

## **PATENTING OF MEDICINES AND ITS SOCIAL IMPACT**

- Anvita Priyadarshi, Symbiosis Law School, NOIDA

Hippocrates said, “Wherever the art of medicine is loved, there is also a love of humanity”. Creation of medicines and discovery of medicinal properties in elements are some of the greatest gifts to mankind. Where one did not have the resource, technology or equipment to manufacture complex compositions or even essential medicines in the past, the present has an abundance of skill, technology and opportunity for enhanced research and development of various medicines which have contributed towards the well-being of society.

The Indian Pharmaceutical industry is one of the *major global players*<sup>1</sup>. With an increase in globalization and foreign investors collaborating with the Indian pharmaceutical companies, the opportunities for innovation have seen a steady growth. Contrary to large scale impact of infectious diseases in India due to its dense population and lack of adequate literacy, it is worth noting that India is the largest provider of generic<sup>2</sup> and low-cost drugs in the world. The pharmaceutical industry of India exports to almost every nation in the world and has created a significant impact in highly regulated developed markets specially in the United States which is a key destination for India’s generic exports. Major Indian players in this field include- Lupin, Torrent, Sun Pharma, Dr. Reddy’s and Glenmark to name a few.<sup>3</sup>

Although India has the resources to manufacture low cost, effective drugs, this is in contrary to the existing situation in India because a large section of the Indian population does not have the access to even essential medicines. A contributing factor which makes these ‘essential medicines’ inaccessible is the price at which they are sold by the pharmaceutical companies. The high prices fixed by these companies have a global protection provided to pharmaceutical patents by *Trade Related Intellectual Property Rights [TRIPS]*. TRIPS agreement was signed by one hundred and seventeen member nations of the *World Trade Organisation [WTO]* to which India is a party to. This agreement applies to all member nations mandatorily. The WTO provides that intellectual property rights are to be protected during trade and this is where TRIPS comes into play. In simple terms, it lays down the minimum, basic standards of Intellectual Property Rights [IPR] in the form of rules for trade and investment in ideas and creations. The Parliament of India passed the Patents (Amendment) Act of 2005 incorporating these minimum standards in the principle legislation making the a few aspects of the treaty admissible in court.

The discretion regarding the trade and distribution of an idea lies with the innovator and this is exactly what the act covers. Respecting the authenticity and creativity of the innovator while rewarding the innovator for efforts put and expenses incurred is the essence of the Patents

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<sup>1</sup>Uday S. Racherla, Innovation, Economic Development, and Intellectual Property in India and China 272 (2019).

<sup>2</sup>See also Interchangeability of WHO- Prequalified Drugs [https://www.who.int/medicines/publications/druginformation/WHO\\_DI\\_30-3\\_GenericMedicines.pdf?ua=1](https://www.who.int/medicines/publications/druginformation/WHO_DI_30-3_GenericMedicines.pdf?ua=1).

<sup>3</sup>Julian Issa, The World’s Pharmacy: India’s Generic Drug Industry, Global Business Reports In. Ref. para 3 (Feb 12, 2020), <https://www.gbreports.com/article/the-worlds-pharmacy-indias-generic-drug-industry>.

