 DOI: *https://doij.org/10.10000/IJLMH.119755*

INTERNATIONAL JOURNAL OF LAW MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

Volume 8 | Issue 3

2025

How Patenting Pharmaceutical and Medical have an Impact on the Aspect of Accessibility, Affordability, and Availability in Relation with TRIPS

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ABSTRACT

This research analyzes the effect of patenting of pharmaceutical and medical products on accessibility, affordability, and availability in the context of India's implementation of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Before TRIPS, India's patent system allowed for a strong generic drug industry through process patents, leading to widespread access to low-cost medicines. The essay delves into the past development of India's patent regimes, the 2005 transition to product patents in adherence to TRIPS, as well as the consequences and adjustments thereof by the stakeholders such as government agencies, NGOs, and local pharmaceutical companies. It also touches on the effects of enhanced intellectual property rights in raising drug prices, market competition, and public health. Mechanisms like compulsory licensing and Section 3(d) of the Indian Patents Act are examined as a means to address TRIPS-related restrictions. Strategic responses by developing countries—fragmentation, mimicry, and counter-harmonization—to maintaining access to essential medicines are also assessed in this paper. Empirical evidence indicates price rises following patenting were moderate but structural changes affected market behavior. The results reflect the fine balance between encouraging innovation via patent protection and protecting public health in developing countries.

I. INTRODUCTION

The text explores India's response to the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement, a significant development that mandated the introduction of product patents on pharmaceuticals in 2005. Prior to TRIPS, India had a thriving generic pharmaceutical industry for three decades, benefiting from the absence of pharmaceutical product patents. The narrative delves into the historical context, including the pre-TRIPS era, the influence of colonial-era patent laws, and the growth of the Indian pharmaceutical sector.

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 [ISSN 2581-5369]

TRIPS, considered a major shift in international intellectual property law, was shaped by the lobbying efforts of multinational corporations advocating for stronger global IP protection. Despite facing opposition, particularly regarding access to medicines, TRIPS mandated pharmaceutical product patents in developing countries. Initially resistant, India eventually accepted TRIPS, negotiating transition periods and flexibilities to mitigate its impact.

The consequences of TRIPS on the Indian pharmaceutical industry are outlined, highlighting a strategic shift towards exports and research and development (R&D) for developed-country markets. Indian companies, originally focused on unregulated markets, entered the U.S. generics market in the mid-1990s. The motivation for entry into new product R&D was partly driven by TRIPS. The text underscores the role of health activists in grasping the implications of TRIPS on access to medicines. Non-governmental organizations (NGOs) and health advocates raised concerns about TRIPS' impact on drug policies and access to medicines. The Doha Declaration on TRIPS and Public Health in 2001 reflected a global effort to address these concerns, extending transition periods and affirming the right to protect public health.

During the implementation of TRIPS, India faced advocacy from various groups, including the Indian National Working Group on Patents, the Indian Pharmaceutical Alliance, and health organizations like Médecins Sans Frontières (MSF). Debates in the Indian Parliament mirrored global concerns, leading to significant changes in the new patent law, such as subject matter exclusions in pharmaceuticals and the reinstatement of a complete pre-grant opposition system. In summary, the text provides a thorough overview of India's adaptation of patent law in response to TRIPS, exploring historical nuances, the influence of global stakeholders, and the dynamics shaping India's pharmaceutical industry. It argues that while TRIPS doesn't compel deep harmonization of patent laws in developing countries, it establishes a potent harmonizing dynamic by involving them in a transnational circuit.[2]

II. HISTORY

The context of India's pharmaceutical market and its developmental history are explored. Despite its substantial population, the global scale of the Indian market is relatively limited, registering sales of about $14.3 billion in 2012. Between 2007 and 2011, the market exhibited swift growth, a departure from more advanced markets like the United States. The 1970 Patents Act played a pivotal role in shaping India's pharmaceutical sector, permitting patent safeguarding for processes but not products. This framework resulted in a robust domestic

[2] Amy Kapczynski, Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector, 97 CALIF. L. REV. 1571 (2009).

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manufacturing industry grounded in reverse engineering practices. Preceding patent reforms, the Indian market markedly differed from traditional Western markets. Absence of a product patent system led to a multitude of companies producing items with identical molecules. The passage accentuates the industry's diversity, with numerous enterprises manufacturing single-molecule products.

Contrasts between the global and Indian markets unveil considerable distinctions. Top-selling drugs globally, protected by patents and distributed by one or two enterprises, starkly contrast with the Indian market, where an average of 23 companies produces each of the top 15 globally highest-selling drugs. The passage underscores the minimal overlap between the most lucrative drugs in both markets and the influence of India's historical approach to intellectual property on market dynamics. The study delves into potential factors influencing observed effects, such as the vintage of molecules, indicating smaller price effects for products patented before 1995. The analysis also explores molecules approved for sale in the United States, revealing a statistically significant 6% price increase post-patent. The impact of substitute products, encompassing both direct substitutes with identical molecules and therapeutic substitutes, is scrutinized. For molecules with only one producer, an almost 20% price increase is noted post-patent, underscoring the role of limited competition in pricing dynamics.

