PHARMACEUTICAL PATENTS: WEIGHING INTELLECTUAL PROPERTY RIGHTS ON THE HUMAN RIGHTS SCALE

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ABSTRACT

Intellectual Property Rights (IPR) and Human Rights originated from unrelated domains of human life. Turn of the civilization in the second half of the last century has pitted IPR against human rights. Pharmaceutical patents and right to health have taken opposing corners in the amphitheater of international relations and policy making. This paper endeavors to chart the relationship between the two jurisprudential streams in recent times and its global implications reflecting certain traits on the Indian scenario. The discussion will encompass the evolution of international intellectual property regime with its implication on pharmaceutical patents and the expansion of concepts of Human Rights to right to health, their opposing theoretical basis, and the way industrialized and less developed states reacted and adapted to this fluid relationship.

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INTRODUCTION

The evolution of Intellectual Property Rights (IPR) and Human Rights took different trails during the yesteryears of civilization. Whereas intellectual property endowed private rights over individual creations and innovations, human rights primarily conferred rights against state interference.[1] Though intellectual property rights had always tried to balance between rewards accorded to the owner of intellectual property against the resultant gains accrued to the society as a whole, the two worlds of intellectual property and human rights never came to face each other so expressively until the second half of the twentieth century.[2] This period also saw the sphere of health-care and medical innovations advance by leaps and bounds. The world faced new challenges from hitherto unprecedented burden of diseases and their enormous toll on human life.[3] When considering access to medicines, the high price-tag of patents in innovative medicines has become a double-edged sword.

This document endeavours to gauge the evolution of intellectual property rights in pharmaceutical patents on the scale of human rights. Chapters 2 and 3 summarize the development of intellectual property rights and of human rights. Chapter 4 pits IPR against Human Rights through the prism of rights of inventors and right to health. Chapter 5 depicts how India reconciled its patent laws with its domestic needs from a Human Rights angle vis-a-vis access to medicines. Chapter 6 outlines the evolution of IPR with the unfolding of WTO and TRIPS agreement and how India responded to it. Chapter 7 details the overarching dominance of the private sector in pharmaceutical patents and the pharmaceutical industry driven TRIPS Plus provisions imposed on trade and investment treaties. Chapter 8 questions the justification of the ends of IPRs in pharmaceutical patents through the prism of Human Rights. Chapter 9 throws light on the possible Human Rights solution to hurdles posed by pharmaceutical patents on the route to access to medicines and right to health, through compulsory licensing and the follow-up to Doha Declaration of World Trade Organisation. Chapter 10 elucidates the real-life challenges faced in the acceptance and implementation of

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[1] Henning Grosse Ruse-Khan, *Linking Intellectual Property and Human Rights: Concepts, Perspectives, and Tools for Integration*, *in* CIPIL SPRING CONFERENCE ON IP AND HUMAN RIGHTS (Mar. 11, 2017), https://www.cipil.law.cam.ac.uk/seminars-and-eventscipil-spring-conference/cipil-spring-conference-2017.

[2] *See* Paul LC Torremans, *Intellectual Property Law and Human Rights*, 34, Information Law Series (2015); *See* Laurence R. Helfer & Graeme W. Austin, *Human Rights and Intellectual Property: Mapping the Global Interface* (2011).

[3] Rachel Hajar, *History of Medicine Timeline*, 16(1) HEART VIEWS, 43–45 (2015), http://www.datesandevents.org/events-timelines/10-history-of-medicine-timeline.htm.

parallel imports of patented medicines under the Doha Declaration. Chapter 11 brings us full circle to competing interests that are in play to balance pharmaceutical patents and human rights.

I. DEVELOPMENT OF INTELLECTUAL PROPERTY RIGHTS

Intellectual property came into vogue during ancient days when craftsmen and artisans would mark their goods to stand out amongst others in the nascent form of trademarks.[4] The Statute of Anne[5] conferred some sort of copyrights to authors that were then assigned to publishers and printers and the guilds of Venice[6] which awarded patents to creators of innovations. The principle was to grant exclusive rights to exploit such intangible property which were the culmination of intellectual creations of individual humans, for a time being, so that afterwards the society can share and reap the benefits of such products of their intellectual effort and generate new creativities.[7]

Different schools of thought in the field of intellectual property took sides in this tug of war as to what extent such exclusive rights could be weighed against the benefits enjoyed by the society. Those who upheld the primacy of the individual argued for stronger scope of intellectual property rights, whereas those with liberal leanings advocated progressive exceptions to such exclusive rights in favour of the people at large, so that the society can partake the benefits of such intellectual property.[8]

Nineteenth century entered the age of industrialization. The West had a head start in the exploitation of resources in the fields of industrialization. Material progress improved quality of life in the Western and colonial powers enormously, while exploitation of the previous colonies continued. To sustain industrialization, the western civilizations had to encourage innovations and as a corollary, industrial intellectual property regimes developed in the form

[4] David Bainbridge, INTELLECTUAL PROPERTY 687 (9th ed. 2012).
[5] *Id*. at 34.
[6] David Bainbridge, *supra* note 4 at 392.
[7] Vishwas Devaiah, *A History of Patent Law*, ALTERNATIVE LAW FORUM, http://altlawforum.org/publications/a-history-of-patent-law/.
[8] *Id*.

of the Paris Convention (1883) and its subsequent revisions; until its culmination as the World Intellectual Property Organization (1967).[9]

II. DEVELOPMENT OF HUMAN RIGHTS

By the mid-20th century, colonial powers started collapsing all around the world. With the rise of new nation states, the latter found a voice in the international stage and gradually these lesser developed states progressively asserted their rights before the world. At the same time, the horrors of Nazi holocaust shook the conscience of the whole world to its core. Human Rights had heretofore existed in the abstract sense, but the events following the Second World War and the exposure of its horrors, forced the hand of the civilized world to lay down norms of rights of individual humans and the obligations and limits of state powers, so as to uphold such human rights.[10]

To begin with, advocates of Human Rights were mainly concerned with protection of the weak and downtrodden from the atrocities of state power.[11] But as the definitions of Human Rights expanded with time, the arena of intellectual property and of Human Rights were bound to confront each other. As industrialization had its lifeline in new innovations to hitherto unsolved problems, the developed countries championed stricter intellectual property rights for economic rewards to innovators; but the intellectual property regimes had no allusion to human rights in their decision-making process.[12]

Meanwhile, the reference to intellectual property rights had already found its way into the international covenants of human rights. The Universal Declaration of Human Rights (UDHR) was endorsed by member states of the United Nations in 1948 which achieved eminence as a universally accepted charter on the aftermath of the Second World War.[13]

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[9] Alathur D. Damodaran, *Indian Patent Law in the post-TRIPS Decade: S&T Policy Appraisal*, 13 JIPR 414-423 (2008).

