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Interface between Human Rights and IPR with special reference to the Patent Regime in India & Right to Health in India

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ABSTRACT

The evolving interface between human rights and intellectual property rights (IPRs) poses significant challenges, particularly in the field of healthcare. While human rights, including the right to health, have been recognized around the world most notably through instruments such as the "International Covenant on Economic, Social, and Cultural Rights (ICESCR)" and General Comment No.14 the TRIPS Agreement's growing emphasis on patent protection has raised concerns about equitable access to essential medicines. The high cost of patented drugs frequently prevents people in developing countries from receiving life-saving treatment, exacerbating global health disparities. This study investigates the complex relationship between India's patent regime and the Right to Health, with a focus on the legal, economic, and ethical aspects of pharmaceutical patenting. It critically examines Section 3(d) of the Indian Patent Act, 1970, which seeks to strike a balance between pharmaceutical companies' innovation incentives and the availability of low-cost medicines for the poor. The paper examines the impact of India's adherence to TRIPS, the Doha Declaration, and global IPR frameworks, emphasizing India's proactive role in promoting public health equity. Using case studies and insights from the COVID-19 pandemic, the paper promotes a rights-based approach that incorporates IPR awareness, patent law reforms, and international cooperation. It concludes that sustainable development necessitates balancing economic interests with human rights obligations, and that patent protections do not jeopardize the universal Right to Health.

Keywords: *Human Rights, Intellectual Property Rights, TRIPS, Right to Health, Indian Patent Act, Section 3(d), Pharmaceutical Patents, Medicine Access, Public Health, Global Health Equity.*

I. UNDERSTANDING INTELLECTUAL PROPERTY RIGHTS AND CLASSIFICATION

Intellectual property rights (IPR) protect human-made creations such as inventions, artistic

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works, symbols, and designs by granting their creators exclusive legal rights.[3] These rights promote innovation by allowing inventors to control and profit from their creations. To receive these benefits, intellectual property must be registered in a tangible form with the appropriate legal authority.[4]

IPR protects unique ideas from unauthorized use, promotes business growth, makes marketing easier, and can help raise funds or enter new markets. It grants monopoly rights to the creation's use and commercialization for a limited time, with penalties for infringement.

The main classification of Intellectual Property Rights include:

a) Patents

b) Trademarks

c) Industrial Designs

d) Layout Designs of Semiconductor Integrated Circuits

e) Geographical Indications

f) Copyright and Related Rights

These rights are protected by specific laws in India, such as the Patents Act and the Copyright Act, which ensure creators are compensated and innovation thrives.

II. WIPO

The *World Intellectual Property Organization (WIPO) was formed in 1967* and became a United Nations specialized agency in 1974. It serves as the global forum for intellectual property services, policy, and cooperation. WIPO, headquartered in Geneva, promotes innovation and the protection of intellectual property rights worldwide through the administration of 26 international treaties. It is critical in balancing the interests of developed and developing countries, promoting economic, social, and cultural development, safeguarding biodiversity and traditional knowledge, and assisting businesses particularly in patent management via a harmonized and effective international intellectual property system. [5]

III. PATENT

A patent is a statutory intellectual property right granted by the government to an inventor for a novel technological discovery.[6] According to Section 2(1)(j) of the Patents Act of 1970, an

[3] WIPO Intellectual Property Handbook: Policy, Law and Use 3-4 (2d ed. 2004)
[4] P. Narayanan, Law of Patents 34-36 (5th ed. 2021)
[5] WIPO, WIPO Intellectual Property Handbook: Policy, Law and Use 7 (2d ed. 2004).
[6] P. Narayanan, Law of Patents 34-36 (5th ed. 2021).

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invention must be a novel product or procedure that incorporates an inventive step and is capable of industrial application.[7] This framework encourages innovation while also providing societal access to information and technology via mandatory public disclosures. Patents, widely regarded as the most commercially valuable sort of intellectual property, are founded on a balance between exclusivity and eventual public domain contribution.

The core requirements for patentability in India are: (i) novelty, which means that the invention has not been anticipated by prior art or made available to the public anywhere in the world; (ii) inventive step, which means that the invention should not be obvious to a person skilled in the relevant field; and (iii) industrial applicability, which means that the invention can be made or used in industry.[8] Failure to achieve any of these requirements renders the invention ineligible for patent.

However, not every innovation qualifies. Sections 3 and 4 of the Patent Act specifically list exclusions. These include frivolous inventions, scientific principal discoveries, compounds obtained by mixing, and inventions that violate public order, morals, or are harmful to human, animal, or environmental health. Notably, ideas related to atomic energy and those harming India's security are excluded.

