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Bridging Patent Rights and Public Health: A Critical Analysis of India's Pharmaceutical Patent Regime

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ABSTRACT

The paper explores the relationship between pharmaceutical patents and public health and how intellectual property laws influence access to essential medicines. Patents are crucial in encouraging innovation but can create monopolies that limit access to lifesaving medicine. This has been a great problem, especially in developing countries where high prices of drugs are an issue to the efforts done about public health. The paper critically analyses the global and Indian views on this issue. It discusses how drug patents, through the provision of exclusive rights, have the dual effect of incentivising research and development and creating barriers to access to essential medicines. Here, key global frameworks— the TRIPS Agreement and the Doha Declaration— are brought to the fore to balance intellectual property rights and public health imperatives.

Within an Indian framework, this paper discusses legislative measures like compulsory licensing and recent development news of the Union Budget 2024 exempting three cancer drugs from customs duties- a positive sign of initiation to improve the approach towards critical treatments, which further signifies that flexible patent policies need to be framed looking at public health objectives.

The paper concludes by making recommendations on how to change patent protection rules by reducing the duration and the scope of pharmaceutical patents and actively using compulsory licensing as a means to address the overpricing and access issues with current patent regimes, which in the end would make the health system more equitable. The paper argues for a balanced approach that supports innovation and public health by reassessing patent laws and including measures like exempting targeted customs duties.

Keywords*: Patents, Healthcare, TRIPS, Pharmaceuticals, Compulsory licensing.*

I. INTRODUCTION

Intellectual property law regulates how intellectual and creative works are created, used, and commercialised.[2] Intellectual property is vital in the form of patents, especially in our scientific

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[2] Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries, (1979) 2 SCC 511.

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era. More often than not, they are either the most used or misused type of intellectual property. Ideally, patents should be about original inventiveness, which in turn encourages continuous research and development and fosters innovation. However, there are cases when patent owners use these rights for misuse, which might be exploitative.[3]

Drug patents give the holder exclusive rights to stop others from making the patented drug. These monopoly rights, granted through intellectual property rights (IPRs), are often seen as obstacles that prevent developing countries from advancing by replicating technologies from developed nations. Protecting IPRs helps maintain the technological leadership and competitive edge of developed countries.[4]

While scientific and technological advancements have greatly enhanced health outcomes, major challenges like HIV/AIDS, malaria, tuberculosis, and avian influenza continue to pose significant threats. Developing new drugs is expensive and time-consuming, requiring substantial investment in research and clinical trials. Patents are intended to encourage this investment by granting exclusive rights to the developers. However, there's a growing conversation about the ownership and licensing of public research and how it could be better managed to maximise the use of public funds and research efforts.

Although patents are designed to make information public and support the commercialisation of new drugs through exclusive rights and licensing, there are concerns about whether this system truly meets public health needs. Critics point out that the current patent framework might not provide enough incentives for developing drugs for neglected diseases and can sometimes limit access to essential medications or drive up their costs.

II. THE INTERSECTION OF PHARMACEUTICAL PATENTS AND PUBLIC HEALTH RIGHTS

(i) Global Affirmation of the Right to Health

The product patent system, implemented to meet India's TRIPS obligations, has both advantages and disadvantages. On one hand, it encourages pharmaceutical companies to innovate and develop new drugs. On the other hand, there are concerns about how this system affects the availability of generic medications. TRIPS Article 30[5] allows member countries to create limited exceptions to patent rights, suggesting that the pharmaceutical sector might

[3] A. Kaur & R. Chaturvedi, Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma, 20 *J. Intell. Prop. Rights* 279, 279-287 (2015).
[4] Cecilia Oh, *Trade-Related Aspects of Intellectual Property Rights and Pharmaceuticals,* GLOBAL POLICY (June 15, 2012), https://www.globalpolicy.org/component/content/article/209/43854.html.
[5] TRIPS Agreement art. 30.

