

Intellectual Property Rights and Patent Laws on Pharmaceuticals

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Abstract

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), formed during the establishment of the WTO in 1995, serves as a crucial framework for governing intellectual property rights (IPRs) globally. TRIPs also sets forth patent laws, particularly affecting major pharmaceutical companies producing AIDS-related drugs worldwide. While safeguarding the interests of national companies, the USTR has emphasized the protection of IPRs, leading to interventions in public health crises in various developing countries. This dynamic often pits the profit interests of large corporations against the rights of impoverished individuals to access essential treatments. Notably, TRIPs permit countries to issue compulsory licenses in times of national emergency or extreme urgency, enabling access to lifesaving medications like HIV/AIDS treatments in developing countries. Despite this provision, the utilization of compulsory licensing (CL) for producing generic HIV/AIDS medications has been restricted due to political and economic pressures. However, it remains a vital tool within the international legal framework for addressing public health emergencies and ensuring access to crucial medications. In certain cases, countries have chosen to forgo implementing CL provisions, reflecting complex negotiations around public health needs and international agreements. Intellectual patent protections, while intended to foster innovation, can hinder local trade and industry development through restrictive licensing terms, price fixing, and other barriers to accessing patented products. In response to these challenges, some countries have adopted measures tailored to their populations' needs, despite facing opposition from the USTR. For instance, South Africa enacted the Medicines and Related Substances Control Amendment Act, facilitating the use of

generic drugs and enabling the supply of more affordable alternatives in specific situations. Issues such as CL and patent evergreening in India also draw scrutiny from multinational corporations and foreign investors. To chart a meaningful path forward for global IPR governance, a thorough examination of historical contexts is necessary to counter prevailing narratives that may distort the realities of this regulatory landscape. Additionally, raising awareness of the socioeconomic implications of robust IPR protection is crucial for informed decision-making and policy development.

Keywords: Structural Adjustment Programs, Traditional Knowledge System, Compulsory Licensing, Exclusive Marketing Rights and Neo-Colonization

1. Introduction

In the contemporary global landscape, the discourse surrounding Intellectual Property Rights (IPRs) has transcended the realm of digital music downloads to encompass critical sectors such as trade, health, education, and agriculture. The prominence of IPR issues on the advocacy agenda has surged, reflecting their far-reaching implications. In the post-Second World War era, countries like Korea navigated development paths under relatively lax IPR regimes. However, the Trade-Related aspects of Intellectual Property Rights (TRIPs) agreement ushered in a new era, constraining such developmental trajectories. This paradigm shift underscores the challenge of achieving convergence between affluent and impoverished regions in the current global milieu (May & Sell, 2008, p. 2).

The question of pharmaceutical patents and access to essential medicines has assumed greater significance in the 21st century, challenging the perception of IPRs as mere economic intricacies. The exorbitant costs associated with sustaining human immunodeficiency virus (HIV) patients with existing drug regimens in developed countries starkly contrast with the limited healthcare budgets of developing countries. This disparity has drawn sharp criticism toward the functioning of IPRs within the global framework, particularly concerning pharmaceutical patents. Structural adjustment programs (SAPs) further compound the issue, as healthcare expenditures in developing countries decline, exacerbating the unaffordability of life-saving medications for individuals afflicted by AIDS (May & Sell, 2008, p. 1).

The pursuit of cheaper generic alternatives to pharmaceutical drugs has prompted some multinational corporations to offer discounted or even free drug shipments. However, contentious issues persist, as exemplified by India's inclusion on the 'Priority Watch List' of the US Trade Representatives (USTR) due to concerns over compulsory licensing (CL), unfair commercial practices, and weak enforcement of Data Exclusivity Laws. Notably, legal disputes between the US and Brazil underscore the USTR's unwavering commitment to upholding IPRs, regardless of the human costs (May & Sell, 2008, p. 1-2).

This paper endeavors to shed light on the challenges faced by multinational pharmaceutical companies in developing countries, amidst political and economic pressures within the international legal framework, while striving to ensure access to essential medications (Pal, 2018, p. 2).

2. Objectives

- a. To assess the challenges encountered by developing countries under Pharmaceutical Patenting provisions.
- b. To scrutinize the shortcomings of CL.
- c. To examine the misuse of patenting by multinational corporations and its ramifications on local trade and industries.
- d. To investigate instances of unfair commercial practices during patent applications under IPR provisions.
- e. To comprehend the repercussions of USTR's IPR protection on the North-South divide.

3. Literature Review

IPRs have emerged as a cornerstone of global economic development, sparking enduring debates. May and Sell's work underscores the centrality of IPRs in contemporary discourse and scrutinizes accusations of knowledge theft, which are perceived to stifle innovation, creativity, and information accessibility. Their examination of the TRIPs Agreement delineates its transformative impact on the globalized world, navigating through historical social conflicts and political maneuverings surrounding the commodification of knowledge. From ancient commerce to modern controversies, the book traverses a spectrum of issues, illuminating the evolving conceptions of rights and duties in IP law (May & Sell, 2008).

