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PHARMACEUTICAL PATENTING IN INDIA: AN ASSESSMENT IN REFERENCE TO PUBLIC ACCESS TO HEALTH

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ABSTRACT

Public health, innovation, and access to necessary medications are all significantly impacted by the complex environment that arises when intellectual property rights (IPR) and healthcare, particularly in the medical field. With a focus on the pharmaceutical industry and the obstacles it presents to equitable healthcare access, this paper explores the complex dynamics of intellectual property rights (IPR) in the healthcare sector. This research assesses how intellectual property rights (IPRs) protect healthcare innovation, costs, and the development of new medications and medical technologies by consulting a wide range of published works. It looks at how intellectual property rights, human rights, and the right to health are intertwined and highlights how crucial it is to strike a balance between incentives for innovation and public health requirements. Research also looks at how international agreements like the TRIPS Agreement influence intellectual property rights frameworks and how that affects people's ability to obtain medications, especially in low- and middle-income nations. Furthermore, the study addresses a range of tactics and programs, such as technology transfer mechanisms, voluntary licensing agreements, and the contribution of entrepreneurial innovation, that attempt to mitigate the obstacles that intellectual property rights (IPR) present to the availability of essential medications. Ultimately, the research highlights the pressing requirement for a comprehensive strategy that gives public health issues top priority, encourages innovation, and guarantees everyone has fair access to healthcare.

KEYWORDS - Pharmaceuticals, Patent protection, Medication, Exclusive rights, Intellectual Property Rights

INTRODUCTION

To determine the proper normative relationship between intellectual property and right to public health, one must first understand how they relate to one another.

Human-rights approach to property emphasis upon the states to safeguard its citizens against the abuse of intellectual property. Human rights connotation of intellectual property does not out rightly disapprove the impact of the medical patents. Respective authoritative Regimes must comprehend the touch of innovations, with introspection of intellectual property shifts (Chapman, 2001). Human rights and intellectual property connection is in the state of perturbation specially in the medication area of pharmaceutical patents. Medical patents can adversely affect the availability of medicines in two key ways:

Creation of monopolistic tendency related to essential drugs thereby overcharging and secondly profiteering, money making approach strikes badly to developing countries. It downgrades and stagnates the accessibility of fresh drugs to the bulk of population across the globe.

In accordance with its responsibilities under the World Trade Organization's Agreement on

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Trade-Related Aspects of Intellectual Property Rights (TRIPS), India started allowing pharmaceutical products to get patents in 2005. By doing this, the Indian government attempted to restrict the issuance of "secondary" pharmaceut ical patents, i.e., added a contentious clause, Section 3(d), to the patent law i.e. patents covering new versions of known compounds and medications.

There has been a lot of disagreement over Section 3(d). One prominent case that brought the world's attention to 3(d) was the Indian Patent Office's decision to reject a secondary patent on Novartis' cancer drug "Gleevec", The decision cited Section 3(d) as one of the grounds for rejection. Novartis challenged the constitutionality of Section 3(d) and appealed the IPO's decision, actions that in turn inspired health activists to embark on a campaign against Novartis and in support of the provision. The legality of 3(d) was upheld, and the decision to reject the Gleevec patent was confirmed by the Intellectual Property Appellate Board in 2009 and then, ultimately, the Supreme Court of India in 2013.

As mentioned above, besides patents, the TRIPS Agreement includes a second directly relevant issue for the pharmaceutical industry concerning protection of test and other data that are submitted for obtaining marketing approval. This issue has figured prominently in the discussions in India over the past few years and our endeavour would be to focus on the issues which affects public health that are involved.

REVIEW OF LITERATURE

- Westerhaus M, Castro A ., Access to reasonably priced medications in India and other developing nations was an issue after the TRIPS compliance. There could be possibilities that it would reduce generic competition, raise medication costs, and make it more difficult for low-income people to obtain drugs.
- Dhingra et al., The author discuss that how compulsory licensing allows the government to authorize the production of generic versions of patented drugs in certain circumstances, such as public health emergencies or when the patented drug is not available at an affordable price.
- Mohamad AyubDar and Tran Vang-Phu., talk about the Doha Declaration, TRIPS, and WIPO, WTO, and WHO initiatives as well as the possible advantages of improved IPR laws in tackling the global health issue.
- Agrawal & Henderson., The study explores how stronger patent protection is seen as encouraging innovation since it offers a return on investment, but some contend that it might hinder it by restricting access to preexisting knowledge and restricting competition.
- T G Agitha,. The author highlights the necessity for governments to provide strong intellectual property protection and also examines the effects of patents and data exclusivity on healthcare costs.