Despite expectations of more substantial price increases following patent reform, the study identifies relatively modest effects on average prices in the Indian pharmaceutical market. Potential explanations include demand dynamics and the presence of substitute products, both direct and therapeutic. The analysis underscores the intricate interplay of factors shaping pricing outcomes amidst heightened patent protection.

III. TYPES OF PATENTS IN INDIA PATENT ASSIGNMENT

Described as the relinquishment by the patentee of rights, title, and interest in a patent to another individual, termed the assignee. The assignment encompasses the transfer of ownership of the patent rights.

Patent Licenses:

A patentee may authorize a license, permitting others to utilize or implement the patented invention under specific conditions. Licensing entails the conveyance of a restricted set of rights, limited by factors such as temporal constraints, geographical boundaries, or designated fields of use. The license may be voluntary, initiated by the patentee, or compulsory, granted by the Controller of Patents under specified conditions.

Compulsory License u/s 84:

Encompasses a statutory license granted by the Controller of Patents under particular circumstances. The government sanctions a third party to manufacture the patented product or process without the consent of the patent owner. Grounds for awarding a compulsory license include the public's reasonable needs not being fulfilled, unavailability at an affordable cost, or non-functioning of the invention within the territory of India. Compulsory licenses can be granted after three years from the patent's issuance.

Case Summary - Natco Pharma Ltd. vs Bayer Corporation:

Highlights a momentous decision granting the initial compulsory license for patents in India.Natco Pharma secured a license for Bayer's drug Nexavar, utilized in treating kidney and liver cancers. Stipulations involve a royalty payment to Bayer, pricing restrictions for the drug, and commitments to furnish complimentary supplies to underprivileged patients. The decision was grounded in factors such as the drug's limited accessibility, pricing that is not affordable, and absence of manufacturing within India.

Compulsory License for Export u/s 92A: Section 92A permits compulsory licenses for the production and exportation of patented pharmaceutical products to nations lacking adequate manufacturing capabilities. The license aims to tackle public health issues in the recipient country. Conditions include the recipient country having granted a compulsory license or allowed the importation of pharmaceutical products from India.

impact of patents on the quantity of drugs sold in the Indian retail pharmaceutical market. It notes that despite relatively modest price effects, the structure of the market allows for the possibility of decreased sales due to differential access across firms to local distribution networks. The market is described as fragmented, with a large number of domestic firms supplying products to carrying and forwarding agents, who then distribute to stockists, and finally to retail pharmacies.

In 2008, there were about 65,000 stockists working with 550,000 retail pharmacies, highlighting the complexity of the distribution chain. The concern is that removing domestic firms with varying access to retail channels could lead to a reduction in the quantity sold, independent of price changes.

Columns 5 and 6 of Table 4 present the results for specifications where the dependent variable is the log of the number of standard daily doses. The findings indicate a small, negative, and statistically insignificant decrease in the quantity sold following a patent grant in both samples. Despite this, the passage acknowledges the potential influence of factors like differential access

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to retail settings and local marketing efforts by domestic firms, as highlighted by Goldberg (2010). The consumer preference for products from domestic manufacturers over foreign multinational firms is attributed, in part, to better access to specific retail settings and potentially more investment in local marketing efforts by domestic firms.[3]

Effects Constraints on Resources:

The content underscores limitations in resources, particularly within patent offices, impacting the consistent and independent application of Indian patent law. Increasing volumes of patent applications, administrative standardization enforced by the Patent Cooperation Treaty (PCT), and alterations in Indian patent law contribute to challenges in available resources.

The significant disparities in resources between India and more developed nations, such as the United States, are noteworthy, and the funding allocated to Indian patent offices is restricted.

Global Legal Influence:

The passage explores the impact of a global legal culture on India's patent offices and judiciary. This legal culture, influenced by the United States and Europe, is a consequence of endeavors to synchronize both the substantive and procedural aspects of international patent law. Transnational regulatory networks, programs offering technical assistance, and training sessions organized by entities like the European Patent Office (EPO) shape the perspectives of Indian examiners, contributing to a more synchronized legal culture.

Utilization of Policy Instruments:

The content indicates that leveraging policy instruments, such as compulsory licensing, might be swayed by extralegal pressures from nations responsive to the pharmaceutical industry based on patents. While TRIPS theoretically limits such pressures, it also collaborates with them, dissuading developing nations from adopting expansive interpretations of the agreement's flexibilities.

Challenges confronted by India, encompassing the requirement for additional examiners, attrition concerns, variations in training in comparison to developed nations, and the impact of transnational networks on the perspectives of Indian examiners. Overall, it underscores the intricacies and difficulties encountered by developing nations, like India, in navigating the global landscape of patent law influenced by TRIPS.[4]

[3] COMPETITION LAW, INTELLECTUAL PROPERTY, AND THE PHARMACEUTICAL SECTOR Author(s): Margaret K. Kyle Source: Antitrust Law Journal , Vol. 81, No. 1 (2016), pp. 1-36 Published by: American Bar Association Stable URL: https://www.jstor.org/stable/10.2307/26478192

[4] The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India Author(s):

Access to pharmaceutical and medical products can be challenging due to patent exclusivity, particularly affecting affordability and availability, especially in developing countries. The Patents Act of 1970 in India addresses this concern through specific provisions:

Compulsory Licensing (Section 84):

Allows the government or third parties to produce patented products without the patent holder's consent. Granted under circumstances like inadequate market supply or unreasonably high prices. A mechanism to ensure broader access to essential medicines.

