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How does protection of Intellectual Property Rights pose a barrier for access to affordable medicines?

By : Shreshthraj Srivastava

Introduction

Patents motivate invention. One of the purposes of granting patents is that it may incentivise the inventor and in turn encourage other individuals to perform similar inventions. Patents grant the inventors with some exclusive privileges over the invention so that he may reap the fruits of his labour. However, in the pharmaceutical industry more safeguards are needed so that no one can use the IPR regime to his benefit.

This essay throws light over how the present Intellectual Property Laws are tactfully used by pharmaceutical corporations to their benefit. Towards the conclusion the researcher examines the ways to prevent it and make access to medicines more readily.

Pharmaceutical Industry thrives and expands through protection of intellectual property rights involved with regard to the pharmaceutical products. The patent law is the key to its growth.[1]

Patenting practices in Pharmaceutical Industry

The pharmaceutical industry is one of the most complicated in the world. Heavily regulated by the government and, on occasion, by the competing interests of its stakeholders and the society. The prominent players of the pharmaceutical industry invest heavily in the research and development of new drugs.[2] Pharmaceutical firms rely largely on the exclusivity provided by intellectual property rights, particularly patents, to preserve their enormous efforts and investments. Patents grant a pharmaceutical business a 20-year monopoly period during which it has market exclusivity and can charge a monopoly price for its medicines. Strong patent protection, according to the authors, is necessary for recouping expenditures and incentivizing companies to participate in more innovation.[3] When a patent expires, however, other businesses

[1] Juan He, *Indian Patent Law and Its Impact on the Pharmaceutical Industry: What Can China Learn from India?*, INNOVATION, ECONOMIC DEVELOPMENT, AND INTELLECTUAL PROPERTY IN INDIA AND CHINA 251–269 (2019).
[2] David Taylor, *The Pharmaceutical Industry and the Future of Drug Development*, ISSUES IN ENVIRONMENTAL SCIENCE AND TECHNOLOGY 1–33 (2019), https://pubs.rsc.org/en/content/chapterhtml/2015/bk9781782621898-00001?isbn=978-1-78262-189-8&sercode=bk.
[3] European Commission (2009) Pharmaceutical sector inquiry final report. http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf. Accessed 31 Jan

may produce generic versions of a branded medicine and compete with the original for market share. This is what is referred to as generic competition. Generic medications are bioequivalent copies of branded pharmaceuticals whose patent protection has expired.[4]

A prevalent practice which has emerged as a response to surge of sale of generic drugs is 'evergreening of patents'. The practice of altering pharmaceuticals in order to extend their patent period and consequently their revenue is known as evergreening patents. However, India has been largely successful in preventing the evergreening of patents of foreign pharmaceutical companies.[5] More light will be thrown on the evergreening of patents in the succeeding chapters of this essay.

Generic Medicines: A generic drug is one that includes the same chemical ingredient as a medication that was previously protected by a chemical patent. After the patents on the original pharmaceuticals expire, generic drugs can be sold. The medical profile of generics is thought to be equal in performance since the active chemical ingredient is the same.[6]

When a pharmaceutical business initially launches a medicine, it is normally covered by a patent, which the corporation may use to keep rivals out by suing them for patent infringement until the patent expires.[7] However, once the patent expires, anyone is free to manufacture that drug and introduce it to the market. The original manufacturers are no longer in position to sue the rival manufacturers. The generic medicines are usually cost efficient as compared to the medicines by original manufacturers.

Historically, India has been a leading supplier of generic medicines worldwide. In the 2019–20 (April–March) fiscal year, India was the world's biggest exporter of generic pharmaceuticals, with a total value of US$20.0 billion.[8]

Evergreening of Pharmaceutical Patents

2021.

[4] Olga Gurgula, *Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?*, 51 IIC - INTERNATIONAL REVIEW OF INTELLECTUAL PROPERTY AND COMPETITION LAW 1062–1085 (2020).

[5] Harsha Agarwal, *Secondary patenting or evergreening: indian ip perspective* SAGACIOUS IP (2020), https://sagaciousresearch.com/blog/secondary-patenting-or-evergreening-india/ (last visited Dec 31, 2021).

[6] *What's the difference between brand-name and generic prescription drugs?*, SCIENTIFIC AMERICAN (2004), https://www.scientificamerican.com/article/whats-the-difference-betw-2004-12-13/ (last visited Dec 31, 2021).

[7] Himanshu Gupta et al., *Patent protection strategies*, 2 JOURNAL OF PHARMACY AND BIOALLIED SCIENCES 2 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3146086/ (last visited Dec 31, 2021).

