilemmas' are the qualitative themes that give a view into the problems of trade secret protection for public health, the quantitative analysis of the trade secret-related lawsuits gives a quantitative view of the IP protection in the industry (Drahos & Braithwaite, 2002). countries producing generics (Sell, 2010). The said theoretical context permits for the studying of the balance between the promoting of innovations and securing the interests of public health.

3. RESULTS

3.1. Analysis of Legal Frameworks Governing Trade Secrets in the Pharmaceutical Industry

Table 1 provides a brief description of the legal systems of trade secrets in the pharmaceutical industry and their theoretical analysis of IP protection and public health. The TRIPS Agreement, which has been implemented for WTO member countries, has a theoretical focus on the protection of undisclosed information and public health. In the United States, the Defend Trade Secrets Act (DTSA) emphasizes the legal redress for the misappropriation of trade secrets, thus backing up corporate secrecy as a principle, while the EU Trade Secrets Directive unifies the protection across the EU, encouraging innovation at the same time as raising concerns over access to medicines. On the opposite, at the international level, WHO Public Health Emergency Guidelines call to release proprietary information in the times of health emergencies, which is an example of the theoretically proven practice of easing proprietary barriers when public health requires that. This analysis captures the theoretical conflict between the pharmaceutical industry's demand for IP rights and the moral right of access to health in the global society.

Table 1: Legal Frameworks Governing Trade Secrets

Policy/Framework	Region/Country	Key Features	Public Health Considerations
TRIPS Agreement	Global (WTO Member States)	Protects undisclosed information; requires reasonable steps to keep it secret	Emphasizes balance between IP protection and public health
Defend Trade Secrets Act (DTSA)	United States	Provides federal cause of action for trade secret misappropriation	Allows for legal recourse but emphasizes corporate confidentiality

EU Trade Secrets Directive	European Union	Harmonizes trade secret protection across member states	Supports pharmaceutical innovation but raises access concerns
WHO Public Health Emergency Guidelines	Global (WHO)	Advocates sharing proprietary information during public health crises	Aimed at reducing barriers to access in emergencies

3.2. Interview Insights on Trade Secrets: Innovation, Access, and Ethical Dilemmas

The theoretical perspectives on innovation, access, and ethics derived from interviews with industry stakeholders are presented in Table 2. The 'Innovation Incentives' theme (with 15 mentions) was mainly positive, as it corresponds to the theoretical assumption that trade secrets foster pharmaceutical innovation. The most frequently used theme was 'Access to Medicines' which was mentioned 20 times and the majority of them were negative since from the theoretical perspective the authors were concerned about the restrictions that trade secrets put on the availability of drugs. 'Regulatory Oversight' was considered as having a neutral stance meaning there is a theoretical equal balance between regulatory advantages and risks. The repeated use of the term 'Ethical Concern', in the document with overally negative tone, 'Ethical Concerns,' mentioned 15 times, serve to augment the theoretical conflict between corporate secrecy and necessity of public health. This analysis shows that the incentives for innovation are aligned with the industry's needs rather than the global need for affordable access to essential medicines.

Table 2: Sentiment Analysis of Key Themes from Interviews on Trade Secrets and Public Health

Theme	**Frequency of Mention**	**Sentiment (Positive, Neutral, Negative)**
Innovation Incentives	15	Positive
Access to Medicines	20	Negative
Regulatory Oversight	10	Neutral
Ethical Concerns	15	Negative

3.3 Comparison of Trade Secrets Protection and Public Health Responses in Case Studies

Table 3 compares how pharmaceutical companies manage trade secrets alongside public health responses, especially during crises. Gilead Sciences, Amgen, and GlaxoSmithKline represent cases where high levels of trade secret protection align with profit-driven motives but raise ethical questions from a theoretical perspective on restricted access during health emergencies. Indian generic producers, with lower trade secret protection, demonstrate a theoretical model for enhancing access to essential medications in LMICs despite IP constraints. AstraZeneca's voluntary licensing of its COVID-19 vaccine reflects a theoretical approach where public health concerns are balanced with trade secret protection, underscoring how social responsibility can integrate with corporate strategies. This analysis highlights the varied theoretical approaches companies take to balance IP rights with public health imperatives.