[10] Akira Iriye et. al, *The Human Rights Revolution: An International History*, REINTERPRETING HISTORY: HOW HISTORICAL ASSESSMENTS CHANGE OVER TIME 3 (2012).

[11] Laurence R. Helfer, *Human Rights and Intellectual Property: Conflict or Coexistence?* 5(1) MINN. INTELL. PROP. REV. 51 (2003), https://scholarship.law.umn.edu/mjlst/vol5/iss1/2.

[12] *Id*.; Audrey R. Chapman, *A human rights perspective on intellectual property, scientific progress, and access to benefits of science*, WIPO/UNHCR Intellectual Property and Human Rights: A Panel Discussion to Commemorate the 50th Anniversary of the Universal Declaration on Human Rights, Publication No. 762E. (1998), http://www.wipo.org/globalisaues/events/1998/humanrights/papers/pdf/chapman.pdf.

[13] Gudmundur Alfredsson & Asbjørn Eide, THE UNIVERSAL DECLARATION OF HUMAN RIGHTS: A COMMON STANDARD OF ACHIEVEMENT (1999).

Article 27 of UDHR[14] under clause 1, advocated community participation in enjoyment of arts and culture and sharing of benefits from scientific advancements; whereas, clause 2 empowered innovators and authors to moral rights and economic benefits, over their individual scientific advancements and creations.[15] But this was a broadly construed consensus and it was left to the member states as to where to draw the balance.[16]

Further progress on the UDHR culminated in two subsequent international covenants. The UDHR provided for "first generation" human rights i.e. civil and political rights as well as "second generation" human rights viz. economic, social, and cultural rights.[17] The former was covered in the International Covenant on Civil and Political Rights (ICCPR, 1996) which mandated states to comply immediately and most member states acknowledged the same.[18] Granting the latter set of human rights became the bone of contention in the then world (polarized between the capitalist and the communist blocs), as to the definition and scope of recognizing the right to own property.[19] Hence the International Covenant on Economic, Social and Cultural Rights (ICESCR, 1966) merely asked the member states to undertake the best possible endeavour as permissible by their resources in a staggered manner to ensure such rights progressively.[20] Thus intellectual property rights, which mainly covered economic rights, did not receive universal traction in this field.[21]

Things came to head as the developing countries had to confront the emerging challenges faced by their populace in the fields of food supplies and health care. Innovations in healthcare in industrialized nations had created marvels in eradicating widespread life-threatening and disabling diseases. But the access to these modern medicines and medical

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[14] Art. 27, THE UNIVERSAL DECLARATION OF HUMAN RIGHTS, 1948, https://www.un.org/en/universal-declaration-human-rights/.

[15]John Peters Humphrey et al, Unit 10.3: The Universal Declaration of Human Rights (UDHR), The Universal Declaration of Human Rights (UDHR) is a declaration adopted by the United Nations General Assembly at Palais de Chaillot, Paris (Dec. 10 1948), [Hereinafter Humphrey et al, Unit 10.3, UDHR], http://dspace.vpmthane.org:8080/jspui/bitstream/123456789/4208/1/FC%20Sem%202%20THE%20UNIVERSAL%20DECLARATION%20OF%20HUMAN.pdf.

[16] Laurence R. Helfer, *Toward a Human Rights Framework for Intellectual Property*, *Public Law and Legal Theory Working Paper Number 06-03*, 40 U.C. DAVIS L. REV., 976 (2007).

[17] LAURENCE R. HELFER & GRAEME W. AUSTIN, HUMAN RIGHTS AND INTELLECTUAL PROPERTY: MAPPING THE GLOBAL INTERFACE 12 (1st ed. 2011).

[18] *See* LOUIS HENKIN ET AL., HUMAN RIGHTS (2nd ed., 2009).

[19] Laurence R. Helfer & Graeme W. Austin, *supra* note 17 at 9.

[20] Laurence R. Helfer & Graeme W. Austin, *supra* note 17 at 12.

[21] Art 15.1., INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS (ICESCR), 1966, https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx.

procedures were beyond the reach of the developing and underdeveloped nations, and were thus unable to cater to their teeming masses. The intellectual property drug patenting regime gave virtual monopoly to patent holders in pharmaceutical industries to decide aspects related to drug pricing.

Thus, we can surmise that in its earlier stages, Human Rights norm-setting had to face teething problems in its advocacy of public interests pitted against private economic rights vested in intellectual property.

III. RIGHTS OF INNOVATORS VERSUS RIGHT TO HEALTH

On one hand, innovations in pharmaceutical industries were time consuming and highly dependent on investment in Research and Development. Not only did that involve resource-intensive research and trials, one innovative success would emerge on the footsteps of innumerable failures, i.e. research which would never see the light of the day.[22] Hence the pharmaceutical companies would seek to recoup their investments by securing monopolies on the market that would deliver higher revenues for the limited term of patent protection. This would incentivize further innovations and thus faced with the lure of higher profit, induce further investment on research and development.[23] They sought to extrapolate the provisions of Article 27.1 of UDHR[24] and sought protection of Human Rights of the innovators. This, the pharmaceutical companies argued, would acknowledge the contributions of the innovators in medicine and reward them so as to further their quest to develop new medicines for newer challenges in healthcare, and mitigate effects of so far untreatable diseases. The advancements of biotechnology and the extension of patent protection to genes opened new avenues to make new drugs that would cure hitherto incurable diseases and prolong human life. The patent holders claimed that weakening of patent protection to new drugs, would lead to potential competitors free riding on their toils and discourage further innovations in medicines.[25]

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[22] Rochelle Cooper Dreyfuss, *Patents and Human Rights: The Paradox Reexamined*, *Public Law Research Paper No. 15-35* 5(3) CEIPI-ICTSD PUBLICATION SERIES ON GLOBAL PERSPECTIVES AND CHALLENGES FOR THE INTELLECTUAL PROPERTY SYSTEM (2015), SSRN https://ssrn.com/abstract=2654301.

[23] Laurence R. Helfer & Graeme W. Austin, *supra* note 17 at 90,91.

[24] *See* text accompanying note 21.

[25] WIPO, INTELLECTUAL PROPERTY READING MATERIAL, WIPO Publication No. 476 (E). (2nd ed., 1998), §4.60, 4.61.

