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PHARMACEUTICAL PATENTING IN INDIA: CHALLENGES OF PUBLIC ACCESS TO HEALTH A CRITICAL LEGAL ANALYSIS

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ABSRACT

One of the most controversial frontiers of the modern international trade law is the intersection of patent law in pharmaceuticals and the interests of health. India plays one of the most interesting roles in this discussion, being both a key provider of cheap generic drugs to the developing world, and a sovereign State that must reconcile its local intellectual property regime with the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). [937]

With the Patents (Amendment) Act, 2005, the Indian patent landscape was essentially reorganized in that the pharmaceutical substances were given the protection of product patent in decades. Although such a legislative change is required to conform to the WTO regulations, it has created severe conflicts between the commercial interests of innovation and the constitutional and humanitarian interests of providing access to affordable medicines to the population.

This essay is a critical legal appraisal of the main issues that patenting of drugs in India presents to the access to health by the populace. It looks at the legislative framework of pharmaceutical patents, the critical nature of Section 3(d) of the Patents Act as an anti-evergreening measure, the extent and extent of compulsory licensing, and the ongoing effect of the Doha Declaration. This paper presents an argument that, despite the fact that the legal framework of India has strong flexibilities in the area of public health, structural, judicial and political barriers still exist that hinder the effective use of these flexibilities. The paper ends with normative suggestions to strengthen the primacy of the public health in the structure of Indian pharmaceutical patent law.[938]

Keywords: TRIPS Agreement, Section 3(d), Compulsory Licensing, Evergreening, Access to Medicines, Novartis, Doha Declaration, Indian Patent Law, Public Health Flexibilities

[937] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

[938] World Health Organization, 'Access to Medicines: Making Market Forces Serve the Poor' (2004), WHO/EDM/2004.2.

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I. INTRODUCTION

Patents play a dual and often conflicting role in the global pharmaceutical order. On the one hand, they grant temporarily exclusive rights to patent, which motivates pharmaceutical innovation in that innovators can recover the large research and development costs it takes to commercially introduce a new drug into the market. However, this right to monopoly gives the owners of patents the ability to charge prices that are beyond the financial ability of the patients in the low and middle income nations and as such, life saving medications have turned into commodities and are now being sold only to those with financial capability.

The role of India in this world equation is outstanding. The deliberately lax patent system in India, which allowed process rather than product patenting in food, chemicals and pharmaceuticals, facilitated the development of a strong domestic generic drug industry, over the course of several decades since the introduction of the Patents Act, 1970. The Indian manufacturers proved to be the pharmacy of the developing world, as they provided millions of patients in sub-Saharan Africa, Southeast Asia and Latin America, with generic versions of vital drugs at affordable prices.[939]

With the entry of India into the World Trade Organization in 1995 and its ensuing commitment to adhere to the TRIPS Agreement, this situation changed dramatically. A paradigm shift in the Indian intellectual property law came with the introduction of the Patents (Amendment) Act, 2005 which provided the protection of product patents on pharmaceutical substances. Although the amended Act included various public health protection measures - the most significant of which were the mandatory licensing measures and the parallel importation rights, there are still serious concerns regarding the effectiveness of these measures, their use and how these measures can be preserved against erosion by bilateral trade agreements and international pressure.

In this paper, the discussion will go through nine substantive sections. Section II follows the history of pharmaceutical patenting in India. Part III looks at Section 3(d) and its groundbreaking judicial interpretation in Novartis AG v. Union of India.[940] Section IV is an evaluation of the compulsory licensing model and the Bayer v. Natco case. Part V and VI place the analysis in context by the TRIPS Agreement, the Doha Declaration, and the international human rights law. Section VII critically examines the main obstacles to the access of the populace.

II. History and legislation.2.1 Pre-TRIPS Era: the Patents Act of 1970.

2.1 Pre-TRIPS Era: The 1970 Patents Act

The 1970 Act Patents Act, 1970 ('the 1970 Act') was a purposeful and foresight legislative tool that was informed by the recommendations of the Ayyangar Committee Report of 1959. The 1970 Act was conceptualized in the context of the national developmental interests of India and the presence of multinational pharmaceutical companies in the Indian market which meant that patenting of any pharmaceutical or chemical substance was limited to process patents and not product patents.[941]

There were a number of consequences of this regime. It helped to create an industry of generic competition at home, capable of making substitute drugs using alternative manufacturing methods and reverse engineering patented drugs. It led to remarkably low pharmaceutical prices, by international standards. And it allowed India to become one of the leading providers of cheap

[939] See Shamnad Basheer & T. Prashant Reddy, 'The Efficacy of Indian Patent Law: Ironing Out the Creases in Section 3(d)', 5 Scripted 232 (2008).