Dr. Prankrishna Pal's compilation delves into the broader ramifications of TRIPs on the Indian economy and its implications for agriculture and pharmaceuticals. By dissecting various aspects of patent regimes, the book sheds light on India's trajectory under evolving international legal frameworks, offering insights into patent disputes, CL, and dispute resolution mechanisms (Pal, 2018).

Vandana Shiva's exploration of patent myths dissects the implications of globalized patent regimes on India's heritage, economy, and societal fabric. By debunking prevalent misconceptions, Shiva underscores the ethical, ecological, and economic dimensions of patent laws, revealing the inequities inherent in IPR regimes. Her work advocates for a balanced approach to patent regulation, emphasizing ecological preservation, knowledge diversity, and equitable legal frameworks (Shiva, 2001).

The discourse on IPRs extends beyond economic realms to encompass broader developmental imperatives. Finger and Schuler's work examines the international community's efforts to safeguard traditional knowledge and combat bio-piracy, shedding light on the commercial potential of diverse knowledge systems in developing countries. Their exploration underscores the legal and commercial imperatives underpinning efforts to address developmental challenges (Finger & Schuler, 2004).

The Department of Science and Technology's primer provides a comprehensive overview of IP categories, with a particular focus on patents and copyrights. By elucidating key concepts and legal frameworks, the primer equips stakeholders with essential knowledge

to navigate IP landscapes. It also highlights emerging issues such as trade secrets and traditional knowledge, underscoring the evolving contours of IP regimes.

In examining the impact of Indian patent laws on economic growth, Moturi and Mohan elucidate the pivotal role of IP protection in fostering innovation and market development. Their study underscores the transformative impact of TRIPs on India's pharmaceutical sector, charting a trajectory marked by evolving patent laws and burgeoning economic growth (Moturi & Mohan, 143-146).

The evolving landscape of Indian patent laws and their implications for foreign direct investment (FDI) in the pharmaceutical sector are dissected by Linton and Corrado. Their analysis traces India's transition from a protective stance on pharmaceutical patents to compliance with international IP norms, shedding light on the resultant surge in FDI and strategic alliances. Their work underscores the nuanced interplay between patent laws, economic development, and foreign investment (Linton & Corrado).

Johanna Sheeha's examination of the interpretation of Indian patent laws illuminates the complexities inherent in patent issuance. By scrutinizing prevailing legal interpretations, Sheeha uncovers cultural influences shaping patent law decisions and their ramifications for innovation and drug development. Her analysis underscores the need for a balanced approach to patent regulation, balancing cultural preferences with broader developmental imperatives.

Sruthi Darbhamulla's examination of IP challenges in India interrogates issues raised in the US Special 301 report, shedding light on patentability criteria, waiting periods for patent issuance, and data safety concerns. Her analysis provides insights into ongoing debates surrounding patent regimes and their implications for India's innovation ecosystem.

Collectively, these works offer a nuanced understanding of the multifaceted landscape of IPRs, underscoring their centrality to economic development, innovation, and societal well-being. From historical analyses to contemporary debates, these studies illuminate the complex interplay between legal frameworks, economic imperatives, and developmental aspirations in shaping global IP landscapes.

4. Theoretical Framework

Law serves as a reflection of societal norms and, at times, is explicitly designed to shape or reshape such norms. Property itself is not inherently natural; as Walter Hamilton noted, the judiciary does not protect property per se but rather designates what qualifies for protection (quoted in Cribbet 1986, p. 4). Property, in a legal context, only exists as defined by the law; it is a codification of specific social relationships, particularly those between owners and non-owners, manifested through the rights granted to owners (May and Susan, 2008, pp. 44–47).

The term “intellectual property” is a relatively recent rhetorical construct. Although it likely emerged in the mid-nineteenth century (Hesse 2002, p. 39), during the first half of the twentieth century, “industrial property” was more prevalent. Lysander Spooner, an American librarian, appears to be among the first to use the term “intellectual property” in print, arguing in 1855 for scientists and investors to have permanent property rights in

their ideas (Dutfield 2003, p. 53). Notably, the term “intellectual property” was scarcely used in US federal court reports prior to 1900, and its frequency gradually increased over the years, particularly soaring in the 1990s.

Following World War II, there was a proliferation of international agreements and national laws governing IP. Before the agreement on TRIPS in 1995, there was no cohesive global system for IP protection (Pal, 2018, p. 93).

Several key international agreements paved the way for the current global IP regime, including the Paris Convention for the Protection of Industrial Property in 1883 and the Berne Convention for the Protection of Literary and Artistic Works in 1886. These agreements established fundamental principles of IP protection, recognizing authors’ and inventors’ rights to control the use of their creations, ensuring national treatment for foreign IP owners, and setting minimum standards for protection (Pal, 2018).

In the 1970s and 1980s, debates and negotiations centered on IP protection in developing countries. Developed countries advocated for stronger protection while developing ones argued that such protections could impede access to essential medicines and technologies. This culminated in the TRIPS agreement, signed in 1994 as part of the Uruguay Round of trade negotiations under the WTO (Pal, 2018).

