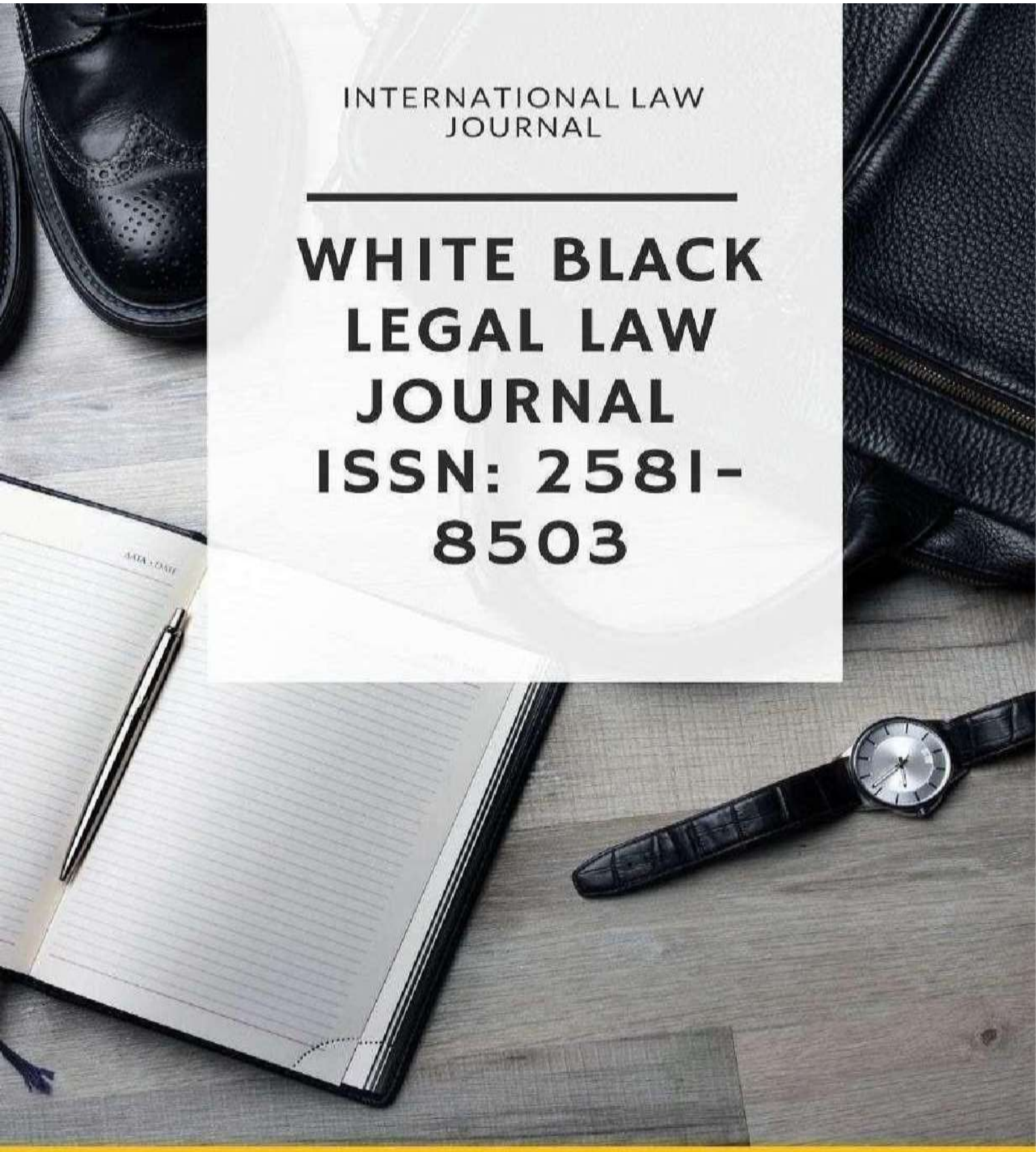

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ABOUT US

WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal providededicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

COMPULSORY LICENSING OF PHARMACEUTICALS (INTELLECTUAL PROPERTY RIGHTS)

AUTHORED BY- RITUL RAJVANSHI,
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1.1 INTRODUCTION

INTRODUCTION

The confluence of compulsory licencing and patents within the pharmaceutical industry gives rise to a multifaceted terrain influenced by legal, economic, and public health factors. Within its fundamental essence, a patent bestows upon a patentee the esteemed prerogative of exclusive rights, thereby endowing them with the power to prohibit third parties from partaking in specific activities pertaining to the patented invention without obtaining their consent. Under Indian Patent Act of 1970, patents are duly granted in India, thereby conferring upon patentees the exclusive rights pertaining to the patented products or processes.

