Journal of Law and Intellectual Property Rights
ISSN: 3049-0979, Volume 1 Number 1 (Dec' 2024) pp. 40-49

https://www.jlipr.in
Article Received: 9 Oct' 2024; Accepted: 27 Nov' 2024.

Research Article

Exploring Patent Law and Public Health by Analyzing the Effectiveness of Intellectual Property Protections in Access to Medicines

Rahul

Department of Electronics & Communication Engineering, Maharshi Dayanand University, Haryana, India.

Email: rahulgudhainiyaan787@gmail.com

ABSTRACT: ***Patents are the exclusive rights bestowed upon inventors for their inventions. This research investigation has analyzed the connection between patent law and public health, and how it might impact access to required drugs. The paper seeks to assess the influence that intellectual property rights have upon drug availability and affordability-especially in low-income environments. The paper argues several issues associated with patent law, such as how it may be used to advance innovation but simultaneously bar access to life-saving medicines. The paper conducts a critical analysis of case studies and legal structures that bring into clear view the contest between protecting innovators' rights and public health requirements. The study concludes by advocating a fair approach with public health considerations at the core for choices regarding patent law. This encourages laws that put public health issues into the intellectual property frames and, on future amendments, has the potential to make medication access better while at the same time still driving innovation. This study focuses on highlighting the need for patent rules to be always discussed and amended to suit public health interests in other parts of the world.***

KEYWORDS: ***Access to Medicine, Intellectual Property, Medicines, Patent Law, Public Health.***

INTRODUCTION

A patent is a license that the State bestows for a predetermined amount of time to forbid third parties from acting in certain ways within that State that are specified by the claims of the patent. The foundation of the patent system is the idea that a contract in which the state grants the patent holder a limited monopoly over the activities covered by the claims for a specified period, as long as the patent holder maintains the invention's confidentiality after the patent expires. Such a monopoly will only be granted by the state if the claimed innovations satisfy certain criteria, such as being unique, showing a notable improvement over earlier work, and being of a technical nature [1]. In the past, intellectual property rights particularly patents have been upheld as the outcome of a deal between the people and the government. British patent holders benefited greatly from the creation of Indian patent laws during the British colonial era. Britain ruled India for more than 200 years, from 1757 to 1947. At this time, in 1856, India developed its first patent laws [2]. India's patent laws can be essentially classified into two

groups: "pre-independence India" and "post-independence India." Figure 1 shows Intellectual property types.

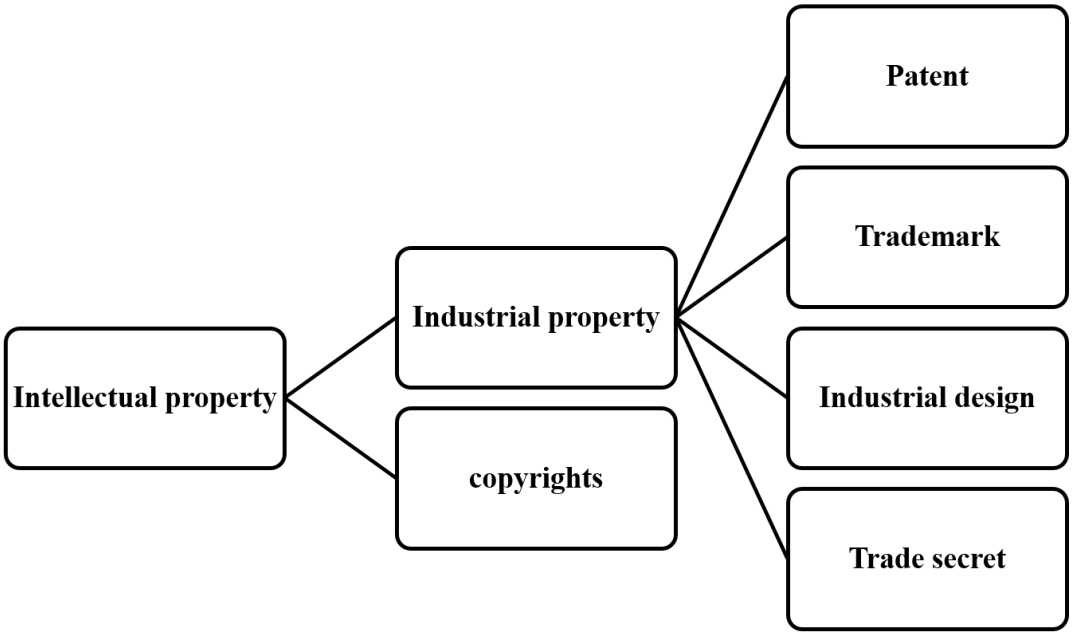

Figure 1: Represents types of intellectual properties.