warrant special exceptions. Generous application of compulsory licensing could help ensure that generic drugs are available to address public health needs effectively. A sovereign nation has the authority to safeguard public health even if it means not fully adhering to intellectual property rights.[6] Article 25 of the Universal Declaration of Human Rights[7] affirms that everyone has the right to a standard of living adequate for their health and well-being. Similarly, Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) guarantees the right to the highest attainable standard of physical and mental health. These provisions collectively imply that the human right to health encompasses access to necessary medicines.[8]

The Doha Declaration, adopted at the World Trade Organization Ministerial Conference, asserts that the TRIPS Agreement should be interpreted and implemented to support WTO members' ability to safeguard public health and enhance access to medicines for everyone.[9] In August 2003, the Decision on the Implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health was adopted, following the Declaration itself.[10] A key goal of the Decision was to help countries with limited pharmaceutical production capacity by enabling them to use compulsory licensing provisions effectively to address and alleviate public health issues.[11]

Pharmaceutical companies claim that product patents are beneficial because they incentivize further research and development, leading to the creation of new essential drugs to address public health challenges.[12] This argument assumes that developing countries like India have the capacity for groundbreaking research. The challenge is whether India can meet its TRIPS obligations while ensuring easy access to medicines. Article 8[13] of TRIPS can be cited to argue that complying with Article 27[14] might harm public health, suggesting that such obligations could be detrimental. Additionally, Article 30[15] of TRIPS allows for "limited exceptions" to patent rights, but this term has faced criticism, especially in emergencies where compulsory

[6] WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, ¶ 2 (Nov. 14, 2001), https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited June 27, 2024).
[7] Universal Declaration of Human Rights, art. 25.
[8] **Minister of Health v. Treatment Action Campaign**, 2002 (5) SA 721 (CC).
[9] **Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001),** available at http://www.wto.org (last visited July 20, 2024).
[10] Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/L/540 (Aug. 1, 2024), available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (last visited June 15, 2012).
[11] *Id.*
[12] P. Cullet, *Intellectual Property Protection And Sustainable Development* 394-98 (LexisNexis 2005).
[13] TRIPS Agreement art. 8.
[14] TRIPS Agreement art. 27.
[15] *Supra note 5.*

licensing is urgently needed.[16] In the Canada-Generic Pharmaceutical case, the Panel concluded that a "limited exception" should be interpreted as a "narrow exception" to patent rights.[17]

(ii) Health Mandates Embedded in India's Constitution

Article 51(c)[18] of the Constitution, part of the Directive Principles of State Policy in Part IV, directs the State to promote respect for international law and treaty obligations. This should be understood alongside Article 37[19], which emphasises that these principles are fundamental to governance. Essentially, Article 51(c) combined with Article 37[20] suggests that the State has a duty to incorporate international standards into domestic law, ensuring they align with and uphold fundamental rights.[21] As a signatory, India is obligated to adhere to the provisions of the ICESCR and UDHR, which include ensuring that its citizens can fully enjoy their right to health.

Article 21 of the Indian Constitution guarantees the right to life, which encompasses the right to good health. Judicial interpretations have affirmed that this right includes access to medical treatment, underscoring its integral role in ensuring the well-being of individuals.[22] The government has a crucial responsibility to ensure that life-saving medications are accessible to all its citizens.[23] The State has a constitutional duty to protect and uphold the fundamental rights of every individual, ensuring they are not infringed upon.[24] The Preamble and the Directive Principles of State Policy (DPSP) of the Constitution emphasise the need for policies that balance social and economic rights. Consequently, when crafting patent laws, it is essential to balance safeguarding public health and addressing the economic interests of the pharmaceutical industry.