Patent Filing Procedure in India

- The Indian patent system is administered by the Controller General of Patents, Designs, and Trademarks under the Ministry of Commerce and Industry and consists of many steps:
- Patent applications are filed with provisional or complete specifications at patent offices in Chennai, Mumbai, Delhi, and Kolkata.
- publishing: Applications are published 18 months after filing, unless an early publishing request is submitted.
- Opposition: Third-party pre- and post-grant oppositions may be made to protect public interest and legislative compliance.
- Examination: Conducted on request, with examiners issuing a *First Examination Report*. The applicant must respond to objections within 12 months.
- Patent Grant: Upon satisfactory resolution, the patent is awarded for 20 years, subject to payment of renewal costs.

[7] Patents Act, 1970, No. 39, Acts of Parliament, 1970 (India), § 2(1)(j).
[8] Id

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- Patents in India can be submitted electronically, resulting in greater accessibility and efficiency.

Rights of the Patentee

Section 48 of the Act allows a patentee exclusive rights to manufacture, use, sell, or license the patented invention in India.[9] These rights are transferable, subject to registration, and can be enforced by legal processes in the event of infringement. The patentee may also relinquish, challenge revocation, or assign the patent using a properly registered instrument.

Historical Evolution and Legislative Reforms

India's patent policy has developed dramatically since the Indian Patents and Designs Act of 1911. The Patents Act of 1970, influenced by the Ayyangar Committee's recommendations, was a noteworthy shift in that it recognized only process patents, particularly in pharmaceuticals and chemicals, in order to preserve public health and foster the generic industry.

The 2005 Amendment to the Act, necessitated by TRIPS compliance, included product patents, broadening the scope of patentable subject matter in pharmaceuticals, food, and biotech. This amendment became a focal point in disputes over patent monopolies vs the right to health since it affected access to important drugs.

In the case of ***Bishwanath Prasad Radhey Shyam v. H.M. Industries***,[10] the SC stressed that the patent system's goal is to promote scientific progress by requiring public disclosure in exchange for temporary monopoly rights.

Compulsory Licensing and Access to Healthcare

Sections 84 and 92 of the Patents Act of 1970 authorize compulsory licensing to address public health concerns and prevent misuse of monopoly rights.[11] In some cases, such as public health emergency or the patentee's refusal to make the patented product available at fair costs, the government may permit a third party to produce the patented product. This is consistent with the larger public interest and right to health provided by Article 21 of the Indian Constitution.[12]

A significant example is the denial of a patent application in ***Novartis AG v. Union of India***,[13] where the Supreme Court construed Section 3(d) to limit 'evergreening' the practice of making

[9] Patents Act, 1970, No. 39, Acts of Parliament, 1970 (India), § 48.
[10] Bishwanath Prasad Radhey Shyam v. H.M. Industries, AIR 1978 SC 1447
[11] Patents Act, 1970, No. 39, Acts of Parliament, 1970 (India), §§ 84, 92.
[12] INDIA CONST. art. 21
[13] Novartis AG v. Union of India & Others, (2013) 6 SCC 1

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minor changes to existing pharmaceuticals to extend their patent life. The Court concluded that only therapeutic advancements are patentable, reinforcing the balance of innovation and public health.

Patent Cooperation Treaty (PCT)

Given the territorial nature of patents, the Patent Cooperation Treaty (PCT), to which India is a signatory, allows for the submission of a single worldwide patent application acknowledged in over 145 nations. Individual grants are granted by national authorities, but the PCT reduces administrative difficulties and offers greater protection.

IV. INTELLECTUAL PROPERTY AND HUMAN RIGHTS

Intellectual property rights (IPR) were developed with the goal of protecting the results of human intelligence. These rights serve two purposes: first, they recognize innovators and creators, and second, they provide economic returns for their time, effort, and creativity. Patents, as a type of IPR, give inventors a negative right—the right to prevent others from using, manufacturing, or selling their invention without permission. Human rights, on the other hand, are natural, inalienable entitlements that every individual possesses just because they are human.[14] "Section 2(d) of the Protection of Human Rights Act, 1993 defines human rights in India as the right to life, liberty, equality, and dignity as protected by the Constitution and international human rights instruments."[15]

The growing interaction of IPR and human rights, notably in the pharmaceutical industry, has sparked criticism. Patent rules, while intended to encourage invention, also have substantial socioeconomic consequences. They can have an impact on the affordability and accessibility of vital medicines, especially in developing countries. This relationship between patent protection and public health gained global attention during the 2001 WTO Ministerial Conference, when the compatibility of TRIPS (Trade-Related Aspects of Intellectual Property Rights) with the right to health was questioned. Several public health concerns in India, especially the HIV/AIDS crisis, which affected 2.1 million people in 2017 and claimed over 69,000 lives each year, have brought this struggle to the forefront.