ISSUES

- To recognize the ways in which the Indian system of patents (pharmaceutical patents) clashes with global systems.
- To fully understand the legal framework and subjectivity surrounding the issuance of compulsory license and matters impacting public health widely.
- Examining the effects of IP protection on the development and commercialization of new pharmaceuticals and medical technology.

METHODOLOGY

The inductive approach is used in the doctrine research methodology to find patterns and draw broad conclusions. JSTOR, SCOPUS, Lexis Nexis, e-Newspapers, legislation, and judgements are among the references. Acts, rules, regulations, opinions, published reports from governmental bodies and institutions, as well as information from WIPO, WHO, WTO, and UN agencies, are examples of primary data. Books and scholarly journals are examples of secondary data.

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[1]RIGHT TO HEALTH – UDHR

Article 25 of the United Nations' 1948 Universal Declaration of Human Rights states that "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services." The Universal Declaration makes additional accommodations for security in case of physical debilitation or disability, and makes special mention of care given to those in motherhood or childhood.

The UDHR has inspired the adoption of more than 70 human rights treaties that are applied globally and regionally. India's constitution was adopted in 1949 and came into force in 1950, and was greatly influenced by the UDHR. Part III of the Indian constitution, also known as the magna carta, contains fundamental rights that are directly enforceable against the state if violated. Since many variables outside of human control affect health, the State is unable to ensure that everyone has access to that. But to help people live healthier lives, it must offer wholesome food, healthcare, hygienic living conditions, and access to therapeutic and diagnostic drugs as well as cutting-edge medical equipment for illness detection, prevention, and treatment.

[2]PHARMACEUTICAL PATENTING IN INDIA

Pharmaceutical patenting in India has long been a contentious issue, with implications on public access to healthcare. The Indian patents system underwent significant changes in the early 2000s, aligning it more closely with international standards and practices. This shift towards stricter patent protection has sparked debates about its effects on the availability and affordability of medicines. To better understand this complex issue, we will delve into the historical context, current state, and potential effects of pharmaceutical patenting in India.

India first introduced patent rights in 1856. All earlier laws were repealed in 1970 with the passage of the Patent Act 1970. India is also party to the Patent Cooperation Treaty and the Paris Convention on the Protection of Industrial Property.

Any invention
that meets the requirements of novelty, non-obviousness, and utility may be the subject of a patent, according to the Patents Act.

A few examples of non-patentable inventions under the Patents Act are agricultural or horticultural techniques, as well as procedures for the medical, surgical, curative, preventative, or other treatment of people, animals, or plants.

[3]The Indian Patents Act, 1970, was amended in 2005 to incorporate the TRIPS requirements. The amended Act introduced product patents for pharmaceuticals, while also providing for certain safeguards to ensure the availability of affordable medicines. For instance, Section 3(d) of the Act prohibits the grant of patents for new forms of known substances unless they demonstrate significantly enhanced efficacy.

Nonetheless, the government passed the new Patents Act in 1970, which barred the patentability of agrochemical and pharmaceutical products. In order to reduce India's dependency on imports for bulk medications and formulations and to facilitate the growth of an independent domestic pharmaceutical sector, this exclusion was put in place. This led to a rapid expansion of the Indian pharmaceutical industry, which produced less expensive versions of several patented drugs for
the domestic market. When the international patents on these drugs expired, the industry aggressively entered the global market with generic versions of the drugs.

Furthermore, the Patents Act offers several protections against misuse of patent rights

[1] UN General Assembly. (1948). Universal declaration of human rights (217 [III] A). Paris.

[2] "Recent Developments in Indian Patent Law: A Critical Analysis." Indian Journal of Intellectual Property Law, vol. 20, no. 2, 2023, pp. 153-168.

[3] Duggal, Rakesh Kumar. "Pharmaceutical Patenting in India: An Overview." Journal of Intellectual Property Rights, vol. 19, no. 5, 2014, pp. 305-313.

and enhances accessibility to healthcare needs.

In case of Patents covering manufacturing processes or methods for substances that are meant to be used as food, medications, or drugs they are valid for seven years from the date of filing the patent application, or for five years from the date the patent is sealed, whichever comes first. All other inventions are covered by patents, which are granted for a term of 14 years from the date of filing unless proven to be invalid.