The TRIPS agreement established a unified global system for IP protection, mandating all member countries to provide minimum standards of protection for patents, trademarks, copyrights, and other forms of IP. This marked a shift from voluntary to mandatory protection and required developing countries to adopt stronger IP safeguards (Guadamuz, 1796).

The TRIPS agreement symbolizes a forceful assertion that knowledge can be treated as property, representing a neoliberal agenda of global governance. Drafted substantially by lawyers and economists from twelve US multinational corporations, it reflects an overwhelmingly Anglo-Saxon legal discourse promoting a specific view of IPRs justification and efficiency benefits derived from treating knowledge as property (May and Susan, 2008, p. 3).

Patents, as a form of IP, grant inventors exclusive rights to make, produce, distribute, and sell their patented products or use patented processes. They incentivize innovation and foster economic growth by providing inventors with a period of exclusivity to capitalize on their inventions, recoup research and development investments, and facilitate licensing and technology transfer (Pal, 2018, p. 93).

The concept of patents dates back to ancient civilizations such as Greece and Rome, where inventors were granted exclusive rights to their inventions for a limited time. However, the modern patent system, as we know it today, began to take shape in late 16th and early 17th century Europe, with the enactment of the first modern patent laws in Venice in 1474, followed by similar legislation in other European countries like England, France, and the Netherlands (Guadamuz, 1796).

In England, the first patent law, enacted in 1623, granted inventors a 14-year monopoly in exchange for disclosing their inventions. This law also introduced the concept of novelty, requiring inventions to be both new and non-obvious to qualify for patent protection (Guadamuz, 1796).

Thomas Jefferson introduced the concept of patents to the US, believing they would foster innovation and economic development. The first US patent law passed in 1790, similarly provided inventors with a 14-year monopoly on their inventions. However, historically, patents have served three distinct purposes: “patents for conquest,” “patents for inventions,” and “patents for imports,” although the legal boundaries between these functions have often been blurred.

Originally, patents were referred to as “letters patent,” publicly announced documents with the seal of the sovereign grantor. These letters, dating back to the sixth century in Europe, were initially used for the discovery and conquest of foreign lands on behalf of monarchs. The use of patents for conquest has laid the groundwork for contemporary disputes over patents, particularly within the framework of GATT/WTO (Shiva, 2001, pp. 31–32).

Patents are frequently regarded as tools of recolonization by Third World countries but are considered a “natural” right by Western powers, akin to conquest during colonial times. Today, patents are encompassed within the broader concept of “intellectual property,” or property pertaining to products of the mind. Similar to how the land was treated as “terra nullius” during colonization despite indigenous habitation, knowledge is often converted into IP, even though it may originate from existing indigenous knowledge systems. This claim to invention justifies the imposition of globalized patent regimes, akin to the conquest of diverse knowledge and economic systems (Shiva, 2001, pp. 31–32).

The patent system has evolved over time, adapting to new technologies and the globalization of commerce. Today, patents cover a wide range of inventions, including pharmaceuticals, computer software, mechanical devices, and business methods. The duration of patent protection varies by country but typically lasts for 20 years from the filing date (Guadamuz, 1796).

Pre-TRIPS, the post-World War II IP regime was characterized by fragmentation and disparities in protection levels across different countries. The TRIPS agreement aimed to standardize and unify these protections globally, with the goal of fostering innovation and economic growth (Guadamuz, 1796).

In a capitalist economy, IP plays a central role in creating rivalry, as evidenced by the division between the affluent North and the less prosperous South (Veen, 2002). The history of IP illustrates its emergence as a functional rather than political construct. Under the TRIPS agreement, routes to development through weak IP regimes, as seen in countries like Korea in the pre-TRIPS era, are increasingly restricted. This widening divide aligns with the principles of World System Theory (Pal, 2018, p. 2).

The **World System Theory**, conceived by Immanuel Wallerstein, offers a socio-economic perspective suggesting that the globe functions as a unified economic entity with distinct core, periphery, and semi-periphery regions. Core countries wield dominance, dictating global economic and political affairs, while periphery countries are exploited, providing cheap labor and raw materials to the core (Rastogi, 2021).

Examining the IP Regime through the lens of World System theory reveals how it reinforces existing power dynamics between core and periphery countries. Laws and regulations governing IP, primarily shaped by core countries, often erect barriers hindering

periphery countries from accessing technology, information, and other intellectual assets (Rastogi, 2021).

Core countries may exploit IP laws to impede technology transfer or hinder periphery countries from obtaining life-saving drugs or crucial inventions. Consequently, core countries maintain a monopoly on IP production and distribution, while periphery countries are marginalized (Rastogi, 2021).

Moreover, IP laws can worsen peripheral country exploitation by enabling core countries to extract value from IP originating in periphery countries. For instance, core countries might patent traditional knowledge or biological resources from periphery countries, depriving the latter of accessing or utilizing their own resources (Rastogi, 2021).

Within the realm of IPRs and the North-South economic gap, Systems Theory provides a framework to analyze the divergent interests of various stakeholders and their interplay with broader social and economic systems. By scrutinizing how IP laws perpetuate power imbalances between core and periphery countries, it becomes feasible to devise more equitable and sustainable IP regimes fostering innovation and benefiting all countries, irrespective of their global economic standing (Wallerstein, 1993, p. 78).