On the other hand, advocates of Human Rights woke up to the new situation, which they perceived as a threat to the basic right to health and medical care as envisioned in Article 25 of the UDHR, that holds this right paramount, at par with the right to life and to freedom from discrimination.[26]

Previously, Human Rights advocates primarily concerned themselves with mitigation and eradication of atrocities of undemocratic and inhumane state powers. But the ramifications of drug patents, the enforcement of product patent regime in medicine patents and the linkage of trade relations with intellectual property,[27] as would be discussed subsequently, opened a Pandora's Box of barriers to attainment of universal human rights.[28]

Thus, the situation was ripe for Human Rights advocates to adapt themselves to meet this new challenge of where to draw the line between the opposing stakeholders in the realm of medical innovations and public health.

IV. INDIA AT CROSSROADS: FUNDAMENTAL RIGHTS AND THE SHIELD PROCESS OF PATENTS

The case of post-independence India became a study in the evolution and face-off between Human Rights and Pharmaceutical patents. The 42nd Amendment to the Constitution of India (1976) envisioned a socialist state in the offing. Though the Constitution does not specify a Right to Health as a Fundamental Right, Article 21 of the Constitution[29] guarantees right to life.[30] Expanding on the concept of Right to Life, the Hon'ble Supreme Court of India had conferred on a "life with human dignity & not mere survival or animal existence" (*vide* Francis Coralie Mullin v. The Administrator, Union Territory of Delhi & Ors., 1981).[31] The Apex Court has time and again gone further to impose the obligation on the Government for preservation of the health of its citizens (*vide* Paschim Banga Khet Mazdoor

[26] Art 25, The Universal Declaration of Human Rights (UDHR), 1948, https://www.un.org/en/universal-declaration-human-rights/.
[27] Laurence R. Helfer, *supra* note 11 at 52.
[28] Hemanat Kumar Varun, *Right to Health*, LEGAL INDIA: LEGAL NEWS & LAW RESOURCE PORTAL (Feb. 22, 2011), https://www.legalindia.com/right-to-health/ [Hereinafter Legal India].
[29] INDIA CONST. art. 21.
[30] Indrajit Khandekar et al., *Review Research Paper: Right to Health Care*, 34(2) J INDIAN ACAD. FORENSIC MED. (2012); Legal India, *supra* note 28.
[31] Francis Coralie Mullin v. The Administrator, Union Territory of Delhi & Ors., 1981 AIR 746.

Samity & Ors v. State of West Bengal & Anr., 1996)[32] and further more to obligate even the private healthcare sector to ensure preservation and protection of life (*vide* Parmanand Katara v. Union of India & Ors., 1989).[33]

Though the Directive Principles of State Policy as laid down by the Constitution of India is thought not persuasive enough to invoke a Fundamental Right to Health, it lays down guidelines to the State to ensure universal healthcare for all its citizens.[34] The Directive Principles also lays down the framework of balancing patent rights of pharmaceutical giants against rights of the public from the prism of a welfare state.[35] The dissenting note of K. Ramaswamy, J. in C.E.S.C. Ltd. Etc. v Subhash Chandra Bose & Ors., 1991 has even gone to the extent of elevating Right to Health as a Fundamental Human Right.[36]

In this light, we can appreciate, in hindsight, how post independent India with its limited resources and its fledgling pharmaceutical industry, had to evolve its own policy to provide innovative medicines to its poor citizens in an affordable and accessible manner. The formation and the resulting report of the Ayyangar Committee bore fruition in the Patent Act 1970. The Report argued that unfettered monopoly rights vested in pharmaceutical companies would pose an insurmountable hurdle before the poor and needy, who comprised the vast majority of India at that time, to have any access to modern medicines. Hence the Report recommended compulsory licensing and process patenting of medicines.[37]

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[32] Paschim Banga Khet Mazdoor Samity & Ors v. State of West Bengal & Anor., 1996 SCC (4) 37, at 5 (per S. C. Agrawal J) ("Article 21 imposes an obligation on the State to safeguard the right to life of every person. Preservation of human life is thus of paramount importance. The Government hospitals run by the State and the medical officers employed therein are duty bound to extend medical assistance for preserving human life."), https://sci.gov.in/jonew/judis/15597.pdf.

[33] Parmanand Katara v. Union of India & Ors., 1989 AIR 2039, at 7 (per Ranganath Misra J), ("Article 21 of the Constitution casts the obligation on the State to preserve life. …. Every doctor whether at a Government hospital or otherwise has the professional obligation to extend his services with due expertise for protecting life."), https://sci.gov.in/jonew/judis/7839.pdf.

[34] INDIA CONST. art 47.

[35] INDIA CONST. art. 39.

[36] C.E.S.C. Ltd. Etc v. Subhash Chandra Bose & Ors, AIR 573 1991, at ¶¶4,5 (per Ranganath Misra CJ), (Article 39(2) of the Constitution enjoins the State to direct its policies to secure the health and strength of workers. The right to social justice is a fundamental right. Right to livelihood springs from the right to life guaranteed under Art. 21. The health and strength of a worker is an integral facet of right to life.), https://sci.gov.in/jonew/judis/12560.pdf.

[37] Shri Justice N. Rajagopala Ayyangar, *Report on the Revision of the Law in India Relating to Patents for Inventions* (Sept., 1959), https://spicyip.com/wp-content/uploads/2013/10/ayyangar_committee_report.pdf; Sharmendra Chaudhry, *Product v. Process Patent: under Indian Patent Law*, SSRN, (Feb., 2011) https://ssrn.com/abstract=1758064; Dr. Anirban Mazumdar, *Study Material On Patent Law*, NUJS Study Material Series No. PL/17, (2017) (on file with author).

At this juncture the idea of process patent deserves mention, as compulsory licensing has wider contemporary implications and scope, and would be discussed later.

Prior to the Patent Act of 1970, India had to buy all medicines from foreign companies at a hefty price. By this Act, patent rights were provided only to the process or method of manufacture of the drug and not to the drug (product) itself (*vide* Section 5, Indian Patent Act, 1970).[38] This allowed the development and growth of the indigenous pharmaceutical industry, who by then, had the opportunity to circumvent the patented procedural steps, to manufacture the same new drugs, albeit at a fraction of the price demanded by the foreign players.[39] This not only ensured meaningful delivery of the drugs at affordable price to poor Indian citizens, but also opened up the export market for Indian pharmaceutical companies who could provide the same drugs at a very competitive price to other developing and third world countries, thereby further expanding the indigenous manufacturers of medicines as well as benefitting other poor countries.[40]

V. EVOLUTION OF IPR: TRIPS AND THE ONSLAUGHT OF PRODUCT PATENTS

However, developments in the last two decades of the twentieth century led to a cascade of events that left its mark everywhere in the world. Intellectual Property Rights and Human Rights were not immune to its pervasive influence. With the breakup of the Soviet Union and the emergence of globalization, individual economies of countries became interdependent, and protectionism to favour internal economies became increasingly difficult. The endeavour to harmonize global trade culminated in the formation of the World Trade Organization (WTO) at the Uruguay Rounds of the General Agreement on Tariffs and Trade (GATT), in 1994.[41]

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[38] Sharmendra Chaudhry, *Product v. Process Patent: under Indian Patent Law*, SSRN, (Feb., 2011) https://ssrn.com/abstract=1758064; The Patents Act, 1970, §5 ("Inventions where only methods or processes of manufacture patentable." - [Rep. by the Patents (Amendment) Act, 2005 (15 of 2005), Sec. 4 w.r.e.f. 1-1-2005]).