[940] Novartis AG v. Union of India, (2013) 6 SCC 1 (India). The Supreme Court unanimously upheld the rejection of Novartis's patent application for imatinib mesylate (Gleevec/Glivec) under Section 3(d) of the Patents Act.

[941] Patents (Amendment) Act, 2005, Statement of Objects and Reasons (India).

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antiretroviral medications, antibiotics, and other critical medicines to the developing countries that were not able to purchase the patented original types.[942]

The 1970 Act was based on a normative philosophy of developmental pragmatism: the right to intellectual property was instrumentalised to address national health goals, economic growth and technology transfer. Such a strategy was in line with the general developmental ethos of the time and echoed the effects of dependency theory on Indian economic policymaking.

2.2 The Road to TRIPS Compliance: The 2005 Amendments

The accession of India to the WTO 1994, and the signing of the TRIPS Agreement in 1994, subjected the country to binding commitments to the extension of patent protection to all areas of technology, such as pharmaceutical products, within a given transitional period.[943] In the case of developing countries like India, the TRIPS Agreement offered a ten-year transitional period up to January 1, 2005, where they would have to have in place a mailbox facility where pharmaceutical patent applications would be filed pending the implementation of the relevant domestic regime.

These TRIPS obligations were fulfilled with the enactment of the Patents (Amendment) Act, 2005. It was the first legislation in a long time since the 1970 Act to provide product patent protection of pharmaceutical substances, food and agrochemicals. But Indian legislators, who were highly aware of this shift in relation to the health of the population, made a number of protective provisions in the amendment. [944]

The key of these protective measures was Section 3(d), which instilled an additional degree of patentability of novel types of familiar pharmaceutical substances. Other safeguards were the increase of compulsory licensing grounds under Section 84, government use provisions under Section 100, parallel importation rights, pre-grant and post-grant opposition mechanisms.[945] All of these provisions were aimed at bringing India to a level of compliance with the requirements of public health access reflecting the spirit of the Doha Declaration on TRIPS and Public Health.

III. SECTION 3(D): THE ANTI-EVERGREENING BULWARK.

3.1 Textual and Teleological Analysis

The most controversial and unique global provision of Indian pharmaceutical patent law is section 3(d) of the Patents Act, 1970. As amended in 2005, it does not cover under the term of patentable inventions the simple discovery of a new form of an existing substance that does not lead to the improvement of the known efficacy of the substance.[946]

That provision was intended to overcome the pharmaceutical industry habit of evergreening, or making slight structural changes to existing drug molecules, by altering salt form, polymorphs, enantiomers, metabolites, prodrugs, or dosage forms, without demonstrably improving therapeutic efficacy in any clinically significant way. The ability to patent these small, insignificant adjustments would allow the originator firms to enjoy an effective monopoly much longer than the original patent, thus precluding generic competition and maintaining elevated prices.

An actual reading of Section 3(d) shows various crucial ambiguities. The efficacy is not defined by statute but its application is a matter of

[942] Médecins Sans Frontières, 'Untangling the Web of Antiretroviral Price Reductions', 17th ed. (2014).

[943] TRIPS Agreement, supra note 1, art. 27(1) (requiring patents to be available for any invention in all fields of technology).

[944] K.M. Gopakumar & Sangeeta Shashikant, 'India and TRIPS Compliance' (2010), Third World Network; see also Sudip Chaudhuri, 'TRIPS and Changes in Pharmaceutical Patent Regime in India' (2005), Working Paper No. 535, Indian Institute of Management Calcutta.

[945] Patents Act, 1970, §§ 84–92 (India). Section 84 allows any person to apply for a compulsory licence after three years from the grant of a patent if the reasonable requirements of the public regarding the patented invention have not been satisfied, the patented invention is not available at a reasonably affordable price, or the patented invention is not worked in India.

