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The TRIPS Agreement: A Roaring Lion or Toothless Tiger: An Analysis

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ABSTRACT

Indian law did not recognize product patents under the Patents Act of 1970 with an avowed object of producing food and medicine at comparatively cheaper price. However, process patent continued to be protected thereby creating an opportunity for the Government to regulate production and distribution of patented drugs imported from outside the country. The pharmaceutical industry was thus able to create generic drugs at mass scale albeit under the covert permissible limits provided by the state. This was done in public interest to address the problem of poverty-stricken diseased populace. After the dawn of globalization, liberalization and openness actuated by the establishment of WTO and the multiple agreements thereof, including the TRIPS Agreement 1994, the international trade promised to become barrier free, be it tariff or non –tariff barriers. But the TRIPS Agreement made the protection of product patents along with process patent as mandatory. This resulted into a drastic change in Indian Patent law by bring out Patent (Amendment) Act 2005, after availing of the benefit of 10 years (1995-2005) as allowed the TRIPS Agreement for developing and least developing countries signatories to the Agreement. Given this shift in the Indian patent law, foreign pharmaceutical companies especially MNCs wanted to invest in a big way on the assured protection of product patents that these companies became entitled to under the patent regime now in operation. However, the Indian pharmaceutical industry continued to produce generic drugs on the tacit governmental approval based often on the formulations patented outside India. This has created a precarious situation for MNCs especially the pharmaceutical companies so far product patents of pharma goods are concerned. The Doha Declaration on public health and lifesaving drugs has simply buoyed the Indian pharmaceutical industry to generate more and more generic goods often to the annoyance of MNCs resulting in unabated litigation. It is in this background that the present paper is conceived to analyze TRIPS compliance of India in the contemporary trading world aiming at harmonizing world trade and access to affordable medicine to the people at large.

1. Introduction

The exclusive right of the inventor includes the use of his invention for a stipulated period of time as provided under the Patents Act, 1970.[1] The Indian Patent Act recognizes only process patents in pharmaceutical and agro-chemical inventions. Only process patents can be granted for the food products, medicines and chemicals. This means that only the method of production can be patented and not the end product.[2] Under the Patents Act, food products and medicine was granted exemption from patentability by excluding these from the operation of the Act.[3] The Central Government can use a patented invention in specific circumstances for public interest even without the payment of royalty to the patentee. The Pharmaceutical Industry in the modern economic conglomeration plays a major role as a contributor to the economy so need to create cushion as a social responsibility by providing drugs at affordable prices. It may be noted that due to the state sponsored economic policy production of generic drugs is carried on at a large scale with the result that nearly 95% of the domestic demand for pharmaceuticals in India is met through indigenous production.[4] Parallel imports is an another way to curtail the monopoly of patentees to ensure the supply of lifesaving drugs, like anti-cancer, cardiovascular, anti-hypertension and other newer drugs that are not yet cleared for indigenous production.[5] This allows Indian companies to reproduce and market newly invented drugs in the Indian market through a different production process, typically within one or two years of its invention, and at only a small fraction of the cost of patented drugs in developed countries.

2. Pharmaceutical Industry: Evolution And Development

The pharmaceutical industry discovers, develops, produces, and markets drugs or pharmaceutical drugs for use as medications to be administered to patients to cure them, vaccinate them, or alleviate a symptom. The pharmaceutical industry has assumed importance in the post-world-war- II due to emergence of new economic order. In 2011, global spending on prescription drugs topped $954 billion, even as growth slowed somewhat in Europe and North America. The United States accounts for more than a third of the global pharmaceutical market, with $340 billion in annual sales followed by the EU and Japan. The TRIPS Agreement which came into existence due to protracted

[1] Usman Sanai, the Indian Patent Act and TRIPS, Economic and political weekly, vol. 28, no 39/30 (1993), pp. 1495-1497.
[2] In addition the state can impose any condition on the grant of patent.
[3] Pradeep Agarwal, P Saibai; TRIPS and India's pharmaceutical Industry, Economic and political weekly, vol. 36, no. 39 (2001), pp. 3787-3790.
[4] Id., p. 3788.
[5] Id., p. 3789.