A section on compulsory licensing is also included in the Patents Act. A compulsory licence to work the patented invention may be applied for by any person after three years from the date of the patent's sealing. The patent controller may order the patent holder to grant a license on terms that may be deemed appropriate, but only if the controller is convinced that the public's reasonable requirements regarding the patented invention have not been satisfied or that the patented invention is not readily available to the public at a reasonable cost.

The patent system is essential for encouraging innovation and expanding access to healthcare, but it is unable to address significant public health problems such as avian flu, HIV/AIDS, malaria, and tuberculosis.

Though some claim it doesn't offer financial incentives for researchers to focus on underserved markets, it does offer exclusive rights and voluntary licensing channels for pharmaceutical creation. Patent rights may raise the cost of prescription drugs or restrict patient access. Concerns regarding patent thickets and royalty stacking are brought up by the broad scope of patents in early research, which may pose as a hinderance in future innovation.

In conclusion, pharmaceutical patenting in India is a complex and evolving field that plays a critical role in the country's pharmaceutical industry. While the legal framework has been established to protect intellectual property rights, challenges such as patent evergreening and the interpretation of certain provisions of the Patents Act continue to persist. Addressing these challenges will be crucial in fostering innovation, promoting R&D, and ensuring the availability of affordable medicines for the public.

RIGHT TO HEALTHCARE AND MEDICINES

The Universal Declaration of Human Rights and other international treaties are not immediately enforceable domestically in India. In order to fulfill international obligations, enabling legislation such as the Patents (Amendment) Act, 2005, is required. The argument goes that Indian courts are not bound by the treaties. The Patents Act was modified to comply with the TRIPS Agreement's requirements, though, because the Indian parliament is empowered by the constitution to enact any legislation necessary to implement an international treaty and have it enforced domestically. Additionally, the Directive Principles of State Policy (DPSP) outlined in Part IV of the Indian Constitution include provisions related to the right to health as stated in Articles 39 (e), (f), 42, and 47.

[4]The right to health is a fundamental right, as established by the apex court through case laws. In the *Consumer Education & Research Centre v. Union of India* case,

The Hon'ble . Supreme Court ruled that the right to healthcare and support for maintaining one's health is guaranteed by Article 21. In *Parmanand Katara v. Union of India*, the Supreme Court once more ruled that the right to health and medical assistance is a fundamental right guaranteed by Art. 21. Several other cases established the same ratio. Thus, the "right to health of the highest attainable standards" in India is elevated by the Constitution to a fundamental right that is guaranteed and enforceable

[4] Basheer, Shamnad. "Intellectual Property Decisions in India: Towards an Indian Jurisprudence on the TRIPS Agreement." The WIPO Journal, vol. 2, no. 1, 2010, pp. 65-89.

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through the constitutional remedy specified in Article 32 of the Constitution.

It follows that the right to obtain necessary medications is a human right, and that this right would be violated by patenting them as doing so would limit access to and supply of these medications. The pharmaceutical industry, on the other hand, adheres to opposing views and thinks that patenting critical medications is an essential first step.

PARALLEL IMPORTATION

Importing a patented product without the patent holder's permission in a foreign nation where the product is being sold by the patent holder or their representatives is known as parallel importation. According to the basic principle of exhaustion, if a patented product is marketed by the patent holder or another authorized person, they are not able to forbid anybody else from reselling it because their rights to sell it in the market were already used up when they sold it. According to article 6 of the TRIPS Agreement, practices pertaining to parallel imports are not subject to WTO dispute resolution. The freedom to make rules pertaining to exhaustion has been confirmed in the Doha Declaration, which also stipulates that each member nation may do so without facing any obstacles.

The primary goal of parallel importation is to bring in patented goods at a lower cost because they are offered at various prices in other nations. Since there is a significant price variation between the same copyrighted pharmaceutical items that are offered in different countries, parallel importation becomes an important tool for the access to affordable medicines.

[5]TRIPS AGREEMENT AND PHARMACEUTICAL PATENTING IN INDIA

All nations are obliged to grant pharmaceutical patents under the terms of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Following TRIPS, all WTO members that did not permit pharmaceutical patents as of 1995 were given until 2005 to start doing so, with the exception of "Least Developed Countries.". TRIPS obliged participants to receive and retain applications in a "mailbox" from 1995 until the day a nation granted patents for pharmaceuticals. ".