[8] Neha Dasgupta, *Exclusive: With U.S. trade under a cloud, China opens to Indian pharma,* REUTERS (2018), https://www.reuters.com/article/us-usa-trade-china-india-exclusive/exclusive-with-us-trade-under-a-cloud-china-opens-to-indian-pharma-idUSKBN1K20IF (last visited Dec 31, 2021).

Evergreening is a rampant practice in the Pharmaceutical industry. Towards the end of the term of a patent, the manufacturer may make a slight change/modification in the composition or form of the drug, thereby making it eligible for being patented and gaining an additional term of protection of 20 years.[9] This practice is called the evergreening of patents.

In the pharmaceutical sector, the evergreening technique has sparked significant debate. Producers of a particular medicine may employ evergreening in this context to limit or prohibit competition from manufacturers of generic analogues to that drug.

How can the evergreening of patents be prevented?

Under the Indian laws, we observe there is a significant effort to prevent evergreening of patents. By the virtue of Sec. 3(d) of the Patents Act, 1970[10], in order for a novel version of a known material to be patentable, it must demonstrate improved efficacy above the substance's known efficacy.[11]

The Hon'ble Supreme Court of India has interpreted the Sec. 3(d) of the Patent Act, 1970 in *Novartis AG & Ors. v Union of India & Ors.*[12] at length. Novartis had submitted the patent application at issue in India in 1998, after India decided to join the World Trade Organization (WTO) and adhere to global intellectual property rules under the TRIPS agreement. At first instance, this application was rejected resulting in this litigation which ended with this judgment. The Supreme Court clarified that "Efficacy" in Sec. 3(d) solely refers to "Therapeutic Efficacy" in the case of medicine, and that all attributes of a medication are irrelevant; the properties that directly pertain to efficacy in the case of medicine are its therapeutic efficacy.[13] Hence, this attempt of evergreening of a patent by Novartis was defeated.

The Hon'ble Supreme Court's decision provides relief to people who cannot afford life-saving medications because pharmaceutical corporations offer them at exorbitant prices, making them

[9] Thomas A Faunce & Joel Lexchin, *"Linkage" pharmaceutical evergreening in Canada and Australia*, 4 AUSTRALIA AND NEW ZEALAND HEALTH POLICY (2007), https://anzhealthpolicy.biomedcentral.com/articles/10.1186/1743-8462-4-8 (last visited Dec 31, 2021).

[10] Subs. by Act 15 of 2005, s. 3, for clause (d) (w.e.f. 1-1-2005).

[11] The relevant Sec. is given as under:

> *"Sec. 3:* ***What are not inventions***
> *(d) 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."*

[12] AIR 2013 SC 1311

[13] Andrew Q. Leba, *Lowering the "Efficacy" Threshold for Section 3(d) of the Indian Patents (Amendment) Act 2005: A Case for a Broader Scope*, 28 EMORY INT'L L. REV. 649 (2014). Available at: https://scholarlycommons.law.emory.edu/eilr/vol28/iss1/15 (last visited Dec 31, 2021).

expensive to the average person. The Court stated unequivocally that India is a developing country in which the affordable supply of medicines is critical for the survival of 1 billion people.[14] This judgment received acclamation and was hailed as a step for social welfare.[15]

Compulsory Licensing

When a government authorizes someone else to make a patented product or process without the approval of the patent owner or plans to utilize the patent-protected innovation itself, this is known as compulsory licensing. It's one of the patent-related flexibilities contained in the WTO's intellectual property accord, the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement.[16]

Compulsory licenses are granted in a number of scenarios under several patent law regimes. The Paris Convention of 1883 stipulates that each signatory State may enact legislation to award compulsory licenses.

Article 5A.(2) of the Paris Convention reads:

> *"Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."*

A compulsory license allows an individual or corporation to use another's intellectual property without first obtaining the rights holder's approval, in exchange for a specified sum paid to the rights holder.

Compulsory licensing in India: In India, the Controller General of Patents, Designs, and Trade Marks may grant a compulsory license under section 84(1) of the Patents Act, 1970, if[17],

1. The public's reasonable expectations in regard to the patented innovation have not been met.

[14] Shanti Kumar, Nitin Shukla & Tanushree Sangal, *Evergreening of Patents and Indian Patents Law*, SSRN ELECTRONIC JOURNAL (2009), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1420003 (last visited Dec 31, 2021).
[15] Sarah Boseley, *Novartis patent ruling a victory in battle for affordable medicines*, THE GUARDIAN (2013), https://www.theguardian.com/world/2013/apr/01/novartis-patent-ruling-affordable-medicines?INTCMP=SRCH (last visited Dec 31, 2021).
[16] *TRIPS and public health: Compulsory licensing of pharmaceuticals and TRIPS*, WTO.ORG (2017), https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Dec 31, 2021).
[17] Hana Onderkova, *Compulsory Licensing in India and changes brought to it by the TRIPS Agreement*, IP HELPDESK (2021), https://intellectual-property-helpdesk.ec.europa.eu/news-events/news/compulsory-licensing-india-and-changes-brought-it-trips-agreement-2021-10-12_en (last visited Dec 31, 2021).