In this framework, compulsory licencing emerges as a key mechanism that grants governments the power to grant licences for the manufacture or commercialization of patented inventions without the patent holder's express consent. The aforementioned mechanism assumes particular relevance within the realm of pharmaceuticals, wherein the availability of cost-effective medications can exert a substantial influence on the outcomes of public health.

It is to be noted that the pharmaceutical industry in India has experienced notable changes, wherein there has been a shift from a scenario primarily controlled by multinational corporations to one that encourages domestic growth and technological advancements. The aforementioned availability of affordable generic medications, driven by legal modifications and policy endeavours, has undeniably served as a crucial factor in enhancing the accessibility of indispensable pharmaceuticals, both within the confines of a specific jurisdiction and on an international scale.

The aforementioned 2005 amendments represent a momentous achievement, as they effectively harmonised India's patent system with prevailing global norms, all the while ensuring the safeguarding of “public health concerns” by incorporating the flexibilities provided under TRIPS.

The aforementioned flexibilities, which encompass provisions for compulsory licencing, were implemented with the intention of striking a delicate equilibrium between safeguarding IPR(s) and fulfilling the crucial obligation of guaranteeing access to pharmaceuticals, particularly within developing nations.

Notwithstanding, the implementation of compulsory licencing continues to be a matter of contention and examination, wherein interested parties must carefully navigate the intricate equilibrium between fostering inventive progress, facilitating availability of reasonably priced pharmaceuticals, and protecting the well-being of the general public. Recent legal precedents, exemplified by Natco v. Bayer, as well as ongoing deliberations pertaining to pharmaceuticals such as Trastuzumab, serve to highlight the intricate nature of this particular field.

In light of the aforementioned circumstances, the present dissertation endeavours to thoroughly examine the complexities surrounding the obligatory granting of licences for pharmaceuticals, all within the confines of the intellectual property rights framework. Upon thorough examination of historical developments, legal frameworks, economic implications, and case studies, the intention is to shed light on the intricate dynamics that influence access to medicines and innovation within the pharmaceutical industry. By means of meticulous examination and meticulous investigation, this study aims to make a valuable addition to the comprehension of the intricate difficulties and potential advantages that arise from the intersection of compulsory licencing, generic drugs, and patents.

1.2 LITERATURE REVIEW

The literature on compulsory licencing and pharmaceutical pricing illuminates the complex pharmaceutical market and its issues for governments, consumers, and industry stakeholders. Robin Feldman and Evan Frondoff's "Drugs War: How Big Pharma Raises Prices and Keeps Generics off the Market" provides a riveting look at how pharmaceutical firms raise prices and block generic competition. The authors use engaging writing and precise examples to show how monopolistic behaviours harm public health and healthcare expenditures, especially in developing nations like India. The book critically examines the pharmaceutical industry and suggests reforms. Martin Voet's "The Generic Challenge: Understanding Patents, FDA and Pharmaceutical Life" illuminates the branded and generic drug industry's regulatory, legal, and commercial dynamics. Voet explains how patents, FDA rules, and the Hatch-Waxman Act drive medication research and market

competitiveness. Voet provides a complete overview of the pharmaceutical industry in the US and worldwide by examining generic medicine issues and prospects. Vishnu S. Warrior's "Understanding Patent Law" covers patent law basics with an emphasis on protecting intellectual property. The book clarifies patent laws in India and abroad by covering patentable ideas, patent applications, infringement, and international patent treaties. Warrior clarifies patent law with extensive explanations and case studies, helping practitioners and researchers navigate patent issues. Elizabeth Verky compares Indian, UK, and US patent systems. Verky illuminates patent laws in various nations by reviewing patentable subject matter, grounds for termination, infringement, and remedies. The book helps readers comprehend patent law and its effects on innovation and IP protection. "Legal Implications of Compulsory Licencing in India" critically examines the legal and policy effects of compulsory licencing on pharmaceutical accessibility, cost, and availability. The book investigates how obligatory licencing affects pharmaceutical innovation and public health in India via case studies and legislative analysis. The seminal case of Natco v. Bayer illuminates India's obligatory licencing laws.

Philippe Cullet studies how patents promote economic growth and sustainable development. Cullet examines the Paris Convention and WTO objectives to explain how IPRs affect sustainable development. The book illuminates the pros and cons of reconciling IP protection with social goals. Nuno Pires de Carvalho's "The TRIPS Regime of Patent Rights" analyses the TRIPS Agreement and its effects on worldwide IP regimes. Carvalho examines TRIPS' patent and intellectual property rules to provide light on its legal and policy consequences for enterprises, governments, and investors. The book is essential for understanding international intellectual property law and its effects on economic growth and creativity.

