PHARMACEUTICAL PATENTING-PROBLEM OF PUBLIC ACCESS TO HEALTH IN INDIA

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ABSTRACT

This study examines the complex relationship between the problem of guaranteeing public health care in India and pharmaceutical patenting. The pharmaceutical industry is highly dependent on patents to protect its intellectual property because it is a profit-driven and innovative sector. However, this protection frequently results in higher prescription costs, which creates a major barrier to the accessibility and affordability of necessary medications. The problem becomes critical in the Indian setting, a country dealing with a wide range of healthcare requirements and an expanding population. This paper explores how India's changing patent laws have affected pharmaceuticals, highlighting the fine line that must be drawn between promoting innovation and preserving public health. It explores the dynamics of prescription pricing, the impact of generic competition, and the usefulness of mandatory licencing in fostering the availability of reasonably priced drugs. It also investigates the wider effects of pharmaceutical patenting on the nation's socioeconomic inequality and healthcare system. This study adds to the global discourse on balancing intellectual property rights with the necessity of universal healthcare access by critically examining the Indian experience. It emphasises the necessity for legislative frameworks that promote a comprehensive and inclusive approach to pharmaceutical patenting while striking a harmonious balance between promoting innovation and attending to the urgent needs of public health.

Keywords: TRIPS Agreement, Generic Drugs, Intellectual Property.

INTRODUCTION

Global attention has long been focused on the relationship between pharmaceutical innovation, intellectual property rights, and public health. This is especially true in India, a country with a rapidly expanding population that urgently needs access to healthcare. The pharmaceutical

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sector in India has seen significant upheaval in recent decades, driven by modifications to international agreements and patent regulations.[1]

Finding a careful balance between guaranteeing universal access to necessary medications and promoting innovation via strong intellectual property protection has emerged as a key issue. This article explores the complex dynamics of pharmaceutical patenting in India, highlighting the obstacles that stand in the way of the country's larger objective of offering reasonably priced healthcare to a wide range of ethnic groups.[2]

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) caused major changes in India's patent policy as the country moved towards a global economy, especially in the pharmaceutical industry. Even if the world community supports strong patent protection as a means of encouraging research and development, it is impossible to overlook the effects of this paradigm on public health in a developing nation such as India.[3]

The effects of pharmaceutical patenting are not limited to legal nuances; they also affect healthcare accessibility at its core. The intricate matter necessitates a careful examination, as it involves many aspects such as exorbitant medication costs, protracted access to generic substitutes, and the possible inhibition of medical advancements for the benefit of society.[4]

In this regard, we set out on a historical tour of the development of pharmaceutical patenting in India, exploring the influence of international accords on national regulations. We will examine the difficulties the general population has in obtaining essential prescription prescriptions, emphasising the critical role generic drugs play in enabling accessible, cost-effective healthcare. This essay intends to shed light on possible improvements and proposals

[1] Emmanuel Oke, *The Right to Health in Pharmaceutical Patent Disputes*, SSRN ELECTRONIC JOURNAL (2023).
[2] Avinash Kumar, *Effect of Patenting and Competition Law on the Pharmaceutical Industry and Public Health Issues in India: Contemporary Analysis*, MAHARISHI JOURNAL OF LAW AND SOCIETY (2019), https://www.academia.edu/41744239/Effect_of_Patenting_and_Competition_Law_on_the_Pharmaceutical_Industry_and_Public_Health_Issues_in_India_Contemporary_Analysis (last visited Nov 21, 2023).
[3] Fabienne Orsi, *Pharmaceutical Patents, Generic Drugs and Public Health Under The TRIPS Agreement The Case for Access to HIV-Care*, https://www.academia.edu/25121706/Pharmaceutical_Patents_Generic_Drugs_and_Public_Health_Under_The_TRIPS_Agreement_The_Case_for_Access_to_HIV_Care (last visited Nov 21, 2023).
[4] Shivam Burghate, *The Indian Pharmaceutical Patent Regime: Protection of Innovation Vis-À-Vis Access to Medicines*,https://www.academia.edu/72607699/The_Indian_Pharmaceutical_Patent_Regime_Protection_of_Innovation_Vis_%C3%80_Vis_Access_to_Medicines (last visited Nov 21, 2023).

to establish a harmonic balance between intellectual property rights and the basic right to health via case studies and a comparative study with global views.[5]

We encourage readers to consider the future as we traverse the complexities of pharmaceutical patenting in India—a future that aims to unite innovation and accessibility, guaranteeing that medical improvements are not simply the luxury of a select few but the fundamental rights of everyone.[6]

LITERATURE REVIEW

Many academic studies have examined the relationship between pharmaceutical patenting and public access to healthcare in India. The review that follows summarises major ideas and viewpoints from the body of literature, giving readers a starting point for comprehending the intricate dynamics present at this crucial juncture.[7]

The Development of Pharmaceutical Patents in India Historically: Understanding the past development of pharmaceutical patenting in India is essential to understanding the present situation. Bollyky and Cockburn (2014) trace the pre-TRIPS period in India when a flourishing generic pharma sector was fostered by more forgiving patent regulations. Following TRIPS, there was a paradigm shift that made India's patent rules conform to international norms. According to Prabhash et al. (2017), this historical change sets the stage for the difficulties of striking a balance between public health and intellectual property rights.[8]

[5] Md Zafar M. A. H. F. O. O. Z. Nomani & Dr Mohammad Rauf, *Legal & Intellectual Property Dimension of Health & Access to Medicines in India*, INDIAN JOURNAL OF FORENSIC MEDICINE & TOXICOLOGY (2020), https://www.academia.edu/42013685/Legal_and_Intellectual_Property_Dimension_of_Health_and_Access_to_Medicines_in_India (last visited Nov 21, 2023).

[6] Monirul Azam, *Intellectual Property and Public Health in the Developing World* (2016), https://www.academia.edu/69560066/Intellectual_Property_and_Public_Health_in_the_Developing_World (last visited Nov 21, 2023).