India was subject to British-imposed patent laws before 1970, which gave foreign inventors an advantage over domestic pharmaceutical manufacturers. The Patents Act of 1856 marked the first attempt by the British to codify patent law in India, possibly in reaction to the ongoing debate concerning the transferability of patents granted in England to India that had been going on since the middle of the 1800s [3]. The British government had been under pressure from interested parties to implement a framework for patent protection for about 20 years. The British Patents Act of 1852 served as the main model for the Act. It allowed British patent holders to register their innovation in India in less than six months and gave inventors "exclusive privileges" for fourteen years.

Multinational corporations (MNCs) primarily sought to maximize profits during the colonial era by using India's patent laws and establishing their domination over the nation's pharmaceutical industry by preventing local producers from creating less costly drugs. India was compelled to import life-saving drugs like penicillin from other countries, where they were later sold for far more than in wealthier countries, despite being one of the world's poorest nations. In practically every country in the world, some sort of drug cost regulation mechanism has been established to ensure everyone has access to pharmaceuticals. Drug prices increased as foreign multinational firms took over India's pharmaceutical industry after the country gained independence [4]. Numerous initiatives were started by the Indian government to provide the general populace with affordable medications. One such step was the government's attempt to control the cost of pharmaceuticals. Pharmaceutical industry patents prevent most patients in developing nations, which make up about 75% of the world's population, from accessing medications, even though global advancements in health technologies and access to medicine have significantly improved and brought about admirable health improvements. AIDS, tuberculosis, malaria, hepatitis, infectious diseases, and neglected tropical diseases have not gotten enough attention, according to a 2016 World Health Organization statistic [5].

Especially considering the TRIPS Agreement of 1995, and subsequent revisions in India, the rise of health technology underlines the essential interrelation of intellectual property rights with the right to health [6]. Both the 2001 Doha Declaration and the TRIPS Agreement incorporated substantive debate on the issue of drug access as a public health problem [7]. This includes the Indian Patent Office's 2006 rejection of the Gleevec patent, which led to a historic Novartis Judgment. In June 2009, Novartis filed appeals with the Madras High Court to challenge the verdict under Section 3(d) of the Indian Patent Act, 1970.

The Madras High Court denied these appeals, stating that Novartis should file a complaint with the WTO's dispute resolution process since it was not possible to request an opinion from domestic courts about international commitments and treaties. The Novartis decision reinforced the entitlement to health care and access to drugs in the community interest rather compared to the private sector. The Indian courts played a crucial role in protecting the right to life, which includes having access to affordable healthcare and prescription drugs, for the benefit of the nation [8], [9]. Essential medications are either scarce or unavailable in many regions of the world, even with the advancement of drug technology. Indirectly, the current patent rules and intellectual property rights are to blame for this. It is crucial to talk about the logic of the law before delving into unequal access to critical medications and taking into account patent laws as one of the most powerful variables influencing access [10]. Patents are given as an exception to reward hard-won discoveries and inventions rather than full disclosure of the entire process, which helps advance knowledge in the field. In other words, the goal is to benefit society in the long run if patents are ever awarded. Nonetheless, the high degree of global commercialization frequently hinders scientific innovation.

Many academic circles argue that to save millions of lives, public health concerns should not fall under the purview of filthy patent protection. To address the issue of medicine access worldwide, innovators, governments, multilateral organizations, and other stakeholders must collaborate. The public as a whole benefit from knowledge sharing for a disease-free society. Access to necessary medications is rarely an issue in high-income nations because of their large incomes. However, the low and middle-income countries (LMIC) have experienced significant losses as a result of both regulatory issues and a lack of financial resources. Global public health regulations must benefit the most disadvantaged people by fostering goodwill rather than huddles for the most people on the planet.