negotiations revolved round protection of economic interest of developed economies having hugely invested in creating technological knowhow especially IPR products including pharmaceutical patents. Thus, despite the TRIPS mandate product patents are rarely protected in India which has raised a question mark about the efficacy of TRIPS to control the misuse of pharmaceutical patents in India. The 2005 amendment of the Indian Patent Act, 1970 allowed the patent grant on pharmaceuticals.[6] This change was fraught with hue and cry from the petite bourgeois and from different luminaries.[7] Product patent on pharmaceutical products has drawn many scholarly writings to the front.[8] Indian Patent Act, 1970 provides a sublime canvas to both, the human rights lawyer, as well as, the individual private rights lawyer. The societal aspect of human rights graces the Indian Patent Act with its presence penned across different provisions of the Act.[9] Diverse provisions in the Indian Patent Act, 1970, point toward the balance which the Act has tried to maintain between the appreciation of public rights and private rights.[10] One such chapter, which has endeavored to shed light on the balance is the chapter related to compulsory licensing.[11]

The question whether the law in operation is sufficient to ensure access to lifesaving drugs to the public at large is quite debatable.[12] Availability of cheap and affordable drugs to the poor and needy raise a fundamental question of equity and human rights which determines the ultimate objective of future sustainable goals.[13]

Needless to say that the pharmaceutical patents were first introduced in India by the British in the colonial era.[14] But the concern about the dominance of foreign pharmaceutical firms and the high price of medicines, prompted India to change course, by passing a patent law prohibiting product patent on medicines.[15] At that time, foreign firms controlled about 70 percent of Indian market, and the Indian drug prices were among the highest in the world.[16]

3. Indian Patents Act and the TRIPS Agreement

The 1970 Act served as a substantial driver of three decades of growth in the domestic pharmaceutical industry.[17] In the years that followed it, the number of patents granted in India dropped quickly.[18] Over time, the Indian industry also evolved to become extraordinary competitive and diverse.[19] Further, numerous surveys indicate that Indian drug prices by the 1990s were among the lowest in the world.[20] Major changes were seen in the pharmaceutical industry in India after 2005, as a result of TRIPS agreement, which endeavored to protect the rights of inventors.[21] The agreement has been the result of active lobbying by multinational pharmaceutical firms and strong pressure from the US and other developed countries.[22] Under this Agreement, norms and standards were provided in respect of seven categories of intellectual property rights, which include copyrights, trademarks and product patents in all areas of technology.[23]

India after the adoption of the TRIPs Agreement has been granting product patents in the most fields of science and technology.[24] However, this shift has ostensibly proved quite difficult to yield the desired result, having an immediate and severe adverse impact on Indian consumers. On a complaint by the US to WTO, India was asked to take steps to amend its patent laws to meet WTO obligations by April, 1999[25]. Finally, in order to fulfill its obligations, the Government of India

[6] Gopakumar G. Nair, Impact of TRIPS on Indian Pharmaceutical Industry, J.I.P.R. 13(5) 2008 at 432-441.

[7] ("The deleteriousness of TRIPS, in relation to health and social justice, cannot be wished away by Parliament since Right to Life, a basic feature and constitutional guarantee, cannot be truncated or trampled upon. So too social justice and right to development in its distributive dimension… articles 14 (equal protection of the law), 19 (right to any trade or business) and 21 (right to life in good health) stand stultified if such glaring inequality between Indian products (denied patent) and foreign import of any commodity granted exclusive selling rights it with no special benefit to the Indian consumer. This is gross inequality writ large, arbitrary, with no rational nexus to the well-being of "We, the People of India… (Article 14).") V.R. Krishna Iyer, Human Health and Patent Law, Frontline, Volume 17, Issue 21, Oct 14, 27-2000.

[8] Laurence R. Helfer, Towards a Human Rights Framework for Intellectual Property, 40 U.C. Davis L. Rev. 971 2006-2007.

[9] The subject matter exclusions, provisions related to compulsory licensing, provision related Bolar exemptions, provision related to parallel importation, provision related to surrender of patent, provision related to research exemption, provision related to making and using the invention by Government for its own use point towards the balance which the Patent Act has tried to restore between the grant of monopoly and human rights.

[10] Shamnad Basheer, Shashwat Purohit and Prashant Reddy, Patent Exclusions That Promote Public Health Objectives, http://www.wipo.int/edocs/mdocs/scp/en/scp_15_3-annex4.pdf, last visited on 13th September 2018.

[11] Chapter XVI – Working of Patents, Compulsory Licenses and Revocation, Indian Patent Act, 1970.

[12] Observation made by the Court in F. Hoffmann-La Roche Ltd. and Anr. v. Copal Limited, 2009 (40) PTC 125 (Del).