According to the *Ayyangar Committee Report*[25], India's status as a developing nation means that granting patents can create monopolistic practices, restricting access to medicines for most

[16] Id. at 394-98.
[17] Canada - Patent Protection of Pharmaceutical Products, WTO Doc. WT/DS114/R (Apr. 7, 2000), discussed in Frederick M. Abbott, *Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO After the Doha Declaration on Public Health* (UNO Occasional Paper No. 9, Feb. 2002), available at http://www.geneva.quno.info/index.php?pageid+indo1 (last accessed July 12, 2024).
[18] INDIA CONST. art. 51, cl. (c).
[19] INDIA CONST. art. 37.
[20] *Id.*
[21] Vishaka v. State of Rajasthan, (1997) 6 SCC 241; People's Union for Democratic Rights v. Union of India, (1982) 3 SCC 235.
[22] Sunil Batra v. Delhi Administration, AIR 1978 SC 1675.
[23] All India Drug Action Network v. Union of India, (2011) 14 SCC 479.
[24] People's Union for Democratic Rights v. Union of India, (1982) 3 SCC 235.
[25] Rajagopal Ayyangar Committee, *Report on the Revision of the Patent Law* (Sept. 1959), available at http://nopr.niscair.res.in/bitstream/123456789/2027/1/JIPR%2013%285%29%20414-423.pdf (last accessed May. 2, 2024).

of its population. This situation suggests that such policies may conflict with the principles outlined in the Preamble and the fundamental rights guaranteed by Article 21[26] of the Indian Constitution. The needs of the domestic population should take precedence over the interests of foreign patent holders. Reflecting this view, former Prime Minister Indira Gandhi stated at the World Health Assembly in 1982 that an ideal world would see medical discoveries free from patents and the avoidance of profiteering from life and death.

The Supreme Court has appropriately broadened the interpretation of Article 21[27] to ensure that life is more than just a mere existence. It has underscored that enhancing public health is a crucial responsibility of the State.[28]

The Indian Constitution outlines individual rights in Part III, known as Fundamental Rights, and addresses societal objectives in Part IV through the Directive Principles of State Policy.[29] Both hold a primary position in the Constitution[30] and are recognised as part of the unamendable basic structure.[31] It is generally understood that conflicts between these two critical sections of the Constitution should be minimized, aiming instead for a harmonious integration of both sets of provisions.[32]

It is acknowledged that legislation designed to implement the Directive Principles of State Policy, as outlined in Part IV of the Constitution, is generally considered reasonable. However, this presumption holds unless it can be demonstrated that the legislation excessively or arbitrarily infringes upon fundamental rights.[33] This indicates that when there is a conflict between Fundamental Rights and the Directive Principles, the initial assumption is that restrictions on Fundamental Rights to implement the Directive Principles are deemed reasonable.[34]

Although the principles discussed suggest a constitutional preference for social benefits over individual rights, it is important to recognize that Parts III and IV of the Constitution address

[26] INDIA CONST. art. 21.
[27] *Id.*
[28] INDIA CONST. art. 47.
[29] Kesavananda Bharati v. State of Kerala, (1973) 4 SCC 225, 902 (Beg, J., opinion) ("[i]n conferring fundamental rights, freedom of individual citizens, viewed as individuals, were sought to be protected, but, in giving specific directives to state organs, the needs of social welfare, to which individual freedoms may have to yield were put in the forefront.").
[30] Kesavananda Bharati v. State of Kerala, (1973) 4 SCC 225, 902 (Sikri, J., quoting Holmes v. Jennison, 10 L. ED 579) ("The use of the term 'fundamental' in Part III and 'fundamental in the governance of the country' in Part IV indicate the importance of the provisions.").
[31] Dalmia Cement (Bharat) Ltd. v. Union of India, (1996) 10 SCC 104, 120.
[32] Chandra Bhavan Boarding and Lodging v. State of Mysore, (1969) 3 SCC 84, 87; AIR 1970 SC 2042, 2044.
[33] Sashibhushan Pati v. Mangala Biswas, AIR 1953 Ori 171; Budhu v. Municipal Board, Allahabad, AIR 1952 All. 753; Bijay Cotton Mills Ltd. v. State of Ajmer, (1955) 1 S.C.R. 752; Narendra Prasadji Anandprasadji Maharaj v. State of Gujarat, (1975) 1 SCC 11, 20.
[34] Kesavananda Bharati v. State of Kerala, (1973) 4 SCC 225.

