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PUBLIC HEALTH & MEDICAL TECHNOLOGY PATENTING INTERSECTION: A DOCTRINAL STUDY

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BACKGROUND

"The goal of patent law is to foster science studies, modern tech, and economic advancement," the Supreme Court stated in *Bishwanath Prasad Radhey Shyam v Hindusthan Metal Industries*[2]. The grant of an exclusive right to possess, use, or sell a patented method or product for a limited time fosters future commercially useful inventions. India has long set an example for the developing world by modifying its pharmaceutical regulations to take into consideration local health concerns, putting a greater emphasis on the demands of the general population, and therefore aligning with its growth. However, the majority of the Indian population lives in poverty, and the bulk of medical bills must be paid out of pocket, indicating that the country is facing a serious health crisis due to shortcomings in healthcare, accessibility, affordability, and pharmaceutical availability. The Indian pharmaceutical sector provided a backbone for the effort by proving that an alternative pharmaceutical industry could be established. According to recent Indian patent law decisions, such as the Supreme Court's Novartis decision, India continues to prioritize public health when deciding whether to grant patents for pharmaceutical items. As a result, generic competition is limited by the pharmaceutical patent system. As a result, costs are rising and underdeveloped countries' access to medications is being impeded.

RESEARCH QUESTIONS

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[2] Bishwanath Prasad Radhey Shyam v Hindusthan Metal Industries AIR 1982 SC 1444

1. Whether patents on medical technologies affect public health?
2. Whether to ensure efficiency of public health, pharmaceutical drugs and technologies should be patented?

PUBLIC HEALTH AND CONSTITUTIONAL PROTECTION

Health is a basic and universal human right. Access to critical medical technologies and health services is an important part of ensuring that everyone has the best possible health. The right to health means the government must generate conditions in which everyone can be as healthy as possible, and have the availability of health services and safe working conditions.

Articles 14 and 21 of the Indian Constitution direct the state to adopt appropriate measures to improve the population's health care. This right to health includes freedom and entitlements. The freedom is to control one's health and body, and the entitlement is to a system of health protection. The Supreme Court of India interpreted Article 21 of the Constitution, which guarantees the right to life, to encompass the right to health in *Bandhua Mukti Morcha v Union of India & Or*[3]*s. In the State of Punjab & Ors v Mohinder Singh Chawla*[4], the Supreme Court declared that the right to health is fundamental to the right to life, and that the government has a constitutional duty to provide health care & medical services. The court went on to support the state's responsibility to sustain health services in *State of Punjab & Ors v Ram Lubhaya Bagga*[5]*.* The court concluded in *Paschim Banga khet Mazdoor Samity v. State of West Bengal*[6] that it is a welfare state's primary responsibility to guarantee that medical treatment is provided.

WHAT ARE PATENT AND PROPRIETARY DRUGS

[3] Bandhua Mukti Morcha v. Union of India & Ors. (1997) 10 SCC 549
[4] State of Punjab v. Mohinder Singh Chawla (1997) 2 SCC 83.
[5] State of Punjab & Ors v Ram Lubhaya Bagga, (1999) 1 SCC 297
[6] Paschim Banga khet Mazdoor Samity v. State of West Bengal, AIR 1996 SC 128

Section 3(h) in the Drugs and Cosmetics Act, 1940, defines proprietary and patent drugs. In layman's terms, a proprietary drug is one that is acquired or managed by a single person or group of people. A copyright or trade name, as well as a patent, holds the ownership of these drugs. The pharmaceutical industry is a market that ensures this requirement of public health is met with and all citizens can avail the benefits of an efficient health care system through these pharmaceutical medicines.

WHY IS THERE A REQUIREMENT FOR PATENTING OF DRUGS AND MEDICAL PROCEDURES?

It is a sort of Intellectual Property Right that prevents others from manufacturing, using, marketing, or selling a design without permission from the owner. The government grants it to ensure that the owner has complete control over their creation or concept. Before obtaining a patent, however, a regulatory authority performs numerous rigorous inspections to ensure that the plan, product, or technique is original and inventive.

