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A Study on Examining the Impact of Patent Protection and Right to Health

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ABSTRACT

The right to health is a fundamental right that is guaranteed to all human beings, regardless of their religion, region, or race. Everyone has the right to get adequate healthcare for themselves or others they care about and loves. Access to healthcare services should not be restricted based on age, gender, race, geography, religion, or political affiliation. The exclusive focus of this article only discusses the impacts caused by patent protection on accessibility of essential medicine. In this situation, it is frequently argued that increased drug prices due to patent protection have a detrimental effect on patients access to medications. The right to health and "having access to healthcare treatment" are also included in the right to life. Every effort must be made by the government to ensure that its citizens have access to life-saving medications. The paper looks into the relationship between India's pharmaceutical sector and patent law in regard to the right to health. The patent system in India and globally how patents increase the price of medications, especially in developing nations and how this hinders people's ability to get the care they require, as well as appropriate ways that might improve the accessibility of medications in India.

***Keywords**: Right to health, pharmaceutical ,medicine ,patent ,developing country, Health care.*

I. INTRODUCTION

People who hold intellectual property rights (IPR) are said to have the power to protect their own ideas, creations, innovations, etc. any creative expressions, and are considered to belong to the originator. In order to reward their efforts and inspire others to create new works or ideas, the authors of these works are given financial benefits or certain exclusive rights. The creator is the only one with the ability to make profit or someone who has been legally granted permission by them. By giving the inventor or creator time-limited commercial rights over the use of their product, IPRs seek to promote invention. Along with this the most important and essential components of the human rights framework worldwide everyone has the right to good health.

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The ongoing challenge of fairly distributing medicines has always been a persistent issue. Ensuring sustainable accessibility to essential medicines remains central to this concern. The United Nations Sustainable Development Goals 2030 (SDG 2030) highlight Universal Health Coverage (UHC) as a crucial objective within Goal 3, which focuses on Good Health and Well-Being to promote equitable access to medicines. Intellectual Property (IP) policies, along with their management and enforcement, aim to strike a balance among various legitimate interests to enhance overall welfare.

However, there is a notable connection between IP laws and the public health sector, represented by the conflict between IP policies that encourage pharmaceutical innovators, granting them monopolies. This situation negatively affects sustainable and equitable access to medicines. Strict IP protections can lead to higher non-accessibility rates for essential prescribed drugs. Developing and least-developed countries are particularly impacted, as they often lack the resources and financial means to manage and distribute essential lifesaving medications when they are patented and sold at high prices. This situation poses a significant risk to achieving the UN Sustainable Development Goal of Universal Health Coverage.

Thus, it is crucial to understand the necessity of improving access to medicines and to address the current challenges in achieving equitable access. Additionally, it is important to examine the relationship between patent policy and those aimed at effectively enhancing equitable access to medicines.

II. INDIA'S PATENT POLICIES WITHIN THE CONTEXT OF THE GLOBAL PATENT FRAMEWORK

A patent gives inventors exclusive government-created rights which protect their developed concepts. Through patent protection rights inventors together with designated parties can stop unauthorized production and utilization or commercialization of their inventions. A patent functions as a negative right which allows its holder to prohibit other people from using their invention without authorization. They also allow specified individuals to produce, use, or commercialize the invention.

The inventor establishes official agreements through patents with governmental entities after revealing their complete invention details to obtain approval. The strategic protection of inventions comes with an agreement that forfeits information sharing between inventor and government. In order to receive patent protection an invention must meet particular conditions established for patentability. After receiving a patent it becomes effective for 20 years starting from its original granting date. All granted rights remain sovereign and only governments can

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enforce them within their territorial boundaries. Legal recourse for infringement or violation of patent rights can only be sought in that particular country. Therefore, inventors must apply for patents in each country where they desire protection. Each individual patent office retains the authority to decide on patent grants even though the Patent Cooperation Treaty (PCT) simplifies global patent application operations.

(A) India's Patent Law Trajectory

The Patents Act of 1970 serves as the primary legislation for patenting processes in India. Initially, the law only allowed process patents for inventions in the fields of food, medicine, and chemicals. However, starting in 2005, product patents became permissible. This change was a result of India's obligation to align its patent laws with the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Treaty upon becoming a signatory. The first amendment came with the Patents (Amendment) Act of 1999, which provided provisional protection for product patent applications concerning drugs and agrochemicals. The Patents (Amendment) Act of 2002 introduced the maximum term of 20 years for all inventions based on additional TRIPS commitments. The third modification, the Patents (Amendment) Act of 2005, brought in the product patent system in India. Patents can only be obtained when inventions fulfill certain requirements which:

- The invention must be original and not publicly known before the patent application is submitted.
- The invention needs to establish technical progress which experts in that domain would not easily recognize.
- The invention must be capable of being manufactured or used in a practical setting

(B) International Patent Standards

The General Assembly Session for Social Development (UNGASS) emphasized the right of citizens to obtain necessary medications at reasonably priced rates yet showed the patents and intellectual property system established by WTO GSP poses a threat to this right. After challenging negotiations, governments agreed that methods to enhance access to life-saving and vital medications can be implemented within international trade agreements. Limited advancement has occurred to guarantee the accessibility of vital drugs for both developed nations together with vulnerable populations.