LITERATURE REVIEW

Jimeno *et al*. [11] assessed the force of patents and their place in the rivalry between the right to public health and the right to intellectual property. This paper underlined how biotechnological patents, or "patents of life," granted monopoly control over biological material. Patents are exclusive rights for the exploitation of products, giving patent products high prices. As a result, there is "bio-precariousness," structural violence against life because of limitations in accessing necessary products, such as vaccines, seeds, medicines, and tests. This investigation determined that this inequality was much more noticeable during the COVID-19 pandemic, where vaccine provision went from equal to highly inconsistent between rich and poor nations. It advocated ethical patent committees that place restrictions based on the responsibility, caution of global justice, and human development.

Carlos André *et al*. [12] examined studies on the effects of the protection of intellectual property on antiretroviral medication access conducted between January 2011 and July 2012.

The paper concentrated on the significance of the TRIPS Agreement and the tenth anniversary of the 2001 Doha Declaration. The application of the Doha Declaration, the contribution of generic competition to the growth of antiretroviral medication, and innovative licensing techniques were among the main topics covered. Initiatives that prioritize public health in patent management, including the UNITAID-backed Patent Pool for Medicines, were recognized in the research. The findings of this research underscored the importance of balancing patent rights with their implications for HIV treatment programs, emphasizing public health-driven approaches to patent policies and fostering equitable access to medicines.

Hazel V. J. *et al*. [13] looked into the impacts of TRIPS and TRIPS-plus regimes on the right to use medicines through intellectual property laws. Under TRIPS, there is a minimum standard in terms of IP protection, including pharmaceutical patents, but also confers some flexibilities to ensure access to medicines. In this investigation, articles relating to cost, pricing, availability, and access were analyzed from 91 articles between 1995 and 2020. The study's conclusions were categorized under four main headings: trade agreements; TRIPS flexibilities including parallel importation and compulsory licensing; TRIPS-plus regulations like data exclusivity and patent extensions; and patent expiration and generic entry. Generally, stronger monopolies under TRIPS-plus rules were linked to higher drug prices, delayed availability, and higher costs for governments and consumers, the review demonstrated. Although flexibilities under TRIPS improved access in some scenarios, these remained available to be used only on limited occasions. A study of research conducted in low-resource settings indicated a scarcity and demanded more investigation.

Warren A. *et al*. [14] used ex-ante and ex-post analysis to systematically examine how IP clauses in trade agreements affect the availability of medications in low- and middle-income nations. In bilateral and international agreements, it concentrated on the effects of IP rights on medicine prices, affordability, consumer welfare, and market launch speed. After looking through 744 titles, the study found 14 relevant studies 7 ex-ante and 7 ex-post that met the requirements for systematic reviews. Both strategies concluded that, to varying degrees, changes to IP-related policies in the context of trade agreements raised medicine prices and reduced consumer welfare. The analysis revealed knowledge gaps about the underlying mechanisms linking changes in IP to access outcomes and highlighted the multifaceted implications of these policy changes. It emphasized that more research is needed to ascertain how specific intellectual property rights affect the accessibility of medications.

Pogge *et al*. [15] presented that the application of IP regulations should be guided by public health principles as outlined in fundamental legal and policy framework mechanisms like the World Health Organization's Constitution. From the human rights perspective, these rules need to be aligned with the public health goals in ensuring accessibility to much-needed medicines. The study observed that earlier, before the TRIPS Agreement, several voices had expressed concerns over IP's effects on access to affordable medicine. Nevertheless, the looming deadlines for developing countries to implement TRIPS provisions added fuel to the fire in the debate.

Atsuko Kamiike *et al*. [16] discussed that in addition to fostering the development of India's pharmaceutical sector, the Patent Act of 1970 and DPCO have improved the country's health and well-being. However, the WTO-TRIPS agreement has presented significant difficulties for the Indian pharmaceutical business since the mid-1990s. The Indian pharmaceutical business was expected to suffer when pharmaceutical product patents were introduced. Drugs with

patents can no longer be produced by the industry through reverse engineering and exported. The Indian pharmaceutical business has been expanding since the TRIPS period, which is in contrast to forecasts. However, there are still worries that the new patent law may limit the availability of generic drugs and make it harder for Indians to obtain medications. Ensuring access to reasonably priced medications is one of the Indian government's top priorities. Given that India is the primary source of reasonably priced generic medications, the problem of pharmaceutical availability is vital for both India and other impoverished developing nations.