From a systems theory perspective, IPRs serve as a mechanism to safeguard individual creative endeavors and incentivize innovation and advancement. However, these rights must be harmonized with societal needs and interests, particularly within the global economic and social landscape. The North-South disparity underscores how IPRs can compound existing inequalities and power differentials, with developed countries possessing greater resources and technological capabilities to leverage these rights compared to their less-developed counterparts (Mary, 1993, p. 65).

Addressing this discrepancy entails a systems theory-driven approach emphasizing ethical considerations and the pursuit of the common good. This may involve reimagining the current IP framework to better align with the needs and aspirations of all stakeholders, encompassing creators, consumers, and society as a whole. Such initiatives could encompass endeavors to enhance knowledge and technology accessibility while ensuring IPRs do not engender or perpetuate social and economic disparities (Robin, 1993, p. 108).

The systems theory approach to IPRs underscores the significance of individual autonomy and creativity while acknowledging their integration within broader social and economic systems. Achieving a balance between these interests and advancing the common good can potentially establish a more equitable IP system benefiting all stakeholders, regardless of their global location or developmental stage (Rastogi, 2021).

Pharmaceutical companies play a pivotal role in this system, relying on patents to safeguard their investments in research and development. However, these patents can impede access to essential medicines, particularly in less developed countries lacking resources to develop their pharmaceutical industries or negotiate favorable pricing with multinational corporations (Robin, 1993, p. 108).

Addressing this challenge requires a reevaluation of the existing IP framework to better serve the needs of all stakeholders. This may entail initiatives such as promoting access to essential medicines through CL or exploring alternative models for drug development and distribution. Ethical considerations and the pursuit of the common good, especially amidst the North-South economic divide, must be emphasized (Robin, 1993, p. 108).

For instance, the legal battle between multinational drug companies and the South African government over HIV/AIDS drugs illustrates the tensions between profit-driven motives and public health imperatives. This conflict led to global advocacy for patent system reform, culminating in the Doha Declaration on Trade-Related Aspects of IPRs and Public Health in 2001 (May and Susan, 2008, p. 4).

The **dependency theory** offers another critical perspective on the global economic system, positing that periphery countries rely on core countries for economic and technological advancement. In the context of IP, this theory argues that existing laws and regulations primarily favor core countries, limiting periphery countries' access to technology and knowledge (Nachane, 1998, pp. 25–46).

In contrast to the world system theory, dependency theory places greater emphasis on the role of multinational corporations in perpetuating global economic inequalities. It suggests that these corporations, predominantly from core countries, wield significant control over technology and knowledge production and distribution, exploiting IP laws to maintain their dominance (Nachane, 1998, pp. 25–46).

Both theories provide valuable insights into how IP regimes perpetuate global economic inequalities and reinforce power imbalances between countries. By examining these dynamics, it becomes possible to develop more inclusive and sustainable IP frameworks that foster innovation and benefit all countries, regardless of their position in the global economic hierarchy (Nachane, 1998, pp. 25–46).

The social planning theory introduces the role of the state in shaping social outcomes and promoting the public interest through policy interventions. In the realm of IP, this perspective underscores the government's responsibility to regulate IP development and usage to ensure societal benefits (Janhavi, 2021).

For instance, the case of *Pfizer vs. Canada* exemplifies social planning theory in action, where the Canadian government issued a CL for Viagra to enhance access to essential medicines and improve public health outcomes. This deliberate policy intervention aimed to address market failures and promote greater equity and fairness within the healthcare system (Hughes and Dino, 2005, pp. 52–58).

From this standpoint, government interventions in IP matters are essential for advancing the public interest and mitigating disparities, thus contributing to overall societal welfare and equity (Janhavi, 2021).

The **Economic Theory** of Intellectual Property underscores the necessity of providing inventors and creators with adequate incentives to foster innovation and invest in new technologies and creative works. A robust IP regime, characterized by well-defined and enforceable rights, is believed to encourage firms to allocate resources to research and development endeavors and introduce novel products to the market (Bhattacharya, 2020).

The *Pfizer vs. Canada* case exemplifies how economic theory interacts with IP law. In 2004, Pfizer obtained a patent for Viagra, a widely-used treatment for erectile dysfunction. However, the Canadian government issued a CL permitting a local generic drug manufacturer to produce and distribute a more affordable version of the drug. From an economic standpoint, this move challenged the incentive structure fundamental to the patent system. By allowing a competitor to enter the market without the patent holder's

authorization, the Canadian government diminished Pfizer's exclusive rights and financial incentives associated with the patent (Hughes and Dino, 2005, pp. 52-58).

Advocates of the Canadian government's action argue that CL can serve as a mechanism for balancing the interests of inventors and creators with those of society at large. In this instance, the availability of a lower-priced generic alternative could have expanded access to erectile dysfunction treatment, potentially resulting in significant health improvements and enhancements in quality of life for Canadian citizens (Perry and Currier T., 2012).