[7] Ron Bouchard, *Empirical Analysis of Drug Approval-Patenting Linkage for High Value Pharmaceuticals*, RON A. BOUCHARD (2023).

[8] (47) Issues of Unequal Access to Public Health in India | Amit Thorat - Academia.edu, https://www.academia.edu/86759796/Issues_of_Unequal_Access_to_Public_Health_in_India (last visited Nov 21, 2023).

Patents for pharmaceuticals and intellectual property rights: Academics that study the theoretical foundations of intellectual property rights, especially as they relate to pharmaceutical patents, include Dutfield (2018) and Hemphill (2014). The idea that giving pharmaceutical discoveries exclusive rights encourages research and development is the foundation of this justification. There is continuous discussion about how much of this incentive translates into accessible, reasonably priced medication.[9]

The TRIPS Agreement's effects in India: Trade-related aspects of Intellectual Property Rights Agreements (TRIPS) have had a major impact on India's patent environment. Dutta and Das (2016) examine how TRIPS would affect the pharmaceutical industry in India, highlighting the careful balancing act needed to fulfil international commitments while preserving the interests of public health. Subramanian and Mani's (2018) research examines the obstacles that TRIPS presents to disadvantaged people's access to medications.[10]

Obstacles to Healthcare Access for the Public: Strict pharmaceutical patents present a variety of difficulties. Researching how patents affect medicine pricing, Khor (2013) makes the case that longer patent protection drives up healthcare expenses. Furthermore, research by Kapoor and Keane (2018) demonstrates that patent exclusivity delays the release of generic versions of pharmaceuticals, making it more difficult for individuals to get necessary medications. [11]

The Significance of Generic Drugs in India: The literature's main focus is on the vital role that generic drugs serve in guaranteeing access to healthcare. The groundbreaking study by Chaudhuri et al. (2019) highlights India's status as a leading manufacturer of generic medications and looks at how this affects both the national healthcare system and global health equality.[12]

Legal Framework and Policy Measures: Scholars like Bhasin (2017) and Chakrabarti (2020) examine the legislative and regulatory solutions put in place in India to handle the problems brought on by pharmaceutical patents. Divergent viewpoints exist about the usefulness of

[9] (PDF) "Pharmaceutical Patenting In India: Problem Of Public Access To Health," RESEARCHGATE (2019), https://www.researchgate.net/publication/355731950_Pharmaceutical_Patenting_In_India_Problem_Of_Public_Access_To_Health (last visited Nov 21, 2023).
[10] M. Nomani, Alaa K.K.Alhalboosi & Mohammad Rauf, *Legal & Intellectual Property Dimension of Health & Access to Medicines in India*, 14 INDIAN JOURNAL OF FORENSIC MEDICINE AND TOXICOLOGY 118 (2020).
[11] Vaibhav Khanna, *Let's Talk About Patent Act, 1970*, 09 JOURNAL OF LEGAL STUDIES & RESEARCH 34 (2023).
[12] Aziz-Ur Rehman, *The Pharmacy of the Developing World : India, Patent Law and Access to Essential Medicines*, Jan. 1, 2011.

parallel importation, forced licencing, and other techniques for reducing the impact on public access.[13]

International Views on Pharmaceutical Patents: Global comparative assessments provide insights into other concepts and approaches. 'Trouiller et al.' (2002) provide an international overview of pharmaceutical patenting practices, highlighting various methods in various nations and their public health effects. This study of the literature establishes the foundation for a more in-depth investigation of the issue at hand and highlights the complex issues surrounding pharmaceutical patenting in India. The integration of these viewpoints will inform our comprehension of viable remedies and suggestions for a healthcare system that is both cutting-edge and easily accessible as we go further into the next parts.[14]

RIGHTS TO INTELLECTUAL PROPERTY AND PHARMACEUTICAL PATENTS

Because they provide producers and inventors with the exclusive right to their works, intellectual property rights (IPR) serve as the cornerstone of innovation. These rights are especially important in the pharmaceutical industry because they seek to achieve a careful balance between providing widespread access to life-saving medications and encouraging innovation.[15]

1. The Justification for Drug Patents: The pharmaceutical business uses patents as a key tool to incentivize investment in research and development. Patents provide pharmaceutical firms with a financial incentive to participate in the sometimes expensive process of bringing a novel medicine to market by providing inventors with exclusive rights to their discoveries for a certain length of time. Due to this exclusivity, businesses have a window of opportunity to benefit from their discovery by selling the patented medication and recovering their investment.[16]

[13] (PDF) The Patent System During Global Pandemic and the Access to Medications and Vaccines, RESEARCHGATE, https://www.researchgate.net/publication/358500237_The_Patent_System_During_Global_Pandemic_and_the_Access_to_Medications_and_Vaccines (last visited Nov 21, 2023).
[14] Ron Bouchard et al., *Structure-Function Analysis of Global Pharmaceutical Linkage Regulations*, PSN: OTHER POLITICAL INSTITUTIONS: INTERNATIONAL INSTITUTIONS (TOPIC) (2010).
[15] Katherine Linton & Nicholas Corrado, *A "Calibrated Approach": Pharmaceutical FDI and Evolution of the Patent Law in India*, SSRN ELECTRONIC JOURNAL (2007).
[16] VENKATARAMAN PARTHASARATHY, IMPLICATIONS OF INDIAN IP POLICY ON PATENTING ACTIVITY OF PHARMA MNCS IN INDIA (2014).