different aspects of individual rights and public interests. Therefore, a definitive position cannot be established solely from these principles. To fully grasp the balance between individual rights and public interest, one must consider the statement made in the *Kesavananda Bharati* case, "*The scheme of the Constitution generally discloses that the principles of social justice are placed above individual rights and whenever or wherever it is considered necessary individual rights have been subordinated or cut down to give effect to the principles of social justice."*[35]

The Supreme Court's clear pronouncement in the *Kesavananda Bharati* case highlights that, under the Indian Constitution, individual interests must often take a backseat to societal needs. While intellectual property rights should be upheld, they must be tailored to protect the public's interest. This involves adjusting the scope and duration of protection for different types of intellectual property to prevent innovators from exploiting their rights for excessive profits.[36]

From a constitutional standpoint, excessive pricing and anti-competitive practices can be seen as infringing upon societal rights and hindering future innovation. This underscores the necessity for reforms to address these issues effectively.

(iii) Public health & the need to access essential medicines

Given the challenges faced by countries like India, including underdevelopment and poverty, a key concern is how rising drug prices under the new patent regime might limit access to essential, life-saving medications for many people. When discussing public health, two primary issues often emerge: ensuring broad access to affordable medicines and encouraging investment in research and development of new treatments.[37] These issues are interconnected and can sometimes conflict, both immediately and over time. A product patent system tends to raise drug prices by granting exclusive rights to certain companies. This exclusivity allows them to invest heavily in research and development but can stifle competition from generic drug manufacturers.

Critics of this system argue that, in line with the World Health Organization's essential drug policy, which obligates governments worldwide to reduce drug prices, any policy that adversely affects access to essential medicines at affordable rates in developing and least-

[35] Charles Allen Black, The Cure for Deadly Patent Practices: Preventing Technology Suppression and Patent Shelving in the Life Sciences, 14 ALB. L.J. SCI. & TECH. 590 (2004).
[36] Pradeep Agrawal & P. Saibaba, TRIPS and India's Pharmaceuticals Industry, 36 *ECON. & POL. WEEKLY* 3787, 3787 -3789 (2001).
[37] Jean O. Lanjouw, Intellectual Property and the Availability of Pharmaceuticals in Poor Countries, 3 *INNOVATION POL'Y & ECON 4* (2002).

developed countries cannot be justified.[38] Another argument against the product patent regime in India is that it may encourage 'evergreening'—strategies used to prolong patent benefits by securing new patents on modifications to the drug's process, dosage form, or administration method, rather than on the active ingredient itself. This practice, observed in the US, can delay the introduction of generic versions and restrict the availability of more affordable drugs even after the original patent expires.[39]

In light of these concerns, many Indian pharmaceutical companies opposed the implementation of the new patent regime. The Indian Drug Manufacturers' Association (IDMA) specifically cautioned that this strengthened patent system could negatively impact both the drug industry and consumers in India.[40]

Since 1970, the Indian pharmaceutical industry has relied on reverse engineering, allowing it to establish a strong position over 35 years. This period has provided ample time to invest in research and development. Additionally, India is recognized for having one of the most extensive compulsory licensing regimes globally.[41] Despite existing gaps in the compulsory licensing provisions, fostering innovation remains crucial. In the Indian context, strengthening the patent regime was essential to encourage the development of original drugs, rather than just replicating existing branded medicines through reverse engineering.[42]

