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GENERIC MEDICINES, PATENTING OF PHARMACEUTICAL INVENTION AND ACCESS TO MEDICINE IN INDIA: A CRITIQUE

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ABSTRACT

In the pharmaceutical industry, firms normally invest hundreds of millions of dollars in R & D and clinical trials on their drugs before it is sold in the market, while their generic medicine rivals are exempted from those requirements and enter the market at low cost with nominal investments. Developed countries medicine companies argue why generic drugs manufacturer should be permitted to reap fruits of patented medicine. However, generic drug manufacturers are of the opinion that big pharmaceutical houses are indulged in unfair practice and they are trying to get extra duration through evergreening patent. The basic formula of the compound is already known, and persons with ordinary skill and knowledge in the art can easily obtain the new crystalline form through general and routine operations. Hence, there is nothing novel to the development of a new crystalline form; instead, it should be manufacturer as a "discovery" of a natural substance, not as an "invention" that can be protected under patent law. Considering the global importance and political-economic stakes involved thereto this paper is an attempt to find out ways for maintaining balance between the Indian Biotech industry, global economic players and government liability to society.

Keywords: Generic Drugs, Evergreening Patent, Access to Medicine, TRIPs Plus, Compulsory Licence, Bolar Principle, Public Interest, and Brand Name Drug

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1. INTRODUCTION

Health laws, national pharmaceutical policy and the patent system are intensely interrelated.[1] None of these laws and policies should be framed or implemented in isolation of the other.[2] It is alleged by the US and European pharma Industry that India lacks an effective umbrella public health system where everybody rights to treatment can be

[1] The Patents Act 1970 is illustrative statutes which clearly lays down under section 3 that any invention which is prejudice to human, animal or plant life or health is non patentable. Further section 47(4) empowers central Government in granting of patent to exercise right of import of medicine or drugs for its own use or for the use of Hospital. Moreover, Drugs Control Order Act and National Pharmaceutical Policy represents the stands of government obligation towards society.

[2] WHO, *TRIPs- IMPACT ON HEALTH AND PHARMACEUTICALS* 4 (Regional Consultation on WTO Multilateral Trade Agreements and Their Implications on Health-TRIPs, Bangkok, 1999).

ensured.[3] Moreover, the gap of prices of generic and patented curative drugs is very big. Since it is market driven and brand oriented society, hence even majority of doctors also promote and protect interest of branded and patented medicine owners.[4] However, it is highly impractical to expect that physicians will individually protect and promote public health when patent rights of pharmaceutical companies conflict with others interest.[5] Even the requirement of product and process patent both in the legal system of all the signatories of the TRIPs agreement has generated substantial controversy across the world from the very beginning of the WTO system.[6]

It is alleged that in the pharmaceutical industry, firms normally invest hundreds of millions of dollars in R & D and clinical trials on their drugs before it is sold in the market, while their generic medicine[7] rivals are exempted from those requirements and enter the market at low cost with nominal investments. Therefore, pharmaceutical companies generally claim that it is impossible to recoup their R&D investments and they face competition with dishonest players.[8]

This could be understood by the fact that Shantha Biotechnics is credited for developing India's first recombinant DNA product, 'Shanvac-B', a Hepatitis B vaccine. Shantha has been granted an Indian patent. However, the same is sold by a number of Indian competitors by application of its pegylation process for this protein.[9] Then a question arose why others should be permitted to reap fruits of Shanta Biotechnics?

There is an urgent need of makeover in policy framing and its implementation. Considering the global importance and political-economic stakes involved thereto this paper is an attempt to find out ways for maintaining balance between the Indian Biotech industry, global economic players and government liability to society. The present research paper is an attempt to identify the solution for the conflict of Pharama R&D investors and human right to health. An attempt is also made to understand the factors which lead to growth of generic industry and how could we mange the interest of economy and health together.

2. BACKGROUND

In India players of generic medicine has a toll claim in favour of their existence and demand for institutional support on the ground of their contribution.[10] Today, generic medicines play an essential role in treating disease by increasing the accessibility and affordability of modern day pharmaceuticals in global healthcare systems.[11] Currently over half of the volume of medicines are supplied as generics medicines but this represents just 18% in value terms.[12] Generic medicines are typically sold at a substantial discount to brand-name medicines, often 80 to 85% less. This is because

[3] Deepika Jain, "Regulation of Digital Healthcare in India: Ethical and Legal Challenges" *Healthcare (Basel).* 2023 Mar 21;11(6):911.

[4] *See,* GL Singal, A. Nanda, & A. Kotwani, "A comparative evaluation of price and quality of some branded versus branded-generic medicines of the same manufacturer in India", *Indian J Pharmacol*. 2011 Apr;43(2):131-6. In their study they submitted that retailer margin for five *branded* medicines were in the range of 25-30% but for their *branded-generic*s version manufactured by the same company it was in the range of 201-016%. Difference in price-to-patient was not as huge as it is expected for generics but margins for retailer were very high for *branded-generic*s.