Drug patents are patents that are only granted to drugs or medicines, and they prevent other companies from promoting, manufacturing, or selling them. Following its acceptance of the TRIPs Agreement, India amended its Patent Act to allow for transitional measu res[7]. The pharmaceutical patent system was designed and is used to assist corporations in protecting their investment and recovering costs associated with discovering, producing, and marketing new pharmaceuticals, hence encouraging future drug research and development and innovation.

Therefore, patenting of drugs and medical procedures, is not essential for assuring that the owner has the right over the creation but also the fact that the such patenting is giving the authors and innovators the

[7] WIPO,https://www.wipo.int/patent-law/en/developments/publichealth.html,(08:24PM, 19 April. 2022).

incentive to create original and authentic products, being beneficial to the public at large and the innovators themselves.

THE INTERSECTION BETWEEN PATENTING OF DRUGS AND THE ACCESSIBILITY OF PUBLIC HEALTH.

Several critics of medical process patenting argue that the public's right to health should take priority above the potential economic benefits of medical procedure patents. It is argued that by making procedures more available, the standard of public health is emphasized. Finally, from an ethical standpoint, some have suggested that patenting medical processes could jeopardize the doctor-patient relationship as well. It is critical not to patent medical processes in order to make them more accessible.

From a commercial aspect, it was considered that if medical treatments were not protected by Patents, market competition would drive down prices to the point where the creator would have no incentive to innovate and only the opportunity cost would be repaid[8]. This could lead to a loss of innovation, which would have a negative influence on the broader public. One of the most significant drawbacks of patenting medical methods is the licensing of those procedures. The prices of procedures are greatly increased by licensing fees and royalties. This would be a barrier to universal access to healthcare[9]. Furthermore, the high transaction costs connected with the medicine may render enforcing medical technique patents very challenging.

The cost of the monopoly is the patent office's disclosure of the innovation, which eventually goes towards the public domain after the

[8] *Patents and the right to healthcare in India*, IPLEADERS, (Feb 06, 2022, 8:24PM), https://blog.ipleaders.in/patent-right-healthcareindia/#Patent_laws_in_India_and_public_health.

[9] Nishith Desai, *India: Patented New Drugs and Orphan Drugs Out Of Price Control In India,* MONDAQ, https://www.mondaq.com/india/life-sciences-biotechnology-nanotechnology/779544/patented-new-drugs-and-orphan-drugs-out-of-price-control-in-india (08:24 PM, 19 April. 2022).

exclusivity period has elapsed." Patents and public health are closely related concepts in light of this. The answer to promoting general health and making medicinal things readily accessible at cheap rates is to establish a reasonable balance, not to limit pharmaceutical patenting. An existing solution is the TRIPS flexibility of compulsory licensing of patented pharmaceuticals. Legislative solutions, compulsory licensing alternatives, and the Generic Market alternative are all options. The difficulty is to put them into practice correctly. Some possible solutions include price reductions in impoverished nations, a health benefits fund, and good corporate citizenship. These answers can be provided by striking a delicate balance.

Compulsory licencing (such as the refusal of voluntary license's) and rival trade policies are examples of this. It has the potential to make crucial medicines more affordable for citizens in impoverished countries. Compulsory licencing lowers consumer prices by increasing competition for patented items. This provision's main purpose is to create an organizational framework for other patent rules that improve health. As a result, it promotes the implementation of these regulations in countries that do not have them. The other is that it presents the dilemma of patentees and customers making competing claims. There were many pharmaceutical companies challenging the South African government in 1998. Their contention was that the Controlled Drugs and Related Substances Amendment Act 17 infringed on their constitutional rights. The Amendment Act established a legal foundation for making affordable medications available by including generic replacements for off-patent drugs, pricing transparency, and parallel importation of patented medicines.

THE INTERFACE BETWEEN DRUG PRICING CONTROL ORDER (2013), THE NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA) AND THE PATENTED DRUGS.