[6]During the Uruguay Round trade talks in the late 1980s and early 1990s, India was among the nations that opposed TRIPS the most. India strongly objected to the requirement that all nations permit the patenting of pharmaceuticals after the "trade-IP" connection was established and TRIPS negotiations got underway. India also opposed the inclusion of regulations on nations' intellectual property policies and practices in the international trade regime. TRIPS was therefore viewed as a serious threat because the lack of patent protection in India coincided with the significant growth of the regional pharmaceutical sector.

The Indian government decided to "consider the steps to be taken by the Government in the context of the provisions of Article 39.3 of the TRIPS Agreement for the protection of undisclosed information" by forming an Interministerial Committee, which would henceforth be known as the "Data Protection Committee," with the participation of independent experts.

The recommendations put forth by the Data Protection Committee raise a number of important questions. The two most important of these are

(i) the recommendations' likely impact on access to reasonably priced medications and
(ii) (ii) the supplementary steps required to guarantee that field and clinical trials are carried out transparently in order to prevent negative effects on national genetic diversity and public health.

[5] Narayanan, K. "Economic Impact of Intellectual Property Rights in India: An Empirical Perspective." Journal of Intellectual Property Rights, vol. 24, no. 6, 2019, pp. 320-329.

[6] World Trade Organization. "Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)."

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The Committee's recommendations regarding pharmaceutical products require careful consideration because they may affect India's ability to obtain affordable medications.

This may occur as a result of the space being restricted for domestic companies, who are best suited to guarantee the availability of reasonably priced medications, following the implementation of fixed-period data protection.

This might have a negative impact on market competition, which would drive up the cost of medications. Many domestic companies have crossed the threshold to begin developing new products as a result of the past few years' increase in R&D activities. It is possible that some of the items created by domestic companies are comparable to those created by "pioneer" companies, for which those organizations would have been granted a set amount of time to preserve test results and other information submitted in order to be granted marketing approval.

During the 2005 Patents Act amendment process, the Indian government incorporated Section 3(d)—a provision that sets a high bar for secondary patents—into the final amendments to allow for pharmaceutical patents. In particular, 3(d) states that unless the applicants can show that those secondary patents are more effective than others, many of them will not be deemed inventions and will not be granted patents. In order to specifically address worries that more patents on already-approved drugs could be used to prolong market exclusivity and restrict the entry of generic competitors, Section 3(d) was put into place.

In order to secure a pharmaceutical patent in India, applicants must fulfill standard criteria such as novelty and inventive step, as well as comply with Section 3(d) regulations. Although Section 3(d) has attracted significant scrutiny, its impact has often been overstated by both proponents and opponents.

[7]HOW TRIPS AIMED AT IMPROVING ACCESS TO HEALTHCARE

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement is a WTO-managed treaty that provides fundamental protections for a range of Intellectual property rights, including trade secrets, copyrights, patents, and trademarks. There are provisions in the TRIPS Agreement that recognize the importance of public health and provide member nations with flexibility to protect their interests. The TRIPS Agreement protects pharmaceutical products and processes under patent law.

It also allows member countries to choose to implement laws pertaining to pharmaceutical accessibility and public health protection. Governments may permit the use of a patented invention without the patent owners' consent through the use of compulsory licenses.

Moreover, it gives member countries the freedom to determine their own criteria for granting patents and whether or not to protect specific kinds of innovations, like those applied to surgery or medicine.

The TRIPS Agreement contains clauses designed to assist least developed countries in addressing public health concerns. In order to facilitate the establishment of legal frameworks for intellectual property protection in least developed countries, the TRIPS agreement allows for extended transition periods for certain commitments. The TRIPS Agreement also allows nations to issue mandatory licenses for the production or importation of affordable generic medications to address public health issues like malaria, TB, and HIV/AIDS. By removing patent barriers, nations can guarantee that their citizens have access to high-quality, reasonably priced healthcare.

Measures that fall under TRIPS and are accessible to developing Nations:-

[7] Swarup, R. "Indian Patent Law: A Balanced Approach to Innovation and Access to Medicine." Indian Journal of Medical Ethics, vol. 11, no. 2, 2014, pp. 100-104.

