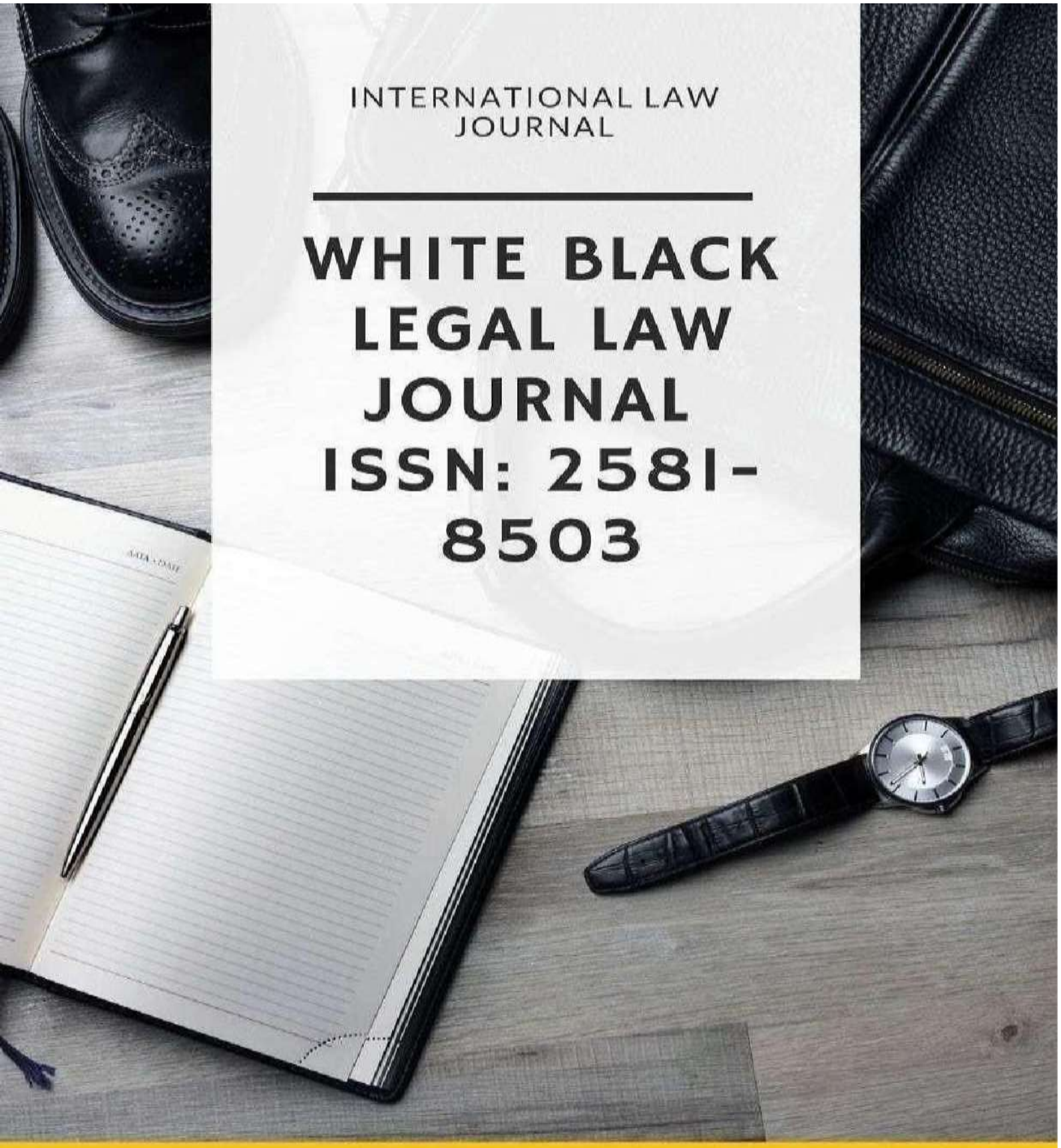

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RIGHT TO HEALTH AND PATENT SYSTEM IN INDIA: ISSUES AND CHALLENGES

AUTHORED BY - SHOBHITHA. M[1] & DR.P.R.L.RAJAVENKATESAN[2]

Abstract:

The achievement of the fundamental human right to health, which guarantees access to healthcare and necessary medications, is fraught with difficulties, especially when it comes to patent system in India. The Indian Patent Act, 1970 and the Right to Health intersect in India, a crucial area of legal discussion that strikes a balance between the preservation of pharmaceutical patents and the demands of public health. Exclusive rights granted to inventors by the Indian Patent Act encourage innovation in the pharmaceutical industry, but occasionally these rights can restrict access to reasonably priced medications. This paper examines the India's patent laws, particularly compulsory licensing and section 3(d) of the Indian Patent Act,1970 as amended in 2005 and also it outlines significant court rulings and legislative initiatives that have influenced the connection between intellectual property and health, including the seminal decision of Novartis AG v. Union of India along with the conflict between India's efforts to maintain fairness and public health and international patent norms under the TRIPS Agreement. Further this paper discuss the well-rounded strategy that upholds the right to health while also promoting innovation in the pharmaceutical sector etc.,.

Keywords: Compulsory licensing, Drugs, Patent Act, Right to health and TRIPS.