[946] Patents Act, 1970, § 3(d) (India) (as amended in 2005): 'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.'

judicial interpretation. Is it therapeutic efficacy, pharmacological efficacy, bioavailability or some more general understanding of clinical utility? The statutory interpretation to Section 3(d) is that salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance will be held to be the same substance, unless they exhibit a significant change in properties with respect to efficacy.

Section 3(d) has a teleological purpose that is, however, unambiguous. It represents an expression of a legislative conclusion that the patent system in India cannot be used as a tool to evergreen pharmaceutical monopolies at the cost of access by the population. In this respect, Section 3(d) is a substantive theory of what should be patented: real pharmaceutical innovation that leads to therapeutic meaningful improvement, and not simply a reformulation.

3.2 The Novartis Saga: A Landmark Ruling

The judicial review of Section 3(d) with the most significant consequences involved Novartis AG v. Union of India, which was decided in April 2013 by the Supreme Court of India.. The case was about Novartis patenting imatinib mesylate, the beta crystalline polymorph of imatinib, the drug that was marketed as Gleevec or Glivec a revolutionary treatment of chronic myeloid leukaemia.

Novartis had patented imatinib (the free base) in numerous places, and the Indian application sought a patent on its beta crystalline mesylate salt form on the basis that the new form had a better bioavailability than previously known forms. The Patent Office, the Intellectual Property Appellate Board and finally the Supreme Court turned down the application on the basis that the compound claimed did not meet the enhanced efficacy criterion of Section 3(d).[947]

The decision of the Supreme Court is outstanding in a number of ways. First, it provided an authoritative resolution of the ambiguity of the meaning of the word efficacy in Section 3(d) through the ruling that efficacy in pharmaceutical context refers to the therapeutic efficacy- the capacity of drug to cause the intended therapeutic effect. Enhanced bioavailability, so far as the Court holds, does not necessarily amount to improved therapeutic efficacy, unless the Court can show that it does result in a meaningfully improved therapeutic outcome.

Second, the Court upheld the constitutionality of Section 3(d) and denied the appeal of Novartis that the provision was not consistent with the obligations of India under Article 27 of the TRIPS Agreement. The Court decided that TRIPS did not require patenting of new uses of known substances where such new uses did not show increased effectiveness, and that member countries had autonomy in establishing exactly what conditions and criteria were necessary to be met to patent such use.[948]

Third, the ruling reinforced the intent of Congress in drafting Section 3(d) as a measure to prevent evergreening of pharmaceutical patents, and placed the provision in a clearer context within the overarching context of protecting public health. The Novartis decision has since been embraced in many other parts of the world as a definitive statement of how flexibilities in favor of pro-public health can be introduced in TRIPS-compliant patent laws.

IV. COMPULSory licensing: Framework and restrictions.Sections 84 92.

4.1 Statutory Framework under Sections 84–92

One of the most potent public health tools that can be used by the Indian law is the compulsory licensing regime under the Patents Act, 1970, as amended. Section 84 entitles any individual who is interested in working with a patented invention to request the Controller of Patents to

[947] Novartis AG v. Union of India, (2013) 6 SCC 1, ¶¶ 57–74. The Court extensively analyzed the legislative intent behind Section 3(d) and emphasised the need to prevent mere reformulations from obtaining patent protection.

[948] See Basheer & Reddy, supra note 4; Prashant Reddy T. & Sumathi Chandrashekaran, 'Create, Copy, Disrupt: India's Intellectual Property Dilemmas' (2017), Oxford University Press.

grant him a compulsory licence after three years of the date of the grant of the patent.

Under Section 84 a compulsory licence can be given on satisfaction of one or more of the following: that the reasonable needs of the people with regard to the patented invention are not met; that the patented invention is not being available to the people at a reasonably affordable price; or that the patented invention is not being worked in the territory of India. Section 89 expounds on the general purposes that the Controller should take into consideration when granting compulsory licences such as the necessity to ensure that the patented article is made available to the public at fairly affordable prices.

Outside Section 84, there are compulsory licences in situations of national emergency or extreme urgency or public non-commercial use, and an export of pharmaceutical products to eligible countries through the TRIPS Protocol Amendment respectively under Sections 92 and 92A respectively.[949] Section 100 use provisions also give the Central Government the authority to use any invention without the permission of the patentee to use it in government purposes. All these provisions offer India a solid set of tools to respond to the emergence of public health without giving undue respect to patent monopolies.