[39] The Patents Act, 1970, §5 (Inventions where only methods or processes of manufacture patentable. - [Rep. by the Patents (Amendment) Act, 2005 (15 of 2005), Sec. 4 w.r.e.f. 1-1-2005]).

[40] Dr. Anirban Mazumdar, *Study Material on Patent Law*, NUJS Study Material Series No. PL/17, (2017) (on file with author).

[41] *See* Katarina Tomasevski, *The impact of globalization on the enjoyment of economic, social and cultural rights in OECD countries*, draft paper commissioned by the American Association for the Advancement of Science, (1997).

Pursuant to the formation of WTO, signatory governments endorsed a general set of rules to be followed with respect to intellectual property relating to international trade and commerce, in the form of Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) at the end of the Uruguay rounds, that prescribed minimum standards for protection of intellectual property rights.[42] The TRIPS agreement resulted in a paradigm shift in the realm of international intellectual property regimes. Firstly, TRIPS agreement provided teeth to ensure the enforcement of these minimum standards by the member states in order to be able to participate in global trade and commerce.[43] The defaulters were liable to trade sanctions that would impose a heavy burden to their individual economies. Secondly, there was a provision for settling disputes before the WTO that prevented escaping any violations of the provisions of the TRIPS agreement.[44] This also mandated adherence to the Paris Convention for protection of industrial intellectual property.[45] Thus most of the countries of the world, ultimately acquiesced to the WTO in directing their domestic laws and policy to ensure enforcement of protection of intellectual property rights.[46]

Some countries had already developed their own punitive measures, like the Super 301 (or Special 301) of the United States.[47] According to these provisions, the United States could launch retaliatory steps, including trade sanctions against a country or entity that was perceived by US to have violated any intellectual property or trade agreement, or have taken any steps which was seemingly unfair or unjustified, so as to impair US commerce.

Given the overwhelming support to right to health worldwide, the linking of intellectual property regime to trade exposed the fault lines between the pathways of intellectual property rights and human rights. Nowhere was this more evident as in the field of healthcare and pharmaceutical patents. On one hand, the developed countries had already amassed a wealth of intellectual property resources, and also the wherewithal to nurture the progress in innovations, by a pre-existing advanced educational background amongst its population. This was pitted against the developing and least developed countries, which were far lagging in

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[42] *Trade topics, Overview: the TRIPS Agreement*, WORLD TRADE ORGANIZATION https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm. [Hereinafter TRIPS].
[43] Humphrey et al, Unit 10.3, UDHR, *supra* note 15 at para 984,985.
[44] *Id.*
[45] TRIPS, supra note 42.
[46] Laurence R. Helfer & Graeme W. Austin, *supra* note 17 at 28.
[47] Trade Act, 1974 § 301, 19 U.S.C. § 2242(a)(1)(A) (2006); Laurence R. Helfer & Graeme W. Austin, *supra* note 17 at 35.

institutional strength and human resources to cope with the competition. The world order thus came back full circle, and a new form of exploitation emerged towards the end of the twentieth century, when the world thought it has transcended the fight to remove inequities among nations. This came to be noted as the North - South divide in the field of intellectual property.[48]

The tremors of the product patent regime (granting patentability to final products in agro-chemical substances and medicines) was felt in India, as also by other developing and poor countries, who had to harmonize with the product-patent regime. As a result, the provision of granting only process patent in Patent Act, 1970 regarding innovations in medicines (and agricultural products) had to be dropped, and the Indian pharmaceutical companies and the Indian drug market had to reconcile with the extension of product patents, amongst other demands of the global community driven by the industrialised nations at the helm of WTO. The very loophole of inventing around a patented medicine by tweaking the process of manufacture to circumvent infringement by cheap generic versions was plugged forever. These countries had to comply with norms laid down by the TRIPS agreement, by 2005.[49] Such was the pressure that despite the beneficent and socialist leanings of the Indian Constitution, the dictates of WTO were incorporated as an ordinance and subsequently led to Amendments to the Patent Act.[50]

Needless to say, to comply with the WTO deadline the amendments were rushed through the Indian Parliament, much to the chagrin of Human Rights groups in India.[51] Thus, policy

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[48] Rafik Bawa, *The North-South Debate over the protection of Intellectual Property*, 6 DALHOUS. J. LEG. STUD., 77-119 (1997), https://ojs.library.dal.ca/djls/article/viewFile/5562/5007.

[49] Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act, 2005*, 1 IJLT, 15-46 (2005), http://ijlt.in/wp-content/uploads/2015/08/Basheer-Indias-Tryst-with-TRIPS-The-Patents-Amendment-Act-2005-1-Indian-J.-L.-Tech.-15.pdf.

[50] The Patents Amendment Act 1999 having retrospective effect from 1st January 1995, published in The Gazette of India, on Friday, March 26, 1999 as The Patent (Amendment) Act 1999, (No. 17 of 1999) states "2. AMENDMENT OF SECTION 5.- Section 5 of the Patents Act, 1970 (39 of 1970) (hereinafter referred to as the principal Act) shall be renumbered as sub-section (1) thereof and after sub-section (1) as so renumbered, the following sub-section shall be inserted, namely:-(2) Not withstanding anything contained in sub-section (1), a claim for patent of an invention for a substance itself intended for use, or capable of being used, as medicine or drug, except the medicine or drug specified under sub-clause (v) of clause (l) of sub-section (1) of section 2, may be made and shall be dealt, without prejudice to the other provisions of this Act, in the manner provided in Chapter IVA"), https://dipp.gov.in/sites/default/files/patact_99_0.pdf.

[51] Lok Sabha Debate, Debate moved by Shri Sikander Bakht, Combined discussion on the disapproval of Patents (Amendment) Ordinance, 1999 and motion for consideration of the Patents (Amendment) Bill, 1998, Mar. 9, 1999, https://indiankanoon.org/doc/1368397/.

makers were caught in the pincer grip of stringent TRIPS demands and the threat of trade sanctions through WTO dispute settlement.