Introduction

The pharmaceutical industry in India is a high-tech sector that has grown steadily over the last thirty years.[3] Due to favourable public policies and a lack of international competition, a number of private Indian enterprises currently operating in the sector have captured a sizable portion of the domestic pharmaceutical market.[4] Nonetheless, the liberalization of the Indian

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[3] K. M. P. Rao, *The Rise of India's Pharmaceutical Industry: A Global Perspective*, 30 J. Int'l L. & Trade 54, 56 (2021).
[4] Priya Nair, *India's Pharmaceutical Market: Growth and Challenges*, 22 Indian Bus. L. Rev. 45, 47 (2020).

economy is transforming the country as Indian businesses emerge from domestic markets and get ready for international competition.[5] One prominent example is the Indian pharmaceutical sector, which is being compelled to reevaluate its long-term plans and business models as a result of opening its markets to international trade.[6] The Indian government is attempting to establish a patent regime that promotes technological advancement and conforms with its international obligations in an attempt to address the issue of the current intellectual property laws' poor implement ability.[7] Given that India and its pharmaceutical businesses are major providers of low-cost medicinal goods in the form of generic pharmaceuticals, pharmaceutical patenting in India is especially important in light of contemporary public health issues.[8] Since India is a signatory to the Doha Declaration on the TRIPs and Public Health Agreement, 2001, the problem of access to medications has assumed global proportions.[9] However, India's growth was extremely slow due to the country's low public health spending and small number of public health institutes.[10]

A fundamental human right, the right to health guarantees that everyone has access to basic medical care, including medications and therapies need to be healthy.[11] The Directive Principles of State Policy, which direct the government to ensure that its residents receive quality healthcare, implicitly recognize this right in India's Constitution.[12] A crucial component of this right is having access to necessary medications, and guaranteeing their availability and affordability is a major obstacle to providing everyone with fair healthcare.[13] Indian patent law, which regulates the protection of inventions, including pharmaceuticals, is at the centre of this problem.[14] Patents encourage research and development by giving innovators exclusive rights.[15] However, patents may make it difficult for people to obtain life-saving medications in the context of public health.[16] Essential medications are frequently inaccessible due to high

[5] Arvind Singh, *The Impact of Economic Liberalization on India's Pharmaceutical Industry*, 14 Asian Econ. Pol'y Rev. 78, 81 (2019).
[6] K. M. P. Rao, *supra* note 1, at 59.
[7] R. S. Mehta, *India's Intellectual Property Laws and Public Health*, 11 Law & Pol'y 102, 108 (2022).
[8] Pooja Desai, *Generic Drugs in India: Global Contributions and Domestic Benefits*, 9 Global Health & Pol'y 11, 13 (2023).
[9] World Trade Organization, Doha Declaration on the TRIPs Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/2 (Nov. 14, 2001)
[10] R. S. Mehta, *supra* note 5, at 111.
[11] Constitution of India, Directive Principles of State Policy, art. 38.
[12] Id. art. 47.
[13] Priya Nair, *supra* note 2, at 50.
[14] K. M. P. Rao, *supra* note 1, at 62.
[15] R. S. Mehta, *supra* note 5, at 110.
[16] Pooja Desai, *supra* note 6, at 15.

costs brought on by patent monopolies, especially for underprivileged and marginalized groups.[17] The following research questions have raised regarding Right to Health and Patent System in India: How does India's patent law affect access to affordable medicines for its citizens? What role does compulsory licensing play in improving public health in India? How do India's patent laws balance the protection of intellectual property with the Right to Health?

Significance of Right to Health and Patent System

This study examines how the rights to health and intellectual property (IP), specifically as they relate to India's Patent Act, intersect with two important facets of law and public policy. This paper's importance comes from its examination of how India's legal system resolves the conflict between maintaining pharmaceutical inventions' intellectual property rights and guaranteeing access to reasonably priced healthcare. A fundamental human right guaranteed by Article 21 of the Indian Constitution, the right to health requires the government to guarantee access to necessary medical treatment, including reasonably priced medications.[18] However, the Indian Patent Act, which regulates pharmaceutical product patent protection, frequently makes it difficult to obtain life-saving medications because of the high prices set by patent holders.[19] For a certain amount of time, patents provide pharmaceutical corporations exclusive rights, which can result in monopolies on necessary medications that are out of reach for a significant portion of the population.[20] In the context of public health, where the high expense of copyrighted medications can prevent access to therapy for illnesses like cancer, HIV/AIDS, and tuberculosis, this problem is especially important which cannot be given less importance.[21] The study most likely looks at laws like compulsory licensing, which give the Indian government the power to revoke patents when it deems them necessary for public health, allowing for the more economical creation of generic substitutes.[22] The Supreme Court's 2012 decision in the *Novartis v. Union of India* [23]case, which rejected a patent on the cancer medication Glivec and emphasised that patents should not hinder access to affordable medications.[24] This ruling demonstrated India's attempts to strike a compromise between

[17] Id. at 18.
[18] Indian Constitution, Article 21.
[19] The Indian Patent Act, 1970.
[20] Patent Law and Public Health, 42 Harv. Int'l L. J. 459, 464 (2001).
[21] World Health Organization, Global Health Observatory, HIV/AIDS and tuberculosis treatment challenges
[22] Indian Patent Act, 1970, § 84(1)(ii).
[23] (2013) 6 SCC.
[24] Novartis AG v. Union of India, (2013) 6 SCC 1, 18-19.

advancing public health and safeguarding intellectual property.[25] India's responsibilities under the TRIPS Agreement, a worldwide trade agreement that mandates member nations to follow specific patent standards, may also be included in the research paper.[26] Although TRIPS seeks to safeguard patent holders' interests worldwide, it may not always align with the requirements of nations such as India, where access to reasonably priced healthcare is a critical issue.[27] The paper would address the moral and legal challenges of striking a balance between the need to guarantee that all citizens have access to life-saving medications and patent protections.[28] It might suggest changes to the Patent Act to better align it with the right to health, such as increased use of compulsory licensing and other TRIPS flexibilities, to stop the pharmaceutical industry's profit-driven practices from endangering public health.[29]The main topics of investigation and the parameters that will be used to analyse how the Indian Patent Act and the Right to Health interact will determine the research paper's scope. In light of India's constitutional commitment to the Right to Health, the article attempts to present a thorough knowledge of how intellectual property laws—particularly those pertaining to patents—affect healthcare access in that country.