[5] A.S. Kesselheim, and J. Avorn, "Biomedical Patents and the Public Health.: Is there A Role for Eminent Domain**?",** 8(6) *Ethics Journal of the American Medical Association* 387-391(2006).

[6] USTR launched investigations (under Section 301 of the Trade Act) into the failure of countries to provide adequate IP protection to pharmaceutical products in Brazil (1987), Argentina (1988) and Thailand (1991)., available at http://www.ustr.gov/html/act301.htm#301_52, (Visited on March 23, 2010).

[7] A generic drug is a pharmaceutical product usually intended to be interchangeable with the original patented drug ("bioequivalent") because it does the same thing. Unless there is a prior agreement with the patent owner, a generic drug is usually made and marketed after the expiry of patent rights held by the patentee. A generic drug is marketed either under a non-proprietary or approved name rather than a proprietary or brand name.

A generic drug is an identical copy (bioequivalent) of a brand name (or proprietary) drug. Generics are exactly the same as their branded counterparts in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. The notable difference between the two is the price

[8] *Id.* at 508.

[9] Shantha Biotechnics Ltd., "Research & Development: Therapeutic Proteins", available at: http://www.shanthabiotech.com/focus_areas_prodsegment.htm (Visited on March 29, 2009).

[10] *See*, SS Joshi, YC Shetty & S. Karande, "Generic drugs - The Indian scenario", *J Postgrad Med*. 2019 Apr-Jun;65(2):67-69.

[11] Alan Sheppard, "Generic Medicines: Essential contributors to the long-term health of society, Sector Sustainability Challenges in Europe" IMS Health, London. (2010) p. 1.

[12] ALAN *Ibid*.

generic medicines don't need to repeat the animal and clinical studies that brand-name medicines require to demonstrate safety and effectiveness.[13] The long-term sustainability of the generic medicines sector relies on fair prices and a level playing field.[14] It is argued that this increases the uptake of these drugs and potentially it may generate long-term savings through the use of a safe and effective therapy at an affordable price.

In developing countries, cost of pharmaceutical products as an important concern because mostly poor people in developing countries pay for their own drugs, and state provision is normally selective and resource-constrained.[15] We need to understand that in developing countries and least developed countries consumer financial conditions are not good and government support for health sector is still not inadequate.[16] At its worst, it causes actual harm. Despite the urgency of improving health in developing countries, quality of care has been largely ignored.[17] Hence, where appropriate treatments exist, access to them depends on affordability, meaning thereby the prices are needs to set on the basis of average consumer purchasing capacity and the availability of the health service infrastructure to support delivery.[18] This is generally not the case in the developed world where costs are mainly met by the state or through insurance schemes. Moreover, the cost of drugs is a controversial and political issue in developing countries, for patients are not covered by effective state or insurance schemes.[19] In developing countries, inadequacy of the infrastructure is an important problem, and may mean that even inexpensive medicines are not used or that they may be misused and contribute to the emergence of drug-resistant pathogens or a virus.[20]

Moreover, in majority of developing countries there is a prejudice opinion prevails against the owner of patented pharmaceutical drugs and it is argued that the Pharmaceutical research by the private sector is driven by commercial considerations and if the effective demand in terms of market size is small, even for the most common diseases such as TB and malaria, it is often not commercially worthwhile to devote significant resources to addressing the needs.[21] Even it is suggested that in many pharmaceutical companies, research objectives are set by reference to threshold returns. There is need to redefine the policies as set by WHO and pharmaceutical companies R&D should be guided as per the country specific need. But this may happen if government initiatives ensure that the potential outcome is a product with annual sales and market. Since the private companies have to be primarily responsible to their shareholders, certainly this leads to a research agenda led by the market demand rather than by the needs of poor people in the developing world. Regardless of the intellectual property regime prevailing in developing countries, in reality there is little commercial incentive for the private sector to undertake research of specific relevance to the majority of poor people living in low-income countries.[22] The Indian health system has also not been effective in its response to health crises and emergencies, nor has it demonstrated close engagement with different stakeholders working in the area.[23]

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[13] *See, 2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report*, Securing Our Access & Savings-Association for Accessible Medicine. https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf

[14] ALAN *Ibid*.

[15] B.K. Keayala, WHO Paper entitled TRIPS- IMPACT ON HEALTH AND PHARMACEUTICALS, tries to depict that in India Prices of Medicines are comparatively low for there was no product patent for medicines under old laws.