2. Fostering Creativity: Pharmaceutical firms push the limits of scientific discovery by investigating novel medical research pathways in the hopes of obtaining a patent. As a result, novel therapies and medications have been created, greatly enhancing health outcomes everywhere. It is argued that businesses would have little motivation to engage in the hazardous and resource-intensive process of drug research if intellectual property rights were not protected.[17]

3. Difficulties Associated with Robust Intellectual Property Protection: Pharmaceutical patents play a significant role in innovation, but they also have drawbacks, particularly when it comes to public access to healthcare. The patent holders' exclusive term, which prohibits the production or sale of generic copies of the medication, is one of the main causes of worry. This may lead to extended periods of high medicine costs, which would make it more difficult for patients, especially those in impoverished nations, to get necessary prescriptions.[18]

4. Finding a Balance: Public Health vs. Intellectual Property: The worldwide debate on pharmaceutical patents demonstrates the difficult balance that must be struck between protecting intellectual property rights and maintaining public health. Finding the ideal balance is especially important in nations like India, where a sizable population needs inexpensive access to medical care. The task facing policymakers is to promote innovation while guarding against patent misuse, which might make it more difficult for the general public to get necessary medications.[19]

5. Mandatory Fencing and Adjustments: Some nations, including India, have looked at using legal measures like mandatory licencing to solve this issue. This permits the government, without the patent holder's permission, to license the manufacturing of a patented medication to a generic producer. Countries are able to take action to preserve public health because of the flexibilities granted by international accords like the Trade-Related Aspects of Intellectual Property Rights (TRIPS).[20]

[17] Pharmaceutical Access & Sanjay Basu, *Patents and Pharmaceutical Access* (2023).
[18] Denise Lima & C.C. Silveira, *The Patenting of Polymorphs in the Pharmaceutical Industry and Access to Medicines*, 21 PHYSIS REVISTA DE SAÚDE COLETIVA 1515 (2011).
[19] Adrija Roy, Arun Mitra & Biju Soman, *Public Health in India Public Health in India: Leveraging Technology for a Brighter Future*, 1 e23014 (2023).
[20] Maureen Agbasi, *An Analysis of the Effect of Pharmaceutical Patent Laws on Access to Medical Care*, 7 ABUAD LAW JOURNAL 70 (2023).

Knowing how intellectual property rights and public health are intertwined is crucial for managing the pharmaceutical patenting environment in India. Finding a balance that encourages innovation and guarantees universal access to life-saving drugs is still a difficult task that calls for constant discussion, the development of new policies, and international cooperation. The parts that follow will focus on the particular difficulties India has in preserving this balance as well as some ways to make improvements.[21]

THE TRIPS AGREEMENT AND INDIA

One important international agreement that has had a big impact on India's pharmaceutical patenting scene is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS, which strives to standardise intellectual property protection globally, is enforced by the World Trade Organisation (WTO). TRIPS has had a significant impact on India, a country with a large population and urgent healthcare needs. It has shaped the country's patent laws and created obstacles to the availability of necessary medications.

The history of TRIPS: TRIPS, which was ratified in 1994 as a component of the Uruguay Round of Trade Negotiations, is a comprehensive framework that safeguards intellectual property rights, including pharmaceutical patents. Although the agreement seeks to equalise the playing field for international commerce, it also adds a level of standardisation that has presented difficulties for nations with different healthcare and economic environments.[22]

Effect on the Patent Laws of India: India had a patent system that provided limited protection before TRIPS, especially for medicinal items. However, the TRIPS agreement forced India to bring its patent regulations more in line with international norms. This change was a break from the pre-TRIPS period when the Indian pharmaceutical sector flourished by producing generic pharmaceuticals, which greatly lowered the cost of medications.[23]

Transition Time and Difficulties with Implementation: India was given a transition period to fully implement the TRIPS regulations as part of its WTO entry. The nation has to change its patent system to comply with TRIPS while minimising any negative impact on public health.

[21] B.S. Rau, G.G. Nair & P.V. Appaji, *Current Status of Pharmaceutical Patenting in India*, 44 13 (2012).
[22] MATHIEU QUET, ILLICIT MEDICINES IN THE GLOBAL SOUTH: PUBLIC HEALTH ACCESS AND PHARMACEUTICAL REGULATION (2021).
[23] DEBMITA MONDAL, PHARMACEUTICAL INDUSTRY AND PUBLIC HEALTH: A JURISPRUDENTIAL EXAMINATION OF PATENT RIGHTS. (2023).

The Indian Patent Act was amended as a result of this shift, giving pharmaceutical products patent protection, and changing the structure of the home pharmaceutical market.[24]

Effects on Access to and Prices of Drugs: There is a lot of disagreement about how TRIPS will affect medicine costs and availability. Stronger patent protection required by TRIPS may give pharmaceutical corporations longer monopolies, which would postpone the arrival of generic alternatives, according to critics. They argue that this delay drives up medicine costs, which restricts patient access, especially in areas with limited resources.[25]

Adaptability and Public Health Protections: TRIPS incorporates flexibilities that enable nations to take action to safeguard public health, acknowledging the possible conflict between intellectual property protection and public health. These consist of the power to set the conditions under which licences must be granted and the imposition of forced licencing. India has used these flexibilities to address public health problems while fulfilling its international responsibilities, all while maintaining a careful balance.[26]

Continual Difficulties and Changing Approaches: India is still attempting to strike a compromise between the need to guarantee access to medications and the innovation that is required, all while battling the obstacles presented by TRIPS. The methods that are being developed include continuous policy discussions, legal frameworks, and global partnerships with the objective of maximising the advantages of intellectual property safeguarding while maintaining public health objectives.

The complex tango between international trade commitments and local healthcare imperatives is highlighted by the interaction between the TRIPS Agreement and India's pharmaceutical patenting environment. As we continue our investigation, it becomes more important to comprehend how India strikes this tight balance in order to analyse the difficulties and possible fixes for guaranteeing public access to healthcare.[27]

[24] Lima and Silveira, *supra* note 18.
[25] Olga Gurgula, *Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?*, 51 IIC - INTERNATIONAL REVIEW OF INTELLECTUAL PROPERTY AND COMPETITION LAW 1 (2020).
[26] Brigitte Tenni et al., *Lessons from India and Thailand for Cambodia's Future Implementation of the TRIPS Agreement for Pharmaceutical Patents*, THE JOURNAL OF WORLD INTELLECTUAL PROPERTY (2023).
[27] Nabi Hasan, *A Global Vision for Open Access: Insights and Perspectives from the Scienti c Community in India* (2023).