Carolyn Deere's "The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries" provides a nuanced view of TRIPS implementation politics. Deere illuminates the difficulties of global intellectual property reform by exploring pressures on underdeveloped states to follow Global North intellectual property policy. The book examines how industrialised nations enforce compliance from underdeveloped nations, revealing power dynamics in international intellectual property systems.

In "The Truth about Drug Companies: How They Deceive Us and What to Do About It," Marcia Angell uncovers pharmaceutical firms' deception and lobbying to retain monopolies. Angell

investigates how pharmaceutical companies influence physicians, lawmakers, and regulators, challenging research and development facts. The book presents real solutions for keeping drug firms responsible and resolving pharmaceutical industry structural concerns.

Michael Kinch and Lori Weiman's "The Price of Health: The Modern Pharmaceutical Enterprise and the Betrayal of a History of Care" chronicles the American pharmaceutical industry's history. The writers examine the history of medication mass manufacturing, the FDA's participation, and the significance of the Orphan Drugs Act and Hatch-Waxman Act. The book identifies pharmaceutical industry difficulties to suggest reforms.

Robin Feldman and Evan Frondorf's "Drug Wars: How Big Pharma Raises Prices and Keeps Generics off the Market" investigates patent-holding businesses' strategies to delay generic medicine introduction. The book illuminates Hatch-Waxman Act flaws and pharmaceutical firms' domination strategy.

Prabodh Malhotra's "Impact of TRIPS in India: An Access to Medicine Perspective" critiques India's healthcare industry, specifically pharmaceutical accessibility and pricing. Malhotra examines how TRIPS affects medicine pricing and suggests healthcare cards like ration cards to lower prices.

Amaka Vanni's "Patent Games in the Global South: Pharmaceutical Patent Lawmaking in Brazil, India, and Nigeria" studies patent law evolution in emerging nations. The book examines how colonialism shaped patent laws and how the Patent Act of 1970 and TRIPS affected medical access.

Studies like "Access to Medicines after TRIPS: Is Compulsory Licencing an Effective Mechanism to Lower Drug Prices?" by Eduardo Urias and Shyama V. Ramani and "The 'Compulsory Licence' Regime in India: Past, Present, and Future" by Shamnad Basheer shed light on compulsory licensing's effectiveness in lowering drug prices and India's compulsory licencing regime's evolution. Other works, such as "How Effective Have Government Measures Been to Control Prices of Anti-Cancer Medicine in India" by Sudip Chaudhuri and "Compulsory Licence under Indian Patent Law" by N.S. Gopalakrishnan and Madhuri Anand, analyse pharmaceutical pricing regulations in India. Finally, "Compulsory Licencing," edited by Reto M. Hilty and Kung-Chung Liu, covers compulsory licencing and its effects on IP and competition law.

1.3 PROBLEM STATEMENT

The pharmaceutical business has seen tremendous changes since India's patent policy was reformed

in 2005. These changes have affected competition, pricing tactics, market dynamics, and accessibility to necessary medications. Concerns about public health, market monopolisation, and the function of mandatory licencing in balancing opposing interests have been brought up by these developments, nevertheless. Drug costs have been deregulated as a result of the change in the patent system, which may allow companies to monopolise the market for novel medications without giving public health issues enough thought. Due to their large investments in drug development, foreign investors aim to protect their interests by restricting the availability of life-saving medications in the Indian market, which exacerbates patient access problems. Despite being designed to remove obstacles to entry and increase competition, the introduction of obligatory licencing has drawn criticism from both local and foreign sources. The mandatory licencing rules in India have been met with opposition from other governments, particularly the US administration, who claim that they violate international accords like the TRIPS Agreement. Given the many obstacles and disputes pertaining to compulsory licencing in India, it is essential to appraise the nation's position regarding this process, analyse the potential future benefits of generic medications, and pinpoint ways to fortify the obligatory licencing structure. This study aims to explore the intricacies of mandatory licencing, pinpoint opportunities for development, and promote policies that will increase the availability of reasonably priced medications while respecting the rights to intellectual property and the interests of the public health.

1.4 SCOPE

Compulsory licencing in medicines is controversial due to IPR(s), public health, and market dynamics. Post-2005 patent policy revisions in India have changed the pharmaceutical business, affecting access to medications, market competitiveness, and innovation incentives. These measures have deregulated medicine costs and allowed businesses to monopolise new drug markets, possibly neglecting public health. Foreign investors have also tried to restrict life-saving drug entrance into India to preserve their interests, worsening patient access. Compulsory licencing, designed to reduce access obstacles and boost competition, has been criticised locally and internationally for violating international agreements like TRIPS. In light of this, India's compulsory licencing policy, generic medicine prospects, and legal framework improvements must be assessed. This study explores these complexities to contribute to academic discourse on pharmaceutical access and intellectual property rights and help policymakers and stakeholders navigate pharmaceutical innovation and public health.