VI. PHARMACEUTICAL PATENTS: HEGEMONY OF THE PRIVATE SECTOR AND TRIPS PLUS REGIMES

The economic globalization and privatization of scientific research in general and pharmaceutical innovations in particular, also posed realistic challenges to the balance between intellectual property rights of innovators and authors, and the right of the general public to enjoy the benefits of those innovations and creations, as envisaged in Article 15 of the ICESCR.[52] The dramatic transition from government funded scientific research to predominant private sector investment driven innovations, turned protection of commercial investments as primary goals of research and development in science and technology, especially in the ever expanding pharmaceutical business. This brought down the partition between basic research, i.e. those seeking to pursue new ideas and findings, and that of applied research that had proprietary goals to attain.[53]

Such was the forbearing influence of private investors, that even bilateral treaties took place to uphold the 'Investment Protection" of intellectual properties of private companies. One such treaty between Germany and Pakistan for "Promotion and Protection of Investments" bear testimony to the enormous powers swayed by industrialised nations over the less developed ones.[54] Economically dominant countries went further beyond minimal obligations mandated by TRIPS agreement, by imposing maximalist protection to their patented products through bilateral agreements with weaker nations, much to the disadvantage of the poor citizens who had minimal bargaining powers. These came to be known as TRIPS Plus agreements.[55]

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[52] INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS, 993 U.N.T.S. 3 (entered into force 3 January 1976), G.A. Res. 2200 (XXI), 21 U.N. GAOR Supp. (No. 16), U.N. Doc. A/6316 (1966), Art. 15, https://www.ohchr.org/en/professionalinterest/December 16, 1966pages/cescr.aspx.

[53] *See* National Research Council, Bits of Power: Issues in Global Access to Scientific Data, (1997), https://doi.org/10.17226/5504.

[54] *See* HENNING GROSSE RUSE-KHAN, THE PROTECTION OF INTELLECTUAL PROPERTY IN INTERNATIONAL LAW, (reprint ed., 2016).

[55] Christine Haight Farley, *Trips-Plus Trade and Investment Agreements: Why More May Be Less for Economic Development*, Law Reviews & Other Academic Journals Scholarship & Research: Washington College of Law Research Paper No. 2014-22, 35(101) U. PA. J. INT'L L. (2014), http://digitalcommons.wcl.american.edu/facsch_lawrev.

Such TRIPS Plus provisions of bilateral trade/ investment agreements demanded patent rights for new uses of known drugs, prohibition on pre-grant patent opposition, enforcing 'test-data exclusivity' periods when drug regulatory authorities would be prohibited from using clinical trial data of patented drugs that was so far used for approval of generic drugs, 'patent term extensions' to compensate for delays in granting patent, 'patent linkage' which would bar any regulatory approval process of generic medicines without consent of patent holder, imposing limitations on compulsory licenses and parallel imports and enhanced obligations on enforcement measures beyond that contemplated in TRIPS Agreement.[56]

Thus, developing and economically challenged countries found themselves at the receiving end of strict one-sided pharmaceutical patent deals far worse than they bargained for when they joined the TRIPS Agreement with high hopes of gaining some foothold in the markets of developed countries.

VII. PHARMACEUTICAL PATENTS: AN IMMINENT IMPEDIMENT TO RIGHT TO HEALTH

The desperation felt by the developing and the underdeveloped nations, mainly in Asia, Africa and South America was largely compounded by the devastation by the HIV/ AIDS pandemic and other widespread communicable diseases like malaria, tuberculosis etc., that piled up the ever increasing death toll in these countries, as well as posed a considerable drain in their material resources.[57]

The patent regime advocated by TRIPS agreement contributed to this challenge and further worsened it. For example, as the generic versions of first generation anti- HIV drugs exhausted their patent protection, their price fell within the reach of the Third World countries, but by that time the second line drugs have been invented which were effective against those viral strains that had developed resistance to first generation drugs. But these being patent protected were beyond the means of the poor countries, and the only option

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[56] United Nations Secretary-General's High-Level Panel Report, November 2015, *Access to Medicines: Promoting Innovations and Access to Health Technologies*, 24-25, (Sep. 2016), [Hereinafter Access to Medicines], http://www.politico.eu/wp-content/uploads/2016/09/HLP-Report-FINAL-Sept-2016.pdf.

[57] Gargi Rajvanshi & Rajeev Gupta, *Intellectual Property Rights Vs. Human Rights: A need to re-examine the relationship between two to enhance social being*, SSRN, (2011), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1887024; Laurence R. Helfer, Supra 11, 47.

for these hapless victims it seemed, were to perish *en masse* until the patents expire on these life-saving second generation drugs so as to make them affordable to the teeming millions.[58]

It fell to the respective states in isolation or following the path of other states, as well as the international bodies to pay heed and resolve to find an end to this atrocious situation. Not only the health but the life of millions were at stake, and the very question as to the utility of according patents was revisited. But this required a robust human rights agenda backed by a responsible state power that would withstand the increasing influence of private investors (backed by their own parent industrialised nation(s), to discharge its model duties as a welfare state. It seemed the lesser developed states were less inclined to stand up for their own people towards the end of the century, and it seemed they had to surrender to the intellectual property regime that had economic agenda as their primary consideration.[59]

Towards the turn of the century, even though about hundred and forty countries were signatories of the ICESCR, Human Rights hardly factored into their policy considerations when dealing with IPR issues. Human Rights advocates had to reorient themselves with science and technology and intellectual property issues.[60] Even the obligatory "list of essential drugs" as mandated by the World Health Organization (WHO) was too meagre to cater to the needs of the whole world. The list of essential drugs was hardly ever updated to meet the ever evolving needs of universal health and even then only a small fraction of those drugs contained patented medicines.[61]Thus existing national and international policy making was completely unsuited to anticipate and redress the clear and present threat to humanity posed by restrictive conditions of pharmaceutical patents on use of lifesaving drugs.

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[58] Joseph Millum, *Are Pharmaceutical Patents Protected By Human Rights?* 34(11) J MED ETHICS. e25 (2008).
[59] Audrey R. Chapman, *supra* note 12.
[60] *Id.*
[61] Laurence R. Helfer & Graeme W. Austin, *supra* note 17 at 129.