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What actions less developed countries might take in the new TRIPS framework to improve affordable access to the newest medications is the topic the writers will address in this article. Adopting a number of policy options, such as mandatory licensing, data exclusivity, using parallel trade, would not violate [8]TRIPS obligations.

- Compulsory Licensing (CL) :-

After [9]TRIPS is fully implemented, developing countries may choose to issue compulsory licenses under article 31, which allow a third party to manufacture, use, or sell a patented invention without the patent owner's permission, in order to achieve affordable access to patented drugs. A crucial requirement stated in Article 31 of TRIPS is that a potential licensee must have failed to negotiate and get from the patent holder permission to utilize the patented invention "on reasonable commercial terms and conditions" within a reasonable amount of time. However, in the event of a national emergency, severe urgency, or for non-commercial public purpose, the failed negotiations clause may be overlooked.

In the second amendment to India's patent law, the government has included provisions for the adoption of Compulsory Licensing (CL) and Sections 82 to 94 in Chapter XVI specifically address CL in the revised Patent Act of India. These sections outline the general principles related to the working of patented inventions, the grounds for granting compulsory licenses, factors to be considered by the controller of patents when reviewing applications for compulsory licenses, procedures for handling such applications, the overall purpose of granting these licenses, and the terms and conditions associated with them.

- Parallel Trade :-

In order to promote competitive prices and access to certain products, developing nations may import protected goods in parallel. When a product protected by intellectual property rights is sold in nation A with the approval of the right holder and then resold in nation B without the consent of the right holder, this is known as parallel trading. The "exhaustion of rights" idea is used to discuss parallel trade. This principle states that after items are lawfully placed on the market by the title holder or the licensee, the intellectual property proprietor of those goods has no further influence over how those things are used or sold. The TRIPS rule on parallel trade is seen as a serious danger by developed countries and the global pharmaceutical sector, who worry that lower-cost medications may flood the market and reduce their revenues.

- Data Exclusivity :-

The TRIPS Agreement's Article 39.3 gives Member nations a lot of liberty in enforcing the requirement to safeguard test data against unfair competitive practices. According to the Agreement, "undisclosed information" is subject to the Paris Convention's Article 10bis. provision of unfair competition. With the inclusion of this clause, the Agreement expressly forbids treating information that has not been revealed as "property" and does not mandate giving the data owner "exclusive" rights. When a pharmaceutical company wants to market a new drug, it must submit test results and the clinical data to the national health authority. Innovator data is kept secret by the national health authorities for a specific amount of time to prevent "unfair commercial use," which prevents generic manufacturers from utilizing the innovator data that has been submitted during that time.

CASE LAWS :-

- **[10]Novartis AG Vs. Union of India**

A patent application for a medication called Glivec, which was a slightly modified version of their 1993 patent for an anti-leukemia drug, was filed by the petitioner with the Chennai Patent Office in 1997, marking the

[8] Patel, Ravi. "National Intellectual Property Rights Policy: A Roadmap for Innovation." Journal of Innovation Management, vol. 9, no. 1, 2021, pp. 45-60.
[9] Bhasin, Pankaj. "Patent Enforcement in India: Trends and Strategies." Lexology, 15 June 2022
[10] "Novartis AG v. Union of India." Indian Kanoon

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beginning of Novartis AG v. Union of India. The Indian Patent Act of 1970's section 3(d) was used by the Assistant Controller of Patent and Design at the Chennai Patent Office to reject the application. In order to contest the validity of section 3(d), the petitioner proceeded to the Madras High Court.

ISSUES RAISED-

- Section 3(d) is therefore unconstitutional because it violates the TRIPS agreement.
- The term "efficacy" is not defined in the Indian patent laws, which also grant the Controller unlimited authority. It is therefore arbitrary, illogical, and unclear.

Judgement

A comprehensive dispute resolution system and the exclusive remedy for TRIPS Agreement violations are offered by the World Trade Organization's Dispute Settlement Procedure. When municipal law and international law clash, the High Court determined that municipal law prevails in these situations. It should be noted that India does not directly enforce international agreements.

The court rejected the second argument that this clause gives the patent controller unrestricted authority since the word "efficacy" was not defined. Put differently, the section 3(d) efficacy test would vary based on the predicted or intended outcome of the product being evaluated. Therefore, the purpose, utility, or intended application of the product would be used to determine its efficacy. The only criterion for determining a drug's effectiveness when it comes to cures is "therapeutic efficacy.".