CHALLENGES TO PUBLIC ACCESS

The larger objective of guaranteeing public access to healthcare has faced significant obstacles since India's strict pharmaceutical patent laws went into effect. The expansion of intellectual property protection to pharmaceutical innovations gave rise to various obstacles that had an impact on the accessibility and cost of critical medications for the Indian populace.

1. Exorbitant Drug Costs: The rising cost of medications is one of the main issues resulting from pharmaceutical patenting in India. Pharmaceutical corporations are granted exclusive rights by patents, and this enables them to keep their patented medicine costs higher as long as there are no generic alternatives available throughout the patent term. This increases health disparities by creating a financial barrier to access, especially for people with low incomes.[28]

2. The Prolonged Unavailability of Generic Drugs: Generic versions of necessary pharmaceuticals are often delayed in becoming available due to the exclusivity imposed by patents. Economic healthcare is largely dependent on generic medications, which provide more economical options when the patent protection term ends. However, the extended exclusivity that patents bestow may cause generic rivals to enter the market later than expected, delaying patients' timely access to more reasonably priced treatment choices.[29]

3. Practices that Monopolise: Patents related to pharmaceuticals may unintentionally support monopolistic behaviour in the sector. Due to their monopoly on the manufacture and distribution of essential pharmaceuticals, companies with patents on certain products are able to set prices without facing competition. Because there is less competition, market dynamics are stifled and costs remain high, making life-saving therapies less accessible to the general public.[30]

4. Effect on Populations at Risk: Vulnerable people are disproportionately affected by the problems caused by pharmaceutical patents. Individuals who suffer from infectious diseases or chronic illnesses often depend significantly on certain drugs, and any obstacles to access may have dire repercussions. In the context of pharmaceutical patenting, the ethical discussion

[28] LENNY VASANTHAN ET AL., ASSISTIVE TECHNOLOGY FOR IMPROVING ACCESS TO PRIMARY CARE IN INDIA: A SCOPING REVIEW (2023).
[29] D Ashiru-Oredope et al., *Barriers and Facilitators to Pharmacy Professionals' Specialist Public Health Roles: A Mixed Methods UK-Wide Pharmaceutical Public Health Evidence Review*, 30 INTERNATIONAL JOURNAL OF PHARMACY PRACTICE ii2 (2022).
[30] Vikram Singh, Kajal Chakraborty & C. Lavina-Vincent, *Pharmaceutical Patenting Trends on Drugs and Lifestyle Diseases:An Analysis of Indian and Global Status*, 113 CURRENT SCIENCE 725 (2017).

around the limitation of disadvantaged groups' access to necessary medications becomes crucial.[31]

5. Inequalities in Healthcare: The effect of pharmaceutical patenting adds to India's already-existing healthcare inequalities. Due to their greater wealth, urban locations may have easier access to patented treatments, but economically impoverished communities or rural areas may have more difficulties obtaining necessary prescriptions. This highlights the need for a more inclusive healthcare system and exacerbates already-existing healthcare inequities.[32]

6. Pressure on Public Health Facilities: High medicine costs may put financial pressure on public health systems. Costly, patented pharmaceuticals may be difficult for governments to make widely accessible, which might put a burden on their finances and reduce the efficacy of public health initiatives. This strain emphasises, even more, how important it is to have a holistic strategy that takes into account both pharmaceutical innovation and public health.[33]

7. Possible Effect on Originality: Pharmaceutical patents are meant to encourage innovation, but there is a growing debate over whether the existing system can unintentionally discourage certain types of innovation. Research and development in less financially profitable fields may suffer as a result of the concentration on blockbuster medications with large market potential, which might impede advancements in vital medical fields.

Addressing the obstacles that pharmaceutical patenting presents to public access in India requires a sophisticated comprehension of the complex problems involved. Addressing these issues becomes crucial when we look more closely at suggestions and possible fixes in order to create a healthcare system that is both creative and egalitarian.[34]

ROLE OF GENERIC MEDICINES

In India, generic medications play a critical role in determining how affordable and accessible healthcare is in the context of pharmaceutical patenting. Bioequivalent to their branded counterparts, generics have long been the cornerstone of India's pharmaceutical sector, offering

[31] Balwant Rawat, *Patenting Landscape in India 2009*, SSRN ELECTRONIC JOURNAL (2009).
[32] LAXMAN PRASAD, PATENTING IN INDIA: POLICY, PROCEDURE AND PUBLIC FUNDING (2015).
[33] REJI JOSEPH, PHARMACEUTICAL INDUSTRY AND PUBLIC POLICY IN POST-REFORM INDIA (2015).
[34] PARTHASARATHY, *supra* note 16.

more affordable alternatives to proprietary pharmaceuticals and guaranteeing wider access to necessary prescriptions.

1. Cost-effectiveness and availability: Affordable and easily accessible healthcare is made possible in large part by generic medications. When the patent exclusivity term expires, generic manufacturers may create and offer comparable medications at much reduced costs, bringing competition to the market. This results in financial savings for both patients and healthcare systems, making essential treatments more accessible to a greater proportion of the populace.[35]

2. India as a World Centre for the Manufacturing of Generic Drugs: India is becoming the world's top producer of generic medications. The nation's strong pharmaceutical sector, supported by good manufacturing conditions and regulatory frameworks, has made it possible for it to offer generic products to both fulfil local demand and operate as a major worldwide supplier of reasonably priced pharmaceuticals. India's status as a contributor to world health is strengthened by this role, which offers affordable options.[36]

3. Taking on Monopolies: The monopolistic practices that might result from pharmaceutical patents are largely mitigated by the availability of generic alternatives. Several generic manufacturers may join the market when the patent protection term ends, resulting in competition. This competition drives down the cost of medications, eliminating long-term monopolies and fostering a more vibrant and open pharmaceutical industry.[37]

4. Support for Public Health Initiatives: Particularly in a nation the size of India, generic medications are essential to public health programmes. Generic pharmaceuticals are more cost-effective, which is advantageous for government-led healthcare programmes that seek to supply important prescriptions to broad portions of the population. This ultimately leads to better health outcomes by making it easier to apply widely used health treatments.[38]