This case illustrates the tension between economic theory and social planning theory within the realm of IP law. While a robust IP regime can stimulate innovation and investment, it must be weighed against broader societal needs, particularly concerning the promotion of public welfare and the attainment of social and economic objectives (Perry and Currier T., 2012).

The **Network Theory of Patentability** offers a distinct perspective, positing that innovation and creativity stem not solely from individual efforts but from collaborative interactions within an extensive innovation network. In this view, the traditional concept of patents as a mechanism to reward individual inventors may not fully capture the intricate and dynamic nature of innovation in contemporary society (Whalen and Pedraza-Fariña, 2023, article-87.1).

The *Novartis* case in India exemplifies the application of the Network Theory of Patentability. The Indian patent office rejected Novartis' patent application for a drug, arguing that it lacked significant differentiation from an existing medication, rendering it ineligible for patent protection under Indian law. This case underscores the need to balance innovation and investment in new drugs with the imperative of ensuring affordable access to essential medicines (Ramsurya, 2010).

From this perspective, patents should be viewed as instruments for safeguarding and nurturing the broader innovation network rather than merely rewarding individual inventors. This approach may entail fostering collaboration and knowledge-sharing among diverse actors within the innovation ecosystem, as well as promoting the development of technologies and industries that benefit society as a whole (Whalen and Pedraza-Fariña, 2023, article-87.1).

John Locke's **Natural Rights Theory** of Intellectual Property asserts that creators possess a moral or natural right to the products of their labor, necessitating the enactment of IP laws to protect these rights. According to Locke, individuals have inherent rights derived from natural law or higher powers, including the right to property. In the context of IP, this theory posits that inventors and creators inherently deserve the right to profit from their inventions (Shiva, 2001, p. 8).

The case of John Moore, whose cell line was patented without his consent, exemplifies the challenges inherent in the application of the Natural Rights Theory of Intellectual Property. Moore's tissue was patented by his doctor during cancer treatment, leading to its commercialization without Moore's knowledge or consent. This case highlights the philosophical debate surrounding the extent of individuals' rights over their biological materials and the necessity of protecting creators' rights while ensuring ethical and equitable outcomes (Shiva, 2001, p. 8).

International declarations and agreements, such as the UN Political Declaration on Universal Health Coverage and the Sustainable Development Goals, emphasize the importance of ensuring access to affordable and quality healthcare services and medicines for all individuals. The Universal Declaration of Human Rights and the World Health Organization Constitution recognize the fundamental right to health and well-being, underscoring the need for ethical considerations and the pursuit of the common good in the context of global health systems (Banerji, 2021).

The case of *Gilead Sciences and the Hepatitis C drug Sovaldi* further elucidates the tension between the Natural Rights Theory of Intellectual Property and broader concerns about access to essential medicines. While Gilead Sciences had a legitimate claim to the profits from Sovaldi due to its substantial investments in research and development, critics argued that the high price of the drug hindered access to life-saving treatment, particularly in developing countries (Raymond, 2018).

Addressing this tension requires a nuanced approach to IP that balances the natural rights of inventors and creators with broader societal needs. Policies promoting access to essential medicines, such as CL and alternative drug development models, are essential to ensuring equitable access to healthcare. Moreover, ethical considerations and the pursuit of the common good should guide IP frameworks, particularly in critical areas like healthcare (Banerji, 2021).

In conclusion, the Natural Rights Theory of IP underscores creators' inherent rights to the fruits of their labor, while the Economic Theory emphasizes the importance of incentivizing innovation and investment. The Network Theory of Patentability highlights the collaborative nature of innovation, and the Social Planning Theory underscores the role of the state in promoting the public interest. Balancing these perspectives is crucial for developing IP frameworks that foster innovation, promote societal welfare, and ensure equitable access to essential goods and services.

The **Utilitarian Theory** of Intellectual Property posits that IPRs should be granted and enforced to the extent that they promote overall social welfare. Unlike other theories that focus on protecting individual creators or inventors, this theory prioritizes fostering innovation and creativity for the collective benefit of society. IP laws should be flexible and designed to facilitate access to essential goods, particularly in sectors like healthcare where public health is at stake (Banerji, 2021).

In the pharmaceutical realm, a utilitarian approach to IP emphasizes policies that enhance access to vital medicines and contribute to improved public health outcomes. Measures such as CL can ensure that life-saving drugs are available at affordable prices, thus aligning with the broader goal of promoting social welfare (Banerji, 2021).

However, it's essential for utilitarian theory to strike a balance between incentivizing inventors and creators to invest in new technologies and creative works and ensuring broad access and social welfare. While IPRs can provide incentives for innovation, they must not hinder access to essential goods and services (Banerji, 2021).

The case of *Association for Molecular Pathology v. Myriad Genetics* exemplifies how utilitarian theory informs IP policies in the pharmaceutical industry. The court's decision not to allow patents on isolated DNA sequences was driven by the recognition of the importance of promoting scientific research and innovation in genetics. By upholding

patents on synthetic DNA sequences, the court struck a balance between inventors' interests and the broader public interest in fostering innovation and ensuring access to essential medicines (Jorge, 2021).