Recognizing these concerns, the Indian government implemented measures such as the Drug Price Control Order (DPCO) in 2013 and worked with the National Pharmaceutical Pricing Authority (NPPA) to control the cost of vital drugs. Nonetheless, the patent system continues

[14] P. Cullet, Human Rights and Intellectual Property Protection in the TRIPS Era, 29 Hum. Rts. Q. 404, 405 (2007)
[15] Protection of Human Rights Act, 1993, No. 10, Acts of Parliament, 1994 (India), § 2(d).

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to provide issues.[16] The cost of patented pharmaceuticals such as Atripla, an antiretroviral medication that costs around $1,300 per month, highlights the financial inaccessibility of life-saving treatments for many low- and middle-income countries. In a country where more than half of the population lacks access to basic health services and healthcare spending has historically been less than 2% of GDP, these dynamics jeopardize the implementation of the right to health.[17]

Article 21 of the Indian Constitution which provides the right to life, which the judiciary has read as include the right to health. This interpretation is consistent with Article 25 of the UDHR of 1948, which guarantees the right to a standard of living appropriate for health and well-being. As a result, the state has a commitment to ensure that healthcare services are available, accessible, and inexpensive. This involves putting in place safeguards to avoid the exploitation of patent monopolies, especially where it impedes access to important medications.

Furthermore, while IPR regimes promote biomedical research and the creation of novel treatments, they also commodify human existence by making access to copyrighted pharmaceuticals a privilege for the few rather than a right for everyone. The COVID-19 pandemic clearly demonstrated the incompatibility between patent holders' business interests and the humanitarian requirement of universal healthcare. Despite the existence of human rights frameworks for regulating clinical trials, drug marketing, and pricing, these principles have not evolved to counteract the growing impact of intellectual property rights in public health legislation. During global health emergencies, this regulatory gap may cause intellectual property safeguards to take precedence over basic human rights.

As a result, the patent regime must be constantly evaluated and altered to comply with the constitutional and international mandates of the right to health. As India strikes a balance between innovative incentives and social justice, it is critical that intellectual property systems protect human dignity, particularly in questions of life and death.

V. THE EVOLUTION OF INTELLECTUAL PROPERTY RIGHTS AND THE RIGHT TO HEALTH: AN INTERNATIONAL PERSPECTIVE

The global recognition and protection of human rights, particularly the right to health, has evolved gradually but trans formatively, paralleling the development of the intellectual

[16] Prashant Reddy T. & Ashish Kumar, Compulsory Licensing in India: An Assessment of its Impact on Pharmaceutical Innovation and Access, 2017 J. Intell. Prop. Rts. 1, 1-2

[17] S. Narayanan, Intellectual Property Rights: Economy vs. Science and Technology, 1 Int'l J. Intell. Prop. Rts. 6, 9-10 (2010)

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property rights (IPR) system.[18] The international community's institutional engagement with the right to health dates back to 1945, with the establishment of the United Nations; nevertheless, it was not until the Alma-Ata Declaration of 1978 that the right to health was articulated as a basic human entitlement. This declaration, spearheaded by the World Health Organization (WHO), endorsed "Health for All," taking a significant step toward recognizing access to primary healthcare as a fundamental human right.[19]

Following Alma-Ata, global intellectual and policy discourse focused on the right to health. Notable attempts included the University of Sherbrooke's 1985 health-rights conference, comparative constitutional studies organized by the American Health Organization, and the American Association for the Advancement of Science's symposium on healthcare rights in the early 1990s. Simultaneously, international legal documents such as the International Covenant on Economic, Social, and Cultural Rights (ICESCR), 1966, and the Universal Declaration of Human Rights (UDHR), 1948, began to strengthen the right to health. Article 12 of the ICESCR recognized "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health," which was later elaborated in General Comment No. 14 (2000) by the UN Committee on "*Economic, Social, and Cultural Rights"*, emphasizing the four essential components: availability, accessibility, acceptability, and quality.