[16] JW Peabody et al. Improving the Quality of Care in Developing Countries. In: Jamison DT, Breman JG, Measham AR, et al., editors. Disease Control Priorities in Developing Countries. 2nd edition. Washington (DC): The International Bank for Reconstruction and Development / The World Bank; 2006. Chapter 70. https://www.ncbi.nlm.nih.gov/books/NBK11790.

[17] *Ibid.*

[18] Patents are used to restrict competition and sustain prices higher than would be available in a competitive market. On a static economic basis, the introduction of pharmaceutical patent protection in countries where such protection formerly was not available will (a) redirect production and sales from generic producers to on-patent producers (b) increase prices of pharmaceuticals to consumers, and (c) result in transfers of patent rents to OECD-based producers.

[19] "Courting Trouble", *The Economist*, 8 June 2002 in CIPR 30 (2004)., available at: http://www.economist.com/.

[20] J.A. Ayukekbong, et al. "The threat of antimicrobial resistance in developing countries: causes and control strategies", *Antimicrob Resist Infect Control* **6**, 47 (2017).

[21] Medicines sans Frontier, "Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases", MSF, Brussels, 16 (2001). Available at: http://www.msf.org/source/access/2001/fatal/fatal.pdf, (Visited on March 23, 2010).

[22] B, Tenni et al., "What is the impact of intellectual property rules on access to medicines? A systematic review" *Global Health* 2022 Apr 15;18(1):40.

[23] Sakthivel Selvaraj at.al, *India health system review*. New Delhi: World Health Organization, Regional Office for South-East Asia; 2022, P. 54.

2.1. EVOLUTION OF STATUTORY INITIATIVES

Indian Patent Act of 1911 had a product patent system even for pharmaceuticals. When India enacted Patent Act of 1970 it was submitted before the drafting committee that due to product patent pharmaceutical product prices are very high. Since India has a constitutional duty to ensure access to medicine to every citizen of India; drafting committee has decided to done away with product patent. Section 5 of old Patent Act 1970 restricted the scope of patent in cases of invention related with pharmaceutical, chemical and food by process patent only. As there was no product patent system in pharmaceutical sector between 1970 and 2005, many Indian drug producers copied expensive original preparations by foreign firms and produced these generics by means of alternative production procedures. This proved more cost-efficient than the expensive development of original preparations as no funds were required for research, which contained the financial risks.[24] Government of India protective system for pharmaceutical has converted Indian pharmaceutical Industry as generic drug manufacturer who is blamed to take unfair advantages of Others R&D.Post 1970 market share and growth of pharmaceutical sector has made Indian companies as a lead player in global market.[25]

2.2. CURRENT STATUTORY FRAMEWORK

Until 2005 Indian patent system lacked the opportunity for product patent protection. Many developed countries and pharma-companies questioned the Indian patent regime and blamed economic incentives for pharmaceutical innovation in India are largely not visible or were absent.[26] Even the global presence and the interference of Indian pharmaceutical players were cause of irritation for the major manufacturer of pharma countries. They got a light of hope through the TRIPs system which provides for process and product patent for all the technology under Article 27(1). Since it creates a system of mandatory compliance; no countries were left with any option. Consequently, India had amended its Patent Act thrice to make it in consistency with the TRIPs Agreement. From 1995 began the process of establishing a new patent regime in India. Also, the price controls were substantially relaxed. Though being a signatory to TRIPS agreement has resulted in recognition of product patents, the flexibilities in the agreement have given India an opportunity to interpret various clauses keeping the national interest in mind. The denial of patents to frivolous inventions, use of compulsory licensing, pre and post grant opposition, parallel imports, bolar exception and not allowing extension of patent period beyond twenty years are some of the safeguards against monopoly that India can exercise. Under section

3(d) of the Indian (amended) Patent Act, the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy or a new use of known substance or process is not to be treated as an invention. Similarly keeping the interest of patients, compulsory licences could be given under section 84(1) of the amended Act.

Eeven though there has been relaxation of drug price controls and provisions of the Indian product patent Act 2005 has made Indian market favourable to the launching of patented drugs, the foreign companies have not yet launched many of their patented products in India.

However, the recent change of government policy and market behaviour has again alarmed all the investors. In November 2006, Indian government officials proposed legislation to ensure that at least one-third of the licensing

[24] *Ibid*.

[25] Indian pharmaceuticals industry grew rapidly in the period 1970 to 1995 in a protective regime marked by process patenting (rather than product patenting) and a strict price regulation on a large number of drugs. This enabled the domestic industry to come up rapidly and achieve considerable technical competence. See, Bishwanath Goldar, et all., 'Effects of New Patents Regime on Consumers and Producers of Drugs/Medicines in India', Revised Report Submitted to the UNCTAD, Institute of Economic Growth University Enclave
University of Delhi, August 2010, p. 1.