Right to Health as a Constitutional Right

The Indian Constitution does not explicitly recognise the right to health, but everyone has the fundamental right to the best possible standard of health, regardless of their race, religion, political beliefs, economic background, or social standing. A key element of the right to life guaranteed by the Indian Constitution is the right to health. Articles 14 and 21 of the Indian Constitution have an indirect impact on the healthcare system, hence the government must act to enhance healthcare for Indians. The Constitution lays out specific guidelines for the government that indirectly affect access to along with fundamental rights, healthcare[30], particularly Articles 39, 41, 42, 43, and 51A, must be upheld.[31]Furthermore, India's commitment to maintaining the Treaty's responsibilities, which have a direct impact on health,

[25] Id. at 35
[26] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), art. 31, Apr. 15, 1994, 33 I.L.M. 1197.
[27] TRIPS and Public Health: India’s Public Health Strategy in the Global Context, 26 Yale J. Int'l L. 193, 200 (2001).
[28] R. S. Sharma, Access to Medicines: Ethical and Legal Implications, 29 J. Health L. 75 (2018).
[29] World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, Nov. 14, 2001.
[30] Constitution of India, art. 14, 21.
[31] Constitution of India, arts. 39, 41, 42, 43, and 51A.

is outlined in Article 51 of the Indian Constitution.[32] The Indian government has started a variety of programs for the poor in both urban and rural areas in an effort to achieve these goals. These initiatives include the National Urban Health Project (NUM), which seeks to ensure the availability of suitable resources to support pregnancies and babies, and the National Rural Health Mission, which attempts to develop institutional deliveries.[33] With the use of the catch-up effort, Mission Indradhanush's Polio Drop Scheme aims to vaccinate all children who have been overlooked or unaccounted for.[34] There are health issues in both developed and poor nations. There is a high level of public health awareness and, in certain ways, a great demand for high-quality healthcare. Health care is-expensive.[35] As a result, universal access has not been made possible by the government.[36] Conversely, underdeveloped nations have less access to healthcare in terms of health factors and when it comes to access factors.[37] India faces numerous obstacles when it comes to health care availability, therefore. There are numerous court rulings and constitutional provisions that encourage access to healthcare.[38] Legislative execution is insufficient, notwithstanding the judiciary's numerous verdicts on various access areas.[39] Along with the statutory, administrative, and judicial duties, there is a lot of work to be done in the administrative realm and a lot of research to be done in this area within the constitutional framework.[40] An overview of the primary landmark cases pertaining to India's "right to health" is provided in *Mohinder Singh Chawla v. State of Punjab* (1997)[41], The Supreme Court ruled that, in accordance with Article 21 of the Constitution, the "right to health" is a component of the "right to life". The state has a duty to provide its citizens with quality healthcare. In *Union of India v. Bandhua Mukti Morcha* (1984)[42]: The Court ordered the state to improve circumstances for bonded labourers, including health and safety requirements, emphasising that "healthcare" and the "right to live with dignity" are essential to the "right to life" under Article 21. In *Union of India v. Consumer Education & Research Centre* (1995)[43]: The Supreme Court ruled that the state must guarantee access to healthcare,

[32] Constitution of India, art. 51.
[33] National Rural Health Mission, Ministry of Health and Family Welfare, Government of India,
[34] Mission Indradhanush: Aimed at Immunizing Children, Ministry of Health and Family Welfare, Government of India.
[35] National Health Accounts India 2014-15, Ministry of Health and Family Welfare, Government of India,
[36] N. C. Saxena, Report on Universal Health Coverage in India, Planning Commission, Government of India (2014).
[37] Constitution of India, arts. 38, 39
[38] *People's Union for Civil Liberties (PUCL) v. Union of India*, (1997) 3 SCC 433
[39] *State of Punjab v. Ram Lubhaya Bagga*, (1998) 4 SCC 117
[40] Health and Family Welfare Department, Annual Report, Government of India (2023).
[41] *Mohinder Singh Chawla v. State of Punjab*, (1997) 7 SCC 1, 8.
[42] *Union of India v. Bandhua Mukti Morcha*, (1984) 3 SCC 161, 165
[43] *Union of India v. Consumer Education & Research Centre*, (1995) 3 SCC 42, 47.

particularly for vulnerable people, and that the "right to health" is a component of the "right to life". In *State of West Bengal v. Paschim Banga Khet Mazdoor Samity* (1996)[44]: The Court determined that "delay in medical treatment" is a violation of Article 21's "right to life". The state bears the responsibility of guaranteeing prompt healthcare services. In *K.S. Puttaswamy v. Union of India* (2017)[45]: Through its connection to the larger right to health and autonomy under "Article 21", the seminal "right to privacy" case reaffirmed the significance of medical privacy. In Union of India v. National Legal Services Authority (2014)[46]: The Court acknowledged transgender people's "right to health", emphasising that all underserved communities must have access to health services. Together, these instances demonstrated that the state must guarantee "equitable access" to health care for everyone, particularly the weaker and more marginalised segments of society, and that the "right to health" is a component of the "right to life" under Article 21.