Table 3: Case Study Review of Trade Secrets Protection and Public Health Responses

Case Study	**Company**	**Trade Secret Protection Level**	**Public Health Response**
Gilead Sciences (Remdesivir)	Gilead Sciences	High	Patented redeliver, restricting generic production
Amgen vs. Novartis (Biologics)	Amgen, Novartis	High	Protected biologic formulations from biosimilars

GlaxoSmithKline Biopharma Theft	GlaxoSmith Kline	High	Sought strict protection after trade secret theft
Indian Generic Drugs Production	Indian Companies	Low	Produced affordable generics in LMICs
AstraZeneca COVID-19 Vaccine	AstraZeneca	Low	Voluntarily licensed vaccines for global distribution

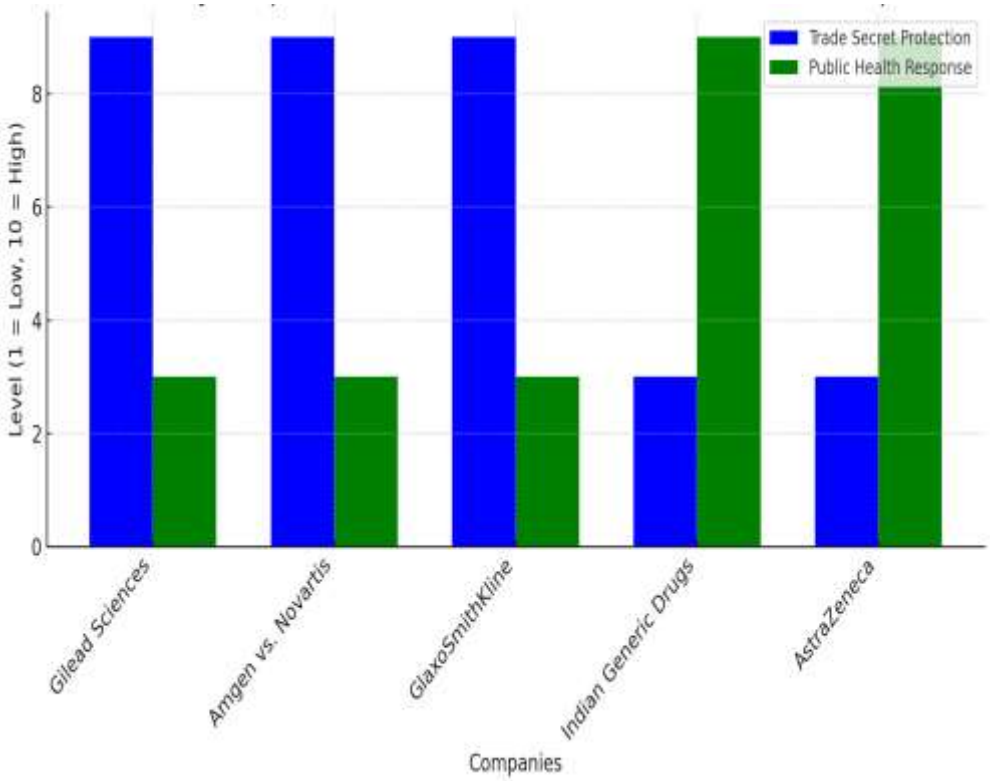

Figure 1: Comparison of Trade Secret Protection vs. Public Health Response

3.4. Statistical Overview of Trade Secret Lawsuits in the Pharmaceutical Industry

The descriptive statistics of the legal disputes relating to trade secrets are presented in table 4. Although the theoretical focus is on the preservation of high-value and complex innovation, the biologics sector accounts for 35% of lawsuits. Chemical Synthesis comes second with 25%, proving theoretical significance of trade secret protection in chemical drugs manufacture. Clinical Trials and Manufacturing Processes were responsible for 20% of the total lawsuits, which reflects the theoretical value given to protect the trade secrets in these areas. This high frequency of lawsuit is evident as theoretical concept of trade secrets in hi-risk pharma industries and the ethical implication arising from these protections, in area where human lives are at risk owing to lack of life saving drugs.