4.2 The Bayer v. Natco Decision

In the landmark case of Bayer Corporation v. Natco Pharma Ltd[950], the Controller of Patents granted the first compulsory licence to be granted under the Indian Patents Act, 1970 in March 2012. The case involved the sorafenib tosylate (Nexavar), a branded oncological medication utilized in managing advanced kidney and liver cancer, and is patented. The price of the patented drug of Bayer was about Rs per year. 2.8 lakh per month making it completely unaffordable to the vast majority of Indian cancer patients.

The Controller issued a compulsory licence to Natco Pharma on three bases: that Bayer had not met the reasonable needs of the populace regarding the drug; the drug was not reasonably priced; and Bayer was not using the patent in India. The licence was issued on the condition of a royalty of 6% of the net sales, which was much lower than the royalty requested by Bayer.

The decision in the case of Bayer v. Natco was later affirmed by the Intellectual Property Appellate Board, and later, by the Bombay High Court. This ruling was celebrated as a breakthrough in the access to public health, and it proved that Indian courts and other quasi-judicial bodies were ready and capable of applying the compulsory licensing system to get over the pricing obstacles imposed by pharmaceutical patent monopoly.

4.3 Structural Constraints on Compulsory Licensing

Despite the importance of the Bayer v. Natco ruling, the mandatory licensing system in India also faces serious structural limitations restricting its real-life application as a health tool. To begin with, the formalities of a compulsory licence are complicated and lengthy, involving negotiations with the patentee prior to application, elaborate applications, oral hearings with the Controller and the possibility of further appeals via the various levels of adjudication.[951]

Second, compulsory licensing has a political economy of strong disincentives to its application. Trade retaliation measures, diminished investment and access to clinical trial information have regularly been threatened by pharmaceutical multinationals in response to actual or threatened compulsory licensing measures. Government of the United States on

[949] TRIPS Agreement, supra note 1, art. 31.
[950] Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013 (Controller of Patents, Mumbai, Mar. 9, 2012), aff'd, Bayer Corporation v. Union of India, 2014 (57) PTC 149 (Bom.).
[951] Pharmaceutical Research and Manufacturers of America v. Walsh, 538 U.S. 644 (2003); see also Jerome H. Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options', 37 J.L. Med. & Ethics 247 (2009).

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behalf of its pharmaceutical industry has put India on its Special 301 WatchList due to the difference in opinion like the Novartis ruling and compulsory licence by Bayer.

Third, the local production capacity in the pharmaceutical manufacturing sector to establish a compulsory licence is not the same across all medicines. The use of complex biologics, e.g., needs advanced manufacturing facilities, which not every Indian generic manufacturer has, making the application of compulsory licence less viable to this rapidly growing category of therapeutics.

V. THE TRIPS AGREEMENT AND THE DOHA DECLARATION

5.1 Article 27 and Patentability Standards

Article 27(1) of the TRIPS Agreement obliges patent protection to any invention in any area of technology, as long as it is a new invention, which entails an inventive activity and is industrially applicable. Some governments of developed countries and pharmaceutical companies have construed this as requiring member states to take a generous standard of patentability, which would make Section 3(d)-type clauses incompatible with TRIPS.

Nevertheless, the text or the negotiating history of the TRIPS Agreement does not dictate this interpretation. The Agreement fails to specify the exact meaning of new, inventive step or industrial application, which gives the member states a lot of policy room to apply these standards according to their developmental goals and health demands of the population. Additionally, Article 7 of TRIPS acknowledges that protection of intellectual property ought to help in promoting technological innovation and transfer and spread of technology to the common good of the producers and users of technological knowledge in a way that does not harm social and economic well being.[952]

Articles 7 and 8 of TRIPS mirror a right-balance in favour of rights of intellectual property holders and the interest of the people, the right to take measures to safeguard the health of the population is expressly noted as a right of member states. Taken purposely, such provisions would help to conclude that Section 3(d) of the Indian Patents Act, which requires new forms of known pharmaceutical substances to have an enhanced therapeutic value, fits squarely into the legitimate policy space of WTO members under TRIPS.