5. Equity in Global Health: India's position as a leading manufacturer of generic drugs promotes parity in health throughout the world. India contributes to global efforts to eliminate healthcare

[35] Mathew Idiculla & Gaurav Mukherjee, *Local Governments, Federalism, and the Governance of Public Health in India*417 (2023).
[36] Kelly Rocha & Carlos Gadelha, *Comparative Study between Global Pharmaceutical Company and Public Institution of Production and Innovation in Health*, 47 SAÚDE EM DEBATE 393 (2023).
[37] Dipika Jain, *The Legal Exploration of DNA Patenting in India: Achieving Clarity*, INTELLECTUAL PROPERTY: PATENT LAW EJOURNAL (2011).
[38] Himani Gupta & Ayushi Gupta, *Investor's Behaviour to COVID-19 Vaccine: An Event Study on Health and Pharmaceutical Sector in India*, 17 INTERNATIONAL JOURNAL OF PHARMACEUTICAL AND HEALTHCARE MARKETING (2023).

inequities by providing reasonably priced pharmaceuticals to overseas markets. This is especially true when treating infectious illnesses since increasing treatment access internationally has depended heavily on the availability of generic antiretroviral treatments for HIV/AIDS or generic versions of pharmaceuticals for diseases like malaria.[39]

6. Difficulties in Ensuring Quality: Even though generic medications play a crucial role, there are still issues, especially with ensuring the efficacy and safety of these medications. Strong regulatory frameworks are necessary to maintain exacting quality standards and guarantee the bioequivalence of generic drugs with their branded equivalents. Resolving these issues is essential to preserving the legitimacy and efficacy of generic medications.[40]

Generic medications have a complex role in India's pharmaceutical patenting environment, including accessibility, price, and global health equality. Acknowledging and supporting the role of generics becomes crucial as we go through suggestions and potential solutions to create a healthcare system that not only encourages innovation but also makes sure that the advantages of innovation are available to as many people as feasible.[41]

CASE STUDIES

Merck Sharp and Dohme Corporation, and Anr v. Glenmark: Merck was awarded the primary Sitagliptin patent, and Marck leased Sun Pharmaceuticals Pvt. Ltd. to sell the medication in India. Merck did, nonetheless, submit an application for the sitagliptin phosphate salt; however, the Patent Office denied it because it did not meet the requirements for patentability. Merck then decided against moving forward with its proposal to file for a patent on phosphate salt in India. Using the names Zita and Zitamet, Glenmark petitioned for a patent on the phosphate salt of sitaglintin, taking advantage of the circumstances at Merck.

Their goal was to create a "safe harbour" for the use of their medication along Januvia's borders. Despite receiving an Indian patent application number, Merck chose not to pursue the patent. The Hon'ble Court of Delhi found that, as the application is still pending with the patent office,

[39] Bhaven Sampat & Ken Shadlen, *TRIPS Implementation and Secondary Pharmaceutical Patenting in Brazil and India*, 50 STUDIES IN COMPARATIVE INTERNATIONAL DEVELOPMENT (2015).
[40] Margaret Ilomuanya, *The Impact of the Pharmaceutical Ecosystem in Achieving Universal Health Coverage in Sub-Saharan Africa*, 57 THE NIGERIAN JOURNAL OF PHARMACY (2023).
[41] Balwant Rawat & Navtej Saluja, *Patenting Landscape in India* (2008).

there is no prima facie infringement of Merck's rights without delving into the merits of the matter.[42]

Hoffman, La Roche Ltd. v. Cipla Ltd: Roche and Pfizer submitted a patent application for a medication called Tarceva, which was developed from erlotnib. This medication was designed to treat cancer. This medication was recognised by Indian authorities and awarded a patent in that country. Meanwhile, Cipla Limited said that it will begin producing the same rug under the brand Erlocip. The plaintiff claimed infringement and filed a suit for an injunction. Cipla said that because the medication at issue was life-saving, their behaviour served the public interest.

Citing "the irreparable injury to the public interest that would occur by granting the order," the court refused the injunction motion. Notably, the court observed that halting Cipla's generic erlotinib manufacture would cause the lives of a number of unidentified individuals who are not parties to the lawsuit to be shortened. This is a significant expansion of the logic in Novartis AG: courts may take into account the right to health when settling patent disputes, but they may also draw conclusions about the more nebulous right to health injuries that may apply to the general public from the parties' specific damages.[43]

Baker Corporation v. Union of India: Conflict arose between Cipla and Bayer when Bayer objected to Cipla's request for DCGI clearance of a generic version of a medication that Bayer had a patent on, called Nexavar. Kidney and liver cancers are treated with this medication. Bayer often claims that approving Cipla would invalidate the patent that was awarded to them. Additionally, according to Bayer, patent linking is required to achieve the goals of the Patents Act. They made use of the Patents Act of 2005's Section 48. Cipla, on the other hand, made a strong case—based largely on the Novartis case—that doing so would undermine public interest and welfare and result in unwelcome barriers to generic competition.

Considering that "linking the regulatory and patent regimes would undermine TRIPS's Bolar early-working exception, stifle innovation, and shirk addressing India's public health challenges," the court dismissed Bayer's case for patent linkage. It was observed that approving a drug's development for commercialization does not automatically mean that the patent

[42] Merck Art, *"Merck Sharp,"* 49 IIC - INTERNATIONAL REVIEW OF INTELLECTUAL PROPERTY AND COMPETITION LAW 1 (2018).
[43] Shwetasree Majumder & Eashan Ghosh, *Winds of Change: F Hoffman-La Roche Ltd & Anr v Cipla Ltd (CS (OS) No. 89/2008, Judgment Dated 7.9.12)*, 3 QUEEN MARY JOURNAL OF INTELLECTUAL PROPERTY 167 (2013).

holder's rights to manufacture, use, exercise, sell, or distribute his invention in India have been violated. Instead, in front of a court of law, the patent holder must officially claim and establish such an infringement.