During this time, intellectual property law gained significance, particularly with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which was agreed during the Uruguay Round by the World Trade Organization (WTO). While TRIPS created strong patent rights for at least 20 years, including for pharmaceutical products, this global standard sparked serious concerns in developing nations regarding the accessibility and price of crucial medicines. These concerns were echoed by the Sub-Commission on the Promotion and Protection of Human Rights (2000/7), which found a potential conflict between TRIPS provisions and international human rights obligations, particularly in ensuring access to health and scientific progress under Articles 12 and 15 of the ICESCR.[20]

Parallel trends in legal interpretation emphasize the intricate confluence between IPR and human rights. Article 27 of the Universal Declaration of Human Rights, for example, draws a careful balance between creators' and the public's rights, noting that, while everyone has the

[18] P. Hunt, Interpreting the International Right to Health in a Human Rights-Based Approach to Health, 18 Health & Hum. Rts. 109, 109-10 (2016)
[19] World Health Org. & UNICEF, Declaration of Alma-Ata, International Conference on Primary Health Care (Sept. 6-12, 1978), reprinted in 1 Int'l J. Health Servs. 28, 127, 129 (1978)
[20] U.N. Sub-Comm'n on the Promotion & Prot. of Hum. Rts., The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights: Report of the High Commissioner for Human Rights, U.N. Doc. E/CN.4/Sub.2/2001/13, ¶ 14

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right to profit from scientific advances, creators have moral and financial rights. This provision paved the way for General Comment No. 17 (2005), which said that the right to benefit from scientific advancement must not be hampered by excessive monopolistic practices incorporated in IPR regimes.

Despite this expanding framework, the relationship between public health and intellectual property remains problematic, especially in developing nations. Infectious diseases such as HIV/AIDS, TB, and malaria continue to take millions of lives each year, disproportionately in Asia, Africa, and Latin America. High medicine prices, which are mostly driven by strong patent protections, aggravate these disparities. According to studies, just one-third of necessary medicines are available in the public sector in many developing countries, forcing people to rely on more expensive private sector alternatives.[21] This "disease of poverty" is primarily the result of inadequate access, rather than a lack of medical innovation.[22]

The legal conflict between patent regimes and the right to health has been addressed in a number of court decisions. In the landmark case of ***Novartis AG v. Union of India***,[23] the Indian Supreme Court maintained the legality of Section 3(d) of the Indian Patents Act of 1970, which prohibits patents for novel versions of existing compounds that do not show considerable clinical value. The Court highlighted the importance of public health over patent monopolies, stating that granting patents for small alterations would deny millions of people access to life-saving pharmaceuticals. Similarly, in ***F. Hoffmann-La Roche Ltd. v. Cipla Ltd.***,[24] the Delhi High Court refused to award Roche an injunction over its patented cancer drug, citing the public interest in guaranteeing access to cheap treatment.

International activities have also addressed these issues. The Doha Declaration on TRIPS and Public Health (2001) said that TRIPS should be construed in a manner that promotes public health, allowing states to deploy flexibilities such as compulsory licensing. However, implementation is patchy, particularly where political and economic factors prevent poorer countries from exercising such rights. The Special Rapporteur on the Right to Health and other UN agencies have frequently argued for aligning IPR duties with human rights standards, emphasizing that states must not only avoid infringement but also actively ensure access to vital medicines.

Legal scholars and policymakers increasingly see the confluence between intellectual property

[21] Mehrdad Shokouhi, The TRIPS Agreement and Access to Essential Medicines: A Human Rights Perspective, 20 J. World Intell. Prop. 196, 197-98 (2017).
[22] Peter K. Lee, Patent Law and the Two Cultures, 120 Yale L.J. 2, 4-7 (2010)
[23] Novartis AG v. Union of India, AIR 2013 SC 1311
[24] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., MIPR 2008 (2) 35

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and human rights as a source of normative tension. While IPR encourages innovation and creativity, it must be properly balanced with public welfare goals. A growing trend in jurisprudence and international discourse advocates a rights-based approach to intellectual property, emphasizing health fairness and acknowledging that monopolistic control over scientific breakthroughs cannot come at the expense of human lives.[25] Indeed, Principle 1 of the Stockholm Declaration (1972), which asserts the right to a decent and healthy existence, emphasizes the importance of intellectual property frameworks that are socially responsive and ethically based.[26]

Finally, the international trajectory of intellectual property and the right to health demonstrates a shift away from compartmentalized legal regimes and toward a more integrated and human-centered approach. The issue now is to put this synthesis into practice by revising global IPR rules, empowering national legal systems, and reinforcing the global commitment to health equity, particularly for the most vulnerable populations.