The Doha Declaration came about through multiple discussions about health sector patents while affirming that public health initiatives do not eliminate patent rights in medical care. It

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asserts that the TRIPS Agreement should be interpreted and enforced in a manner that allows World Trade Organization members to prioritize public health and facilitate access to medicines for everyone. While the declaration does not create new pathways concerning TRIPS, it bolsters existing efforts to maximize the flexibility provided by the TRIPS framework.

The Doha Declaration is significantly grounded in issues like compulsory licensing associated with patents. The 1970 Patents Act incorporated both compulsory licensing and rights within a detailed structure. Although the TRIPS Agreement has not abolished the concept of mandatory licenses, it establishes a more rigorous framework than the current system in India. The Doha Declaration serves as an essential instrument for India because it received approval through a parliamentary committee evaluation. However, the World Trade Organization (WTO) has not effectively addressed the health needs of developing countries overall. Adopting product patents in 2005 appears to have created obstacles for millions of people gaining access to medicines because the government supported its pharmaceutical industry.

III. THE EFFECT ON THE RIGHT TO HEALTH OF INDIA'S PATENT SYSTEM

The right to health is recognized as a constitutional right in India and several other countries, with the TRIPS Convention allowing member nations to make exceptions for public order and moral reasons. Healthcare institutions within nations must adjust to societal economic structures. Although not explicitly stated in the Indian Constitution, the right to achieve the highest possible standard of health is a fundamental human right. The Constitution of India indirectly shapes the healthcare landscape, mandating the state to enhance the health conditions for its citizens. Relevant articles 39, 41, 42, 43 and 51A together with fundamental rights function as important components.

International treaty compliance standards have significant effects on health results within India. The government has launched programs aimed at assisting the impoverished in both urban and rural settings, such as the National Rural Health Mission, National Urban Health Project (NUM), Polio Drop Scheme, and Mission Indradhanush. Health challenges persist in developed and developing nations because of increasing public health consciousness together with rising healthcare service demands and increasing costs.

The healthcare availability in developing countries faces limitations due to multiple factors that include poverty together with education levels and population-wide unawareness about health benefits and risks. India faces multiple obstacles that prevent people from accessing healthcare even though the constitution and court decisions provide support for accessibility although laws alone remain insufficient. The administration requires significant improvement while the

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constitutional framework and roles of statutes and the judiciary together with the administration need comprehensive inspection.

(A) Pharmaceutical Patents in India Affecting The Right To Access Medicines

In 1957, the Indian government appointed the Justice N. Rajagopala Ayyangar Committee to review potential amendments to the Patent Law. Following two unsuccessful attempts in 1965 and 1967, the Patent Act was enacted in 1970, with most of its provisions taking effect on April 20, 1972. At that time, foreign pharmaceutical companies dominated the local market and set high prices for medications. In response, the Indian government implemented the Patent Act of 1970 to tackle public health issues and abolish product patents on pharmaceuticals. Specifically, Section 5 of the Act prevented pharmaceutical companies from obtaining product patents, allowing them to pursue only simple process patents.

The global generic pharmaceutical sector selected India as a leading player while domestic companies took control of major segments within their home market. The World Trade Organization membership in 1995 established India as a trustworthy trading partner which led to multiple changes in its Patent Act during 1999, 2002, and 2005. Since 1970, India did not grant product patents for pharmaceuticals, leading to the widespread creation of generic medications. The position allowed Indian pharmaceutical producers to become primary generic drug manufacturers which provided cost-effective medicine access to millions. Nevertheless, due to its commitments under the TRIPS agreement, India was compelled to revise its patent law in 2005 to reintroduce product patent protections for pharmaceuticals and extend the patent duration from several years to 20 years.

(B) Access To Necessary Medical Supplies

Developing nations must navigate between their requirement of necessary medical drugs while operating under current pharmaceutical patent laws. The pharmaceutical sector of capitalist models includes an internal contradiction which blocks people's access to affordable healthcare. Confidential patent procedures and uncontrolled medication distribution cause additional difficulties to existing healthcare system challenges in these countries. Most developing countries struggle to put WHO recommendations into practice regarding improved regulatory systems and medicine distribution systems. The main dispute exists because developed and developing nations maintain different sets of organizational priorities throughout this conflict. The majority global population which consists of developing countries wants more access to patented medications due to their direct health implications for citizens. The World Intellectual Property Organization (WIPO) received a proposal from South Africa alongside the African

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Group intended to enable developing and least developed countries access to patent flexibility tools for enhancing public health needs. These countries demonstrate their goal to modify international patent systems to enhance their public health care through this program.