In practice, the amendment has yielded significant positive outcomes. It has led to heightened investment in research and development and facilitated collaboration through mutual licensing, mergers, and acquisitions. Consequently, the amendment has enhanced access to medicines by enabling the sharing of foreign research in India and allowing Indian research to reach global markets.[43]

Concerns about significant price increases in medications have largely been addressed by the relatively modest rise in costs. Government sources indicate that for drugs subject to price controls, the increase has been just 1%. In contrast, medications not covered by price controls have seen an average price rise of approximately 7% over the past decade.[44] Since the 2005

[38] Sajeev Chandran, Archna Roy & Lokesh Jain, Implications of New Patent Regime on Indian Pharmaceutical Industry: Challenges and Opportunities, 10 *J. INTELL. PROP. RIGHTS*, 273, 273-274 (2005).
[39] Discussion Meeting on EU Competition Commission's Report on the Pharmaceutical Sector: What Lessons for India (Aug. 7, 2009) (New Delhi), available at http://www.centad.org/events_56.asp (last accessed June 29, 2024).
[40] Janice M. Mueller, The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation, 68 *U. PITT. L. REV.* 540 (2007).
[41] *Id.*
[42] *Id.*
[43] Corporate Catalyst of India, *Report on the Indian Pharmaceutical Industry*, available at http://www.cci.in/pdf/surveys_reports/indias_pharmaceutical_industry.pdf (last accessed March 30, 2024).
[44] Padmashree Gehl Sampath, Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry, *United Nations Univ.-Inst. for New Techs.*

Amendment, drug prices have not surged significantly. This stability can be attributed to changes in the Indian pharmaceutical sector, including increased focus on innovation and regulatory measures such as compulsory licensing and strict price controls enforced by the government. Consequently, access to medicines has expanded in terms of availability and variety. This suggests that the right to health, as envisioned by the Constitution and supported by this Amendment, has been effectively upheld.

Recent developments in the 2024 Budget reflect a positive shift towards enhancing access to essential medicines. The exemption of customs duties on critical cancer drugs such as Trastuzumab Deruxtecan, Osimertinib, and Durvalumab signifies a governmental effort to alleviate the financial burden on patients. Furthermore, the increased allocation for the Health Ministry and the substantial hike for the Ayush Ministry underscore a commitment to improving healthcare infrastructure and research. Despite these advancements, there are calls for further increases in healthcare spending and reforms in indirect taxation. The measures outlined in the Budget illustrate a growing recognition of the need to balance public health priorities with economic considerations, reinforcing the importance of ensuring affordable access to essential medicines.[45]

III. ENSURING THE RIGHT TO HEALTH UNDER THE CURRENT PATENT REGIME

Although TRIPS is not seen as a beneficial bargain, it cannot be criticised thoroughly. Various clauses of the agreement (Articles 7, 8, 27, 30 and 31) reflect liberal treatment towards the developing nations and seek to balance rights and obligations, thereby driving way towards public policy goals, including access to essential drugs.

(i) Article 7[46] of TRIPS balances innovation and social and economic welfare. Intellectual property rights should be regulated in such a way that they should contribute to promoting technological innovation. Similarly, they should be transferred in a manner conducive to social and economic welfare.

(ii) Article 8[47] provides autonomy to the states so that they can adopt measures necessary to protect public health and promote public importance in sectors of vital importance to their socio-economic and technological development.[48]

(UNU-INTECH), available at http://www.who.int/intellectualproperty/studies/PadmashreeSampathFinal.pdf (last accessed April 26, 2012).

[45] Bindu Shajan Perappadan, Budget provides customs duty exemptions for three cancer treatment drugs, The Hindu, July 24, 2024, at 1.

[46] TRIPS Agreement art. 7.

[47] *Supra note 13.*

[48] TRIPS Agreement art. 8.

(iii)Article 27(2)[49] allows a State to restrict the patentability of inventions on various grounds, such as a threat to human life or health.

(iv) Article 30[50] of Trips provides that the WTO members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, provided that the legitimate interests of third parties have been taken into consideration.