[13] ("We want to carve out a law without permitting any ambiguity under the TRIPS agreement to come in our way, to enable us to safeguard our national security, national interests, public health and ensure availability of medicines at affordable prices, which is one of the human rights.") Excerpts from Minister's opening remarks in Parliament while moving for consideration of the Patents (Second Amendment) Bill, http://commerce.nic.in/writereaddata/publications/wto_may2002.pdf, last visited on 17th October, 2011.

[14] P.Narayana, Patent law, P.5, 4th Ed., 2006.

[15] The Patents Act, 1970, No. 39, 5 (India), Reprinted in P.Narayana, Patent law, P. 546, 3rd Ed., 1998.

[16] Amy Kapczynski, harmonization and its discontents: A case study of TRIPS Implementations in India's Pharmaceutical Sector, California Law Review, vol 97, no. 6, pp. 1571-1649 2009

[17] Jean O.Lanjouw, The introduction to pharmaceutical product patents in India, Heartless Exploitations of the poor and suffering? 3, National Bureau of economic research, working paper no. 6366, available at: www.oipre.ox.ac.uk/ejwp0799.pdf last visited on May 5, 2018.

[18] Id., p. 3

[19] Aradhana Agarwal, strategic approach to strengthening the international competitiveness in knowledge based industries. The Indian pharmaceutical industry, 16, research and information system for developing countries, discussion paper no. 80 (2004).

[20] K.Bala and Kiran Sagoo, patents and prices, HAI news, April 2000 available at www.haiweb.org/pubs/hainews/patents%20and%20price.html last visited on May 5, 2018.

[21] Sudip Chaudhuri, patents and pharmaceutical in India, The WTO and India's pharmaceuticals Industry: Patent Protection, TRIPS and developing countries, p. 341, Oxford University Press, New Delhi (2005).

[22] Id., p. 341.

[23] Jayashree Watal, implementation the TRIPS Agreement: policy options open to India, available at www.jstor.org/stable/4405898 last visited on May 5, 2018.

[24] Supra note 23

[25] Subsequently, the Rajya Sabha passed the amended bill in December 1998 but the government could not bring it for consideration in the Lok Sabha due to resistance from both the treasury and the opposition benches.

promulgated the Patents (Amendment) Ordinance in January 8, 1999 changing the Indian Patents Act, 1970 in line with the WTO norms[26].

All member countries of WTO were expected to comply with the provisions under TRIPS from January 1, 1995. However, the agreement provided a transition period of 10 years for developing countries i.e. until January 1, 2005 to enact a bill incorporating product-patent protection[27]. Further, all member countries are also required to take steps to provide for exclusive marketing rights (EMR) for 5 years or till the patent is granted, whichever is earlier.[28]

The Trade Related Aspects of Intellectual Property Rights (TRIPS)[29] Agreement heralded an era of uncertainty over the flexibilities[30] proffered by the Agreement. TRIPS envisaged a future where the two rights, socio-economic rights and rights of the intellectual property owners[31] can be foreseen to be at loggerheads with each other. The documentation of TRIPS is so structured, so as to stretch the balance betwixt the competing interests.[32] The principle of consistency is stretched in the form of compulsory licensing provisions in the text of TRIPS. Though, not worded in unambiguous terms,[33] Article 30 and 31 of the TRIPS point towards compulsory licensing in cases where it becomes imperative for the utilization of the patent.[34]

4. Doha Declaration

The cloud of ambiguity over the TRIPS flexibilities[35] has vanished by the dictum of Doha Declaration, 2001.[36] The mandate of the Declaration was to provide "access to medicine for all".[37] Accessibility and affordability has been on the charts of various stakeholders who challenge the very grant of patents to pharmaceutical substances.[38] The mandate laid down under Article 27 of TRIPS was fulfilled by India by the year 2005[39].

5. The Trickle-Down Effect of Product Patent in India on the Developing World

The Indian IPR Regime in the post-independence era revolved round social justice and socio-economic policy actuated by Directive Principles of State Policy, hence thrust on production of cheap and affordable drugs in the form of generic products.[40]. Patent developments in pharmaceutical industries in India have impact well beyond its borders, given the reliance of the developing and least developed countries, on the supply of low-cast, quality Indian generic pharmaceutical products.[41] India has been the main supplier of essential medicines for developing countries. 67% of medicines exports from India go to developing countries. Approx. 50% of the essential medicines that UNICEF distributes in developing countries come from India. 75-80% of all medicines distributed by the International Dispensary Association (IDA) to developing countries are manufactured in India. In Zimbabwe, 75% of tenders for medicines for all public sector health facilities come from Indian manufacturers. The state procurement agency in Lesotho, NDSO, states it buys nearly 95% of all ARVs from India.[42] This is the reason why India is known as the doctor without borders. But the recent change in the Patents Act to harmonize it with the TRIPS Agreement may leave a bitter taste with the Least Developing nations and the developing ones, who were dependent on India's Generic pharmaceutical industry[43].