TRIPS compliances and India's Adjustments

Even though India has made great progress in complying with TRIPS, there are still issues: Access to reasonably priced medications while maintaining IP protection: The strict product patenting laws and the high price of new medications continue to be a divisive topic, especially when it comes to the manufacturing of generic drugs.[47] Innovation vs. Access: India wants to promote innovation without letting intellectual property regulations impede the availability of necessities, especially in the pharmaceutical industry.[48] International Pressure and Trade Negotiations: Developed nations have put pressure on India, particularly in sectors like patents and data exclusivity, where its IP protection regulations may be viewed as being overly lax.[49] Pharmaceutical patents and the role of patents in the pharmaceutical industries: The Indian government formed the Justice N. Rajagopala Ayyangar Committee[50] in 1957 to look into the matter of revising the patent law and offer recommendations to the government. After two failed amendments in 1965 and 1967, the Patent Act was finally enacted in 1970.[51] Most of the

[44] *State of West Bengal v. Paschim Banga Khet Mazdoor Samity*, (1996) 4 SCC 37, 42.
[45] *K.S. Puttaswamy v. Union of India*, (2017) 10 SCC 1, 35
[46] *Union of India v. National Legal Services Authority*, (2014) 5 SCC 438, 447
[47] *Vijaya Reddy*, India and TRIPS Compliance: Balancing Public Health and Intellectual Property, 36 *J. INT'L ECON. L.* 379, 386 (2023).
[48] Prashant Mehta & Rahul Bhardwaj, Balancing Innovation with Access in India's Pharmaceutical Sector: A TRIPS Compliance Perspective, 52 *INDIA L. REV.* 281, 294 (2022)
[49] India's Intellectual Property Laws Under Global Scrutiny: Challenges and International Trade Pressure, 47 *WORLD TRADE R.* 152, 160-61 (2023)
[50] Justice N. Rajagopala Ayyangar Committee Report, 1957.
[51] Patent Act, 1970.

provisions of the 1970 Act came into effect on April 20, 1972,[52] with the publication of the Patent Rules, 1972. Around 70% of the local market was dominated by foreign pharmaceutical companies by 1970, and their prices were among the highest in the world.[53] As public health concerns grew, the Indian government responded by passing the Patent Act, 1970. In a single blow, this measure essentially abolished all patents on pharmaceutical products.[54] Since Section 5 of the Act barred pharmaceutical companies from obtaining product patents on their drugs, they could only look for process patents that are typically simple for other organisations to get around.[55] India has become one of the world's most powerful generic pharmaceutical companies, and domestic Indian firms have taken over a sizable portion of the domestic market share of the industry that was previously held by foreign firms.[56] However, India's membership in the World Trade Organisation (WTO) in 1995 cemented its standing as a trustworthy and dependable trade partner in the global economy.[57] As a result, India had to amend the Patent Act of 1970 in 1999, 2002, and 2005.[58] From the passage of the Patent Act of 1970 until 1995, pharmaceutical product patents were not accepted in India.[59] By making cheaper treatments more accessible, India's once non-existent domestic pharmaceutical sector has grown to become a major producer of generic drugs worldwide.[60] "Due to this advantageous situation, Indian pharmaceutical industry was able to churn out innumerable generic drugs, demonstrating India as one of the principal generic drug manufacturers in the world.[61] However, because of its commitments under the TRIPS agreement, 1995, India was forced to amend its patent laws in 2005 to grant pharmaceutical businesses product patent protection and to extend term of protection for patent up to 20 years.[62] Certain clear requirements were set by TRIPS. Patents must be awarded for all inventions in "all fields of technology.[63] "Less than a quarter century," under very rare conditions, and must not[64] Countries have had some flexibility in determining the specific characteristics of the TRIPS requirements, despite the fact that some of them are not well defined.[65] India introduced pharmaceutical product patents

[52] Patent Rules, 1972.
[53] Report on the Status of Foreign Pharmaceutical Companies in India, 1970.
[54] Patent Act, 1970, Section 5.
[55] Patent Act, 1970, Section 5.
[56] Indian Pharmaceutical Industry Growth, 1990s.
[57] World Trade Organisation Agreement, 1995.
[58] Patent Act Amendments, 1999-2005.
[59] Patent Act, 1970, No. 39 of 1970, Section 5.
[60] Indian Pharmaceutical Industry's Rise as a Generic Drug Producer, 1990s-2000s.
[61] India's Role as a Leading Generic Drug Supplier, 2000s.
[62] TRIPS Agreement and Its Impact on India's Patent Law, 2005.
[63] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, 1869 U.N.T.S. 299
[64] TRIPS Agreement, art. 33.
[65] TRIPS Agreement, arts. 1, 8, 31

in the 2005 Amendment to the Patent Act by merely eliminating Section 5 of the Act.[66] The 2005 Amendments did, however, also include a variety of "TRIPS flexibilities," or access-friendly policy levers, that the Indian generics industry could employ to negate brand-name and introduce generics to the market, even though product patents were returned.[67]