Sevgi *et al*. [17] pointed out the conflict between a patent right and the ultimate right to health. It focused on the high prices of patented drugs and how they hamper millions of people around the world from accessing the essential medicines they need, which denies them their most basic right to health. It analyzed policies and approaches addressing this conflict using health sciences and legal databases. It opined that although the cost of the patent regime is distributed worldwide, only a few citizens of developed countries reap its benefits. Thus, the dispute arose as a result of pharmaceutical companies negotiating patent protection for their products through TRIPS, underscoring the function of government agencies in controlling access to medications. Compulsory licenses and parallel imports were said to be used for this purpose. The study emphasized that states should balance patent protection with the public interest to ensure technological advancement without compromising health rights.

DISCUSSION

At the beginning of independence, one of the primary debates was on how to successfully strike a balance between the need to safeguard the public interest and advance industry growth and the incentives for innovation offered by patent rights. When India gained its freedom, the cost of medications was among the highest in the world, with foreign multinational companies providing about 85% of its pharmaceuticals. Between 1947 and 1970, the Indian parliament recommended several revisions to the patent statute to address the problem and ensure that it aligned with one of the objectives of making pharmaceuticals inexpensive. When India gained its independence, its authorities soon realized that the Act of 1911's provisions were inadequate to meet the demands of a sovereign India; on the contrary, they had successfully helped foreign businesspeople establish their hegemony over the Indian market [18], [19]. Thus, shortly after leaving British control, the Union Government established a Patents Enquiry Committee, which was led by Bakshi Tek Chand, a former Lahore High Court judge and member of the Constituent Assembly that drafted the Indian Constitution, to assess the patent system.

The process of creating a drug is expensive, hazardous, and difficult in and of itself, even though there is a continuing demand for new medications to treat new illnesses and health issues. According to Scherer (2010), a pharmaceutical manufacturer seeks a patent to safeguard his market interests for a product that has withstood close examination by regulatory bodies. A pharmaceutical manufacturer should be rewarded with patent protection rights for the expenses, risks, and difficulties they encounter. New developments are essential to the pharmaceutical industry's success since they maximize sales and profits. Innovation and competition are what drive pharmaceutical companies. In the competitive pharmaceutical market, businesses that innovate more and more can prosper and remain in business. The industry is constantly evolving and changing for the better due to the competitive environment. Figure 2 depicts the function of patents in access to medications and public health. All members and prospective associates of the organization of world trade are required to abide by all of the terms of the TRIPs contract. The member nations were required to ensure that every invention

had patent protection, including methods and products, for a minimum of twenty years. While least developed countries (LDCs) were granted a patent protection relaxation till 2033, developing nations were granted a transition period relaxation to adopt the rules by 2005. Essential medications are still scarce in low-income nations despite these relaxations. After TRIP compliance, inaccessibility in LDCs was not a novel occurrence. Older problems that impacted accessibility included poverty, a tiny market, the lack of laws governing generic substitution, and a lack of local production capacity. However, TRIP compliance was so strict that it made the accessibility problem worse. The impoverished can buy generic medications under a non-patent regime, but under a patent regime, they are either ignored or receive inadequate treatment.