Since process patent is granted for a new process of manufacturing an already known product or for manufacturing a new product, or for manufacturing more articles of the same product that can reduce the cost of the already known product. This helps in achieving a key-objective of policy-makers in the developing world to ensure the availability of new medical treatments to save millions of lives by production of cheap

[26] The ordinance provided for:
1. Filling of Applications for product patents in the field of agro-chemicals and pharmaceuticals.
2. Grant of EMRs for the applicant after a set of conditions is fulfilled.

[27] Accordingly, the patents law now provide for the exclusive rights of production and marketing to the inventor in all the member countries of WTO for 20 years.

[28] Pradeep S. Mehta, TRIPS and Pharmaceuticals: Implications for India, p. 97-106

[29] Agreement on Trade Related Aspects of Intellectual Property Rights, April 15, 1994. Marrakesh Agreement Establishing the World Trade Organization, Annex 1C.

[30] (The flexibilities included freedom to determine the scope of subject matter for product patent protection (Article 27), determination on the grounds on which compulsory licenses can be issued (Article 31), identification of exceptions to patent (Article 30), provisions for parallel import (Article 6), provisions for protection of test data (Article 39.3) etc.) N.S. Gopalakrishnan, TRIPS Agreement and Public Health: An Overview of international Issues, J.I.P.R. 13(5) 2008 at 395-400.

[31] ("Recognizing that intellectual property rights are private rights.") Preamble, Agreement on Trade Related Aspects of Intellectual Property Rights, April 15 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C.

[32] 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 development, provided that such measures are consistent with the provisions of this Agreement. [Article 8, Agreement on Trade Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh] Agreement Establishing the World Trade Organization, Annex 1C.

[33] Sherman P.B. and Oakley E.F., Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs, American Business Law Journal, 41 (1 & 2) 2004 at 353.

[34] Raadhika Gupta, Compulsory Licensing under TRIPS: How Far it Addresses Public Health Concerns in Developing Nations, J.I.P.R. (15) 2010 at 357-363.

[35] Carlos M. Correa, Implications of the Doha Declaration on the TRIPS Agreement and Public Health, World Health Organization, 2002.

[36] Declaration on the TRIPS Agreement and Public Health, WT/MIN (01)/DEC/W/2, 14 November 2001.

[37] Declaration on the TRIPS Agreement and Public Health, WT/MIN (01)/DEC/W/2, 14 November 2001 at para 4.

[38] Outterson Kevin, Pharmaceutical Arbitrage Access and Innovation in International Prescription Drug Markets, Yale Journal of Health, Policy, Law and Ethics, 5(2005) at 193-194.

[39] One of the major developments in India that occurred in the post TRIPS adoption was, shifting paradigm from process patents to product patents which hitherto facilitated the Government of India, to deny the pharmaceutical patents.

[40] Allowing only for process patent and not product patent by virtue of Section 5 of the Indian Patent Act, 1970 and providing the same only for a period of 7 years.

[41] At http://indiagovernance.gov.in/files/medicine-patent.pdf (last accessed on 3th of May, 2018).

[42] Examples of the importance of India as the pharmacy of the developing world, campaign for access to essential medicines.

[43] TRIPS and pharmaceutical patents: fact sheet (2006) available at: https://www.wto.org/ English/tratop_e/ trips_e/ pharmpatent_e.htm.

generic versions of on-patent drugs for domestic markets, as well as for export to other countries with similar patent regimes in place.[44]

6. The New Situation

Using the process of reverse engineering, various Indian pharmaceutical industries started mass production of on-patent drugs giving birth to generic drugs, [45] enabling affordable access of these to under-developed and developing nations.[46] India may not be able to afford the escalated costs of new entrant drugs developed in western countries. For example the cost of new anti-cancer drug Glivec is expected to raise 20 fold. On the contrary Shanvac, a recombinant DNA vaccine for Hepatitis B, indigenously developed countries by *Shanta Biotech of India* is being supplied to UNICEF for 50 cents per dose, whereas the same vaccine was being sold for US $15 per dose. Hence for India to afford newer and better drugs, and provide affordable drugs to the suffering millions of the third world countries, either we should be allowed to reverse engineer or we should innovate.[47]