VI. THE RIGHT TO HEALTH AND PATENTS IN INDIA

In India, the relationship between the right to health and the patent regime is a vital nexus where constitutional guarantees, intellectual property rights, and public interest all intersect. The Indian Constitution, specifically Article 21, establishes the "right to life," which the judiciary has broadly interpreted to encompass the "right to health." This viewpoint was firmly established in ***State of Punjab v. Mohinder Singh Chawla***,[27] when the Supreme Court recognized that the right to health is an essential component of the right to life and that the state is required to provide basic healthcare. Similarly, in ***C.E.S.C. Ltd. v. Subhash Chandra Bose***,[28] the Court underlined that health and medical care are protected under Article 21, emphasizing the state's role to ensure medical access and wellbeing.

This judicial technique has been expanded in the context of pharmaceutical patents. The Delhi High Court's ruling in ***Hoffmann-La Roche Ltd. v. Cipla Ltd***.[29] exemplified the delicate balance between intellectual property rights and public health. The Court rejected to issue an injunction against Cipla for producing a generic version of a patented drug, citing the public interest and access to affordable medication as important considerations under Article 21. This case exemplifies the judiciary's readiness to interpret patent law in light of basic rights,

[25] avid B. Resnik, The Human Right to Health and Intellectual Property Rights, 23 Kennedy Inst. Ethics J. 195, 200-02 (2013).
[26] Stockholm Declaration on the Human Environment, U.N. Doc. A/CONF.48/14/Rev.1, Principle 1 (June 16, 1972).
[27] State of Punjab v. Mohinder Singh Chawla (1997) 2 SCC 83.
[28] C.E.S.C. Ltd. v. Subhash Chandra Bose, A.I.R. 1992 S.C. 573.
[29] F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd., MIPR 2008 (2) 35 (Delhi High Court Mar. 19, 2008).

acknowledging that the enforcement of patent monopolies must be balanced against the requirement of health equity.

Despite the constitutional position of the right to health, its practical application in India and other developing countries has been inconsistent. According to WHO data, over one-third of the world's population does not have access to vital medications, owing to poverty, poor health infrastructure, and high prescription costs issues that are sometimes compounded by tight patent protections. As a member of the World Trade Organization (WTO), India is bound by the TRIPS Agreement, which establishes basic requirements for intellectual property protection, including pharmaceutical patents. India was forced to alter its Patent Act of 1970 through modifications in 1999, 2002, and 2005 to comply with TRIPS commitments.[30]

To strike a balance between public health concerns and intellectual rights, India included many TRIPS flexibilities in its own legislation. Notably, Section 84 of the Patents Act of 1970 provides for compulsory licensing, which allows third parties to create a patented invention without the patentee's approval under certain conditions. These include: (a) the patented invention failing to meet reasonable public requirements; (b) the drug being unavailable at an affordable price; and (c) the patent not working in India. Section 92 also authorizes the issuing of obligatory licenses in emergencies or situations of great urgency. These restrictions are consistent with Article 31 of the TRIPS Agreement and are supported by the 2001 Doha Declaration, which states that TRIPS should not prevent members from taking actions to protect public health.[31]

The most notable implementation of these rules occurred in ***Natco Pharma Ltd. v. Bayer Corporation***,[32] which gave India's first compulsory license for the cancer medicine Sorafenib Tosylate (Nexavar). The authorization was justified by the fact that Bayer's medicine was unreasonably expensive and inaccessible to the majority of Indian patients. This ruling emphasized the government's capacity and responsibility to disregard patent rights in favor of public health imperatives. However, subsequent petitions by BDR Pharmaceuticals and LEE Pharma were rejected for failing to meet the statutory requirements under Section 84, demonstrating the stringent standards used in compulsory licensing proceedings.

Pharmaceutical businesses frequently resist forced licensing, claiming that it undercuts

[30] P. Narayanan, Law of Patents 4-7 (5th ed. 2021)
[31] TRIPS Agreement, art. 31; World Trade Org., Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, ¶ 4 (Nov. 14, 2001).
[32] Bayer Corp. v. Union of India, 2014 (60) PTC 507 (Mad.)

innovation and R&D investments. While patent regimes provide incentives by guaranteeing inventors exclusive rights for twenty years, issues arise when these rights limit access to life-saving drugs. The Indian Patents Act includes restrictions such as Section 3(d), which prohibits evergreening by prohibiting patents for new versions of known substances that lack clinical effectiveness. Sections 3(e) and 3(i) further restrict the patentability of simple admixtures and medical treatment procedures, reinforcing a public health-focused approach to patent law.[33]

Beyond domestic legislation, India has agreed to international human rights frameworks such as the "*Universal Declaration of Human Rights (1948) and the International Covenant on Economic, Social, and Cultural Rights (1966)*." Article 25 of the Universal Declaration of Human Rights recognizes the right to a healthy quality of living, which includes access to medical treatment. These accords require the Indian government to ensure that IPR enforcement does not violate basic human rights.