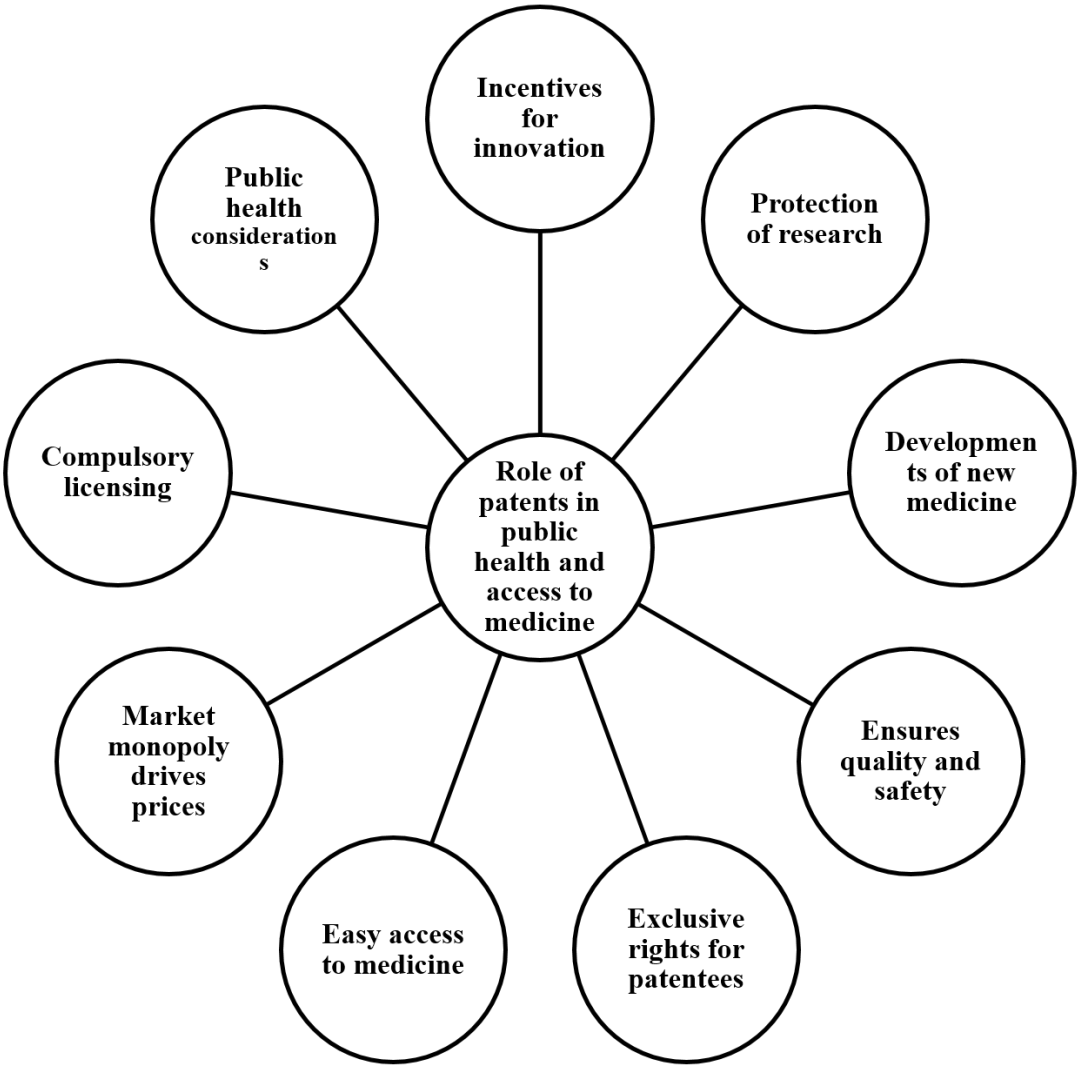

Figure 2: Represents the function of patents in public health and drug access.

The first official patent law was introduced in independent India in 1972. This statute permitted process patents rather than product patents. However, patented medications were covered by both process and product in 1995 when Trade-Related Intellectual Property Rights (TRIPs) were introduced. A patent law weakness in the pre-TRIPs era benefited generic manufacturers. Generic manufacturers reverse-engineered the patented process to create generic medications on a wide scale. Reverse engineering involved changing the manufacturing process by adding or removing certain molecules, guaranteeing that the generic medication would continue to be

as safe and effective as the proprietary ones [20]. The cost of capital to produce a medicine is less than the cost of finding a novel chemical. India's generic brands benefited greatly from the 1972 Patent Act. Without making R&D investments, pharmaceutical companies in India swiftly created a different patent process for producing new drugs and experienced increased revenue. Lately, things have changed, making it more difficult for Indian businesses to support the country's public health initiatives. In India, opposition to pharmaceutical patents is notably effective, as Table 1 illustrates.

Table 1: Represents Prominently Effective Oppositions to Pharmaceutical Patents in India.