The Drugs Prices Control Order, 1995 is an order made by the Government of India to regulate drug prices under Section 3 of the Essential Commodities Act, 1955[10]. The Order includes, among other things, a list of price-controlled pharmaceuticals, methods for fixing drug prices, the manner of implementing prices set by the government, and penalties for violating the rules. Manufacturers, importers, and marketers of new medications patented in India are exempt from price restriction for a period of five years after commercial marketing begins. Therefore, at the end of the five years, the drug also comes automatically under the regulation of the drug pricing control order (2013). This is only applicable if the drug is considered an essential commodity and is significant to public health. It will be convened by a member secretary of National Pharmaceutical Pricing Authority (NPPA), who will oversee the implementation of the Drug Price Control Order (DPCO), including complexities in pricing and brand extensions. The National Pharmaceutical Pricing Authority (NPPA) is an Indian government institution that regulates pharmaceutical drug prices. The National Pharmaceutical Pricing Authority (NPPA) was established by Government of India Resolution dated August 29, 1997 as an attached office of the Ministry of Chemicals and Fertilizers' Department of Pharmaceuticals (DoP) as an independent Regulator for drug pricing and to ensure the availability of and access of medicines at affordable prices.[11]

However, the problem that arises is that even though the order regulates the pricing of medicines and drugs, it doesn't cover 80% of the drugs in the market[12]. Many crucial and significant medicines have

[10] VIKASPEDIA, https://vikaspedia.in/health/nrhm/national-health-policies/faqs-on-drug-pricing (08:24PM, 19 April. 2022).
[11] Commercializing a pandemic – how to balance patents and public health emergencies, https://www.iam-media.com/commercialising-pandemic-how-balance-patents-and-public-health-emergencies, (08:24PM, 19 April. 2022).
[12] Nishith Desai, *India: Patented New Drugs and Orphan Drugs Out Of Price Control In India,* MONDAQ, https://www.mondaq.com/india/life-sciences-biotechnology-nanotechnology/779544/patented-new-drugs-and-orphan-drugs-out-of-price-control-

been left out of the picture, leading to high expenses for these particular medicines for the diseases.

The current DPCO doesn't cover combination drugs, therefore, the drugs for diabetes and hypertension will move out of the drug pricing list, as they are used in combination only. Therefore, the DPCO and the NPPA even though regulating bodies for the pricing of the drugs, are not sufficiently regulating all the drugs, and hence are not entirely adequate for the needs of the Public and the requirements to cater to the public healthcare needs.

ALTERNATE SOLUTIONS RECOMMENDED ON THE ISSUE OF DRUG PATENTING IN INDIA AND ACCESSIBILITY TO THE PUBLIC.

TRIPS obligatory licensing flexibility The TRIPS Agreement, which took effect in India in 2005, is one of the most important international accords ever negotiated. Prior to the TRIPS framework, India did not grant drug product patents. Despite strong patent laws in industrialized countries, India's generic medication business thrived during the time. As a result, drug accessibility in India was not a concern under this regime.

Similarly, even drugs that were prohibitively expensive in other places were cheap in South Korea. It is critical for underdeveloped countries to have access to low-cost medications. As a result, regulations should be constructed in such a way that they do not establish barriers to drug regulation in order to ensure that compulsory licencing is neither oppressive but also not overly liberal, causing people to misuse drugs.

The industry's preferred solution: price reductions for underdeveloped countries, which, if correctly executed, could vastly enhance access to medications. Price reductions, a health impact fund, and good corporate citizenship are just a few examples of feasible solutions. These answers

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can be provided by striking a delicate balance.

Prescription drug costs are regularly discussed by pharmaceutical firms, patients, advocacy groups, prescribers, payers, and regulators. The availability of competitive products influences prescription medicine prices, but it is not the only issue. Competitors' goods, such as generic versions and biosimilars, cannot be made available promptly due to patent rights and/or exclusive marketing rights given by the federal govt to the innovator business. By giving exclusivity, the goal is to encourage the development of better, safer, and more effective prescription drugs. The majority of medicine prices can be cut in this way if the patent owner and regulator can work together.

CONCLUSION

Fundamental rights are grossly infringed in poor countries like India because of the way healthcare is structured. The principle of fairness is breached in the lack of basic minimal healthcare. Patented inventions can only benefit industry and the economy if they are used locally. As a result, imaginative effort must lead to new ideas. India's patent rules are among the best in the world, aiming to strike a balance between inventor and common man interests. Pharmaceutical businesses in India can now obtain patents following the implementation of the product patent regime.

Despite progress in the Indian pharmaceutical business, huge players' financial interests continue to jeopardize access to life-saving pharmaceuticals at affordable costs. Therefore, through this paper, the author has analyzed the issues, subsequently the alternative suggestions are recommended to be implemented.