To meet its constitutional and international commitments, the Indian government has developed a number of healthcare schemes, including the National Health Mission (NHM), Ayushman Bharat, Pradhan Mantri Jan Arogya Yojana (PMJAY), and others, aimed at increasing healthcare access. However, the cost of patented drugs remains a significant barrier. With only one obligatory license given thus far, vital treatments for diseases such as cancer, HIV/AIDS, and tuberculosis remain out of reach for the economically poor.[34]

Thus, the Indian patent regime must be more responsive to the right to health, using TRIPS flexibilities more aggressively and awarding compulsory licenses where the public interest requires it. By doing so, India may strengthen the constitutional promise of Article 21 and connect its patent system with a human rights-based strategy that promotes health justice over commercial exclusivity.

VII. FROM TRIPS 1994 TO DOHA DECLARATION 2001 AND TRIPS PLUS

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), signed in 1994 and effective on January 1, 1995, marked a watershed moment in global intellectual property (IP) governance, including within India's legal framework. It signified the introduction of intellectual property into the World Trade Organization's (WTO) international trade framework. TRIPS required member governments, especially developing countries like India, to update their laws to meet minimal criteria for intellectual property protection. As a

[33] Patents Act, 1970, §§ 3(e), 3(i)

[34] Prashant Reddy T. & Ashish Kumar, Compulsory Licensing in India: An Assessment of its Impact on Pharmaceutical Innovation and Access, 2017 J. Intell. Prop. Rts. 1, 4-5

result, India revised its Patents Act of 1970 in three key phases 1999, 2002, and 2005 aligning its domestic patent system with TRIPS responsibilities, most notably introducing product patents in medicines in 2005.

The TRIPS Agreement includes particular clauses that deal directly with public health and human rights. Articles 27-34 deal with patents, whereas Article 31 allows for the issuing of compulsory licenses authorizations allowing other parties to utilize a patent without the patentee's approval in certain instances, such as public health emergency. Article 8 supports this by allowing member states to take the appropriate steps to protect public health and nutrition, recognizing health as a policy problem within the IP domain.

The transition from TRIPS to the Doha Declaration of 2001 was influenced by growing dissatisfaction among developing countries with the inaccessibility of life-saving pharmaceuticals due to rigorous IP enforcement. The 2001 WTO Ministerial Conference in Doha responded by adopting the Doha Declaration on the TRIPS Agreement and Public Health, which reaffirmed WTO members' prerogative to prioritize public health over intellectual property enforcement. Paragraph 4 of the Declaration stated unequivocally that TRIPS should not hinder members from taking actions to protect public health.[35] Paragraph 5(b) maintained that each country has the discretion to grant compulsory licenses, while Paragraph 6 addressed the challenges that countries with low manufacturing capacities confront in effectively utilizing compulsory licensing.[36]

This acceptance of flexibilities under TRIPS was a watershed event in reconciling IP rights with human rights, particularly the right to health, as guaranteed by Article 21 of the Indian Constitution. The Doha Declaration also approved measures such as parallel importation and compulsory licensing to improve access to inexpensive medications. However, wealthier countries and pharmaceutical lobbyists opposed these flexibilities. To preserve their financial interests, they began supporting "TRIPS-Plus" provisions in bilateral and multilateral trade agreements, which frequently require higher levels of intellectual property protection than TRIPS itself, restricting the space for public health safeguards.

The conflict between public health and intellectual rights became more apparent during crises such as the HIV/AIDS epidemic and, more recently, the COVID-19 pandemic, when proposals to waive certain IP responsibilities gained traction. The underlying question is whether pharmaceutical companies, which invest extensively in R&D, should be allowed

[35] World Trade Org., Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001) [hereinafter Doha Declaration], ¶ 4.
[36] Id

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impregnable monopolies for twenty years, even if such monopolies result in expensive drug costs and limited access to important treatments. While firms claim that the patent system encourages innovation and secures returns on investment, critics contend that exorbitant pricing and tight patenting might impede the implementation of the right to health, particularly in low-income nations.