[26] In the absence of strong VC support, one of the ways that the government is attempting to support start-up biotech businesses is through the creation of Special Economic Zones (SEZs) and biotechnology business parks. A biotech SEZ in Pune, India is the first of several such incubator parks envisioned by the Indian government

revenues obtained from intellectual property created in publicly-funded projects would be "passed on to an individual/team of scientists who created the patented product."[27]

3. DOMAIN OF CONFLICT

It is no doubt that Indian pharmaceutical manufacturer has made a notable presence in the global market especially its generic medicines have demand across the world. India's pharmaceutical exports have increased from $15.07 billion in 2013-14 to $27.85 billion in FY 2023-24.[28] India exports to around 200 countries and territories, with the top five destinations being the USA, Belgium, South Africa, the UK, and Brazil. India is the world's largest supplier of generic medicines, accounting for 20% of the global supply by volume. India produces over 60,000 generic drugs in 60 therapeutic categories.[29] In 2001, India's pharmaceutical industry became the focus of public debate when Cipla, the country's second-largest pharmaceuticals company, offered an AIDS drug to African countries for the price of US $ 300, while the same preparation cost US $ 12,000 in the US. This wide gap of price of Indian manufacturer and developed countries pharmaceutical companies' price has started a regime of direct conflict. This was possible because the Indian company produced an all-in one generic pill which contains all three substances required in the treatment of AIDS. This kind of production is much more difficult in other countries as the patents are held by three different companies.[30] This has led to global criticism of Indian patent policy and India has to face US litigation before WTO dispute settlement panel regarding its patent system.

4. THE TRIPS AGREEMENT, GENERIC DRUGS AND ACCESS TO MEDICINE

Before the International regime of the TRIPS Agreement was enforced many countries had the restricted process patents systems for pharmaceutical inventions. Since in some countries product patent was not granted and it had given statutory access to the process of patent to the rivals as licensee and they easily come with generic copies of those drugs. This often resulted in lower price of generic medicines in competition to the patented drugs. The TRIPS Agreement tries to partial control this by mandatory product and process patents system.[31] However, it still provides sufficient scope to the signatories to maintain balance between social and economic interest.[32] Here the question arose, does TRIPS leave options for increasing access to affordable medicines?

4.1. TRIPS AND ACCESS TO MEDICINE

The TRIPS agreement attempts to harmonise the system of IPR protection by introducing a minimum level of protection for every kind of technological inventions. It also tries to root out the differences in the manner by which IPR is protected around the world. The agreement provides that every new invention involving inventive steps and industrial applicability will get process as well as product patents except the exception given therein.[33] The Preamble of the

[27]"Biotech Policy Seeks Major Incentives for Scientists", *Economic Times* (INDIA), Nov. 26, 2006 available at: http://economictimes.indiatimes.com/articleshow/576519.cms.

[28] Ministry of Chemicals and Fertilizers, "INDIA: THE WORLD'S PHARMACY", Press Notes, 2024, https://www.pib.gov.in/PressNoteDetails.aspx?NoteId=152038&ModuleId=3&reg=3&lang=1.

[29] Raveesh malik, "Formulating success: The Indian pharmaceutical industry**",** *Investor India*, 2023. https://www.investindia.gov.in/sector/pharmaceuticals#:~:text=The%20nation%20is%20the%20largest,through%20the%20government%20approval%20route.

[30] *Id.* at 3.

[31] *Patents, International Trade Law and Access to Essential Medicines* - Revised, May 2002 p. nos. 2-3., available at: http://www.umich.edu/~spp638/Coursepack/ipr-msf.pdf.

[32] Article 7 of The TRIPS Agreement says the monopoly rights created by patents need to be balanced against other important interests. It says that protecting and enforcing intellectual property rights should contribute to promoting technological innovation and to the transfer and dissemination of technology. Furthermore, TRIPs says that this should be to the benefit of both producers and users of technological knowledge, and should occur "in a manner conducive to social and economic welfare, and to a balance of rights and obligations"

[33] Article 27(1) of The TRIPs Agreement 1995 read with Article 27(2), 27(3) (a) (b), and Article 7 and 8.