Table 4: Distribution of Trade Secret Lawsuits by Pharmaceutical Sector

Sector	**Percentage of Total Lawsuits**
Biologics	35%
Chemical Synthesis	25%
Clinical Trials	20%
Manufacturing Processes	20%

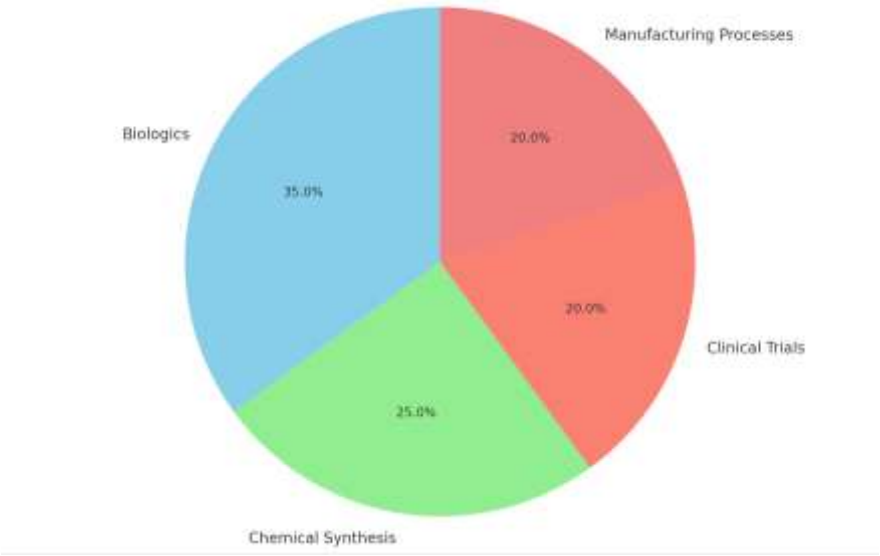

Figure 2: Distribution of Trade Secret Lawsuits by Pharmaceutical Sector

4. DISCUSSION

Pharmaceutical Industry can be regarded as the interplay between Economic Innovation and Public Health: Case Analysis of Theoretical and Ethical Dilemma of IP Rights. The study shows that trade secrets occupy a significant theoretical position in sustaining pharmaceutical companies' competitive advantage but present difficulties in the access to public health. This discussion, therefore, adopts a theoretical analysis of the legal factors, strategic directions, and ethical implications of IP protection in relation to public health requirements as demonstrated in this study through case studies, interviews, and legal review. The TRIPS Agreement, the U.S. Defend Trade Secrets Act (DTSA), and the EU Trade Secrets Directive demonstrate different theoretical frameworks for protecting undisclosed information necessary for pharmaceutical competitiveness (Lemley & Melamed, 2013). Despite making these elements obligatory within any GATT member, TRIPS sets a minimally acceptable protection standard for trade secrets that LMICs must meet; moreover, it also makes allowances for exceptions to allow LMICs to make accessibility of medicines for diseases like COVID-19 a priority – in theoretical terms, the stipulation about there being a 'balance between IP protection and public health' (Azam, 2016) Indeed. The DTSA offers the American pharmaceutical companies a legal tool to prevent misappropriation, thus, strengthening a theoretical justification of IP as an incentive for innovation. However, the Amgen vs. Novartis case shows the theoretical conflict between the promotion of biologic innovation and affordable biosimilars, raises ethical issues regarding the delay in access to treatment (Feldman & Frondorf, 2017).

The EU Trade Secrets Directive that standardizes the protection of trade secrets across member countries affirms the theoretical role of IP protection in encouraging innovation, but it has potential negative effects on public health in crises, including the COVID-19 crisis (Stevens et al., 2011). The theoretical conflict between IP protection and the principle of access to essential medicines was illustrated by the Gilead Sciences case: patent protection of Remdesivir restricted the availability of generics during the pandemic (Flynn & Silva, 2021). The industry's desire to recover R&D costs must be weighed against the theoretical obligation of the industry to protect public health in crises. Health care businesses, more so, pharma companies particularly restrain themselves and their innovative products through IP protection to maintain profitability, continuous innovation and future funding of research. However, theoretical critiques argue that operations of such corporations affecting access to critical medicines compromise public health. The case of Remdesivir from Gilead Sciences shows how controversy lies in applying trade secrets and how public health stakeholders claim that patient should come first rather than the company's revenue (Kapczynski, 2007). This theoretical conflict is a manifestation of the clash of interest between the corporate world and the global health responsibility. In the Amgen vs. Novartis case on biosimilars, the theoretical need to protect biologics for innovation is diametrically opposed to affordable access to essential medicines. This is particularly important in developing countries where availability of expensive treatments is often a mirage. This may prolong the time taken to grant access to biosimilars, which reasserts a theoretical paradox between encouraging innovation and providing affordable healthcare (Kyle & McGahan, 2012).