The United States together with other developed nations maintains that medicine accessibility problems do not stem from weak patent protection regulations. The argument presented it is that infrastructure issues together with distribution problems remain the main barriers directly impacting access to medicine. The medical accessibility needs of nations are recognized by this perspective which disregards the financial and healthcare structural obstacles faced by developing countries The US proposed alternative strategies focused on identifying non-patent barriers and conducting studies on the benefits of patent systems in developing countries. The proposed information gathering methods face criticism because they risk overshadowing the main patent-related obstacles that limit patients' medicine access. Knowledge Ecology International reports that market monopolies created by patents result in drugs that are unaffordable to developing nations thereby denying them proper healthcare services.

The dispute showcases how profound the disagreement is between developed nations and developing countries about pharmaceutical patent rights and medicine distribution. Traditional nations dedicated their efforts to change patent laws for better health services but developed nations preserve their reluctance to modify innovation protections. There exists today a critical challenge for the global community to establish a patent system which safeguards intellectual property yet ensures equal access to essential medication for every person.

(C) **Compulsory License**

The World Trade Organization (WTO) has the option of compulsory licensing under Article 31, which was adopted in 2003 The licensing process under this system proves to be both cumbersome and the system also struggles because it covers an unclear range of diseases while the covered diseases remain restricted under the Decision. The system operates exclusively for WTO Member States although it does not include lower-income developing countries like Somalia and Eritrea as well as South Sudan. The TRIPS is to be amended when two-thirds of WTO Members have ratified the Article 31 waiver. Despite these criticisms, compulsory licenses can promote access to medicines if used non discriminatively and with some changes and clarifications. Brazil and Thailand have used compulsory licensing legislation to improve the right to health, even without issuing a single license. The 2003 system was only used once by Rwanda and Canada, but it is a valuable tool for improving access to medicines.

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(D) Generic Competition Alternative

Generic pharmaceutical competition has successfully decreased the price levels for costly medication with patents. The practice of generic pharmaceutical delivery through developing countries ended in 2005; today they exclusively rely on compulsory licensing for essential medicines' supply. The United States and other developed nations have impeded the progress of legislation for generic production and compulsory licensing. Off-patent essential medicines demand the development of generic versions by developing countries in order to enhance market supply. The WHO endorses timely exploitation of patented medicines and promotes worldwide competition for pharmaceutical businesses. Pharmaceutical businesses should develop specific agreements to let generic drug production for markets belonging to developing nations.

(E) Price Reductions

Differential pricing schemes function as a possible solution to resolve the pharmaceutical patents' dispute with medication access. The foundation of DP model comes from equity pricing that provides medicines at manufacturing price levels in developing countries and marginally elevated price levels in middle-income nations. Various pharmaceutical industry members consider parallel importation under DP as an infringement of their intellectual property rights. The doctrine of exhaustion also known as the first sale doctrine functions as the solution to resolve this matter. The adoption of this solution requires careful implementation along with a strategic approach for stopping contraband cheap medications from entering developed nations.

(F) Health Impact Fund

The Health Impact Fund (HIF) functions as a project created by Professor Michael Abramowicz and eminent academics to achieve medicine accessibility together with enhanced pharmaceutical innovation for developing countries. The fund operates to eliminate existing obstacles which include high prices and diagnoses of poverty-related illnesses along with priority bias toward maintenance drugs and expensive legal battles and counterfeiting products and excessive promotions and inadequate health facilities. HIF operates through governmental financing to provide patent holders options for rewarding medications according to their worldwide health benefits. The fund would receive up to 6 billion every year and share the money according to how well drugs decreased human suffering as well as fulfilled healthcare requirements in both developed nations and developing countries.

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IV. CONCLUSION

The patent law in India is a model of legislation designed to find a middle ground between the needs of the general public and those of inventors. With the advent of the product patent system, a broad array of pharmaceutical products is now eligible for patent protection in India. Researchers need to perform a detailed assessment of patentability criteria before patent application and expert consultation about patents remains mandatory. The patent ownership acquired through acquisition or patenting can be transferred via licensing agreements to different parties. Academic institutions together with universities can utilize patents as their main tool to conduct technology transfer activities because they often lack sufficient manufacturing or marketing resources. The entities can enter agreements with external parties where they license their patented products or processes to allow the recovery of development expenses. A compulsory license presents an opportunity to sell patented products under specific conditions.

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