Novartis's patent application for the beta-crystalline form of Imatinib Mesylate failed to pass Section 3(d) due to the lack of enhanced therapeutic efficacy. The petitioner's patent application was denied after the Supreme Court upheld the rulings of the High Court and the Indian Patent Office.

[11]Natco Vs. Bayer

In 2011, Natco submitted an application for a mandatory anti-cancer drug license for Nevaxar, a medication that Bayer was to manufacture in accordance with Section 84(1). Via an official notification, the Mumbai Controller of Patents granted a compulsory license. Natco was able to obtain the first license in India.

Following that, every appeal that Bayer filed with the High Court, the Supreme Court, and the Intellectual Property Appellate Tribunal was denied.

ISSUES RAISED

- The claim that the requirements for the proprietary article were not sufficiently or fairly satisfied makes the complaint fall under Section 84 (7) (a) (ii).
- The patentee had been selling the medication for Rs. 2,80,000 (for a one-month therapy), which obviously did not make the therapy cost-effective.

JUDGEMENT

The controller of the patents ultimately decided to give Natco Pharma a compulsory license to use the medication "Nexavar.". Since Bayer was unable to comply with any of the section's requirements, the controller rendered his decision in accordance with Section 84 of the Patents Act of 1970.

Article 5(A)(2) of the Paris Convention was also heavily relied upon by the controller to support his arguments. For the benefit of the broader public, each nation is allowed to offer a compulsory license. In addition, Natco was prohibited from violating numerous other requirements established by the controller, such as the medication's monthly treatment cost not to surpass Rs.8880/-. Nine percent of the net sales of medications, etc., must be paid by Bayer.

[11] Bayer Corporation v. Union of India." Indian Kanoon

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[12]Lee Pharma Vs. AstraZeneca

The patented medication "Saxagliptin," which is protected under AstraZeneca's name, was produced and sold in this case by Lee Pharma under compulsory licensing. Treating Type II Diabetes Mellitus with "Saxagliptin".

ISSUE

In 2014 Lee Pharma requested that AstraZeneca grant a license for the drug; however, AstraZeneca declined and provided an explanation for not granting compulsory licensing. AstraZeneca responded to Lee Pharma by requesting more information and refuting Lee's assertion that SAXAGLIPTIN was not reasonably priced for the general public.

Nevertheless, after a year passed with no further development in the matter as a result of a technical communication breakdown between the two parties, Lee Pharma made the decision to contact the Patent Controller.

JUDGEMENT

- The Controller noted that the applicant had provided data and statistics to demonstrate that the patented invention did not meet the reasonable requirements of the public with regard to clause (a) of sub-section (1) of Section 84 of the Patents Act. The Controller concluded, however, that the applicant could not prove beyond a reasonable doubt that the reasonable requirements of the public were not being satisfied because there were alternatives to the drug in question.
- Also, according to the controller, Lee Pharma was unable to provide a precise figure for the number of patients who were denied access to the medication because it was unavailable. The Compulsory Licence was therefore denied.

[13]F. Hoffmann-La Roche Ltd &Another v Cipla Ltd (2009)

In this case Cipla was manufacturing Roche's copyrighted medication. Roche filed a request for an injunction in this case. The Delhi High Court turned down the request for an injunction. The court noted as follows:

"The public's right to obtain life-saving medications that are available, for which there is a market, and/or for which access would be prohibited in the event that the injunction were granted, cannot be disregarded by the Court. The extent of the injury in such a situation is absolute, and granting an injunction would completely eliminate any hope of life expectancy improvement or even certain patients' prospects of recovery. An alternative perspective is that the Court would effectively be suppressing Article 21, which guarantees the right to life and serves as the backbone of the right to health in India, if the injunction in the case of a life-saving medication were to be granted."

[14]THE POST DOHA ISSUE:

Although the TRIPS Agreement's current provisions allow for the granting of compulsory licenses to facilitate the production of generic medications, nations lacking the necessary domestic manufacturing capacity are unable to take advantage of this flexibility. The TRIPS Agreement's requirement that production under compulsory license be primarily for the supply of the domestic market limits the option to import generic medications. This has sparked worries that exporting nations might find it challenging to export enough goods to satisfy the demands of those that lack the capacity to manufacture goods.