The generic drugs are as effective as the original brand drug, using the same active drug molecules, and are a lot cheaper, because they don't have to go through the process of drug development, including clinical trials, multitude of test, marketing, promotion etc. which a new patented drug has to go through.[48]

Among Indian industries, the average investment in R&D is only 0.7 per cent which is extremely low by world standards. The lack of R&D investment is largely attributed to protectionism and a non-competitive market, since high import duties are imposed on imported drugs.[49] Though the number of Indian Institutions as Patent Applicants in the pharmaceutical industry has been quite a few.[50] These are simply "Incremental innovation" (sequential developments that build on the original patented product) allowed by our Patent regime being different from "Evergreening" of patents[51].

This shows that product innovation has not found its ground in India, and we are involved in the production of already existing medicines for diagnosed diseases. Juxtaposing this issue with the fact that the developed nations focus on either global scale diseases or those pertinent to their areas, and have not paid attention to the tropical diseases like malaria, tuberculosis etc. means that drug companies are yet to come to attend to the more pressing needs of the developing nations (mostly tropical). These areas are generally neglected by foreign investors as the returns are not very high from marketing in developing countries.[52]

Given this lopsided approach adopted by the MNCs, the Indian pharmaceutical industry need to fill this gnawing gap by producing generic products as a social responsibility. This approach may culminate in getting patent protection of such pharmaceutical products as a legitimate way not only in India but abroad as well.[53] Needless to assert that patent protection provide a degree of assurance for investors to risk the capital necessary in the long development process and to fund new R&D initiatives. Hence, legislative changes that diminish the value of patents could have a detrimental impact on decision makers considering investing in R&D-based ventures, and could negatively affect needed long-term innovations.[54]

7. Costing Of Drugs

The biggest hurdle in the process of making drugs available to the needy is the high prices attached to patented drugs. But due to monopoly of pharma giants over patented drugs it becomes difficult to negotiate prices at reasonable rates. According to Donald Light, professor of comparative health care at the University of Medicine and Dentistry of New Jersey, it's impossible to determine how far prices are truly rising because of increasing developmental costs, as drug companies keep a tight grip on their financial data, releasing dribs and drabs on occasion, but only to economists with industry ties.[55] Today, almost half of all prescriptions are filled with generic drugs. [56] The data, however, were not made available to other researchers, and drug-industry watchdogs say this lack of transparency is typical. Warburton says it is in the best interests of drug companies, who often lobby governments to loosen price regulations and increase patent protection, to overstate costs and lacking transparency makes things even fishier[57].

Another criticism of studies that produce numbers in the billion-dollar range is that large portions of those estimates aren't out-of-pocket expenses. About half of the 10-figure price

[44] Veena Mishra, TRIPS products patents and pharmaceuticals, Economic and Political Weekly, December 1, 2001, p. 4464.
[45] At http://www.clihouston.com/news/the-role-of-reverse-engeenering-in-the-development-of-generic-formulations.html (last accessed on 4th of May, 2018).
[46] The product patents regime means, that India can no longer manufacture drugs by reverse engineering.
[47] Such cost difference needs to be justified logically or else will go down the abyss in the name of dastardly exploitation of the poor. Available at: http://www.brainleague.com/case_studies/indianpatentregime.pdf (last accessed on 3rd of September, 2018).
[48] At http://www.innovation.org/documents/file/pharmaceutical_patent.pdf (last accessed on 2nd of May, 2018).
[49] At http://www.brainleague.com/case_studies/indianpatentregime.pdf (last accessed on 4th of May, 2018).
[50] Council of Scientific and Industrial Research has filed maximum number of applications (183), followed by National Institute of Pharmaceutical Education and Research (NIPER) at 11 along with Indian Council of Medical Research, it is to be noted that they have not been for a new medicine to cure a new disease. At http://ipindia.gov.in/cgpdtm/annualreport_english_2010_2011.pdf (last accessed on 6th of May, 2018).
[51] Report of the technical expert group on patent law issues, December, 2006, 5.10.
[52] At http://www.ipfrontline.com/depts/article.aspx/id=1994&deptid=6 (last accessed on 5th of May, 2018).
[53] At http://www.innovation.org/documents/file/pharmaceutical_patents.pdf (last accessed on 4th of May, 2018).
[54] Ibid.
[55] Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2630351/ (last accessed on 3rd of May, 2018).
[56] The US $802-million figure was based on the research-and-development costs of 68 drugs at 10 companies.
[57] Drug companies are sometimes accused of passing these big numbers on to the media to deflect public criticism about price gouging. But research costs and retail prices in Canada are in no way linked, according to R&D, the national face of the Canadian brand-name drug industry.