Prior to the Patent Amendment of 1999, 2002, 2005, not the substance itself but merely the manufacturing process was protected for a period of seven years. India's patent legislation had frequently been the reason for legal disputes with large western drug firms, especially from the US. In line with international standards, the sector is now subject to product and process patents valid for a period of 20 years. Indian companies seeking to copy drugs before the patent expires are forced to pay high licence fees.

agreement provides that all member countries would adopt minimum standard laid down therein. However, it stipulates enough scope for the member countries to uphold the policy objectives of their national systems. Moreover, it is envisaged in the objectives and principles of the TRIPs agreement that member country can frame or amend their patent system to ensure balance of rights and obligations.[34] The TRIPS Agreement also incorporates principles of public interest in sectors of vital interest and seeks promotion of those sectors.[35] It is worth noting that the TRIPS Agreement recognizes the rights of member states to take measures that are necessary to protect their interests, especially with respect to *public health and nutrition*.[36] Given these nuts and bolts, countries have considered that they have room for creating a domestic patent law tailored to their local needs.[37] A country may prevent the commercial exploitation of some inventions if "necessary" in order to protect human life and

health, by refusing to recognize their patent admissibility.[38] However, few things were not clear; such as what will be extent of domestic requirement? Secondly, in case of global pressure of economic interest whether civil rights will be given priority or economic interests. How to determine whether this is necessary action of state only to protect civil rights or it has ulterior motive to discriminate. Further, a country may include in its patent laws "limited exceptions" to the rights of a patent owner to exclude others from making, using, importing or selling an invention, taking into account the legitimate interests of others.[39] Moreover, article 6 of The TRIPS Agreement says that nothing in it prevents a country from allowing parallel imports. Meaning thereby if you are getting same medicines from other countries market on cheaper rate you could go ahead without violating The TRIPs. Further, The TRIPS Agreement does not limit the grounds on which governments or courts may issue compulsory licences.[40]

4.2. DOHA AND LIFE SAVING DRUGS

The feasibility of incorporating public health has been strengthened by the DOHA Ministerial Declaration 2001. The Doha Declaration promulgated a new strategy and stated that rendering services with regard to public health is the duty of every nation. It states that the TRIPs Agreement "does not and should not" prevent countries from taking measures to protect public health, and "can and should" be interpreted in a way that supports countries' rights to protect public health and, in particular, to promote access to medicines for all.[41] It concluded that the TRIPS Agreement does not prevent WTO Members taking measures aimed at the protection of public health.[42] The Declaration on TRIPs and Public Health agreed at Doha is an important step forward in the global campaign for affordable Medicine.[43] This in turn could help bring about real benefits in the health of poor women and men.[44]

Paragraph seven of the declaration instructed the TRIPS Council to allow least developed countries to defer introduction of patent protection for pharmaceutical products and protection of confidential test data until at least 2016. We can appreciate the intention behind this paragraph, but it also creates and highlights a number of anomalies. At least 70% of the population in LDCs are in countries that provide pharmaceutical patent protection, and 27 of the 30 LDCs in Africa also have patent protection. These countries perhaps required to amend their legislation to take advantage this

[34]Article 7, The TRIPs Agreements, The basic concepts laid down in this article are that the new regime should aim at balancing of rights and obligations for both producers and users of technological knowledge in a manner conducive to social and economic welfare.

[35] WHO TRIPS REGIONAL CONSULTATION, p. 1.

[36]Article 8 of the TRIPS Agreement declares that:

Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological de development, provided that such measures are consistent with the provisions of this Agreement.

[37] Michelangelo Temmerman, *The TRIPS Agreement, the Evergreening of Patents and Access to Medicines: Novartis v. India*, NCCR Trade Regulation, Working Paper No. 2008/16, available at: http://ssrn.com/abstract=1185282.

[38] The TRIPs Agreement (Article 27).

[39] The TRIPs Agreement Article 30.

[40] *See*, Article 31 of the TRIPs Agreement.

[41] World Trade Organization, Ministerial Declaration of 20 November 2001, 4, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002), *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (refer to paragraph 4).

[42] The Doha Declaration was a response to the AIDS/HIV crisis by allowing compulsory licences for the production of pharmaceuticals meant for export to countries that do not have the necessary infrastructure to produce them; an action which previously was illegal under the TRIPS Agreement. In India, this possibility has been implemented by Section 92A of the 1970 Patents Act as Amended by Section 55 of the 2005 Patents Amendment Act.

[43] TRIPs and Public Health: The Next Battle, Oxfam Breifing Paper, 2002.

[44] *Ibid.*

extension. It may well be in their interest to do so in view of the length of the extension granted. However, amendments to legislation may not be retrospective and thus current patents would remain valid[45] unless and until things are given retrospective effect. But this may start a global opposition and countries may have to face litigation.

Further, para 6 of the declaration also opened option for protection of public health. The implementation of Para 6 of the Doha Declaration represents a means for developing countries to address their public health problems. A number of other options emanates from there such as compulsory licensing, the use of parallel importation and the development of generic medicines to combat HIV/AIDS, malaria and tuberculosis. In July 2007, Rwanda informed the WTO that it had incorporated essence of Para 6 to import cheaper generics made under compulsory licensing elsewhere, and became the first country to avail of this provision.[46] India has also availed of the benefit of Para 6 and inserted Section 92-A in the Patent Act of 1970.