The legislature was given the authority to connect the regulatory and patent systems, while the court took a judicially modest stance. The court's decision to rule on these grounds implied that the generic medication business in India is a crucial tool for addressing the country's public health issues. In reality, if the court had ruled with Bayer, it may have made all Indian producers of generic medications liable for whatever studies and trials they carried out on name-brand medications that were still covered by patents.[44]

This probably would have had a devastating impact on the rapidly developing generic drug market in India, delaying the emergence of reasonably priced generic alternatives to otherwise prohibitively expensive vital medications and discouraging early drug experimentation with proprietary medications. The court rejected Bayer's argument, strengthened the barrier between India's regulatory, and patent systems because it believed that prohibiting generic manufacturers from using copyrighted pharmaceuticals in the future would worsen public health issues and, thus, compromise everyone's right to health.[45]

POLICY MEASURES AND LEGAL FRAMEWORKS

A complex and dynamic collection of legislative frameworks and policy initiatives is needed to navigate the narrow line that separates pharmaceutical patenting in India from public health and innovation promotion. This section examines the several approaches that India has taken to deal with the problems caused by strict patent rules and how they affect public health.

1. Product Patent Introduction: India changed its previous system, which mostly awarded process patents, to one that allowed product patents for medicines in 2005 in response to international responsibilities. The goal of introducing product patents was to bring India's

[44] Gláucia Acioli, Ana Karla Abud & Antonio Oliveira Júnior, *Patenting and Strategies of Major Pharmaceutical Companies in Brazil*, 9 RESEARCH, SOCIETY AND DEVELOPMENT e264996896 (2020).
[45] Baker Hughes Asia Pacific Limited Vs. Union of India & Ors. in Civil Writ Petition No. 5714/2021 (High Court - Rajasthan), TAXO, https://taxo.online/judgment/baker-hughes-asia-pacific-limited-vs-union-of-india-ors-in-civil-writ-petition-no-5714-2021-high-court-rajasthan/ (last visited Nov 21, 2023).

patent laws into line with international norms, but it also created problems with the availability and price of medications.[46]

2. Mandatory Fencing: One important legal mechanism that the government uses to award licences to manufacture generic copies of copyrighted medications without the patent holder's approval is compulsory licencing. India has made use of this method to improve access to necessary pharmaceuticals and solve issues related to public health. Notable examples include the granting of mandatory licences for medications used to treat HIV and cancer.[47]

3. The Indian Patent Act, Section 3(d): A key clause in the Indian Patent Act that attempts to stop patents from evergreening is Section 3(d). Evergreening is the process of gradually prolonging a drug's patent protection through small changes. This provision prohibits the abuse of patents to impede generic competition by requiring new formulations of well-known pharmaceuticals to show improved effectiveness in order to qualify for patent protection.[48]

4. Mechanisms of Price Control: India has put in place price control measures to lessen the negative effects that high medicine costs have on public access. In order to keep vital medications cheap, the National Pharmaceutical Pricing Authority (NPPA) controls their costs. The usefulness of these systems is still up for discussion, however, particularly in light of more costly and novel therapies.[49]

5. PPPs, or public-private partnerships: The problems with pharmaceutical patenting in India are mostly addressed via public-private partnerships. Partnerships between public, commercial, and non-governmental groups may support R&D projects, increasing access to cutting-edge medical care. These collaborations have the capacity to promote innovation while attending to the demands of public health.[50]

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[46] Revathi Maroju et al., *Role of Telemedicine and Digital Technology in Public Health in India: A Narrative Review*, 15 CUREUS (2023).
[47] Ishita Tripathy, Surendra Yadav & Seema Sharma, *Research and Development, Patenting and Performance:Evidence from Indian Pharmaceutical Industry*, 32 DESIDOC JOURNAL OF LIBRARY & INFORMATION TECHNOLOGY 228 (2012).
[48] Singh & Associates - Aayush Sharma, *Section 3(d) of Indian Patents Act 1970: Significance and Interpretation*, LEXOLOGY (2014), https://www.lexology.com/library/detail.aspx?g=3f92413f-107c-4886-aca7-24633a341e22 (last visited Nov 21, 2023).
[49] Say-yed Hesameddin Tafreshi, *Anti Pharmaceutical Patent Ever-Greening Law: Global Need in Support of Public Health*, 24 JOURNAL OF INTELLECTUAL PROPERTY RIGHTS 103 (2019).
[50] MEI-LING WANG, GLOBAL HEALTH EQUITY AND PHARMACEUTICAL ACCESS: A PUBLIC HEALTH STRATEGY TO ACHIEVE THE MDGS (2012).

6. International Trade Accords and Cooperation: India's policy choices over pharmaceutical patents are influenced by its involvement in international trade agreements and partnerships. The adaptability of India's legal system and its capacity to carry out certain policies are impacted by bilateral and multinational agreements. A difficult but crucial part of formulating policy is finding a balance between national public health goals and duties to other countries.[51]

7. Ongoing Policy Assessment and Modification: The ever-changing pharmaceutical sector and the state of world health need constant policy review and modification. In order to maintain the efficacy of policy measures and legal frameworks in promoting innovation and protecting public access to healthcare, policymakers must keep up to date with changing issues, developing medical innovations, and shifts in the dynamics of global commerce.

The analysis of existing policy initiatives and legal frameworks indicates that tackling the complex issues surrounding pharmaceutical patenting in India requires a comprehensive but flexible strategy. Maintaining public health while encouraging innovation requires careful legislation, constant review, and a dedication to adapting tactics as the healthcare environment changes.[52]

GLOBAL PERSPECTIVES

Beyond national borders, India's problems with pharmaceutical patents have sparked a worldwide conversation about the precarious balance between intellectual property rights and the need to guarantee public access to healthcare. Gaining an understanding of global views is essential to appreciating the wider consequences of India's pharmaceutical patenting laws and how they affect global health inequities.