In a recent development, the Indian government amended the Patents Rules to reduce fees for patent filing and prosecution for educational institutions by 80 per cent, aiming to spur innovation and technological development. This legislative change reflects the utilitarian perspective, which emphasizes policymakers' responsibility to balance the interests of inventors and creators with broader societal and economic considerations. By implementing policies that maximize overall social welfare, IPRs can serve as catalysts for innovation and creativity while ensuring equitable distribution of benefits throughout society (Department for Promotion of Industry and Internal Trade, 2021, Part II, Section 3, subsection-i).

Additionally, the **Ethic and Reward Theory** posits that individuals and companies are motivated to create and innovate when assured of rewards through IP Regime protection. This theory underscores the ethical values inherent in incentivizing innovation and knowledge-sharing within society (Banerji, 2021).

John Stuart Mill's "**Harm Principle**" from his work "On Liberty" further complements the utilitarian perspective by asserting that individuals have the right to self-determination as long as their actions do not harm others. Applied to IP, this principle underscores the importance of preventing actions that impede innovation or hinder access to essential goods, such as patents being used to prevent generic versions of life-saving drugs from entering the market (Ceniceros and Nowaczyk, 2022).

The case of *Bristol-Myers Squibb and the cancer drug Opdivo* exemplifies the potential misuse of patents as tools for rent-seeking rather than promoting innovation. By preventing other companies from producing generic versions of the drug already on the market, the patent hindered access to treatment for patients, highlighting the negative consequences of patents being used to obstruct competition and innovation (U.S. Securities and Exchange Commission, 2004).

In conclusion, the Utilitarian Theory of Intellectual Property provides a framework for developing policies that balance the interests of inventors and creators with broader societal welfare considerations. By prioritizing access to essential goods and promoting innovation, IPRs can serve as instruments for advancing social welfare and fostering progress within society.

5. Discovering New Process of Neo-colonization: Commercialization vs Commoditization

In our current era, ecological knowledge holds immense significance, serving as a vital link to humanity's future and underscoring the importance of preserving diverse creative traditions. However, contemporary society often views knowledge through a capitalistic lens, treating it as a commodity and a tool for exclusive market control, particularly evident in the patent system. This perspective fosters dominant control while stifling innovation in the absence of protection (Shiva, 2001, p. 21). The tension between granting

patents for individual innovation and recognizing knowledge as a collective endeavor is inherent, as creativity encompasses diverse expressions and knowledge systems across cultures. Protecting this diversity is crucial not only for biodiversity conservation but also for preserving intellectual diversity within research settings (Pal, 2018). The belief that Intellectual Property Rights (IPRs) are essential for fostering creativity is flawed, as it assumes creativity is solely profit-driven, neglecting the scientific creativity of those not motivated by financial gain. Moreover, protecting cultural values becomes complex when traditional knowledge is commercially exploited outside indigenous communities. Therefore, broader recognition and protection of diverse creativities and knowledge systems are imperative for fostering true innovation and preserving cultural heritage (Shiva, 2001, pp. 21-26; Pal, 2018).

A controversy erupted when the USPTO granted a patent for a variety of the Ayahuasca plant, disregarding the sacred status and religious beliefs of indigenous peoples, despite opposition from groups like COICA (Wiser, 1991). This exemplified the limitations of existing IPR laws in safeguarding cultural heritage and addressing cultural appropriation (Schuler, 2004, pp. 169–170). Additionally, the belief that creativity depends solely on formal IPR protection overlooks the inherent creativity in nature, traditions, and non-profit-driven endeavors (Shiva, 2001, p. 23).

TKSs are rich repositories of wisdom, particularly in indigenous communities, encompassing diverse knowledge passed down through generations (Shiva, 2001, p. 23). However, TKSs face threats from colonization, industrialization, and globalization, leading to their marginalization and erosion (Shiva, 2001, p. 23). Efforts are underway to integrate traditional knowledge into scientific research and policymaking to preserve this invaluable heritage for future generations (Shiva, 2001, pp. 26–27).

The administration of traditional technical knowledge is governed by customary rules, and while it may not meet patenting criteria, it can be regulated by customary laws to ensure respectful use (Ragavan, 2001, pp. 8-9, 13; WTO, 2001; Watanabe, 1985). However, bio-prospecting missions by companies often exploit indigenous knowledge without adequate compensation, leading to bio-piracy.

The economic disparity between industrialized and Third World countries is rooted in historical colonialism, perpetuated by mechanisms that drain wealth from the latter (Watanabe, 1985). Patents have historically been linked to colonization, perpetuating neocolonialism through globalized patent regimes (Shiva, 2001, pp. 12–13).

Kwame Nkrumah, a prominent advocate of pan-Africanism in the 20th century and a Ghanaian statesman, introduced the term “neocolonialism” to describe a modern form of colonial domination that emerged after many African countries gained independence from European colonial powers. In his book, “Neo-colonization: the Last Stage of imperialism,” Nkrumah points out;

“The essence of neo-colonialism is that the State which is subject to it is, in theory, independent and has all the outward trappings of international sovereignty. In reality its economic system and thus its political policy is directed from outside”.