tag is an estimate of the profits a drug company might have made, over the course of bringing a product to market, if it had instead invested its capital elsewhere. Calculating forgone profits is, according to Light, a reasonable way for a company to determine if it should go ahead with a project. "What is not reasonable", he says, "is to then take that estimate, which is a calculation of investment, and claim it as a cost against society".[58] The cost estimate of successful drug development also includes the cost of research that fails to net new products. About two-thirds of true research and development costs, are incurred in phase III trials, where the odds of success are about 3 in 5.[59]

Only high prices of the patented products are not an incentive for companies to produce new drugs, to survive in the market, due to extreme competition, companies need to keep developing new medicines or improving the existing ones. If medicines for tuberculosis, polio are restricted to patented drugs, they defeat the purpose of their innovation i.e. protecting people from the same, since it wouldn't be available to the major chunk of the population because major chunk of the population wouldn't be able to afford it.

8. Compulsory Licensing

India fought hard against product patents on medicines. Though it lost that battle, it did score an important victory. It got inserted in the Agreement on TRIPs, a provision whereby member countries would retain the right to issue compulsory license to domestic firms for a patented medicine if the patent holder did not provide the medicine at an affordable price.[60] Since March 3, 2008, when it got the Indian patent, Bayer has imported Nexavar, selling its monthly dose at the whopping price of 2, 80,428 or $5,420. Unsurprisingly, only 2% of Indian patients have been able to afford it. In its application for compulsory license to the Controller General of Patents, Natco offered to sell the monthly do se at 8,800 ($170), a mere 3% of Bayer's price. Kurien obligated the numerous patients suffering from liver and kidney cancer, by ruling in favor of Natco.[61] In its defense, Bayer had argued that its high price of the drug was necessary to defray the cost of invention. This is a spurious argument. If drug companies counted on poor countries to recover the costs of their inventions, they would invest in research to treat tropical diseases such as tuberculosis and malaria. They do not, which means that to justify their argument they are ready to use "differential pricing".[62]

As compulsory licensing can be used only for drugs not available to people at affordable prices, with a company ready to manufacture it at cheap prices, it might not encourage generic industries to the extent as process patent did. Hence, using Article 7 of the TRIPS Agreement, country can make compulsory licensing flexible to provide for its domestic market and perform its responsibility of being the "pharmacy of the world". Considering the dependence of other nations on India's generic drug industry, India needs to provide sustainable and affordable access of drugs to them and its domestic market (considering their inefficiency in satisfying the market at the current rates of patented drugs). For the same, pricing of patented products has to be looked into, its anomalies removed and supported by flexible compulsory licensing.

9. TRIPS and Pharmaceuticals in India

The Indian Patent law chalks the jurisprudence behind the balance between grant of monopoly and the guarantee of socio-economic rights.[63] Section 83 (g) also puts forth the point that "patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public." That the state is obligated to maintain right to health and achieve the scribbled destination of the Constitution, is further supported from the reading of section 83(e) of the Indian Patent Act, 1970. It states that "patents granted in any way do not prohibit the Central Government in taking measures to protect public health." [64]

The first week of April produced two landmark judgments for multinational pharmaceutical companies trying to make their mark in India. The approach of the judiciary as the custodian of constitutional guarantees of public health has largely favoured the public interest rather than corporate interest. The Supreme Court denied patent protection for Glivec.[65] Similarly, the Delhi High Court dismissed a claim by Merck's Indian subsidiary, [66] that Mumbai-based Glenmark Pharmaceuticals should be barred from marketing generic versions of these three drugs to flood its market. The courts seems to be sending a strong message that pharmaceutical manufacturers outside its borders will not have unlimited pricing power over its market of 1.2 billion people. But at the same time from a global perspective, India's denial of patent protection, questions the pharmaceutical industry's ability to make a profit in the world's second-most populous country[67].