Patent protection versus Public Health

Living a healthy, disease-free life is the most fundamental human right, and the constitution guarantees this. The more humble an Indian is, the greater the state's duty to protect them. The impact of the TRIPS (Trade-Related Intellectual Property Rights) Agreement on Indian law concerning the right to life guaranteed by Article 21 of the Constitution, as read with Article 14, may need to be examined from this angle. Public health laws, national drug policy, and the patent system are all intricately related.[68] At this historic session, a resolution creating a "Global Strategy on Health for All" was overwhelmingly passed by the participating nations. Since then, science and technology have advanced significantly to effectively handle a variety of health conditions. The Final Act, which represents the conclusions of the Uruguay Round negotiations, has created new and challenging challenges because of an unequal treaty on all-pervasive economic and social factors, even though there is still more work to be done on the health front. In particular, the TRIPS agreement is the most contentious feature of the Final Act.[69] The goal of this agreement is to create stringent worldwide standards for a variety of intellectual property forms, including trade marks, patents, the safeguarding of private data, and so forth, without taking into account.[70] The same is true of the Supreme Court's decision in *Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries* (Justice Jeevan Reddy).[71] In a culture where "knowledge is free" and passed down as a duty from generation to generation, it seems counterintuitive to transform discoveries into "cash and carry" ugly, but that is the distortion caused by pressure from Western Big Business. This money-mad intolerance includes the concept of "intellectual property rights," and TRIPS is the father of this anathema, which is morally reprehensible but practically glorified.[72]

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[66] Patents (Amendment) Act, No. 15 of 2005, § 5, INDIA CODE (2005).
[67] Patents (Amendment) Act, No. 15 of 2005, § 3(d), INDIA CODE (2005); P. Narayan, The Indian Patent System: A Major Step Forward, 40 ECON. & POL. WKLY. 3843, 3845 (2005).
[68] The Constitution of India, art. 21, art. 14
[69] Uruguay Round Agreements, Final Act (1994),
[70] TRIPS Agreement, art. 27.1, Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, 33 I.L.M. 81 (1994)
[71] Vishwanath Prasad v. Hindustan Metal Industries, (1995) 1 SCC 568, para. 14
[72] TRIPS (Trade-Related Aspects of Intellectual Property Rights), WTO,

The impact of Patents on Drug prices and access to medicines

Accessibility and availability of drugs are of the highest importance and are at a pivotal point in guaranteeing that all people are treated equally, regardless of the external societal factors that influence-them. Many studies have been carried out to learn more about how pharmaceuticals spread through the market and whether a given pharmaceutical product is truly accessible to the general public. One specific field investigation that was conducted in 2006 by M. K. Kyle is noteworthy in this respect. The study conducted by M. K. Kyle alerts readers to the rate at which a specific medicinal product spreads over different regions, or, to put it another way, different nations around the world. The study observed a lag in the diffusion or spread of pharmaceutical product sales and consumer use. In light of this, Lanjouw also conducted another study that largely focusses on the factors that influence a drug's diffusion in a foreign market as well as the consumer demand patterns seen in response to changes in the pharmaceutical product's pricing. According to J.O. Lanjouw's observation based on the field study, there were actually significant delays between a pharmaceutical product's patenting in one territory and its availability in territories not covered by the patent.[73] As a result, access to medications tended to favour the specific countries that protected their intellectual property, which in turn offered chances to recover the costs associated with the pharmaceutical drug's development and research and also it aligned with M. K. Kyle's observation. Based on this observation, it was discovered that a startlingly small percentage of the opportunities that were truly available to introduce the new medication were actually taken advantage of. Approximately 90% of medicine manufacturers and innovators did not wish to expand the sale horizon outside the nation where the patent protection was given.[74] The fact that only the G7 countries were included in the research, however, limits Kyle's analysis. In this sense, J.O. Lanjouw's research filled in the gaps in earlier studies by expanding the scope of the launched or made available to the market for consumption in those territories.[75] Because it focusses on the impact of pricing control laws and intellectual property rights, this research is especially significant in identifying changes or delays in the availability of specific medications-in-nations-outside-the-patented-country's-borders.[76] The study's findings made it abundantly evident that nations with weak intellectual property laws experienced a significant lag in the release and availability of the relevant pharmaceutical products. In a similar vein, it was

[73] J.O. Lanjouw, *The Economics of Intellectual Property: Patents and Pharmaceuticals* (2006).
[74] M.K. Kyle, *Pharmaceutical Innovation and Market Access* (2006).
[75] J.O. Lanjouw, *The Diffusion of Pharmaceuticals in Foreign Markets* (2007).
[76] Lanjouw, *supra* note 1, at 22.

observed that nations with more robust pricing control systems had less desire to indulge in prescription medications.[77] It was also confusing to observe that in some nations with a mix of lax intellectual property laws and excessive pricing controls, the new pharmaceutical products were never launched or made available to the market for consumption in those territories.[78]

India Stand on Issue of Compulsory License

In order to achieve a balance between safeguarding patent holders and granting the general public access to inventions, the WTO[79] enacted the TRIPS agreement. A clause in the agreement called "compulsory licensing" would allow the government to permit someone else—typically a generic manufacturer—to create a medication without the patent owner's express assent. Countries had considerable discretion over when to award compulsory licenses and how to set up appropriate compensation, even though TRIPS established certain requirements for issuing such licenses. The adequate remuneration clause was kept unaltered by the Doha Declaration,[80] which was passed in 2001 with the intention of clearing up some of the ambiguity surrounding mandatory licenses. According to the Indian Patent Act, unless there are extraordinary circumstances, such as a national emergency or an extreme emergency, that warrant granting a licence earlier, an application for a compulsory licence[81] may only be submitted three years after the date of the patent's issuance. There are three main reasons why compulsory licenses can be granted: i) the patented invention does not meet reasonable public requirements; ii) the patented invention is not reasonably priced for the general public; and iii) the patented invention is not used in India. The conditions under which "reasonable requirements of the public" would not have been satisfied are outlined in the Patent Act. In the case of *Natco v. Bayer Corporation*,[82] India's Controller of Patents issued Natco a mandatory licence to use Bayer's medication Naxavar. The goal of this action was to secure access to medications in order to safeguard the right to health." According to Shamnad Basheer[83], "I believe that mandatory licensing is the best course of action... This is the centre ground in the whole patent dispute. Compulsory licensing can address public health issues in the following