Therapeutic drug	Patent Application Number	Opponent(s)	Date of Decision
Imatinib (Gleevec)	1602/MAS/1998	Hetero, Cipla, Natco, and the Association for Cancer Patients' Assistance	2006
Combivir	2044/CAL/1997	INP+ and Manipur Network of Positive People	2007 (Application abandoned)
Abacavir Sulphate	872/CAL/98	INP+	2007 (Application abandoned)
Tenofovir	2076/DEL/1997	INP+, DNP+, Cipla	2009
Valganciclovir	959/MAS/1995	Organizations including Cipla, Bakul Pharma, as well as associations like the Indian Network of People Living with HIV/AIDS and the Delhi Network of People Living with HIV/AIDS.	2010
Ritonavir and Lopinavir (Kaletra)	339/MUMNP/2006	Cipla, Initiative for Medicines, Knowledge, Access, Okasa,	2010 (Application abandoned)
Atazanavir Sulphate	6425/DELNP/2006	Matrix and Cipla	2010
Raltgravir Potassium	4187/DELNP/2007	INP+, DNP+, Mylan	2020

To expedite the patent awarding process the Indian Prime Minister's Economic Advisory Council planned variations to patent law in August 2022. To expedite the pre-grant opposition process, the main suggestion is to set a deadline of six months from the day the First Examination Report (FER) was issued. As of right now, there is no deadline for submitting pre-grant objections. After a patent application has been published but not yet granted, a representation for opposition may be submitted at any time without incurring any fees. The public interest in closely examining patent grants is not taken into account by the plan to shorten the pre-grant objection period to six months. Granting patents to unworthy parties is a real-world problem. Any limitations on a thorough examination of patents will increase the number

of unjustified patents, which will harm society. A paper with suggestions to expedite the pre-grant opposition process was released in January 2023 by Hidayatullah National Law University's (HNLU) Centre for Intellectual Property, Innovation, and Technology. Giving opposition to current patent applications a 6- to 12-month window from the date of the FER issue is one of the report's main recommendations.

The TRIPS Treaty of 1995 and the application of pharmaceutical patents in developing nations for the development of antiretroviral (ARV) medications for HIV/AIDS and other tropical diseases have raised serious concerns and presented ongoing challenges. To achieve sustainable development goals, human rights audits, and intellectual property rights demand that people have access to affordable pharmaceuticals. In addition to the adaptability granted by the Doha Declaration, the TRIPS Agreement of 1995 should encourage pharmaceutical companies to prioritize public health goals in their research with public funds [21]. Natural consequences of a regime that restricts the patentability of health-related products include decreased access to medications and violations of human rights standards.

A third of people on the planet lack access to basic pharmaceuticals, and those who are less affluent are disproportionately impacted by pharmaceutical patents. India provided an excellent example of patent opposition by effectively utilizing both substantive and procedural flexibilities. India is acting in the best interests of the country by increasing the substantial threshold requirements for patent eligibility. Because generic versions of prescription medications are now available, the higher threshold requirements will ease the strain on India's healthcare system [22]. India is a welfare nation, and its legislative approach is in line with its constitutional duties to provide its population with quality healthcare.

Because it gives third parties a chance to challenge dubious patents by utilizing India's higher substantive standards for patentability, the country's strategy for bolstering its stricter patentability requirements through procedural methods of patent opposition is well-considered. The claim that the Indian patent opposition model is influenced by national interest and public health goals is supported by the legislative history of the country's patent laws. In light of India's constitutional duty to provide its inhabitants with quality healthcare under Article 47 of the Indian Constitution, this approach was created to encourage generic competition that lowers prices.

CONCLUSION

In the medical field, a patent is a state-granted legal license granting the owner's exclusive right to produce, utilize, and market an invention for a predetermined amount of time, preventing others from using such inventions. This paper investigates the intricate connection between public health and patent laws by looking at how intellectual property restrictions affect the availability of essential medications. It discusses historical backgrounds, especially in India, the impacts of international agreements such as TRIPS, and the ongoing challenges that low- and middle-income countries face to access affordable drugs. Conclusion In total, while patents are intended to spur innovation, they often make it hard to access critical medications, particularly in less resourceful regions. The study emphasizes how patent rules need to be changed fast to balance creator rights with requirements placed by public health. Alternative methods that focus on access to medications fairly without limiting innovation, such as flexible license agreements and improved stakeholder participation, are important avenues of further

research. Solving these problems would help ensure that the advance of medicine would start benefiting all people on earth.

REFERENCES

[1] P. C. W. , S. J. S., A. R. R., and K. R. G., "A Review on Intellectual Property Rights," *Int. J. Multidiscip. Res.*, 2023, doi: 10.36948/ijfmr.2023.v05i03.2831.