4.3. TRIPS PLUS

On August 30, 2003, a temporary waiver was issued by TRIPs Council allowing for the issuance of compulsory licences. Countries without the requisite manufacturing capability were permitted to import drugs from countries with local manufacturing capacity.[47] This was based on the caveat that exporting countries would not use the Declaration ''to pursue industrial or commercial policy objectives''. Least developed countries or those countries capable of proving an absence of manufacturing capability could avail of the provision.[48]

Two years later, WTO members agreed to transform this decision into a permanent amendment of the TRIPS Agreement ("2005 TRIPS Amendment"). However, the amendment will only take effect after two thirds of the WTO members ratify it, which has not happened thus far.[49] The proposed amendment paves the way for exporting patented medicines to states that are in need of such medications ("Eligible Importing Members"). This is achieved by an "authorized" circumvention the compulsory licensing rules, as set out in TRIPS Article 31.[50] Notably, the least developed countries are authorized to utilize this model without prior notification to the WTO of their intent to do so, while most countries are required to notify the WTO about their intent to export or to import pharmaceutical drugs under the compulsory licensing mechanism. This system constitutes an important step towards finding. It essentially recognizes that different states have different needs and that the TRIPS structure needs to be amended in order to address these variable needs

5. LEGISLATIVE FRAMEWORK IN INDIA

5.1. THE PATENTABILITY OF MEDICINAL PRODUCTS AND PROCESSES IN INDIA

Original Patent Act of India 1970 excludes product patents for 'drugs or medicines', 'food' and 'pesticides'[51], which limited patentability in those fields to processes patents only, moreover for a limited period of 5 to 7 years.[52] These measures aimed at incentivizing the local production of (generic) medicines were successful, whereas multinational

[45] Commission on Intellectual Property Rights Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London September 2002, p. 51.

[46] Gemma O Farrell, "One Small Step or One Giant Leap Towards Access to Medicines for All?", *E.I.P.R.* 212 (2008).

[47] The 2003 decision is referred to as the "paragraph 6 system" because it facilitates the implementation of paragraph 6 of the 2001 Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights Agreement and Public Health. Notably, this decision has been subject to considerable debate.

[48] *Ibid.*

[49] On December 6, 2005, WTO members approved changes to TRIPS, rendering the 2003 decision permanent. *See* Amendment of the TRIPS Agreement, WT/L/641 (Dec. 8, 2005), *available at* http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm [hereinafter 2005 TRIPS Amendment].

[50] Articled 31 bis defines an eligible importing Member as follows:

Any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex ('system') as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circum-stances of extreme urgency or in cases of public non-commercial use.

[51] Unamended Section 5 of the Patent Act 1970.

[52] Duration of Patent in India in areas restricted under section 5 was 7 years only. See, Section 53 the Patent Act 1970 (unamended).

companies owned 70% of the Indian pharmaceuticals market in the 1970s[53], this figure is no more than 30% today[54]. As there was no efficient patent protection between 1970 and 2005, many Indian drug producers copied expensive original preparations by foreign firms and produced these generics by means of alternative production procedures.[55] This proved more cost-efficient than the expensive development of original preparations as no funds were required for research, which contained the financial risks.[56] Indeed, India allows all manufacturers of generics that were already producing a certain medicine before 1 January 2005, to continue making and selling that pharmaceutical regardless of whether it would fall under a patent after 1 January 2005, provided the manufacturer of the generic has made 'significant investments' and pays 'reasonable' royalties. Even, all compositions 'invented' before 1995, fall outside any Indian patent protection. Moreover, India has implemented mechanisms of price controls on essential medicines. Further, The Indian criterion of inventiveness itself is rather weak. It even allows economic significance to render an invention inventive. India has the world's broadest implementation of the Doha Declaration allowing the generic industry to manufacture[57], under a compulsory licence, pharmaceuticals meant for export to countries not having the infrastructure and/or know how to produce these medicines.

5.2. BOLAR PRINCIPLE AND INDIAN PATENT ACT

This pharmaceutical sector specific provision, inherited from the American IPR regime, is called the "Bolar" provision. It has been drafted on the basis of exemption principle of Article 8 of the TRIPS agreement. It was also confirmed by a WTO Panel report adopted by the Dispute Settlement Body (DSB). Under this principle generic manufacturer are authorised to produce alternative R&D of any patented medicine and if they succeed to develop any parallel competitive medicine on the basis of patented medicine literature; they will get defence of non infringement.[58]

5.3. PUBLIC INTEREST AND PATENT

In accordance with Articles 8 and 40 of the TRIPS agreement, governments can take steps to prevent patent owners from abusing their rights, by "unreasonably" restraining trade or hampering the international transfer of technology. Contrary to general impression TRIPs agreement has tried to ensure that although patent has an inevitable inherent impact of monopoly but no member country or any owner of patent will be permitted to apply non competitive mechanism with regard thereto. Indian Patent Act section 83 and 84 is an example of policy framer assurance that even under patent regime interest of common segment of society is not going to be compromised.