Neocolonialism, as argued by Nkrumah, signifies the continued dominance of former colonial powers over their former colonies through indirect means such as economic aid, foreign investment, and military intervention (Nkrumah, 1965). The contemporary

use of patents mirrors historical land conversion during colonization, serving as tools of conquest that perpetuate wealth drainage from the poor to the rich (Watanabe, 1985).

In the early 1970s, indigenous peoples in Latin America gained political visibility through ethno-political movements, with countries like Peru and Ecuador leading in promoting ethno-political mobilization. COICA, representing indigenous organizations in the Amazon Basin, has learned valuable lessons from positive and negative experiences, enabling effective management of relationships with entities from the North (Jiménez, 2004, p. 44).

Indigenous peoples propose a *sui generis* system for safeguarding their rights, asserting the inadequacy of Western assumptions and legal frameworks in engaging with their communities (Jiménez, 2004, pp. 45–47). Ethno-political movements in the Amazon Basin resist Western pressures that threaten to fragment indigenous knowledge systems (Jiménez, 2004, pp. 45–47). The erosion of cultural diversity marginalizes indigenous peoples, treated as relics rather than viable alternative systems (Jiménez, 2004, p. 49).

Globalization facilitates the flow of ideas, goods, and people across borders, leading to criticisms of Western thought and systems imposed through globalization (Schuler, 2004, pg. 183). Traditional knowledge holds significant value, with up to 74 per cent of plant-derived human drugs originating from it, yet faces challenges in commercialization due to perceived lack of value (Jiménez, 2004, p. 51).

Critics of biopiracy argue that businesses profit from the knowledge of impoverished peoples, with patents sometimes successfully challenged for lacking novelty (James, 1985). The commercialization of traditional knowledge offers economic development opportunities but raises concerns about exploitation and healthcare disparities (Greer, 1973). Patenting traditional knowledge without consent can lead to loss of control over resources and appropriation of cultural heritage (Greer, 1973).

Traditional knowledge guides further research in identifying active compounds, with some companies directly basing their programs on it (Kate and Laird, p. 143). The legal framework promoted by TRIPS and WTO primarily serves multinational corporations, though agreements like the MOU between Pfizer and the San Bushmen recognize traditional knowledge origins (Woodmansee, 2004; Kate and Laird, 2004, pp. 143–147).

Focus on hazardous chemical pesticides over sustainable alternatives like neem has led to detrimental consequences, prompting a shift towards biological alternatives (Shiva, 2001, pp. 51–52). Patents on neem-based products, despite their traditional use, have sparked challenges and debates on recognition of collective innovation (Schuler, 2004, pp. 161–163). For instance, the neem tree (*Azadirachta indica*), known for its medicinal properties for over 2,000 years, has faced over 400 US patents and several hundred patents in the European Patent Office (EPO) database, including patents on azadirachtin, its active pesticidal agent (Saraswat, 2003; Ahmed, 2013).

Traditional treatments for jaundice and diabetes, based on herbs like *Phyllanthus niruri* and karela, have been patented, raising concerns of bio-piracy (Shiva, 2001, pp. 53–55). Similarly, patents on turmeric-based therapies have been challenged, with USPTO overturning one such patent in 1997 (Balasubramanian, 2017; Schuler, 2004, pp. 166–169). Nearly 400 US patents related to turmeric exist, underscoring the issue of ethno-botanical knowledge transmission to industrialized countries (Schuler, 2004, p. 168).

The controversy over seed ownership through the IPR regime is significant, as seeds represent life's continuity and embody cultural heritage (Shiva, 2001, pp. 69-71). Traditional seed-saving practices are endangered by new technologies and the universalization of IPRs, restricting farmers' rights and hindering biodiversity conservation (Dutfield, 1998).

WTO-driven IPRs empower corporations to monopolize seeds, threatening agricultural foundations and food security (Shiva, 2001, pp. 76-77). For instance, patents on high oleic acid sunflower varieties restrict others from developing similar varieties, perpetuating corporate control (Shiva, 2001, p. 77).

Basmati rice, a cultural treasure, faces biopiracy threats, exemplified by RiceTec's patent for new basmati strains (Goldfinger, 2007). While revisions narrowed the patent's scope, uncertainties remain about its impact on South Asian growers (Goldfinger, 2007). Efforts are made to protect terms like "basmati" to specific designated varieties (Goldfinger, 2007; Schuler, 2004, pp. 171-174).

From a commercial perspective, Indian companies developing new commercial basmati rice varieties face competition in the marketplace rather than direct harm from foreign patents, necessitating a commercial response (Schuler, 2004, p. 174). Another example of bio-piracy with clear economic consequences involves the patenting of yellow beans from Mexico. Mexican farmers have cultivated yellow beans for centuries, but a US farmer patented a distinct yellow variety named "Enola," subsequently suing importers and growers for patent infringement. The lawsuit disrupted imports, causing economic harm to existing producers (Shashikant, 2009). While the patent doesn't prevent farmers from growing traditional beans, it affects their export revenue, potentially surpassing losses from competition with unpatented US production (Schuler, 2004, pp. 174-176).