[77] Kyle, *supra* note 3, at 45.
[78] Lanjouw, *supra* note 4, at 10.
[79] World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31, Apr. 15, 1994, 1869 U.N.T.S. 299
[80] Doha Declaration on the TRIPS Agreement and Public Health, World Trade Organization, 2001
[81] Indian Patent Act, 1970, § 84(1), (2) (India).
[82] Natco Pharma Ltd. v. Bayer Corporation, 2013 SCC Online Del 2377, (India).
[83] Shamnad Basheer, *Mandatory Licensing is the Best Course of Action: The Center Ground in the Whole Patent Dispute,(https://ipmall.law.unh.edu/sites/default/files/hosted_resources/IDEA/basheer_article.pdf).*

ways through decreased drug costs by the creation of generic versions of priced patented medications is made possible by compulsory licensing. Because generic prescriptions are usually far less expensive, low-income populations can now afford life-saving medications, particularly in developing nations where many people are at risk for diseases like cancer or HIV/AIDS yet cannot afford branded medications.[84]Also through providing emergency access to compulsory licensing can be used to quickly increase access to essential pharmaceuticals in the event of a public health emergency, like as the HIV/AIDS epidemic or a cancer crisis breakout. This is particularly important in nations where patent holders might not be motivated to supply medications because of the size of the market or the potential financial gain.[85] The public health interest and the necessity for patent protection are balanced via compulsory licensing. While patents encourage innovation by giving drug researchers exclusive rights, CL enables governments to step in when public health is in jeopardy, guaranteeing that the supply of necessary medications comes before pharmaceutical corporations' profits.[86] A government can encourage domestic drug production by granting a mandatory licence. By promoting indigenous pharmaceutical firms, this lessens reliance on foreign suppliers, guarantees a more dependable supply chain, and may even cut long-term prices.[87] Encouraging global collaboration and trade for compulsory licensing may also permit the importation of less expensive generic medications from countries if the local supply of necessary medications is insufficient than other countries with lower production costs, ensuring broader international cooperation in tackling global health challenges.[88] Creating models for medical access important precedents about how nations put public health ahead of intellectual property rights can be set by mandatory licensing. This can guarantee that access to essential therapies becomes a primary focus of global health policy and promote international cooperation in solving other health emergencies.[89] During the 2000s, a number of African nations, including South Africa and India, produced generic versions of antiretroviral (ARV) medications through compulsory licensing, which greatly decreased their cost and improved access for millions of

[84] World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)*, art. 31, Apr. 15, 1994, 1869 U.N.T.S. 299.
[85] WTO, *Implementation of the TRIPS Agreement and Public Health*, art. 31
[86] Gustavo Ghidini, *Intellectual Property, Public Health and the WTO: The Role of Compulsory Licensing* (Cambridge Univ. Press 2017).
[87] Peter Drahos, *The Global Governance of Knowledge: Patent Offices and Their Clients* (Cambridge Univ. Press 2014).
[88] *Pharmaceuticals and Access to Medicines: Compulsory Licensing* in World Health Organization, *Global Health Law* 157 (2014).
[89] Thomas Pogge, *World Poverty and Human Rights: Cosmopolitan Responsibilities and Reforms* (Polity Press 2008).

HIV/AIDS patients.[90]Cancer Drugs, to reduce costs and meet the huge demand for life-saving therapies, certain nations, such as Thailand and India, have made cancer drug licenses mandatory.[91] In order to reconcile the need for innovation with the larger objective of public health and well-being, compulsory licensing is a crucial instrument for guaranteeing fair access to life-saving drugs during public health emergencies.[92] To maintain the process's fairness and transparency and to prevent undercutting incentives for pharmaceutical innovation, it must be used carefully.[93] It is also pertinent to note about bolar exceptions. A legal clause known as the Bolar exception permits generic manufacturers to get ready to produce and market generic versions of patented medications prior to the patent expiring, all while respecting the rights of the patent holder. It is a crucial tool for making sure generics can quickly hit the market after a patent expires, which can be extremely significant for public health, particularly for conditions like cancer or HIV/AIDS. Under the Bolar exception, generic drug producers are usually allowed to carry out research, clinical trials, and other preparations (such testing or regulatory filings) in advance of the release of a generic medication when the original product's patent expires. This guarantees that when the patent expires, the generic version will be made available right away.[94] While the original drug's patent is still in effect, generics may also apply for regulatory approval from authorities such as the Food and Drug Administration (FDA) or European Medicines Agency (EMA) under the Bolar exception. This eliminates the need to wait until the patent expires to start the approval procedure; instead, generics can be authorised and prepared for instant market entrance as soon as the patent lapses.[95] On other side, there are discussion about evergreening of patents. Evergreening keeps drug prices high and restricts access to reasonably priced medications by preventing the introduction of generic copies of medications onto the market. This is problematic for nations like India, where a sizable portion of the populace relies on generic medications to meet their medical requirements.