VIII. COMPULSORY LICENSING AND DOHA DECLARATION - THE HUMAN RIGHTS ANSWER?

The member states of international human rights and intellectual property regimes had to face the writing on the wall -- some solution had to be adopted to mitigate the disastrous consequence of this North – South intellectual property divide that denied life saving measures to those millions who needed them the most.[62]

Hence, the U.N. Committee on Economic, Social and Cultural Rights under the aegis of the ICESCR, revisited the issue of intellectual property regimes vis-à-vis human rights, and issued a General Comment in 2005,[63] that viewed intellectual property rights through a new prism. It established the primacy of human rights, which were attributed as fundamental inalienable entitlements bestowed upon humans, right from the moment of their existence on the face of the earth. Intellectual property rights were relegated subservient to human rights, as products of legal statutes that may be awarded, restricted in time and scope, traded, modified and even surrendered or withdrawn, just akin to tangible property. This rekindled the debate about the scope and extent of property rights that was the core of the dispute between the capitalist and socialist blocs in the post-World War II era.[64]

At about the same time, the United Nations' Special Rapporteur on Right to Health, identified in its report on 2004 about the detriments of the strict drug patent regimes of TRIPS agreement and the scope and limitations of compulsory licensing systems, as outlined subsequently.[65]

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[62] Rafik Bawa, *supra* note 48.

[63] UNITED NATIONS COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS, General Comment No. 17 (2005), E/C.12/GC/1712 GE.06 -40060 (E) 020206 (Jan., 2006), I. INTRODUCTION AND BASIC PREMISES, http://docstore.ohchr.org/SelfServices/FilesHandler.ashx?enc=4slQ6QSmlBEDzFEovLCuW1a0Szab0oXTdImnsJZZVQcMZjyZlUmZS43h49u0CNAuJIjwgfzCL8JQ1SHYTZH6jsZteqZOpBtECZh96hyNh%2F%2FHW6g3fYyiDXsSgaAmIP%2BP.

[64] Joseph Millum, *supra* note 58.

[65] Paul Hunt, *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, United Nations Special Rapporteur, Report to U.N. General Assembly, U.N. Doc. A/59/422 (16 Feb. 16, 2004) https://documents-dds-ny.un.org/doc/UNDOC/GEN/G04/109/33/PDF/G0410933.pdf?OpenElement; Laurence R. Helfer & Graeme W. Austin, Supra 17.

Developing nations encountered this patent barrier with the policy of compulsory licensing. They sought to stretch the exigent provisions entailed in the TRIPS agreement (Article 31)[66] regarding compulsory licensing of life saving drugs, to extricate their vulnerable and ailing populace from the pincer grip of product patents and punitive sanctions.[67] Countries like India, Brazil, South Africa and Thailand etc. which were able to erect sufficient indigenous infrastructure needed to manufacture patented essential drugs, extended statutory protection to entities who could produce cheaper and affordable versions of those drugs, thereby bypassing the monopolistic drug pricing of the multinational pharmaceutical giants.[68]

Despite the protests and litigations by the patent owning pharmaceuticals and the looming threat of punitive sanction, the licensing process prevailed, mostly because of steadfast government policies and overwhelming pressure from the public and civil society worldwide. However even though the multinational pharmaceutical companies had to settle for only miniscule remuneration as licensing fees compared to their sky-high drug pricing, they wielded the threat of withdrawing patented drugs from the market as a retaliatory measure.[69] This would potentially deny patients any access to innovative medicines for which no generic version exists.[70] In addition threats of "isolation from the global biotechnology investment community" loomed large.[71]

However compulsory licensing had two limitations. Firstly, the provisions for compulsory licensing of patented drugs only extended to domestic use.[72] This provided no redress to those least developed nations, who lacked the wherewithal to manufacture patented life-saving drugs and were at the mercy of the patent-holders. Ironically, the countries of sub-Saharan Africa, fell into this group, who were the very countries in dire need of relief from the HIV/ AIDS pandemic. Secondly, compulsory licensing could provide relief to

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[66] AGREEMENT OF TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, WTO, (Apr. 15, 1994), Annex 1C of the Marrakesh Agreement, 333, Art. 31, [Hereinafter TRIPS], https://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

[67] TRIPS and Health: Frequently Asked Question, Compulsory licensing of pharmaceuticals and TRIPS, WTO (2018), https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.

[68] *Trade topics: Doha agenda, The Doha Declaration explained*, WTO (2018), https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm.

[69] Laurence R. Helfer & Graeme W. Austin, *supra* note 17 at 121; *See* Cynthia M. Ho, *A New World Order for Addressing Patent Rights and Public Health*, 82, CHI.-KENT L. REV. 1501 (2007).

[70] Access to Medicines, *supra* note 56 at 24.

[71] *Id.*

[72] TRIPS, *supra* note 66, (Article 31*f* of TRIPS Agreement quotes "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use").

developing nations only in treatment of those diseases which attracted enough research investments in the industrial world so as to result in meaningful innovations in effective medicines. Such diseases are those which mostly occur in less developed countries, yet have some prevalence in the developed world, so as to have a sufficient market to warrant innovative research. But severely neglected diseases, like African sleeping sickness and other parasitic infections which overwhelmingly occur in poorer countries, do not attract any research interest by profit driven drug research institutions. Innovations had come to standstill in those fields and no amount of compulsory licensing can address the amelioration of those diseases.[73]

Hence any revisionist approach to reconcile the human rights issues of intellectual property regimes had to come from within the international intellectual property system. Member states of the WTO/ WIPO were not idle either. The period from the turn of the new millennium witnessed serious activities spearheaded by developing countries. The first expression of the backlash against the strict TRIPS regime and the terrible TRIPS Plus negotiations was evident in the Doha (Ministerial) Declaration on TRIPS and Public Health, adopted by the WTO membership in 2001.[74]

This Declaration advocated to further the cause of compulsory licensing for poor countries, who possessed the capacity of manufacturing patented drugs in lieu of minimal royalties, and even to circumvent the need for compulsory licensing in case of least developed countries (LDCs) with such capabilities. It also promoted a differential standard of strength of patent protection system for countries with differing economic standards, thereby extending deadlines of LDCs to comply with patent regimes at a future date until they are able to shore up their economic resources. Thus, such countries would be spared from enforcing patent protection to lifesaving medicines for the time being.[75]

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[73] Laurence R. Helfer & Graeme W. Austin, *supra* note 17.

[74] DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, WT/MIN(01)/DEC/2 (Nov., 2001), ¶6, [Hereinafter WT/MIN(01)/DEC/2], https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

[75] Alan O. Sykes, *TRIPs, Pharmaceuticals, Developing Countries, and the Doha "Solution"*, John M. Olin Law & Economic Working Paper No. 140: 2D Series, Chicago, (2002), http://papers.ssrn.com/abstract=300834; *THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, ESSENTIAL MEDICINES AND HEALTH PRODUCTS, WTO publication No. WT/MIN(01)/DEC/W/2*, WORLD HEALTH ORGANIZATION (2001), http://www.who.int/medicines/areas/policy/doha_declaration/en/.