5.2 Doha Declaration: Affirmation and its Limits

This is the most authoritative and politically significant statement regarding the relationship between intellectual property and public health in international trade law, and is the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO Ministerial Conference on November 14, 2001.[953]

Paragraph 4 of the Doha Declaration confirms that the TRIPS Agreement does not and must not deny members the right to take measures to safeguard their health, and that it must be read and understood in a way that would support members in their right to safeguard their health, and especially their right to ensure access to all medicines.[954] In particular, paragraph 5 confirms the right of member states to issue compulsory licences and freedom to decide what are the reasons why such licences are issued, and the right to decide what is a national emergency or other circumstance of extreme urgency.

Although the Doha Declaration has a normative meaning, its practical effect has been limited due to various reasons. It is not a legal document, rather it is a political statement and its interpretation is disputed. Governments of developed countries and pharmaceutical corporations have attempted to restrict its reach and to sabotage its application by bilateral free trade agreements with TRIPS-Plus

[952] TRIPS Agreement, supra note 1, arts. 7–8.

[953] Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration].
[954] Doha Declaration, supra note 7, ¶ 4.

measures to limit the exercise of TRIPS flexibilities.[955]

India has been a steadfast and outspoken supporter of the principles of the Doha Declaration in multilateral forums. Nevertheless, it has been under constant pressure by the United States and the European Union to either drop or water down its pro-public health patent provisions in bilateral trade talks and this has cast doubt on the future viability of the policy space that India has established under the present law.

VI. Pharmaceuticals Patents And The Right To Health.6.1 International Human Rights Obligations.

6.1 International Human Rights Obligations

Article 25 of the Universal Declaration of Human Rights and Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) contains the right to enjoyment of the highest attainable standard of physical and mental health and India has ratified both. In its General comment No. 14 (2000), the Committee on economic, social and cultural rights explained that the right to access essential medicines is part of the right to health, as defined by the WHO Action Programme on Essential Drugs.

The conflict between pharmaceutical patent monopolies and right to health has been widely reported by international human rights organs. In consecutive reports, the former UN Special Rapporteur on the right to health cited the overwhelming scope of pharmaceutical patent safeguarding and the shortcoming of states to use the TRIPS flexibilities as the major hindrance to achievement of the right to health in developing nations.

The international human rights law normative framework offers a strong foundation to the subordination of intellectual property rights to the imperative of access to public health. The obligations of states under the ICESCR are that they should do what they can, both singly and with the help and cooperation of others, to the utmost of their means, with a view of eventually realizing the full actualisation of the rights proclaimed in the Covenant. A state which upholds patent monopolies which allow vital medicines to be unaffordable to its citizens might be breaching this requirement.[956]

6.2 Constitutional Dimensions: Article 21 and Beyond

In the Indian constitutional system the right to health has been identified as a subset of the fundamental right to life as stipulated in Article 21 of Constitution. The Supreme Court has, in a succession of landmark cases, construed the Article 21 broadly to encompass the right to life with human dignity, which includes the right to health and medical attention. The policy implications of this constitutional status as far as pharmaceutical patent is concerned are significant: a patent regime which actively blocks the access to vital medicines may not only contravene the statutory duties but also may involve the fundamental rights guarantees.

In addition to the normative basis of pro-public health patent policies offered by the Directive Principles of State Policy, which are not justifiability, there is the extra normative basis. Constitutional articles 38, 39, 41, and 47 have brought about a duty on the state to obtain social and economic justice, a proper way of living, and the level of diet and health of the people. The policy of pharmaceutical patent, in this sense, needs to be evaluated not only by the conditions of the intellectual property law but also by the more general constitutional requirement to serve the common good.

[955] Ellen F.M. 't Hoen, 'The Global Politics of Pharmaceutical Monopoly Power' (2009), AMB Publishers; see also Frederick M. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', 5 J. Int'l Econ. L. 469 (2002).

[956] 't Hoen, supra note 24, at 75–82.

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VII. CHALLENGES to PUBLIC ACCESS: A CRITical ASSESSment.Evergreening and Secondary Patenting.

7.1 Evergreening and Secondary Patenting

Although it has been safeguarded by the anti evergreening provision of section 3(d), evergreening still poses a risk to the public access in India. Pharmaceutical firms have been using more elaborate methods to secure patent protection to incremental innovations such as combinatorial patents, formulation patents, dosage form patents and patents on method of treatment.