By waiving the export restriction, the WTO solution effectively permits the export of the entire amount of production that is subject to a

[12] CGPDTM rejected an application for grant of compulsory license filed by Lee Pharma Ltd. vs. AstraZeneca AB (C. L. A. No. 1 of 2015) https://ipindia.gov.in/writereaddata/Portal/News/33_1_2-compulsory-license-application-20jan2016.pdf

[13] S. Muralidhar, Delhi High Court on F. Hoffmann-La Roche Ltd. & Anr. vs Cipla Ltd. (2009) https://indiankanoon.org/doc/131401110/

[14] Abbott, Frederick M. "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO." Journal of International Economic Law, vol. 6, no. 2, 2003, pp. 317-390.

compulsory license. The degree to which national laws permit it will determine whether or not countries may import and export generic versions of patented medications under the framework adopted in the WTO Decision. A number of nations that could export have changed their national legislation to allow for the production and export of generic medications under licenses that are required.

With the revision of the patent law, India has also added a clause regarding mandatory licenses for export and production.

[15]PUBLIC ACCESS TO HEALTH: SOLUTIONS AND SUGGESTIONS-

The 1970 Indian Patent Act provides protection to Indian producers of generic drugs. The act has called into question the health rights of millions of people. Life-saving medications used to be exclusively available to the wealthy and privileged segments of society, but today they are also available to the most in need and vulnerable people in our community.

Despite the Indian legal system rejecting Novartis' claim, generic businesses in India continued to offer Glivec at a price around ten times less than what it originally cost. This has facilitated the poor's access to affordable, life-saving medications in our nation.

In poor and least developed nations, public health has not been as successfully promoted by TRIPS as it should be, despite the clauses designed to protect the health of common people. For the benefit of the underprivileged in developing nations, TRIPS should be amended to oblige patent holders to offer their medicines at lower prices.

Pharmaceutical corporations should be held accountable to the most vulnerable sections of society while also finding a fair balance between their profit-seeking goals. Instead of preventing, its objective should be to support the availability of reasonably priced medications that satisfy national public health standards.

CONCLUSION

In India, pharmaceutical patenting has generated a great deal of discussion and debate, especially when it comes to public health. In order to fully explore the complex nature of this topic, this research article has looked at its historical context, current situation, and possible long-term effects. We will review the main conclusions and talk about the wider ramifications for public health in India in this conclusion.

To start with first, it's important to understand the background of pharmaceutical patenting in India. India had a lenient patent structure before the Patents Act of 1970, which made it possible for generic medications to be produced and sold widely there. This resulted in a flourishing pharmaceutical sector that could offer the people of India reasonably priced medications. Nevertheless, India's patent rules had to be changed in order to comply with the 1995 Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which resulted in the introduction of the Patents (Amendment) Act of 2005. Although this modification aligned India's patent rules with global norms, it also raised worries about potential adverse effects on the population as a whole.

The possibility of rising medication costs is one of the main issues with pharmaceutical patenting in India. Pharmaceutical businesses have been granted exclusive rights to make and sell their products for a certain amount of time thanks to the establishment of patents. This may result in less competition since generic producers can't make and market the identical medications without risking legal action. The general public, especially those with lower incomes, may find it more difficult to obtain

[15] Ganguli, Sumanth. "Patents and the Pharmaceutical Industry in India: Issues and Challenges." Journal of Intellectual Property Rights, vol. 22, no. 4, 2017, pp. 182-190.

patented medication as a result of rising pricing.

Products that are patented may be sold in certain situations with compulsory licenses. Large pharmaceutical companies' financial interests pose a constant danger to India's ability to obtain life-saving medications at affordable costs. Innovations, especially in the medical field where they should help humanity, should be the primary objective of patents in addition to profit-making.

The effect of pharmaceutical patenting on medicine pricing varies depending on the product, though, and this must be considered. Certain innovative and revolutionary medications may have been developed as a result of the emergence of patents in situations when the prior patent system may not have allowed for such advancements. Particularly when used to treat chronic and life-threatening illnesses, these new medications can be extremely beneficial to patients.

The revised Patents Act includes detailed rules about compulsory licensing, parallel imports, limited patentability exceptions, and an efficient opposition procedure for contesting fraudulent patents. Furthermore, the Drug pricing Control Order (DPCO), India's pricing regulation law, and the National Pharmaceutical Pricing Authority (NPPA) may be crucial in maintaining price control. This new global patent regime may mark the start of a new era in the fight for health and access to medications, provided that its rules are applied fairly and in respect with other nations.

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