The theoretical weakness within trade secret protection, especially in competitive markets, was illustrated in the 2018 theft of GlaxoSmithKline's biopharmaceutical trade secrets by a former employee. On the one hand this argues the need for strict IP laws to support global pharmaceutical development, on the other it shows the ethical dilemma that occurs when the sharing of information affects global population drug supply and special access to health enhanced drugs (Balogh et al.,nd) On the other hand, AstraZeneca's voluntary licensing of the COVID-19 vaccine theoretical model of corporate social responsibility trying to preserve trade secrets, which serves the interest of global health, as well as competitive advantage. This example implies that there is a possibility of the existence of a framework that companies can apply in the determination of public health responsibilities and IP rights with the help of elasticities of IP in the event of public

health disasters (Maskus, 2000). AstraZeneca's strategy is a conceptual model for how pharmaceutical companies can give back to the world without necessarily losing their place in the market.

Thus, theoretical discussions of trade secret protection in the pharmaceutical industry raise ethical issues. Big pharma has every right to IP protection, but public health imperatives require openness and availability of essential medicines (Ragavan & Vanni, 2021). The theoretical conflict between 'Innovation Incentives' and 'Access to Medicines' is evident in the interviews and case studies. Although trade secrets promote investment in R&D, they also deny people in low- and middle-income countries access to cheap medicines.

This is due to the COVID-19 pandemic elucidating the need for more flexibilised trade secret protection measures during public health crises, which institutions like WHO are calling for IP-solutions for treatment availability. Theoretical frameworks indicate that there is a need to strike a better balance between the protection of IP assets and the provision of innovation requirements and public health concerns (Merges & Nelson, 1990). From cases like Amgen vs. Novartis, one discerns the ethical dilemmas of getting biologic patent protection; though such incentives are required for the production of new therapeutic goods, they also serve to slow down biosimilars, which means reduced access to cheaper healthcare for patients in poor populations (Sheppard, 2021).

5. CONCLUSION

The tradeoff between trade secret protection and public health in the pharmaceutical industry remains a theoretical challenge, situated at the intersection of legal, ethical, and corporate interests (Kapczynski, 2019). Intellectual property laws play a critical theoretical role in encouraging innovation, as they provide pharmaceutical companies the assurance needed to invest heavily in research and development. Frameworks such as the TRIPS Agreement, the U.S. Defend Trade Secrets Act (DTSA), and the EU Trade Secrets Directive support companies' efforts to protect proprietary knowledge, enabling the pharmaceutical sector to justify substantial R&D expenditures for new drugs, therapies, and technologies. Without these protections, companies argue that the financial incentive for pharmaceutical innovation would significantly diminish, potentially impacting future advancements in medical treatments. However, the case studies demonstrate the ethical and theoretical difficulties in enforcing these protections strictly during public health crises. For instance, Gilead Sciences' Remdesivir patent enforcement during the COVID-19 pandemic limited access to this life-saving drug in low- and middle-income countries. The theoretical tension here reflects the ongoing conflict between profit-driven motives and the ethical obligation to ensure global health access. Similarly, the legal dispute between Amgen and Novartis over biologics and biosimilars represents a theoretical struggle to protect complex innovations while also allowing for the creation of affordable alternatives once patents expire. These examples illustrate the theoretical and ethical challenges companies face in attempting to balance proprietary interests with the societal demand for accessible healthcare.

In contrast, AstraZeneca's voluntary licensing of its COVID-19 vaccine technology on a no-profit basis during the pandemic provides an example of how companies can reconcile social responsibility with competitive advantage. AstraZeneca's approach highlights a theoretical model for companies to consider public health imperatives during crises while maintaining long-term market credibility and profitability. This example suggests that public-private partnerships and voluntary licensing can serve as frameworks for balancing IP protection with public health needs. The study's findings advocate for a more flexible and ethically driven approach to trade secret protection, especially in public health emergencies. This includes encouraging international cooperation and policy adjustments that allow pharmaceutical innovation to flourish without compromising essential drug access. Solutions could involve public-private partnerships, compulsory licensing, or international agreements that reconcile public health interests with the legitimate IP rights of pharmaceutical companies (Geiger & Izyumenko, 2020).

As global health challenges continue to intensify, the theoretical and ethical dimensions of IP protection will require both policymakers and the pharmaceutical industry to work collaboratively. The study concludes that innovation must be safeguarded, but not at the expense of public health, especially in times of global crises. Embracing more flexible and ethical approaches to trade secret protection could enable simultaneous progress in pharmaceutical innovation and advancements in global health, particularly in underserved regions.

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