By having the proliferation of secondary patents on a single active pharmaceutical ingredient or substance, a phenomenon termed a patent cluster or patent thicketing, a web of patent protection is created such that even generic manufacturers have to navigate even after the primary product patent has expired. The patent landscape surrounding blockbuster drugs is often analysed to show dozens of secondary patents, which could give the effect of extending the market exclusivity by several years beyond the initial patent term.[957]

The pre-grant opposition mechanism in the Indian patent system, which is granted under Section 25(1) of the Patents Act, offers a civil society organisation, generic manufacturer, and health advocates in India with a procedural mechanism to oppose doubtful patent applications prior to their grant. The mechanism has been used effectively by organisations like Initiative for Medicines, Access and Knowledge (I-MAK) and Medicins Sans Frontières to challenge several secondary pharmaceutical patent applications. But practical effects of such oppositions are restricted by the constraint of resources and the complexity of the patent examination process.

7.2 Data Exclusivity and TRIPS-Plus Pressures

Data exclusivity the right of clinical trial information submitted to drug regulators to be used by generic drug manufacturers over a certain duration is an important TRIPS-Plus provision which can cause de facto generic competition even in the absence of patent protection.

Article 39(3) of the TRIPS Agreement obligates the protection of undisclosed test data against unfair commercial use but not the exclusivity of rights to such data. Nonetheless, governments of developed countries have continued to push to add data exclusivity features to bilateral free trade agreement negotiations with India and other developing nations, citing that data exclusivity is a valid element of intellectual property protection of pharmaceutical products.

India has so far opposed the introduction of data exclusivity into its local legislation, which public health lobbyists have argued is justified by the fact that this would cause such a protection to bar generic pharmaceutical companies to use originator clinical trial data in their marketing approval submissions, which already presents many barriers to generic entry into the market other than patent protection. The Indian regulatory framework of Drugs and Cosmetics Act does not yet acknowledge a separate data exclusivity right, although it is an active topic of bilateral trade negotiations.

7.3 Judicial and Institutional Capacity

Effective use of the flexibilities of Indian public health does not only require legal provisions to be in place but also the institutional ability to exercise it uniformly and properly. The Indian patent examination framework has been criticised as having an inconsistent application of the patentability standards in Section 3(d) which casts doubt on the fact that some secondary pharmaceutical patents have been allowed which ought to have been denied under a strict interpretation of the anti-evergreening standard. [958]

[957] Knowledge Ecology International, 'Selected Documents on TRIPS Flexibilities and Pharmaceutical Access' (2012).

[958] Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), 'Public Health, Innovation and Intellectual Property Rights' (2006), World Health Organization.

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The backlog of patent applications awaiting the Indian Patent Office, resource limitations and the technical complexity of pharmaceutical patent cases all present circumstances in which error of either over-grant or under-grant is possible. The dissolution of the Intellectual Property Appellate Board (IPAB) in 2021, and taking over its role with the High Courts, has created additional uncertainty, since the High Courts, despite having more judicial resources and prestige, might not have the specific expertise in complex technical patent cases.[959]

VIII. COMPARATIVE PERSPECTIVES

Comparison of the pharmaceutical patent law and access to public health in various jurisdictions can help to understand both the uniqueness of the Indian approach and the international policy arena. Brazil, South Africa, Thailand, and Ecuador are jurisdictions that have attempted the use of TRIPS flexibilities in support of public health goals, with varying levels of success,[960] like India.

Brazil has a mature compulsory licensing system and has granted compulsory licence to antiretroviral drugs, most famously the efavirenz in 2007, over long-lasting objections of the United States government and pharmaceutical industry. The Brazilian example shows the usefulness and the political costs of the obligatory licensing, and the significance of the national manufacturing strength to the successful realization of these licences.

In 2006, 2007, and 2008, Thailand provided compulsory licences on a variety of patented medicines, such as antiretrovirals and cancer medicines, in its provisions concerning government use. The compulsory licensing programme in Thailand sparked much international criticism and threatened trade retaliation, showing how governments of developing countries are vulnerable to foreign pressure when exploiting flexibilities of TRIPS.

The experience of South Africa is especially educative. In 1997, South Africa revised its Medicines Act to offer such measures as parallel importation and compulsory licensing to introduce a landmark case of thirty-nine pharmaceutical companies that was eventually dropped under immense international pressure. The South African experience electrically charged the world civil society campaign to support the Doha Declaration, and showed the high stakes and the potential of pro-public health pharmaceutical patent policy.