5.4. INTERNATIONAL FRIENDLY OBLIGATION

Following the 2001 Doha agreement a country can issue a compulsory license for a drug that treats a disease causing a severe health emergency in that country without royalties being paid.[59] The Patents (Amendment) Act, 2005 of India incorporates Doha Para 6 resolution and allows grant of compulsory licence in cases where the importing country has by notification or otherwise, allowed importation of patented pharmaceutical products from India.[60] This provision is

[53] Up until the 1970s India's pharmaceuticals market was mainly supplied by large international corporations. Only cheap bulk drugs were produced domestically by state-owned companies founded in the 1950s and 60s with the help of the World Health Organisation (WHO).

[54] The Pharmaceutical industry in India meets around 70% of the country's demands for the bulk drugs, drug intermediates, drug formulations, chemicals, tablets, capsules, orals and injectibles. See, A Brief Report Pharmaceutical s Industry in India, January 2011. available at: http://www.cci.in/pdf/surveys_reports/indian-pharmaceuticals-industry.pdf.

[55] India's pharmaceutical industry on course for globalisation, Deutsche Bank Research, April 9, 2008, p. 3, available at: http://www.dbresearch.ru/PROD/DBR_INTERNET_EN-PROD/PROD0000000000224095.pdf.

[56] *Ibid*..

[57] India tops the world in exporting generic medicines worth US $ 11 billion and currently, the Indian pharmaceutical industry is one of the world's largest and most developed. Moreover the report claims that Indian Generic drugs market is likely to grow at a CAGR of 17% between 2010-2011 to 2011-2012. *See,* A Brief Report Pharmaceutical s Industry in India, January 2011.

[58] Section 107(b) of the Indian Patent Act 1970.

[59] AIDS, drug prices and generic drugs, http://www.avert.org/generic.htm., (accessed 17-05-2010).

[60] Section 92 A of the Patents Act 1970 provides:

(1) *Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has*

introduced to address the public health concerns of the countries having insufficient or no manufacturing capacity in the pharmaceutical sector to implement the decision of the TRIPS council on Para 6 of the Doha Declaration on TRIPS Agreement and Public Health.

6. GENERIC DRUGS PRODUCERS AND BIOTECH PATENTEES IN POST WTO

WTO system, TRIPs agreement and TRIPS plus has given enough scope to the members to override patents to produce generic drugs in times of national emergencies by giving option of national interest and rights with regard to life saving drugs,[61] This exception has evolved into re-emergence of conflict between patent-holding pharmaceutical companies and developing countries. By 2005, Malaysia, Indonesia, and several African countries officially issued licenses for the generic production of antiretroviral drugs. India, Brazil, and Thailand followed in 2006 and 2007.[62] The WTO expanded the compulsory license rule in 2003 to allow developing countries with no capacity to produce drugs on their own to import them from other countries operating under a compulsory license. In 2007, Canada became the first country to issue a compulsory license to export generic drugs under this rule.[63] While poor countries maintain the only way they can afford medicines to combat epidemics is through domestic production of generic drugs, the pharmaceutical industry argues that developing new drugs depends on the defense of patent rights. It also asserts that rather than being unable to afford medicines, some countries are just opting to spend the money elsewhere.[64]

Moreover, it has also restarted the traditional conflict between branded medicine manufacturer and generic medicine identified that Generally a brand-name drug manufacturer obtains a patent for an original compound having medical efficacy, it may subsequently develop related technologies, such as new manufacturing methods, new uses, new dosage forms, new crystalline forms, etc., for which patents may be separately filed. Faced by potential business constraints from such patents, generic drug manufacturers hold an opposing view on the patentability of such new technologies.[65]

In the case of new crystalline forms, generic drug manufacturers are of the opinion that the basic formula of the compound is already known, and persons with ordinary skill and knowledge in the art can easily obtain the new crystalline form through general and routine operations. Hence, there is nothing novel to the development of a new crystalline form[66]; instead, it should be manufacturer as a "discovery" of a natural substance, not as an "invention" that can be protected under patent law.[67]

Another concern has been raised by generic drugs manufacturer against the ability to obtain multiple patents on a product, over a period of many years, effectively extends the term of exclusivity that the patent holder obtains.[68] They

been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.

(2) *The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.*

(3) *The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under any other provision of this Act.*

Explanation.—for the purposes of this section, 'pharmaceutical products' means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use

[61] Tony Johnson, "The Debate over Generic Drug Trade", available at: http://www.cfr.org/drugs/debate-over-generic-drug-trade/p18055.