2. The patented innovation is not readily available to the general public at a reasonable cost.

3. The patented innovation is not used in India's region.

In March 2012, India gave Natco Pharma, an Indian generic pharma company, its first compulsory licence for Sorafenib tosylate, a cancer medication patented by Bayer.[18]

The WTO's Pharma Agreement: A Step by World Trade Organisation (WTO) for easing availability of Pharmaceutical Products

The 1994 Agreement on Trade in Pharmaceutical Products abolishes tariffs and other duties and charges on a large number of pharmaceutical products and the substances used to manufacture them, ensuring that they remain duty-free for the foreseeable future. The Agreement was signed by and applied to just a small number of countries during the Uruguay Round of trade negotiations, who also agreed to implement the conclusions on a most-favoured-nation basis.[19]

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization (WTO) aims for the harmonisation of intellectual property rights (IPRs) rules across all WTO member nations. In rising economies like India, this reduces the danger of IPR infringement. Within the pharmaceutical sector, it has resulted in a division of labour. The pharmaceutical sector has become more worldwide as a result of the TRIPS Agreement.[20] There has always been constant voicing within WTO (mostly by the developing nations) for easing down the constraints put by the TRIPS Agreement with respect to the pharmaceutical products. This has gained momentum by the outbreak of COVID-19 pandemic. The recent waiver proposal in WTO by India and South Africa in the wake of COVID-19 is in furtherance of the same efforts.[21]

[18] Maricel Estavillo, *India Grants First Compulsory Licence, For Bayer Cancer Drug*, INTELLECTUAL PROPERTY WATCH (2012), http://www.ip-watch.org/2012/03/12/india-grants-first-compulsory-licence-for-bayer-cancer-drug/ (last visited Dec 31, 2021).
[19] *The WTO's Pharma Agreement*, WTO.ORG (2018), https://www.wto.org/english/tratop_e/pharma_ag_e/pharma_agreement_e.htm (last visited Dec 31, 2021).
[20] Atsuko Kamiike, *The TRIPS Agreement and the Pharmaceutical Industry in India*, JOURNAL OF INTERDISCIPLINARY ECONOMICS (2019), https://journals.sagepub.com/doi/full/10.1177/0260107919875573 (last visited Dec 31, 2021).
[21] I*ndia, South Africa's patent waiver proposal in WTO achieved tremendous mileage, progression: Commerce Secretary*, THE HINDU (2021), https://www.thehindu.com/news/national/india-south-africas-patent-waiver-proposal-in-wto-achieved-tremendous-mileage-progression-commerce-secretary/article34778668.ece (last visited Dec 31, 2021).

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Conclusion

Protection of Intellectual Property Rights are necessary for the promotion of innovation and to reward research and development. However, the same IPR regime can be tactifully used to create monopoly and harness the potential of the market. In this attempt, the interests of buyers get risked. This is true particularly for the pharmaceutical industry. Often, the pharmaceutical corporations artificially surge the price of medicines which pose life-threatening challenges for the public. This hypothesis is valid for life saving drugs too. *Zolgensma* (onasemnogene abeparvovec-xioi) is a textbook example for this thesis whose price is Rs. 16 crore/dose.[22]

Evergreening of pharmaceutical patents has to be acknowledged as a problem and provisions like Sec. 3(d) of the Patent Act, 1970 have to be incorporated in international conventions as well to fight this problem. Compulsory Licensing is another remarkable practice to make the medicines available to everyone. But it is a matter of regret that the full potential of compulsory licensing provision has not been harnessed. Only few medicines get compulsorily licensed. WTO has taken several steps for making access to medicines more easy but only few nations have come forward to accept it wholeheartedly. An international consensus at international level and suitable policies at the national level are needed to make the medicines easily available to the members of the public.

Certainly, these steps and policy measures shall make the medicines more available and affordable despite the protection by Intellectual Property Laws.

[22] *Learn how gene therapy stops the progression of SMA*, ZOLGENSMA (2021), https://www.zolgensma.com/what-is-zolgensma (last visited Dec 31, 2021).