Pharmaceutical patenting began in India during TRIPS, and it encompasses a variety of categories such as drug component patents, formulation patents, and technology patents. Despite India's strong legal safeguards, including the use of Section 3(d) to prevent evergreening and Section 84 for compulsory licensing, implementation remains restricted. Due to the high cost and restricted availability of Bayer's anti-cancer medicine, Nexavar, India has awarded Natco Pharma only one compulsory license to produce a generic version of it. This decision, legally supported by Section 84, reaffirmed India's commitment to putting public health over exclusive economic rights.[37]

Despite the Doha Declaration's flexibility and India's accommodating legislative structure, developing countries remain wary of imposing compulsory licensing due to geopolitical pressures and the prospect of trade sanctions from wealthy countries. TRIPS-Plus regimes worsen this quandary by limiting the opportunity for adopting TRIPS flexibilities, forcing countries to adopt more rigorous IP protection policies that are frequently incompatible with their socioeconomic circumstances.[38]

Globalization has unquestionably facilitated trade and the interchange of ideas, but it has also created disparities in pharmaceutical access between wealthy and developing nations.[39] The ongoing dispute in international law revolves around balancing private commercial interests and public health imperatives. The right to health, which is a fundamental human right recognized not only by the Indian Constitution but also by international covenants such as the Universal Declaration of Human Rights (1948) and the International Covenant on Economic, Social, and Cultural Rights (1966), requires states to ensure access to affordable healthcare and essential medicines.

In conclusion, while TRIPS and its later interpretations through the Doha Declaration aimed to address the conflict between intellectual rights and public health, the introduction of TRIPS-Plus has complicated this balance. For countries like India, the difficulty remains in

[37] Bayer Corp. v. Union of India, 2014 (60) PTC 507 (Mad.)
[38] Reddy T. & Kumar, supra note 9, at 15-18
[39] Peter Drahos, The Global Governance of Knowledge: Patent Regimes and Development 175-78 (2010)

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successfully employing legal flexibilities to ensure that patent regimes do not impede, but rather promote, the attainment of everyone's right to health.

VIII. THE IMPACT OF DEVELOPED NATIONS ON PATENTS AND THE RIGHT TO HEALTH IN INDIA

The junction of global intellectual property regimes with the fundamental right to health continues to highlight a significant disparity between industrialized and developing countries. While the TRIPS Agreement ostensibly provides a consistent framework for all member nations, in fact, the discrepancy between economically advanced and developing countries is apparent in terms of access to crucial medications.[40] Developed countries, particularly the United States and members of the European Union, hold disproportionate influence by leveraging bilateral trade agreements and TRIPS-plus clauses that go beyond the TRIPS framework's baseline norms. This activity jeopardizes the health rights of people in the Global South, where life-saving medications are frequently unavailable due to high prices and limited patent protections.

Although the TRIPS Agreement provides flexibilities to protect public health, such as compulsory licensing, wealthy countries routinely hinder their implementation. Instruments such as Free Trade Agreements (FTAs), the Anti-Counterfeiting Trade Agreement (ACTA), and the Trans-Pacific Partnership (TPP) are used to diminish the effectiveness of TRIPS flexibilities by requiring poorer economies to adopt tougher patent systems.[41] These policies are being driven by huge pharmaceutical corporations, who oppose measures such as compulsory licensing, citing negative effects on R&D, despite actual evidence to the opposite.[42] Ironically, even the United States has threatened to use forced licensing during health crises, demonstrating their dishonesty in opposing its use overseas.

Thailand, South Africa, and India's experiences demonstrate how the use of TRIPS flexibilities is met with opposition from wealthy countries. Thailand's issuing of forced licenses for heart disease and HIV drugs landed it on the US Special 301 Watch List. Similar dynamics played out in India's landmark ***Bayer Corporation v. Union of India*** case, in which NATCO was granted the first obligatory license for the cancer medication Naxavar. NATCO agreed to deliver the same medicine for ₹8,800 per month, challenging Bayer's high pricing of around ₹2,80,000 per month. This decision sparked criticism from US officials, who

[40] Peter Drahos, The Global Governance of Knowledge: Patent Regimes and Development 10-15 (2010)
[41] S. F. Musungu & Cecilia Oh, The Use of Flexibilities in TRIPS by Developing Countries: A Handbook 17-20 (2005)
[42] Jerome H. Reichman, Compulsory Licensing of Patented Pharmaceutical Inventions: A Critical Review of the Current Debate, 2009 Duke J. Comp. & Int'l L. 1, 10-14

eventually included India in the Special 301 Report, citing noncompliance with TRIPS obligations a move widely regarded as an act of intimidation rather than a legitimate trade issue.[43]