The Indian approach, characterized by the inclusion of improved patentability criteria via Section 3(d), is more of a preventative type as compared to the corrective compulsory licensing approach that is favoured in Brazil, Thailand and South Africa. Instead of issuing patents and then granting compulsory licences, the Indian system tries to avoid the granting of unwarranted patents in the first instance. This normatively appealing approach puts a significant burden on the patent examination system and creates a litigation risk, as the Novartis case shows.

IX. NORMATIVE RECOMMENDATIONS

It is on the foundation of the above analysis that this paper makes the following normative recommendations towards enhancing the relationship between the law of pharmaceutical patent and access to health by the population of India.

Improving the Quality of Patent Examination.

The Indian Patent Office needs to be heavily invested in technical capacity, training of examiners, and information technology infrastructure to guarantee stringent and uniform enforcement of Section 3(d) and other standards of patentability. Improved examination quality would be achieved by the creation of publicly available, evidence-based analysis guidelines of pharmaceutical patent applications based on WHO Essential Medicines standards and clinical evidence, to prevent the inadvertent granting of evergreening patent.

[959] National Pharmaceutical Pricing Authority (NPPA), India, 'Working of the Drug Price Control Order' (2013), Ministry of Chemicals and Fertilizers, Government of India.

[960] Carlos Correa, 'Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options' (2000), Zed Books.

Making a Comprehensive Compulsory Licensing Policy a Law.

The government ought to come up with and post a clear, publicly visible policy framework on compulsory licensing, which outlines clear criterion, timeline, royalty, and decision making procedures. This type of framework would minimize uncertainty to generic manufacturers thinking about applications, discourage hairsplitting, and buffer perceptions of political intent of individual compulsory licensing decisions.

Opposing TRIPS-Plus Provisions in Bilateral Trade Agreements.

India should continue to uphold its principled opposition to the inclusion of data exclusivity, linkage of patents, and other TRIPS-Plus features to bilateral free trade agreements. Such inclusion would seriously undermine the policy space that was created by the amendments of the Patents Act 2005 and the Novartis case, and it could have very dire repercussions on the ability of the population to access the necessary medicines both in the country and internationally.

Operationalising Right to Health as a Constraint to the Constitution.

Pharmaceutical patent cases under Article 21 of the Indian Constitution should be more directly addressed by Indian courts and regulatory bodies in terms of the constitutional right to health. The right to health would be more deeply ingrained into the framework of patent adjudication by the creation of a constitutional proportionality framework that would mandate courts to determine the public health impact of patent grant and enforcement decisions.

Empowering patient engagement and Civil Society.

Pre-grant opposition mechanism under Section 25(1) has been an effective tool of civil society participation to the patent system. Increased transparency in the process of examining patents and capacity-building programs on patient organisations, public health advocacy organizations and generic manufacturers interested in leveraging this mechanism would empower the democratic oversight of pharmaceutical patenting.

X. CONCLUSION

Governance of pharmaceutical patents in India exemplifies a miniature of the most basic conflicts in modern international law: between the rights to act privately and the duty to act by the state; between the need to innovate and the need to access; between the principles of an international trade regime and the principles of human rights. India has shown, in its legislative innovation in Section 3(d) and in its ground breaking judicial ruling in Novartis and its historic compulsory licence in Bayer v. Natco, that developing countries may and must take the policy space afforded to it under TRIPS to make public health a priority.

However, as this paper will show, the legal architecture in India has long-standing problems of evergreening, bilateral trade pressure, institutional capacity limits, and the complexity of the patent adjudication process in a world of ever more sophisticated pharmaceutical innovation. India is still in the process of implementing a pro-public health strategy; the sustainability of this strategy will be measured by the process of ensuring the existence of the current legal provisions and their active, systematic and principled implementation by the courts, administrative authorities, and even by the civil society.

Finally, to resolve the conflict between drug patents and access to medicine at large, the global intellectual property regime needs to be more fundamentally realigned around a regime that better balances the needs of innovation and access. The experience of Indian law provides an example imperfect, contested, yet substantively meaningful--of how that reorientation can start on a national level. Whether such a model will hold up under the strains of bilateral trade talks, geopolitical rivalry, and the shifting demands of pharmaceutical innovation will decide, in no

small part, whether the right to health will continue to be a real and achievable dream of the most vulnerable patients around the globe.

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