[58] At http://www.ncbi.nlm.gov/pmc/article/PMC2630351/ (last accessed on 3rd of May, 2018).
[59] At http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2630351/ (last accessed on 5th of May, 2018).
[60] At http://articles.economictimes.indiatimes.com/2012-05-30/news/31900229_1patent-act-product-patent-patent-law (last accessed on 3rd of May, 2018).
[61] At http://articles.economictimes.indiatimes.com/2012-05-30/news/31900229_1patent-act-product-patent-patent-law (last accessed on 3rd of May, 2018).
[62] Differential pricing is a solution favored by some health officials. This would allow drug companies to recover most of their costs in richer markets while selling and licensing production at lower prices in poorer companies. GlaxoSmithKline has offered its combination therapy to South Africa at $56 for a month's treatment for one patient, an 84% discount on the average world price. Yet even at these reduced rates, charity groups say the cost of drugs remains well beyond the reach of millions of HIV-infected people.
[63] Section 83(c), Indian Patent Act, 1970 states that "that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conductive to social and economic welfare, and to a b0alance of rights and obligations"; see also Article 7, Agreement on Trade Related Aspects of Intellectual Property Rights, April 15 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C.
[64] Section 83(d) of the Indian Patent Act, 1970 provides that "patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest especially in sectors of vital importance for socio-economic and technological development of India."
[65] (Spelled Gleevec in the U.S.), a cancer drug made by Novartis that is patented in nearly 40 other countries.
[66] Merck Sharp and Dohme.
[67] Besides, it adds fire to the debate over whether the industry's obligation to provide access to life-saving drugs should outweigh its drive for profits.

The decision of the Indian Supreme Court to deny Novartis' application for patent protection for an improved version of its Glove drug – the culmination of a seven-year battle – has certainly made world headlines and put the spotlight on generic drugs and the practice of ever greening, which could have a significant impact on the local pharmaceutical industry. The key issue is a practice known as "ever greening"[68] whereby smaller changes to a drug, at the fake end, in order to gain a new patent by its manufacturer. It is called evergreening as it ostensibly extends the patent life without producing a new and novel product.[69] 'The judgment is significant as it sends out a strong message to the world that while we respect international agreements, we also have a responsibility towards the poor and will not support any measure to extend patents beyond their normal lives'.

The impact of TRIPS on prices for pharmaceuticals and other healthcare inventions has become quite debatable. It is now being ascertained as to how the TRIPS can provides way-out for low-income consumers in developing countries from obtaining life-saving medications and equipment, and how these concerns are responded by the WTO by issuing a Declaration at the Ministerial Meeting in Doha, Qatar in 2001 in which measures to protect public health were taken. It explores how public health is reaffirmed by the right of governments to use compulsory licenses to override the exclusive rights conferred by patents[70].

10. Evergreening of patents

In contrast to other countries in the TRIPS agreement, India also introduced laws that prohibited an industry tactic called "ever greening". [71] For example, they might release the original drug in its salt form, even if this does not bring a therapeutic improvement. India – alongside Brazil, Thailand and South Africa – is one of the few countries with laws against ever greening. The Indian Patent Act, as amended by the Patents (Amendment) Act 2005, states that drugs cannot be patented if they result from "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." This has allowed the continued production of cheap generic versions of drugs by Indian companies.

Data exclusivity provides exclusive rights to technical data generated by innovator companies through clinical trials and prevents competitors from producing low-cost generic versions of the drug during the period of exclusivity. The TRIPs Agreement already provides for data protection. However, data protection is different from data exclusivity. "Article 39(3) of TRIPs prevents unfair commercial use or marketing by generic companies of the data generated by clinical trials from innovators companies and submitted to the drug regulator. However, this is not the same as data exclusivity. As of now, Indian firms that make generic versions of innovator medicines get their approvals after proving that their product is bio-equivalent to the original drug. The drug regulator uses the data submitted by the innovator to decide the safety and efficacy of the generic drug. Data exclusivity will prevent this. The regulator will not be able to use the innovator's data to make decision. This will in turn oblige generic companies to undertake clinical trials and delay the entry [into the market] of generic drugs". Compulsory licensing – the granting of a license to produce a generic version of a product – is explicitly protected by WTO treaties to help countries improve public health and ensure access to medicines.

When India finally adopted its expanded patent law, it was widely hailed and multinational firms began expanding with gusto. They now sell their latest branded medicines here, expecting the burgeoning middle class and slowly growing health insurance system will pay for them. Pharmaceutical manufacturing has boomed, as has the clinical trial industry.