[62] Generic drugs overall have jumped from 49 percent of the global drug market in 2000 to 78 percent in 2010. *See*, < http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf.>

[63] Briefing Note Access to Medicines, WHO, Western Pacific Region, February 2008. This note provides a brief overview of countries' experiences in using the safeguard mechanisms available in the TRIPS Agreement to protect public health and access to medicines.

[64] See, Steve Seidenberg, Patent Abuse, *Inside Counsel Magazine,* February 2008 Issue, available at: http://www.bannerwitcoff.com/_docs/news_events_archive/news/JI%20InsideCounsel.pdf.

[65] Lee and Lee, "Patentability and Infringement Analysis of New Crystalline Form Inventions", available at: http://www.leeandli.com/web/bulletin/artical.asp?id=4699, visited on 11.02.2012.

[66] In March of 2011, two decisions were rendered by the Taiwan Intellectual Property Court (IP Court) regarding the issues of whether the development of a new crystalline form should be recognized as an "invention," whether it is a patentable objective, and whether the legal requirements for patentability such as "novelty" can be met. IP Court of Taiwan given affirmative opinion with regard thereto.

[67] *Supra* Note 61.

[68] "Evergreening refers to attempts by owners of pharmaceutical product patents to effectively extend the term of those patents on modified forms of the same drug, new delivery systems for the drug, new uses of the drug, and the like."

further assert that this practice is abusive, impedes the introduction of generic medications, and has a negative effect upon public health.[69]

Another cause of conflict is data exclusivity[70], which resulted into restriction over generic drugs manufacturer.[71] An expanded right of "data exclusivity" threatens to preclude registration of generic medicines even when patent rights are bypassed through lawful means.[72] This is because the follow-on producer and drug regulators cannot use the earlier registrant's data (or the fact of prior registration) to establish the safety and efficacy of the follow-on product even if it is proven bioequivalent. Patent Amendment Act 2005 has tried to restrict the scope of evergreening patent in[73] India and Chennai High Court decision in Novartis Case[74] is manifestation of Indian stand.

7. CONCLUSION

In view of the size and diversity of the Indian pharmaceutical industry; and its importance to the growing economy, one needs to make significant advances in the development of regulation to give impression that India has a land of equal opportunity to every player of the market. So far India became a world leader in high-quality generic drug manufacturing by deliberately excluding pharmaceutical products from patent protection for the previous 41 years. The regulation of drugs in India has been bedevilled by inefficiency on the one hand and a far-reaching delegation of responsibility to the States on the other. The result has been a failure to guide or control the market in the interests of public health. Self proclaimed emerging superpower still mired in immense domestic poverty and public health crises. It is far too early to predict, whether India's adoption of stronger patent laws will catalyze a significant shift from generic drug manufacturing to indigenous pharmaceutical innovation. What is clear, that the implications of India's tumultuous patent system transformation are felt not only within India but also around the globe. Although, undernourished, diseased, dying, undereducated, or extremely impoverished populations are viewed by many as negative externalities but there is a need to give space to other side of the coin. Moreover, if the instrumental mandate of intellectual property law is to get broad acceptance from every segment of the society as well as economic sectors and developing nations, then there must be fuller consideration of the provision of basic needs of global public goods such as food, security, education, and health care.

CONFLICT OF INTERESTS

None.

ACKNOWLEDGMENTS

None.

[69] *See*, http://ipmall.info/hosted_resources/crs/R40917_091113.pdf.

[70] Data exclusivity protects the clinical trial data that a drug maker submits to a regulatory agency to prove the safety and efficacy of a new drug. This protection prevents other companies from using the original drug maker's data to support their own applications for marketing authorization

[71] Diependaele L, Cockbain J, Sterckx S. Raising the Barriers to Access to Medicines in the Developing World - The Relentless Push for Data Exclusivity. Dev World Bioeth. 2017 Apr;17(1):11-21.

[72] The Union Commerce and Industry Minister of India , clearly stated that data exclusivity would not be permitted, as it is a TRIPS-plus demand and that allowing it would considerably impact the entry of generic medicines into the market.

[73] Section 3 (d) of the Patent Act requires that *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.*

[74] Madras High Court Observed that "*going by the meaning for the word "efficacy" and "therapeutic" … …, what the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease/ having a good effect on the body? In other words, the patent applicant is definitely aware as to what is*

the "therapeutic effect" of the drug for which he had already got a patent and what is the difference between the therapeutic effect of the patented drug and the drug in respect of which patent is asked for."

Court Further Observed, "Due to the advanced technology in all fields of science, it is possible to show by giving necessary comparative details based on such science that the discovery of a new form of a known substance had resulted in the enhancement of the known efficacy of the original substance and the derivatives so derived will not be the same substance, since the properties of the derivatives differ significantly with regard to efficacy."