Subsequent attempts to get compulsory licenses in India, such as Lee Pharma v. AstraZeneca and the BDR Pharma case, were denied. This reflects both procedural conservatism under Section 84 of the Patents Act of 1970 and increasing governmental hesitation as a result of international pressure. Furthermore, the rejection of these applications had an influence on generic medicine manufacture and thus public health outcomes in India. Compulsory licensing, designed to balance intellectual rights with public interest, has been eroded, posing serious human rights concerns. The struggle to obtain inexpensive healthcare in India, despite the constitutional acknowledgment of the right to health under Article 21, highlights the contradiction between IPR enforcement and fundamental rights protection.[44]

The 2001 Doha Declaration on TRIPS and Public Health aimed to reassert the importance of health over trade. However, its voluntary character and the absence of involvement from numerous significant countries limited its impact. While the Office of the United Nations High Commissioner for Human Rights (OHCHR) has issued guidelines to pharmaceutical corporations on how to align their actions with the human right to health, such ethical requirements have not been included into the worldwide patent framework. As a result, life-saving pharmaceuticals continue to be considered as commodities, particularly during public health catastrophes such as the COVID-19 epidemic.[45] Developing countries, with limited manufacturing and administrative capacities, were unable to effectively use TRIPS flexibilities during the crisis.

Another major worry is the failure to reinterpret publicly sponsored IPR contracts. The public, as a critical stakeholder in such developments, is not recognized in the traditional approach. During COVID-19, the UN Committee on Economic, Social, and Cultural Rights (UNCESCR) advised including provisions for fair pay while emphasizing that pharmaceutical companies have social duties beyond profit. Initiatives such as the "Open COVID Pledge" and medical patent pools represent progressive developments. However, for such models to be successful, they must be logically linked with TRIPS security exclusions under Article 73 and broader patentability standards under Article 27.

[43] Bayer Corp. v. Union of India, 2014 (60) PTC 507 (Mad.)
[44] INDIA CONST. art. 21; see also David B. Resnik, The Human Right to Health and Intellectual Property Rights, 23 Kennedy Inst. Ethics J. 195, 196-98 (2013)
[45] Peter K. Lee, Patent Law and the Two Cultures, 120 Yale L.J. 2, 4-7 (2010)

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Finally, the clash between intellectual property rights and the right to health in India represents a larger worldwide issue. Policy decisions frequently reflect economic rather than ethical imperatives, compromising the state's position as a protector of the public good. The Indian government's 2016 response to the NHRC's notice, relating its claimed private guarantee to the US to reduce compulsory licensing, exemplifies this policy shift.[46] The rapid abandonment of appeals by Lee Pharma and BDR Pharma following license denials demonstrates the chilling effect caused by international pressure. Such changes jeopardize India's welfare promises and raise serious concerns about sovereignty, human rights, and the future of egalitarian healthcare.

Striking a balance between promoting pharmaceutical innovation and protecting the right to health remains a critical challenge. Intellectual property rights, when separated from human rights commitments, serve only a narrow economic purpose. A comprehensive, rights-based strategy is required, with patent laws operating within the frameworks of public interest and socioeconomic justice. The role of developed countries in creating this discourse must shift from gatekeepers of innovation to enablers of universal healthcare access.

IX. Conclusion

The intersection of human rights and IPR, particularly in the context of India's patent law and the right to health, emphasises the critical need for balance. While IPRs promote innovation, they frequently impede equal access to life-saving medications, particularly in underdeveloped countries. The Doha Declaration and TRIPS Agreement acknowledged this issue, but political will particularly from rich countries remains biased in favor of pharmaceutical corporations, limiting the use of forced licensing, as witnessed in India's Bayer case.

Sections 84 and 3(d) of India's Patent Act try to establish a fair balance between public health and patent protection. Nonetheless, exorbitant medicine prices and widespread opposition to forced licensing highlight a greater failure to prioritize human welfare. The COVID-19 pandemic demonstrated the global nature of public health problems and the importance of collaborative methods that go beyond national interests.

The right to health, as contained in Article 21 of the Indian Constitution and international human rights standards, must take precedence. Patent laws should be established to protect both innovators' rights and public health. Promoting access through flexible licensing, global

[46] National Human Rights Commission, Notice to Government of India over reports on India giving private assurances to US on compulsory licences (Apr. 1, 2016); Ministry of Commerce & Industry, Dep't of Indus. Policy & Promotion, Press Release: Compulsory Licensing and India's Patent Regime (Mar. 22, 2016).

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cooperation, and ethical policymaking is critical to ensuring that profit-driven intellectual property regimes do not jeopardize public health.

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