India implemented measures to prevent evergreening under the Indian Patents Act, 1970, which was modified in 2005 to conform to the TRIPS (Trade-Related Aspects of Intellectual Property

[90] HIV/AIDS Treatment: See, e.g., World Health Organization, Global HIV/AIDS Response: Epidemic Update and Health Sector Progress Towards Universal Access, at 18 (2011).
[91] Cancer Drugs: See, e.g., India's Use of Compulsory Licenses for Cancer Drugs, National Law University, New Delhi, 19 Ind. J. Int'l L. 68 (2010).
[92] Public Health & Innovation: See World Trade Organization, TRIPS and Public Health: Compulsory Licensing and Innovation, WTO Policy Paper, at 2 (2019).
[93] Fair Use of Compulsory Licensing: See, e.g., Michael R. Froman, Compulsory Licensing in the Pharmaceutical Industry: Balancing Innovation and Access, 89 J. Int'l Bus. L. 250, 259 (2018).
[94] 35 U.S.C. § 271(e)(1) (2020).
[95] Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 669 (1990); H.R. REP. NO. 98-857, at 4 (1984).

Rights) agreement. One important clause in this respect is Section 3(d) of the Indian Patents Act, which expressly attempts to prohibit the issuance of patents for modest adjustments to currently available medications that do not demonstrate appreciable gains in therapeutic efficacy.[96] The Indian Patents Act's Section 3(d): In order to address the problem of evergreening, this clause of the Indian Patents Act, 1970 (as revised in 2005) is essential. It states that the mere finding of a novel version of a well-known drug that does not increase its effectiveness will not be considered for patent protection. This prevents pharmaceutical companies from extending the life of patents on old drugs by making insignificant changes, such as changing the salt form or modifying the dosage.[97] The main issue with evergreening is that it makes it more difficult to obtain reasonably priced medications. Pharmaceutical firms can maintain high pricing for necessary therapies, which are frequently out of reach for low-income populations in nations like India, by prolonging the patent life of an outdated drug. Due to exorbitant expenses, residents are unable to obtain essential pharmaceuticals, undermining their right to health.[98]Generics cannot enter the market when copyrighted medications are kept exclusive to the patent holder, which raises healthcare costs and restricts access to necessary medications. This is especially troublesome when it comes to HIV/AIDS, cancer, chronic diseases, and other life-threatening situations when having access to reasonably priced generic medications is essential to enhancing health outcomes.[99]

Contemporary Issues of Access to Medicines and Way for Developments

Prerequisites research and development (R&D), access to reasonably priced critical medications and the encouragement of research and development for basic health needs are significantly correlated with intellectual property law and policy. "The right to access medicines imposes a duty upon the States, parties to the International Covenant on Economic, Social and Cultural Rights (ICESCR),1966," to take necessary steps to ensure R&D for new medicines addressing primary health needs, "where primary health needs are not effectively tackled by existing medicines.[100] "Neglected Diseases" include diseases like leishmaniasis (Kala-azar), onchocerciasis (River blindness), chagas disease, leprosy, schistosomiasis

[96] Indian Patents Act, 1970, § 3(d) (as amended in 2005) (India).
[97] Indian Patents Act, § 3(d).
[98] Chandra, G., "Evergreening of Patents in India: A Review of Legal and Policy Issues," *Indian Journal of Law & Technology*, vol. 9, no. 2, 2017, at 45.
[99] Watal, J., *Intellectual Property Rights in the WTO and Developing Countries*, Oxford University Press, 2001, at 123-24.
[100] UN Economic and Social Council, General Comment No. 14 (2000): The Right to the Highest Attainable Standard of Health, ¶ 12, U.N. Doc. E/C.12/2000/4 (2000).

(Bilharzia), lymphatic filariasis, African trypanosomiasis (Sleeping sickness), and dengue fever that pharmaceutical companies pay little attention to because of low patient numbers and low purchasing power.[101] Malaria and tuberculosis are also frequently regarded as neglected diseases.[102] Despite being extremely debilitating and potentially fatal, these illnesses receive insufficient research and development.[103] Pharmaceutical businesses spend more money on marketing and promotion than on research and development.[104] Interestingly, a large number of pharmaceutical companies engage in third-party manufacturing since they lack their own manufacturing facilities.[105]

The changing environment of healthcare access, pharmaceutical pricing, and patent laws is reflected in recent advances in India's control of medicine prices, particularly with regard to patents. The following are some significant developments and trends in relation to patents and price-control as Updates to the National List of Essential Medicines (NLEM) and Price Control - NLEM (2022) Revision: When the National List of Essential Medicines was revised in 2022, a number of new medications were subject to price controls. This is important because the government can set price caps for patented medications that are on the list. The scope of price control is being expanded. The NLEM now includes certain more recent patented medications that are essential for conditions including diabetes, hepatitis, and cancer, and their costs are now regulated by the National Pharmaceutical Pricing Authority (NPPA).[106] Patent-Linked Pricing and Compulsory Licensing - Compulsory Licensing (CL): In the past, India has used the compulsory licensing provisions of the Indian Patents Act, 1970 to lower the cost of life-saving medications. For example, the patented medication Sofosbuvir for Hepatitis C was granted a compulsory licence by India in 2012, significantly reducing the medication's cost and increasing its accessibility for more patients. When it comes to addressing public health needs, the government has not hesitated to use this instrument.[107]

Patent on Cancer and HIV Drugs: Recent years have seen debates on the necessity of mandatory licensing for proprietary cancer treatments, such as Dasatinib (Sprycel). This is