It also led to permissive attitude towards "parallel imports" of essential life-saving drugs to LDCs who were not competent for indigenous manufacture of patented drugs. The principle of parallel imports is intricately linked to the doctrine of territoriality. Parallel import allows importing of patented products to a country from another country, where the product has already been legally sold or manufactured with the consent of the patent holder. This then raises the question as to whether patent rights are exhausted at the international, regional or national level. Again, as per exhaustion principle the patent holder would lose any right in any material containing their patented product, once they have sold the product or licensed it in lieu of some remuneration. But differential pricing of the same product in different countries would then interfere with their right of exploitation of the patent according to the principle of territoriality.[76]

Thus, a concerted endeavor spearheaded by developing countries and bolstered by LDCs found strength in numbers at the multilateral trade and intellectual property fora and gradually progressed in tilting the overall mindset of IP regimes away from a solely market driven profit-making angle towards a socially beneficent perspective.

IX. PARALLEL IMPORTS IN PHARMACEUTICAL PATENTS: CHALLENGES TO DOHA

In case of pharmaceutical patents, the permissiveness to parallel imports faced a new challenge in view of the granting of compulsory licenses on patented drugs. The TRIPS agreement (provisions of Article 31*f*) allows compulsory licenses on patented medicines in exigent circumstances, only for domestic consumptions, and forbids export of low-priced versions of patented drugs, to prevent undercutting the market of the patent holder in other countries. But withdrawing this export barrier would be a boon to solve the problems faced by LDCs who cannot manufacture essential drugs themselves, as outlined previously. Cheaper versions of patented essential drugs would enable their people to afford and have access to such medicines, bypassing the exorbitant prices demanded by the patent holders. The WTO Ministerial Doha Declaration, endeavoured to bring parallel imports to the

[76] Alan O. Sykes, *TRIPs, Pharmaceuticals, Developing Countries, and the Doha "Solution"*, John M. Olin Law & Economic Working Paper No. 140: 2D Series, Chicago, Vol 19, (2002), http://papers.ssrn.com/abstract=300834.

mainstream of drug supply to these underdeveloped states.[77] Not only were member states with ability to manufacture medicines allowed to export cheap generic versions of patented medicines to LDCs, i.e. the Article 31 (TRIPS Agreement) restrictions to domestic use were waived; the recipient LDCs were exempt from paying licensing fees to the patent holders with the manufacturing states bearing the cost of those royalties.[78] The condition that compulsory licenses were permissible only in case of emergency situations was effectively waived as LDCs had the discretion to determine the grounds to issue compulsory licenses.[79]

However, even this attempt was fraught with various hurdles in its implementation. Differently situated LDCs would take advantage of the parallel import mechanism, and negotiate a lower price from a non-patent holding vendor.[80] Developing Patent – licensing system systems for the sole purpose of export of cheap priced drugs, posed a complication in itself, requiring overcoming the pharmaceutical lobbies.[81] Past sanctions and bilateral or TRIPS Plus deals have dissuaded developing countries to confront patent holders.[82] The onus of remunerating the patent holder being shouldered by the exporting country discouraged such drug licensing-export ventures.[83] Even though Human Rights groups championed the Doha Declaration, the same did not possess the strength of TRIPS agreement itself and was, at the most, considered soft laws.[84]

This was further evident from the fact, that even in 2008, consignments of cheaper versions of essential drugs from Indian pharmaceutical firms were seized as counterfeit materials, en route to their destinations at needy LDCs, during trans-shipment at European ports.[85] The general picture was so dismal that even fourteen years after the Doha Ministerial Declaration, as late as in in 2015, the Report of the UN Special Rapporteur addressing "the implications

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[77] Laurence R. Helfer & Graeme W. Austin, *supra* note 17.

[78] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, ¶3, WT/L/540 and Corr.1, (September 1, 2003). (Decision of the General Council of 30 August 2003), https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

[79] Access to Medicines, *supra* note 56.

[80] Alan O. Sykes, *supra* note 76 at 19,20.

[81] Laurence R. Helfer & Graeme W. Austin, *supra* note 17 at 124; Katri Paas, *Compulsory licensing under the TRIPS Agreement – a cruel taunt for developing countries?*, 31(12) E.I.P.R. 612-613 (2009).

[82] Laurence R. Helfer & Graeme W. Austin, *supra* note 17 at 124.

[83] Supra note 81.

[84] Alan O. Sykes, *supra* note 76 at 24.

[85] John W. Miller & Geeta Anand, *India Prepares EU Trade Complaint*, WALL ST. J., (Aug. 6, 2009); Nirmalya Syam, *Seizures of Drugs in Transit: Why Europe's Law and Actions Are Wrong*, 3 SOUTH BULLETIN (Sept. 22, 2009); Laurence R. Helfer & Graeme W. Austin, *supra* note 17; Paul Hunt, *supra* note 65 at 22.

of patent policy for the human right to science and culture"[86] stated that: "According to the Global Commission on HIV and the Law, current international intellectual property laws have failed to promote innovation to treat diseases that primarily affect low- and middle-income countries."[87] The Doha Ministerial Declaration had to negotiate such an array of minefields that it was only in the beginning of 2017[88] that the agreed-upon amendment to TRIPS agreement in the form of Article 31*bis* of TRIPS agreement of 2005[89] ultimately became ratified and adopted by the required two-thirds of WTO member states.[90]

The tussle to etch out human rights on the landscape of pharmaceutical patent regimes was not an easy fought one and developing and least developed countries had to overcome many an obstacle to secure a foothold in this multilateral intellectual property arena.

X. COMPETING INTERESTS – TIPPING THE BALANCE

As the member states on either side of the North-South divide continued in their adversarial posturing, of late the political situation looked seemingly favourable towards diverting the schema of WIPO, from further strengthening and expanding intellectual rights, towards a "Development Agenda" aimed at taking into consideration various stakeholders in the intellectual property regime, promotion of technology transfer and more equitable sharing of benefits arising from game changing innovations.[91] Perhaps, even though not explicit, this Development Agenda (2007) can be construed to encompass right to health and access to medicines while formulating policy making on patents in medicines.[92] This is perhaps most palpable, in the ways developing countries have asserted their rights to extend incremental access to patented medicines, despite resistance from multinational corporates.[93]

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[86] Farida Shaheed, *Report of the Special Rapporteur in the field of cultural rights*, 2 U.N. DOC. A/70/279, GENERAL ASSEMBLY, (Aug. 2015), http://ap.ohchr.org/documents/alldocs.aspx?doc_id=25540.
[87] Id., at 14.
[88] WTO, *WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicine*, WTO 2017 NEWS ITEMS: TRIP, (Jan. 23, 2017), https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm.
[89] Amendment of the TRIPS Agreement, Annex to the Protocol Amending the TRIPS Agreement, Art. 31bis, ¶1-2, WT/L/641 (Dec. 8, 2005). (Decision of 6 December 2005), https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.
[90] AMENDMENT OF THE TRIPS AGREEMENT, INTELLECTUAL PROPERTY: TRIPS AND PUBLIC HEALTH, https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.
[91] John W. Miller & Geeta Anand, *supra* note 85.
[92] Laurence R. Helfer & Graeme W. Austin, *supra* note 17at 126.
[93] John W. Miller & Geeta Anand, *supra* note 85; Laurence R. Helfer, *Regime Shifting in the International Intellectual Property System*, 7(1) PERSPECT. POLITICS., 41 (Mar., 2009).