11. Novartis Verdict

In 2006 the drug company Novartis applied to the Indian government for a patent on their cancer drug imatinib mesylate (marketed as Glivec), which was rejected as contravening anti-ever greening laws because it was based on a compound that already existed. [72] However, the Patent Office didn't consider this sufficient to meet the "enhanced efficacy" requirement of the Indian Patent Act. The Indian Supreme Court has rejected Novartis appeal for patent protection of Glivec & held that Glivec was an example of "incremental innovation" under Section 3(d) of the Indian Patents Act and, as such, not liable for protection[73]. What constitutes an "incremental" change is, of course, a matter of judgment and the ruling brings back into the spotlight the patent wars that have been fought in India over the past few years[74].

Novartis challenged the decision, taking their case to the Supreme Court stating that the judgment violated Word Trade Organization (WTO) rules on intellectual property set in 2005 that India had adopted, but its request was rejected by Chennai's Court in 2007[75].

The Swiss firm, however, did not give up and appealed to the Supreme Court of India in 2009, arguing that Glivec was a "new product" under section 3(2) of the Act, attributed to beta crystalline form of Imatinib Mesylate. For this reason, the drug in question, they claimed, had much better properties: it was easier to absorb, had better thermodynamic stability and lower

[68] Faunce TA The awful truth about Evergreening. The age. 2005-12-20. Retrieved 2007-09-21.
[69] Evergreening of pharmaceutical market protection. European generic medicines association. Retrieved 2007-10-19.
[70] Ibid
[71] Ever greening is where a company extends its patent on a drug by repatenting slightly modified versions of the drug.
[72] Imatinib mesylate is used to treat several forms of cancer including chronic myelogenous leukaemia and is the salt form of its precursor imatinib Novartis showed that imatinib mesylate had a 30% increase in bioavailability (the proportion of the drug absorbed into the bloodstream) compared with imatinib.
[73] Ajay Chandru & Gowree Gokhale, Novartis Indian Supreme Court judgment: what is efficacy for pharmaceutical invention? Manupatra Intellectual Property Reports v May 2013 at 165
[74] There has been a lot of debate about a judgment given by the Supreme Court. It's not an issue of law because section 3(d) is embedded in the Indian Patent Acts, which is TRIPS compliant.
[75] Numerous western pharmaceutical companies have struggled to patent their drug molecules in the country; for example, Pfizer was granted a patent for anti-cancer agent Sutent (sunitinib) in 2007, but this was revoked last year. Merck & Co is currently also suing Indian firm Glenmark over generic versions of its diabetes treatment Januvia (sitagliptin) and Janumet (sitagliptin plus metformin).

hygroscopicity and therefore qualified for a fresh patent[76]. The court rejected the plea based on a law aimed at preventing companies from getting fresh patents, making only minor changes to existing drugs, a practice known as "ever greening". The bench also explained the meaning of the word "invention" when it ruled out the plea, as "something different from a recent previous or one regarded as better than what went before or in addition or others of the same kind" and Glivec failed to fulfill any such features and certainly did not qualify enough to warrant a patent.

Well, if that tweak advances medical science in any way, then the answer to that question is yes. Bringing a new drug to market carries Vegas-like odds and putting up barriers to protecting intellectual property will only discourage innovators from taking those risks.

A recent Indian Supreme court decision prohibited pharmaceutical companies from extending patents through "ever greening". Ever greening delays availability of more affordable generic drugs through minor changes to the existing drug. Ever greening is a strategy with a great return on investment.[77]

12. Conclusion

The landmark judgment by the Supreme Court on Novartis has far reaching effects on the patentability of therapeutic drugs, though it may seem to be an advantage for generic drug companies as against the pharmaceutical giants, but there lies a hope for the common man- access to affordable drugs for his survival. **T**he judicial approach in this regard has been pro-people but not in derogation of the Indian Patents Act. The test of patentability sets up a second and higher tier of qualifying standards, especially for chemical substances/medicines, in order to leave the door open for true and genuine inventions, but, at the same time, check any attempt at extension of patent term on spurious grounds. It is not a strike against the pharmaceutical industry, nor is it a ruling meant to appease the masses. It will be a grave mistake to read the judgment to mean that the Act bars patents for all incremental inventions of chemical and pharmaceutical substances. The judgment attempts to strike a balance between public interest and inventor interest. The TRIPS Agreement has created opportunities to create new drugs, invest in R&D and incentivize the inventors and create an equitable environment for both the pharmaceutical companies and the consumers but there is lot to be achieved by balancing the otherwise conflicting interests of corporates and users of pharma products in India.

[76]However, the court discovered that the package of the drug described its product as Imatinib Mesylate and not the beta crystalline form of the compound.

[77] That's because pharmaceutical companies spend $19 for promotion and marketing to every $1 spent on basic research.