(v) Article 31[51] lays down a list of provisions applicable in all situations where the law of a WTO Member country permits use of the subject-matter of the patent without authorisation of the patent-holder.[52]

IV. TRIPS AND PATENT EXCLUSIONS

The interpretation of exclusions from patentability in the Patents Act should adhere to the literal rule of interpretation. This rule underscores the human rights aspect of these exclusions, emphasizing the significance of public health and social welfare alongside technological advancement, as enshrined in the Constitution.

(i) Compulsory Licensing

With the establishment of a product patent regime in 2005 for pharmaceuticals, and the resulting broader scope of patents, the issue of compulsory licensing has become highly significant in India.[53] Compulsory licensing typically involves the government issuing a license to use a patent without the consent of the patent holder.[54] A compulsory license is essentially a legally enforced contract between a willing buyer and an unwilling seller.[55] The TRIPS agreement permits compulsory licensing as a measure to balance access to existing drugs with the promotion of research and development for new drugs. Interestingly, the term "compulsory licensing" does not explicitly appear in the TRIPS agreement. Instead, Article 31 uses the phrase "other use without authorization of the right holder," which encompasses compulsory licensing as well as government use for their own purposes. Members may allow narrow exceptions to the exclusive rights granted by a patent, provided these exceptions do not

[49] TRIPS Agreement art. 27(2).
[50] TRIPS Agreement art. 30.
[51] TRIPS Agreement art. 31.
[52]Abhayraj Naik, Pharmaceutical Patents and Healthcare, 2 *SOCIO-LEGAL REV.* 46 (2006).
[53] The "Compulsory Licence" Regime in India: Past, Present and Future, available at https://www.researchgate.net/publication/228173575_The_'Compulsory_Licence'_Regime_in_India_Past_Present_and_Future (last accessed June 13, 2024).
[54] Anthony P. Valach, Jr., Review of TRIPS, *Int'l Trade Daily News* (BNA) INT'L TRADE REP. D7 (1999).
[55] Arnold J.G., International Compulsory Licensing: The Rationales and the Reality, 33 *IDEA* 349 (1993).

significantly interfere with the standard use of the patent or unfairly harm the patent owner's legitimate interests, while also considering the legitimate interests of third parties.[56]

Compulsory licensing occurs when a government permits a third party to manufacture a patented product or use a patented process without the consent of the patent owner, or when the government itself intends to use the patented invention. This mechanism is one of the flexibilities provided in the WTO's TRIPS agreement regarding patent protection.[57]

The Indian government's introduction of the National IPR Policy in 2016 has given a significant boost to establishing robust and effective IPR laws that strike a balance between the interests of rights holders and the broader public interest.[58]

Furthermore, the 2017 amendment broadens the scope of compulsory licensing. If a developing country needs to use compulsory licensing to produce affordable pharmaceuticals, overseas producers can step in and supply the necessary products, even if compulsory licensing is required in the producing country. This approach facilitates the production of pharmaceuticals in one country for export to meet the public health needs of one or more other countries.[59] The rationale behind compulsory licensing is that patents should not hinder public health and should serve the public interest, especially in crucial areas for socio-economic and technological development. Patents are intended to ensure that the benefits of a patented product are available at a reasonable and affordable price to a broad segment of the population. To facilitate this, a compulsory license can be issued to make the patented product accessible.