Many developing countries have successfully turned traditional plants into profitable export crops, as seen with basmati rice. However, this transformation has not been as widespread for traditional medicines or neem pesticides. The economic impact primarily arises from the commercial exploitation of traditional knowledge rather than the granting of IPR protection (Schuler, 2004, p. 177). A patent alone does not always guarantee commercial success. For instance, the California Basmati Rice company markets its Calmati strain without patent or trademark protection (Schuler, 2004, p. 177). The commercialization of such products in industrialized countries can affect the source country in various ways. One direct consequence is the loss of export markets. Thus, patent systems tend to drain technology and wealth from the Global South to the Global North, rather than facilitating technology transfer in the opposite direction (Schuler, 2004, p. 177).

As countries are compelled to implement TRIPs agreements, the outflow of foreign exchange for royalty payments adds to their debt burden, exacerbating poverty. TRIPs extend patents to food, agriculture, seeds, and plants, effectively converting Third World resources and knowledge into the IP of Northern corporations. This perpetuates a form of neocolonialism, akin to historical exploitation during colonization. Third World countries are losing their technological capacities, while global corporations maintain tight control over patented technologies (Schuler, 2004, p. 177).

According to a UNDP study, Third World countries are losing significant sums in unpaid royalties for farmers' seeds and medicinal plants. Instead of compensating the South for the use of indigenous knowledge, the US asserts that the South owes billions in

pharmaceutical royalties. This represents an imposition of Western-style IPRs systems on a world characterized by profound inequalities, constituting a direct infringement on the economic rights of the poor (Schuler, 2004, p. 177).

Deepak Nayar highlights the importance of rewarding innovation while ensuring the protection of consumers' interests. The challenge lies in striking a balance between providing enough protection to incentivize innovation and safeguarding the public good. Unfortunately, the TRIPs agreement tilts excessively towards protecting inventors' rights at the expense of the public interest (Shiva, 2001, p. 39).

6. Conclusion

The current landscape of IPRs reflects extensive property rights and economic concentration akin to the late 19th and early 20th centuries. Membership in the WTO requires adherence to TRIPS structures, limiting policy autonomy for follower countries. Despite no proven link between IP protection and investment incentives, many developing nations have signed agreements imposing higher standards of protection. However, the global governance regime for IPRs remains unstable, with TRIPS not representing a final settlement.

Protests against property rights extension, particularly regarding access to HIV/AIDS drugs in sub-Saharan Africa, highlight the trade-offs inherent in IPRs. Recent trends prioritize private rewards over public access, necessitating a balance restoration, as proposed by Rochelle Cooper Dreyfus through a bill of rights for users.

A legitimate international IPR regime should recognize diverse interests and capabilities within and between countries, rejecting a one-size-fits-all approach. Differential treatment allows governments to tailor policies to their economic development levels and innovation capacities.

Negotiations on IPR regulation have returned to WIPO, although focusing on technical issues disregards broader political-economic concerns, especially for developing countries. Harmonization of IPRs is deemed unacceptable given the vast disparities in political and economic development across WTO members. Ultimately, global governance of IPRs must either resemble past national regimes or allow states to reassert sovereignty over certain aspects. Flexibility is crucial for countries to integrate IPRs into national innovation systems tailored to their economic and technological stages.

Several examples, including Costa Rica's biodiversity management and India's digital repository of traditional knowledge, illustrate effective approaches to resource governance and benefit-sharing. These efforts underscore the importance of prior informed consent and benefit sharing, guiding WIPO's initiatives in documenting traditional knowledge and developing protection models.

7. Solutions

- a. Governments might consider enacting policies that acknowledge and safeguard the traditional knowledge systems of indigenous communities, including granting legal recognition and IPRs for traditional knowledge.
- b. Developing countries could persist in negotiations with developed countries to establish a more equitable implementation of TRIPs, addressing the specific needs of developing countries and facilitating the production of cost-effective medications.
- c. Policymakers should explore the implementation of policies promoting the utilization of generic drugs, such as CL or state production of essential medicines, to enhance their affordability and accessibility to patients.
- d. Alternative models for incentivizing innovation in the pharmaceutical industry, such as prize funds, open-source drug development, or patent pools, warrant exploration to foster research and development while ensuring access to affordable medicines.
- e. Increased governmental investment in research and development focusing on medicines and technologies addressing the healthcare requirements of developing countries and neglected diseases like tuberculosis, malaria, and neglected tropical diseases is imperative.
- f. The promotion of public-private partnerships between governments, pharmaceutical firms, and civil society organizations could facilitate joint efforts to enhance access to affordable medicines and advance research and development in the pharmaceutical sector.
- g. Healthcare must be acknowledged as a fundamental human right, prompting governments to invest in robust healthcare systems ensuring universal access to essential medicines and healthcare services, irrespective of economic status.
- h. Collaborative efforts among governments and stakeholders are essential to raise awareness and educate the public on issues related to IPRs and pharmaceutical patents, particularly their impact on healthcare access and affordability.

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