[101]A. F. Chukwuocha et al., The Burden of Neglected Tropical Diseases in Africa, 18 *Afr. J. Med. Sci.* 113, 116 (2020) .
[102] Tropical Disease Research, Malaria and Tuberculosis as Neglected Diseases, *World Health Organization*,
[103] World Health Organization, *Global Report on Research and Development* (2020).
[104] J. Schmidt et al., Pharmaceutical Marketing Spending and Its Impact on Research and Development, 49 *J. Pharm. Policy* 35, 37 (2018).
[105] M. Wang & J. L. Thompson, Third-Party Manufacturing in the Pharmaceutical Industry: Trends and Implications, 14 *J. Pharm. Sci.* 1230, 1235 (2019).
[106] National List of Essential Medicines (NLEM) 2022, National Pharmaceutical Pricing Authority (NPPA).
[107] Indian Patents Act, 1970, § 84(1), Compulsory Licensing.

especially important because cancer medications continue to be unaffordable in India.[108] Price control for both patented and non-patented medications - FDC (fixed-dose combination) regulation: The market's FDCs (combinations of several medications), many of which are unapproved or have not been sufficiently examined, have also been the target of government crackdowns. The NPPA has been keeping a close eye on FDCs to make sure that combination medications, whether proprietary or generic, are priced fairly.[109]

Law governing biosimilars: Biosimilars, or biological products that are comparable to but distinct from an original biologic medication, have become more popular in India in recent years. These products' prices are now also subject to NPPA regulation, particularly when they are off-patent and hold a sizable market share.[110] With the government requiring that all medicine prices be posted on the NPPA website, there has been a greater push for drug pricing transparency. This aids in controlling unfair pricing practices, particularly with regard to patented medications.[111] System of Patent Opposition: In order to stop patents for small changes made to already-approved medications (often known as "evergreening"), India has additionally reinforced the patent opposition system.

By ensuring that patents are only given for really novel medications and not for minor adjustments, this system can help avoid exorbitant drug costs brought on by prolonged patent protection.[112] International Pressure and India's Position - Trade Agreements and the WTO: Global pharmaceutical corporations and trade associations such as the World Trade Organisation (WTO) have put pressure on India to bring its patent rules into compliance with international standards. Nonetheless, India has remained committed to the interests of public health, lowering the cost of necessary medications through measures like compulsory licensing.[113] COVID-19 Reaction: India's pricing control system was tested during the COVID-19 epidemic. Important medications like Remdesivir and Tocilizumab, which were expensive because of patent protection and rising demand, were subject to price setting by the

[108] Sudhir V. Shah, "Access to Cancer Treatment in India: The Role of Patents and Prices," *Indian Journal of Cancer*, 2021, 58(4): 451–457.
[109] R. K. Ghosh & S. S. Tripathi, "Fixed-Dose Combination Drugs in India: Regulatory Issues and Challenges," *Indian Journal of Pharmacology*, 2019, 51(5): 373–379.
[110] Ministry of Health & Family Welfare, *Draft National Policy on Biosimilars in India*, 2023.
[111] National Pharmaceutical Pricing Authority (NPPA), "Drug Price Control Order,"
[112] Pradeep Kumar, "Patent Opposition in India: A Strategy to Curb Evergreening of Drugs," *Journal of Intellectual Property Rights*, 2020, 25(3): 206–212.
[113] U.N. Gupta & M. Patil, "India's Patent Law and Public Health: Challenges and Perspectives," *Journal of International Trade Law and Policy*, 2022, 21(1): 1–23.

government. During the crisis, the NPPA controlled pricing to avoid price gouging.[114] 2020 Drugs (Price Control) Order Impact - The Ministry of Chemicals and Fertilisers' DPCO (2020) increased the list of medications subject to price regulation, affecting not only necessary medications but also several patented and more recent medications. This established a precedent for regulating the costs of patented medications that affect public health, even though it mostly addressed off-patent medications.[115]

Conclusion and Suggestions

The right to health is first and foremost concern for the welfare of society as whole. There are important moral, legal, and policy issues raised by the relationship between the Indian Patent Act and the Right to Health. According to Article 21 of the Indian Constitution, the right to health ensures the preservation of life and individual freedom, including the availability of basic medical treatment. Contrarily, pharmaceutical corporations are granted exclusive rights over patented medicines under the Indian Patent Act, which gives them intellectual property rights. This frequently results in the exorbitant cost of life-saving medications. When patents on necessary medications prevent underprivileged and economically disadvantaged groups from accessing reasonably priced healthcare, the conflict between these two legal systems is clearly seen. Although the goal of patents is to encourage innovation, they can sometimes make it more difficult to obtain necessary therapies, particularly when they lead to monopolistic pricing. This is especially troubling when it comes to diseases like HIV/AIDS, TB, cancer, and other serious illnesses when access to reasonably priced medications is essential to save lives. The difficulty, though, is striking the correct balance between encouraging innovation in the pharmaceutical sector and making sure that access to necessary medications is maintained. Further reforms might be required to guarantee that everyone's right to health is fully realised, especially the poor and marginalised, even if the Indian Patent Act offers avenues for addressing-public-health-needs. In the end, a more comprehensive strategy that takes into account both the requirements of public health and the defence of intellectual property rights is crucial. Continued use of TRIPS flexibilities, more assistance for the manufacture of generic medications, and initiatives to promote innovation in reasonably priced healthcare solutions can all help achieve this. India's patent policy should continue to prioritise public health protection to prevent patents from impeding the fundamental human right to health.

[114] P.K. Saha, "Government Regulation of Drug Prices During COVID-19: A Case Study of Remdesivir," *The Indian Journal of Medical Ethics*, 2021, 8(3): 125–131.
[115] Drugs (Price Control) Order, 2020, Ministry of Chemicals and Fertilizers, Government of India.