Section 3(d) of the Indian Patents Act:

Sets criteria for patentability, stating that a new form of a known substance must demonstrate enhanced efficacy for patent protection. Prevents the granting of patents for trivial modifications, ensuring genuine innovation. Guards against evergreening, preserving the availability of affordable generic versions of essential medicines.

IV. BALANCING INTELLECTUAL PROPERTY AND PUBLIC HEALTH:

Recognizes the need for a balance between intellectual property rights and public health concerns. Acknowledges the role of patents in promoting innovation while emphasizing the importance of access to medicines.

Global Perspective:

Governments, international organizations, and civil society collaborate to ensure access to affordable and essential medicines, especially during public health emergencies. The issue of access varies globally, with different jurisdictions having their own patent laws and provisions.

the legal framework in India, including compulsory licensing and Section 3(d), demonstrates a commitment to addressing the challenges posed by patents on access to pharmaceuticals. The emphasis on balancing intellectual property rights with public health needs reflects a broader global effort to ensure equitable access to crucial medical products.

Developing countries, exemplified by India, can employ three key strategies to effectively implement flexibilities within the Trade-Related Aspects of Intellectual Property Rights (TRIPS) framework. These strategies, namely Fragmentation, Mimicry, and Counter-Harmonization, are outlined below:

Mark Duggan, Craig Garthwaite and Aparajita Goyal Source: The American Economic Review , JANUARY 2016, Vol. 106, No. 1 (JANUARY 2016), pp. 99-135 Published by: American Economic Association Stable URL: https://www.jstor.org/stable/43821398

Fragmentation:

Involves adopting distinct national variations in patent laws to create legal obstacles that impede transnational influence. Aims to make a country less identifiable within global dynamics, providing a level of protection against an overwhelming influx of patent applications.[5]

Mimicry:

Encompasses transformative copying, where recipient countries model their local laws after those of dominant nations but adapt them to suit their specific needs. Seeks to mitigate unilateral pressure by framing local laws as analogous to high-protection jurisdictions, potentially complicating objections from these jurisdictions.

Counter-Harmonization:

Involves coordination among countries sharing similar TRIPS implementation goals to collectively reduce administrative costs and create a transnational counter-culture. Countries collaborate to identify invalid patents, share examination efforts, and provide mutual guidance, thereby opposing the prevailing transnational legal culture. Aims to reshape the global circuit of patent law by coordinating legal frameworks, making political retaliation more costly for developed nations.

Evaluation and Outlook:

Fragmentation offers some protection but has limited applicability, especially in resource-constrained settings. Mimicry is a useful strategy but may face challenges in sustaining mimicked interpretations over time due to transnational legal discourse. Counter-Harmonization emerges as the most promising strategy, enabling countries to coordinate efforts, share resources, and collectively advocate for alternative visions of patent law. India stands as a potential leader in Counter-Harmonization, leveraging innovative tools and capacity, with examples like the adoption of section 3(d) inspiring emulation by other countries such as the Philippines and Zanzibar.

V. CONCLUSION

In 2005, India brought about a substantial transformation in its pharmaceutical patent framework by issuing a multitude of patents to both local and international companies. This move marked a groundbreaking initiative to introduce an entirely new patent system into an already established market. Despite initial apprehensions regarding potential escalations in

[5] International Journal of Drug Development & Research |July-September 2012 | Vol. 4 | Issue 3 | ISSN 0975- 9344 | Available online http://www.ijddr.in

prices and constrained access to pharmaceuticals, the investigation discloses minimal indications of noteworthy alterations. The restructuring did not lead to a reduction in the number of companies producing molecular compounds. However, there was a perceptible shift in sales concentration at the molecular level, favoring the firms originating the products. The introduction of new product patents resulted in marginal price increases, exerting limited influence on the quantity of products sold. The study proposes that regulatory elements within TRIPS, such as the Indian government's capacity to enforce price controls, might have mitigated the anticipated price surges. The results unveil both favorable and adverse consequences for the Indian market, underscoring the intricate interplay of factors shaped by the patent overhaul. While indications of static inefficiencies are scarce, the modest estimated effects also suggest controlled profit-maximizing pricing. This poses implications for the pharmaceutical industry's incentives for innovation and prompts inquiries about the efficacy of the patent system in fostering dynamic efficiency and innovation.[6]

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[6] Intellectual Property and Pharmaceutical Drugs: An Ethical Analysis Author(s): Richard T. De George Source: Business Ethics Quarterly, Oct., 2005, Vol. 15, No. 4 (Oct., 2005), pp. 549-575 Published by: Cambridge University Press Stable URL: https://www.jstor.org/stable/3857978

 [ISSN 2581-5369]