(ii) Indian Legislation

The grant of compulsory licenses in India is governed by Sections 82 to 94 of the Patents Act, 1970, and Rules 96 to 102 of the Patents Rules, 2003.[60] The Controller of Patents may grant a compulsory license in various scenarios: under Section 84[61] for general cases, Section 91[62] for related patents, Section 92[63] for specific provisions following Central Government notifications, and Section 92-A[64] for exporting patented pharmaceutical products in

[56] *Supra note 50*.
[57] Compulsory Licensing of Pharmaceuticals and TRIPS, available at https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last accessed April 9, 2024).
[58] Legal and Legislative Framework of the National Intellectual Property Rights (IPR) Policy, http://dipp.nic.in/English/Schemes/Intellectual_Property_Rights/National_IPR_Policy_08.08.2016.pdf (last visited May 19, 2024).
[59] *Id.*
[60] Patents Act, 1970, No. 39 [*amended* by Patents (Amendment) Act, 2005].
[61] Patents Act, 1970, No. 39, § 84.
[62] Patents Act, 1970, No. 39, § 39.
[63] Patents Act, 1970, No. 39, § 92.
[64] Patents Act, 1970, No. 39, § 91-A.

exceptional circumstances.

The Natco case[65] has marked a significant shift in the Indian pharmaceutical sector by demonstrating how patents can be managed to align with both TRIPS obligations and domestic laws. This landmark decision has proven that developing countries like India can effectively utilize TRIPS flexibilities to enhance public healthcare and uphold the constitutional right to life under Article 21[66]. Additionally, the Bombay High Court supported the Controller General of Patents' and the Tribunal's conclusions regarding compulsory licensing under Section 84 of the Patents Act.

Other applications for compulsory licensing have also been submitted but rejected by the Controller. For instance, BDR Pharmaceuticals sought a compulsory license to produce a generic version of Dasatinib, an anti-cancer drug patented by Bristol-Myers Squibb in India.[67] In 2015, Lee Pharma also applied for a compulsory license to produce Saxagliptin, a drug for type II diabetes mellitus. However, this application, along with BDR Pharmaceuticals' request for Dasatinib, was rejected because neither could establish a prima facie case for granting the compulsory license.[68]

Although the comparative analysis[69] indicates that India's compulsory licensing provisions align with TRIPS requirements, the concept of compulsory licensing remains inherently paradoxical and presents fundamental challenges.[70] India has issued only one compulsory license, largely due to the procedural complexities involved. While the theoretical framework for compulsory licensing appears robust, its practical application is constrained by the current practices of the patent office. Strengthening these provisions requires more comprehensive policy formulation and the issuance of detailed guidelines by the Indian Patent Office.

(iii) Doha Declaration and Public Health

Governments have often struggled with interpreting the flexibilities within the TRIPS Agreement and understanding their limits. The Doha Ministerial Declaration of November 14, 2001, addressed these concerns by emphasizing the importance of implementing TRIPS in a manner that supports public health. It highlighted the need for balancing access to existing medicines with the promotion of new drug development, and allowed nations the flexibility to

[65] Bayer Corp. v. Union of India, (2014) SCC OnLine Bom 963.
[66] *Supra note 25*.
[67] BDR Pharmaceuticals Int'l Pvt. Ltd. v. Bristol-Myers Squibb Co., (2013) CLA No. 1.
[68] Lee Pharma Ltd. v. AstraZeneca AB, (2015) CLA No. 1.
[69] Compulsory Licensing of Pharmaceutical Patents in India: A Research Study, *Eur. J. Pharm. & Med. Res.*, 2016, at 538, available at http://shodhganga.inflibnet.ac.in/bitstream/10603/130490/19/19_annexure.pdf (last accessed Sept. 26, 2018).
[70] Daniel R. Cahoy, Breaking Patents, 32 *MICH. J. INT'L L.* 461, 462 (2010).

tailor their legislation to their socioeconomic conditions. Despite the TRIPS Agreement's role in intellectual property protection and drug development, the Declaration recognized its potential to impede access to affordable medicines, thus stressing the need for measures that address public health concerns.[71]

The Doha Declaration affirmed that public health should take precedence over private patent rights. It reinforced the rights of governments to utilize WTO public health safeguards and other measures to ensure access to affordable medicines.[72] The Declaration also touches on the concept of intellectual property rights exhaustion, clarifying that the TRIPS Agreement allows each member to establish its own regime for parallel imports. However, this freedom is subject to the general TRIPS provisions, which prohibit discrimination based on nationality.[73]