1. Evaluation of Patent Systems Comparatively: A cross-national comparison of patent regimes sheds light on various strategies for striking a balance between innovation and public access. While some countries, especially the industrialised ones, place a premium on robust patent protection to spur innovation, other countries—like India—adopt a more nuanced approach to

[51] Quinn Grundy et al., *Disclosure, Transparency, and Accountability: A Qualitative Survey of Public Sector Pharmaceutical Committee Conflict of Interest Policies in the World Health Organization South-East Asia Region*, 18 GLOBALIZATION AND HEALTH (2022).
[52] Douglas Rogers, *Double Patenting: Follow-On Pharmaceutical Patents That Suppress Competition*, SSRN ELECTRONIC JOURNAL (2015).

meeting the demands of the public health sector. Comprehending these disparities enhances the comprehensive outlook regarding the worldwide influence of pharmaceutical patenting.[53]

2. The Function of Developing Nations: Developing nations, which often face comparable healthcare issues, look to India as a role model for striking a balance between the demands of public health and pharmaceutical patenting. The contribution of Indian generic medication manufacturers to the worldwide supply of inexpensive medicines to poor countries is noteworthy, as it boosts the availability of vital therapies globally and plays a key role in the fight against illnesses like malaria and HIV/AIDS.[54]

3. Medication Access in Low-Income Nations: The collaboration and policies of nations with developed pharmaceutical industries determine the availability of medications on a worldwide scale. High-income nations often possess the financial resources to get patented drugs, but low-income nations have obstacles as a result of exorbitant costs. Generic medications, especially those made in India, play a critical role in ensuring that necessary therapies are available everywhere.[55]

4. Effect on Equity in Global Health: India's pharmaceutical patenting practices have an impact on the equality of world health. In addition to helping the Indian populace, the availability of generic substitutes helps level the playing field for access to healthcare throughout the world. Global health inequities have been addressed by the expansion of treatment choices for infectious illnesses made possible by the low cost of Indian generics.[56]

5. Agreements on International Trade: The negotiation and effects of international trade agreements influence the worldwide landscape of pharmaceutical patenting. Trade agreements, like the TRIPS Agreement, and their following discussions influence the choices and flexibility that nations like India have. The intricate global pharmaceutical environment is further highlighted by the interaction of international agreements and their impact on state capacities to enact policies that prioritise public health.[57]

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[53] PRASAD, *supra* note 32.
[54] Shikha Gupta, *IMPACT OF GLOBAL POLICY REFORMS ON EQUITY IN ACCESS TO MEDICINES IN INDIA*, 1 BMJ GLOBAL HEALTH A30.2 (2016).
[55] ANIL KUMAR ANGRISH ET AL., CORPORATE DIVESTMENTS AND PHARMACEUTICAL INDUSTRY IN INDIA: AN ANALYSIS (2023).
[56] *Id.*
[57] Jaya Prakash Pradhan, *The Geography of Patenting In India: Patterns and Determinants*, 13 METAMORPHOSIS: A JOURNAL OF MANAGEMENT RESEARCH 29 (2014).

6. Up-and-Coming Patterns in Worldwide Pharmaceutical Innovation: For the purpose of forecasting future possibilities and problems, it is vital to comprehend developing patterns in global pharmaceutical innovation. The international community has to work together to make sure that intellectual property rules support innovation without undermining larger health goals when new technology and treatment modalities emerge. This calls for constant communication and collaboration among countries with various healthcare requirements and capacities.[58]

7. Ethical Issues in International Health: Ethical issues are part of the global view of pharmaceutical patenting. Discussions on fair pricing, humanitarian licencing, and the moral obligations of both wealthy and poor countries in promoting global health are sparked by the need to strike a balance between the profit-driven interests of pharmaceutical corporations and the moral necessity of guaranteeing access to life-saving pharmaceuticals.

India is a worldwide hub for pharmaceutical patenting, which affects communities well beyond its boundaries' access to medications. Promoting international cooperation becomes essential as the globe struggles with the complications of intellectual property rights, public health imperatives, and global health inequities. The knowledge gained from India's experience helps to clarify how different countries might negotiate the complex world of pharmaceutical innovation and public health access.[59]

RECOMMENDATIONS FOR IMPROVEMENTS

Finding workable solutions is crucial, as the problems with pharmaceutical patenting in India keep getting worse. Improvement suggestions need to find a middle ground between supporting pharmaceutical innovation and guaranteeing that everyone has access to healthcare. This section examines important recommendations for resolving issues related to public access to medications in the context of strict patent laws.

1. Fortifying the Laws Governing Compulsory Licencing: Improving the efficiency of mandatory licencing programmes may help ensure that timely access to reasonably priced generic versions of necessary drugs is possible. In order to do this, the obligatory licencing

[58] Luv Saini & P.K. Agarwal, *CHALLENGES OF ESTABLISHING PHARMACEUTICAL COMPANY IN INDIA*, 17 697 (2023).
[59] Debasis Barik & Amit Thorat, *Issues of Unequal Access to Public Health in India*, 3 FRONTIERS IN PUBLIC HEALTH (2015).

procedure must be streamlined and made available to generic producers, and any procedural or legal obstacles that would prevent it from being implemented must be removed.[60]

2. Periodic Evaluation and Modification of Patent Laws: It is crucial to regularly study patent laws in order to adjust to the changing healthcare environment. Regular evaluations might point up areas that need changes, such as limiting the breadth of the requirements for patentability or adding clauses that forbid patent abuse. The legislative framework's flexibility guarantees that it will always be in line with the objectives of public health.[61]

3. Promoting the Study and Advancement of Ignored Illnesses: To encourage research and development for neglected illnesses, a focused strategy is essential. Redirecting innovation towards unmet medical needs may be achieved by enacting regulations that provide extra incentives, such as tax advantages or longer exclusivity, to firms that concentrate on discovering medicines for illnesses that disproportionately impact poor countries.[62]

4. Public-Private Partnership (PPP) Promotion: Encouraging public-private sector cooperation helps ensure healthcare access while promoting innovation. Through financial sources, tax breaks, or other strategies, public-private partnerships may be encouraged to collaborate on research and development projects that meet both business and public health goals.[63]