The downside is the burning question as to, at what point the investment in innovations, especially in the field of path-breaking innovations in pharmaceutical industry, would suffer, consequent to diminishing returns to the profit driven private enterprises. Market dynamics may hold the answer to lowering of drug prices, as lesser investment would be required by outsourcing and technology transfer to developing countries. Also, in order to bypass the concerted opposition by advocates of Human Rights in sympathetic fora like WHO, Food and Agriculture Organization (FAO) and Convention on Biological Diversity (CBD), industrialized patent- rich states have taken to sidestep the WIPO/ WIPO/TRIPS regime of protecting their intellectual properties through bilateral and regional trade and investment treaties, many containing TRIPS Plus norms.[94] In lieu of expanded market access and foreign investment, these countries demand more stringent adherence to protection of intellectual property, far exceeding the most protective multilateral agreements.[95]

Many have tried to misuse the existing patent rules, by making minimalistic modifications of patented medicines, to extend the duration of protection, by artificially creating innovativeness in the endeavour to perpetuate extraction of exclusive benefits from their patents. The case of *Novartis* raised this issue before the Hon'ble Supreme Court of India, in which the patent holder tried to extend patent protection to an anti-cancer drug, by claiming that the modified end-product was better absorbed into the body.[96] Delving into the facts of this case, the pharmaceutical giant had patented the drug *imatinib* (parent drug) and also its subsequent derivative *imatinib mesylate*. They subsequently sought patent on their newly invented beta-crystalline form of *imatinib mesylate* (derivative of mesylate salt) shrewdly claiming improvement in bio-availability (proportion of administered drug reaching the target organ) over the *mesylate* (first derivative) salt, but factually disclosing improvement over the parent drug only. This landmark decision elaborated on Section 3(d) of the Indian Patent Act of 1970[97] choosing to grant such a privilege of patent protection to any such technical improvement shown by a new drug only if it demonstrates increased therapeutic

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[94] *Id.*

[95] Laurence R. Helfer & Graeme W. Austin, *supra* note 17 at 125; Humphrey et al, Unit 10.3, UDHR, Supra 15, 976; Frederick M. Abbott & Jerome H. Reichman, *Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions*, 10 J. INT ' L ECON, L . 921, 963 (2007).

[96] L Novartis AG v. Union of India (UOI) & Ors.; Natco Pharma Ltd. v. UoI & Ors.; M/S Cancer Patients Aid Association v. UoI & Ors., Decided on Apr. 1 2013, Civil Appeal No. 2706-2716 (2013).

[97] The Patent Act, 1970, §3(d), http://ipindia.nic.in/writereaddata/Portal/ev/sections/ps3.html.

efficacy over the prior art, and put an end to the attempts of pharmaceutical companies in 'evergreening' their products, i.e. securing patents on minimal incremental improvements of patented drugs, taking advantage of a patent system that sets a low bar for inventive step.[98]

The dismissal of this infringement suit brought by Novartis allowed cheaper generic versions of the beta-crystalline form of *imatinib mesylate* to be available to needy cancer patients in India. This demonstrated that even the established IP regime could be used to ensure affordable innovative drugs to developing countries.

To summarize, it ultimately boiled down to safeguarding the self-interests of predominantly innovation-creating and predominantly innovation-consuming states by exploiting the leeway and nuances in multilateral agreements to their own advantage, based on their fortitude and relative bargaining power in the marketplace.

CONCLUSION

Pharmaceutical patents have reignited the jurisprudential debate between Intellectual Property Rights and Human Rights. Whereas traditional human rights issues encompassed Civil and Political Rights to eradicate the most egregious actions of oppressors; these were primarily related to negative liberties, to force the state powers to refrain from actions that infringe inviolable human rights. Advocacy related to Economic, Social, and Cultural Rights are more controversial and more difficult to implement. Achieving these goals entail taking affirmative steps, which poses different challenges when placed before countries with dissimilar cultural background and socio-economic standing, requiring weighing of costs and benefits and policy consideration about competing rights. This has been never more relevant

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[98] Shamnad Basheer & Prashant Reddy, *The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5(20), *SCRIPTED*, (Aug., 2008), http://ssrn.com/abstract=1086254; Novartis AG v. Union of India & Others, Natco Pharma Ltd v. Union of India & Others, M/S Cancer patients Aid Association v. Union of India & Others, A.I.R. 2013 S.C. 1311 (India), at 94-96 (per Aftab Alam, J) ("189. (T)he positions that emerges is that just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. Whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data. …192. Section 2(1)(j) defines "invention" to mean, "a new product or…", but the new product in chemicals and especially pharmaceuticals may not necessarily mean something altogether new or completely unfamiliar or strange or not existing before. It may mean something "different from a recent previous" or "one regarded as better than what went before" or "in addition to another or others of the same kind". However, in case of chemicals and especially pharmaceuticals if the product for which patent protection is claimed is a new form of a known substance with known efficacy, then the subject product must pass, in addition to clauses (j) and (ja) of section 2(1), the test of enhanced efficacy as provided in section 3(d) read with its explanation."), https://sci.gov.in/jonew/judis/40212.pdf.

than in its implication on protection of Intellectual Property Rights of pharmaceutical patents and ensuring the Right to Health as a Fundamental Right. Even the UN led General Comment no 17 on ICESCR could not fully reconcile its stand on primacy of human rights over intellectual property rights, and its acknowledgement of the justifiable material interests of authors to enable them to maintain an enjoyable living.[99] The national entities on either side of the North – South divide have used intellectual property rights and human rights in one way or other, to adapt to emerging situations in this arena of international relations related to these two pathways, which though began with different objectives, were destined to face each other. Only time will tell as to whether this will result in further confrontation or conciliation.

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[99] Rochelle Cooper Dreyfuss, *supra* note 22 at 12.