The TRIPS Agreement and the Doha Declaration aim to strike a balance between incentivizing research and ensuring public health through improved access to medicines. However, these measures have not fully resolved the challenges faced by developing countries. Many such nations are reluctant to issue compulsory licenses, as it could be seen as a disregard for intellectual property rights, potentially harming trade relations and deterring investment.[74] Developing countries often have stringent patent systems that allow for flexible compulsory licensing, primarily due to limited incentives. Conversely, developed countries lack incentives to issue compulsory export licenses, making these TRIPS flexibilities difficult to access in practice.

V. CONCLUSION

According to Competitive Market Theory, the price of a good should be set based on a comprehensive assessment of all associated costs.[75] Setting a price that does not account for all relevant costs can lead to either overpricing or under-pricing. This mispricing can cause imbalances such as overproduction or underproduction, resulting in economically inefficient outcomes.[76] Monopolistic regimes often lead to overpricing and under-consumption, as evidenced by the high costs of AIDS drugs in South Africa and Nepal. While such regimes are seen as necessary to protect intellectual property and incentivise innovation, it is crucial to

[71] Dr. S.C. Roy, Health Security and National Strategy Under the Patents Regime: Issues and Concerns, 6 *CNLU L.J.* 80 (2017).
[72]US Bullying on Drug Patents: One Year after Doha (Oxfam Int'l Briefing Paper, 2002), available at http://www.oxfam.org/eng/pdfs/pp021112bullyingpatents.pdf (last accessed July 6, 2024).
[73] Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_Tripse.htm (last accessed April 14, 2024).
[74] Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, ¶ 5(d) (Nov. 14, 2001), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_Tripse.htm (last accessed May 23, 2024).
[75] Mitchell A. Polinsky, *An Introduction To Law And Economics* 88 (Little, Brown & Co., 2nd ed. 1989).
[76] *Id.*

remember that their primary goal is to benefit society by promoting innovation. Economic theory indicates that to achieve optimal outcomes, these regimes' scope, duration, and nature must be carefully considered.

This paper highlights that other factors should also be taken into account. Based on Indian constitutional principles and the observed issues of overpricing and anti-competitive practices, it is argued that excessive intellectual property protection may infringe on societal rights and the interests of future innovators.

Therefore, a uniform patent regime that offers the same level of protection to all innovations may not be ideal. To address concerns about public health and balance innovators' interests with societal needs, it is suggested that the scope and duration of patent protection for pharmaceuticals be reconsidered. Developing countries like India should advocate for a more flexible intellectual property regime, particularly for essential medicines, to foster competitive markets. This approach could lead to reasonable profits for innovators while aligning with societal needs and promoting overall welfare.

(A) Suggestions

To address the pressing issues surrounding pharmaceutical patents and public health, several key recommendations are proposed. First, it is crucial to shorten the duration and narrow the scope of patent protection for pharmaceutical innovations. This adjustment would help balance the need for innovation with the imperative of providing affordable access to essential medicines. Each country should also tailor its patent laws to align with its unique socio-economic conditions and public health objectives while still honouring international commitments. We can better address public health challenges by moulding patent regulations to enhance access to medicines, particularly for impoverished populations.

A legal framework that is responsive to health needs is essential, especially for enabling swift and effective government action during emergencies such as epidemics. Developing a framework specifically focused on ensuring access to life-saving medications will further support public health goals. Additionally, compulsory licensing options should be utilised more in developing and least-developed countries. Simplifying the process for issuing compulsory licenses could significantly improve access to necessary treatments. Moreover, considering the allowance of parallel imports for crucial medications would also help meet public health needs. Implementing these changes could pave the way for a future where individuals overcome serious illnesses and enjoy healthier, disease-free lives.

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