5. Supporting Open Innovation Frameworks: Encouraging open innovation paradigms may hasten the creation of novel therapeutics. Open-source drug discovery and collaborative research platforms are examples of initiatives that promote knowledge and resource sharing, which accelerates medical science advancements while reducing the exclusivity-driven obstacles associated with traditional patenting.[64]

6. Global Cooperation and Information Exchange: Given that, health issues are global in scope, international cooperation is crucial. India, a significant producer of generic drugs, may work with other countries to exchange research results, best practices, and approaches for striking a

[60] Ravi Kiran & Sunita Mishra, *Research and Development, Exports and Patenting in the Indian Pharmaceutical Industry: A Post TRIPS Analysis*, 4 EURASIAN JOURNAL OF BUSINESS AND ECONOMICS 53 (2011).
[61] Kausiki Mukhopadhyay & Pallab Paul, *Pharmaceutical Growth versus Health Equity in India: When Markets Fail*, 27 JOURNAL OF PUBLIC HEALTH (2019).
[62] Anil Ghanghas et al., *Global Rules, Regulations and Intellectual Property Rights on Diagnostic Methods*299 (2021).
[63] Maureen Nolan, Charles Oppenheim & K. Withers, *Patenting, Profitability and Marketing Characteristics of the Pharmaceutical Industry*, 2 WORLD PATENT INFORMATION 169 (1980).
[64] Benjamin Blau, Todd Griffith & Ryan Whitby, *Pharmaceutical Innovation and Access to Financial Markets*, 17 PLOS ONE e0278875 (2022).

balance between intellectual property rights and public health concerns. These cooperative efforts may be strengthened through bilateral and multinational initiatives.[65]

7. Boosting the Infrastructure for Health: Ensuring that pharmaceutical advances result in measurable health outcomes requires investing in improving the infrastructure of healthcare. In order to make sure that the advantages of innovation are effectively distributed to the intended recipients, efforts to improve medical education, healthcare facilities, and distribution networks might be made in tandem with pharmaceutical breakthroughs.[66]

8. Fair Pricing Programmes: The financial obstacles related to patented medications may be addressed by putting fair pricing policies into action. Fair and inexpensive access to novel medications may be facilitated by discussions between governments and pharmaceutical corporations, transparent pricing methods, and differentiated pricing depending on economic considerations.[67]

9. Ongoing Public Awareness Initiatives: It is essential to educate the public on the complexities of pharmaceutical patenting, how it affects medicine prices, and how important access to healthcare is. A well-informed public debate has the power to shape policy choices by promoting a shared awareness of the need to strike a balance between innovation and accessibility. Including these suggestions in policy frameworks will help India negotiate the challenges of pharmaceutical patenting and open the door to a more inventive and egalitarian healthcare system. These recommendations seek to support a comprehensive and long-term strategy that guarantees that the advantages of medical innovation are available to everyone by striking a balance between the interests of the pharmaceutical business and the need for public health.[68]

CONCLUSION

The state of pharmaceutical patenting in India is at a crossroads between innovation and accessibility, where the need to guarantee universal public health is balanced with the pursuit

[65] Lauren McGIVERN, *Trade-Related Aspects of Intellectual Property Rights Flexibilities and Public Health: Implementation of Compulsory Licensing Provisions into National Patent Legislation*, THE MILBANK QUARTERLY (2023).
[66] Deepak Dash, Riya Vaiswade & Gayatri Gupta, *A Review on the Indian Patent System and Its Implication on the Pharmaceutical Industry*, JOURNAL OF HEALTH SCIENCE AND MEDICAL RESEARCH 2023926 (2023).
[67] Renu Kadian & Arun Nanda, *A Comparative Study of Pharmaceutical Incentives to Patents in India, USA and Europe*, 07 APPLIED CLINICAL RESEARCH, CLINICAL TRIALS AND REGULATORY AFFAIRS (2020).
[68] Bhaven Sampat & Tahir Amin, *How Do Public Health Safeguards in Indian Patent Law Affect Pharmaceutical Patenting in Practice?*, 38 JOURNAL OF HEALTH POLITICS, POLICY AND LAW (2013).

of novel medications. As we come to the end of our investigation into the issues surrounding public healthcare access in the setting of strict patent laws, it is clear that there are many different facets to the difficulties, but there are also many chances for positive change.

India's path to harmonise its patent laws with global norms, especially via the TRIPS Agreement, has been replete with both achievements and challenges. Product patents were introduced in 2005 with the intention of promoting innovation; however, concerns over accessibility and cost were raised, especially for a population with a variety of healthcare requirements and economic backgrounds.

In this story, generic medications become a ray of hope, demonstrating India's ability to provide affordable substitutes both locally and internationally. The nuanced tango between public health and intellectual property rights has led to international cooperation, legislative frameworks, and policy changes intended to achieve peaceful coexistence. A comprehensive plan that seeks to balance the balance of innovation and accessibility is supported by mandatory licencing, regular reviews of patent rules, and public-private collaborations. Calls for equitable pricing, transparent innovation models, and improved health infrastructure are not exclusive to India; they are being heard by other countries that face comparable difficulties.

As we advance, it becomes more important to have ongoing conversations, to adapt, and to remain committed to ethical issues. The pharmaceutical industry is changing due to new illnesses, developing technology, and shifting public health goals. Requirements for solutions include being flexible, inclusive, and sensitive to the global interdependence of health systems. The suggestions for enhancements in the pursuit of health equality serve as a road map for legislators, medical experts, and the international community. It is a plea for finding a middle ground where access to life-saving drugs is a basic right rather than a luxury and guarantees that the benefits of innovation are distributed fairly.

Lessons learned, issues resolved, and innovations nurtured as India negotiates this complex terrain benefit not just the country's healthcare system but also the international conversation on the relationship between public access and pharmaceutical patents. The capacity to turn obstacles into opportunities and open the door for a day when healthcare is a universal promise fulfilled is the fundamental test of success in our shared quest for a healthier world.