[2] B. N. Sampat and K. C. Shadlen, "Indian pharmaceutical patent prosecution: The changing role of Section 3(d)," *PLoS One*, 2018, doi: 10.1371/journal.pone.0194714.

[3] R. Rastogi and V. Kumar, "The Influence of TRIPS Compliant Patent Laws on Indian Pharmaceutical Industry," *Adhyayan A J. Manag. Sci.*, 2014, doi: 10.21567/adhyayan.v4i1.10192.

[4] A. Kamiike, "The TRIPS Agreement and the Pharmaceutical Industry in India," *J. Interdiscip. Econ.*, 2020, doi: 10.1177/0260107919875573.

[5] R. Kiran, "IPR scenario and factors for promoting IPR culture: A post- TRIPS period analysis of selected pharmaceutical firms in North India," *Econ. Res. Istraz.* , 2017, doi: 10.1080/1331677X.2017.1311223.

[6] N. Lalitha, "Doha declaration and public health issues," *J. Intellect. Prop. Rights*, 2008.

[7] S. Chaudhuri, "The larger implications of the Novartis-Glivec judgment," *Economic and Political Weekly*. 2013.

[8] J. Chan, "Patent law and community interest in public health: Should patent law be supplemented by a health impact fund?," *J. Law, Inf. Sci.*, 2014.

[9] A. D. Mitchell and T. Voon, "Patents and public health in the WTO, FTAS and beyond: Tension and conflict in international law," *J. World Trade*, 2009, doi: 10.54648/trad2009023.

[10] D. Matthews, *Access to Medicines and Vaccines Implementing Flexibilities Under Intellectual Property Law*. 2022.

[11] S. Jimeno, "Bioprecariousness. The power of patents and their impact on Public Health," *Rev. Bioet. y Derecho*, 2023, doi: 10.1344/rbd2023.58.39484.

[12] E. 'T Hoen and C. A. Passarelli, "The role of intellectual property rights in treatment access: Challenges and solutions," *Current Opinion in HIV and AIDS*. 2013. doi: 10.1097/COH.0b013e32835b6e5a.

[13] B. Tenni *et al.*, "What is the impact of intellectual property rules on access to medicines? A systematic review," *Globalization and Health*. 2022. doi: 10.1186/s12992-022-00826-4.

[14] M. D. Islam, W. A. Kaplan, D. Trachtenberg, R. Thrasher, K. P. Gallagher, and V. J. Wirtz, "Impacts of intellectual property provisions in trade treaties on access to medicine in low and middle income countries: A systematic review," *Globalization and Health*. 2019. doi: 10.1186/s12992-019-0528-0.

[15] T. Pogge, "Access to Medicines," *Public Health Ethics*, 2008, doi: 10.1093/phe/phn023.

[16] Atsuko Kamiike, T. Sato, A. Kamiike, and T. Sato, "The TRIPs Agreement and Pharmaceutical Industry: The Indian Experience," *Policy*, 2011.

[17] H. Ersöz Seçer and S. Şar, "Pharmaceutical patents and right to health," *Ankara Universitesi Eczacilik Fakultesi Dergisi*. 2019. doi: 10.33483/jfpau.545266.

[18] V. Khanna, "Let's Talk About Patent Act, 1970," *J. Leg. Stud. Res.*, 2023, doi: 10.55662/jlsr.2023.9401.

[19] A. Raza and G. Alam, "Patent Law Declared by the Supreme Court of India," *J. Intellect. Prop. Rights*, 2023, doi: 10.56042/jipr.v28i1.543.

[20] K. Karbowski and W. Sujka, "Reverse engineering in medicine," *Mechanik*, 2015, doi: 10.17814/mechanik.2015.12.567.

[21] B. N. Sampat and T. Amin, "How do public health safeguards in Indian patent law affect pharmaceutical patenting in practice?," *J. Health Polit. Policy Law*, 2013, doi: 10.1215/03616878-2208594.

[22] M. Z. M. Nomani, A. K. K. Alhalboosi, and M. Rauf, "Legal & intellectual property dimension of health & access to medicines in india," *Indian J. Forensic Med. Toxicol.*, 2020, doi: 10.37506/v14/i1/2020/ijfmt/192878.