(Amendment) Act, 2005. However, pharmaceutical companies engaged in commercial activities often view the benefits of the patent as a method of increasing their profit margin. While this is partly how the costs of research, technology and man force are met but an increased price means fewer people can afford these drugs. These costs can also be met by reducing the exorbitant amount spent of advertising and marketing of these drugs and regulated use of rights granted by patents. *Right to Life and Personal Liberty*<sup>4</sup> is given paramount importance and right to health<sup>5</sup> is often associated and covered under this *fundamental right* and upheld in many judgments<sup>6</sup> by the Hon'ble Supreme court. However, this difference between protection of fundamental rights and intellectual property rights has created a paradoxical situation. The Indian constitution gives supreme importance to fundamental rights specially the Right to life which has some of its essence picked up from *right to health*, a directive principle.<sup>7</sup> However, excessive protection is also provided to patent owners which make the balancing act difficult. ***The protection of intellectual property rights is more innovator based and this often influences the supply of drugs because companies tend to become selective, examining which distribution might give maximum returns.*** In a global crisis such as a pandemic caused by the corona virus, supply of vaccines after its development would be of utmost importance. Hypothetically, if XYZ Pvt. Ltd. comes up with a vaccine and acquires a patent assuming that all this happens in a short span of time unlike normal scenarios in which new medicinal compositions often take up to 10-15 years including testing and acquiring patent. If this company decides to be selective and sell the vaccine at a high price then the situation would remain unresolved and only the affluent sections of the society would be able to afford the treatment. This hypothetical situation is similar to something which has happened in the past. One such example could be the Anti-Retroviral (ARV) therapies that have had considerable success in curtailing the death rate from HIV/AIDS. They are available in the West and cost about \$10,000-15,000 per person per year.<sup>8</sup> This already excludes a large section of the country as an average worker in the United States earns \$ 48,672 per year. Anti-Retroviral therapy is something which is still new indicating that pharmaceutical companies still maintain the rights to the medication's patent; as a result, a generic option isn't available. Generic medications are recommended due to lower costs and similar effectiveness. India, however, has improved by making this drug available in almost every government medical colleges, district health care centers and providing two-thirds of the total to developing countries making the drug accessible to developing nations.<sup>9</sup>

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<sup>4</sup>IN. Const. art. 21.

<sup>5</sup>K.Mathiharan,The Fundamental Right to Healthcare, Indian Journal of Medical Ethics(2003), <https://ijme.in/articles/the-fundamental-right-to-health-care/?galley=html>.

<sup>6</sup>In re. Bandhua Mukti Morcha v. Union of IndiaAIR 1984 SC 802.

<sup>7</sup>IN. Const. art. 47.

<sup>8</sup>Mohit Rohatgi &Ritwik Bhattacharya, Access to Patented Medicines: Issues Faced by the Pharmaceutical Industry, India Law Jurnal (2007).

<sup>9</sup> Accord. India calls for expanding antiretroviral therapy coverage to combat HIV/AIDS, Business Standard, Jun 4, 2019[https://www.business-standard.com/article/pti-stories/india-calls-for-expanding-antiretroviral-therapy-coverage-to-combat-hiv-aids-119060400159\\_1.html](https://www.business-standard.com/article/pti-stories/india-calls-for-expanding-antiretroviral-therapy-coverage-to-combat-hiv-aids-119060400159_1.html).

Contrarily, nearly ten million die due to acute respiratory infections, diarrhea, tuberculosis and malaria. However, for all these conditions, inexpensive, essential drugs can be lifesaving.<sup>10</sup> About 66 % of the expenditure incurred is on public healthcare facilities and even then, the lowest strata of the society cannot access the essential drugs. Government has introduced price cap on medicines which forces the company's marketing in India to reduce their price. This hampers their profit margin and often forces them to withdraw from the Indian market as it occurred after the National Pharmaceutical Pricing Policy, 2011. Patents often work contrary to principles of human rights and are responsible for extra ordinarily high prices. They confer the creators with exclusive monopoly rights i.e. a company can choose to be the sole supplier of the drug or be selective in its distribution. This is mostly to honor the creation and effort put in to innovate the drug with the qualities that it has.

Before 1995, India was staunchly against rigid protection of Intellectual property. This can be supported by many judgments passed by the Hon'ble Supreme Court of India. Priority is always given to the greater good, human rights and social justice in general while protecting the intellectual property rights of the creators at the same time, but not at the cost of a greater well-being. In fact, The India Patents Act of 1970 incorporated major provisions to reduce the social costs of the foreign-owned patents. It prohibited *patents on products useful as medicines and food, shortened the term of chemical process patents, and significantly expanded the availability of compulsory licensing.*<sup>11</sup> This also led to the exponential growth of Indian pharmaceutical industry. Further, in '*Novartis vs. Union of India*'<sup>12</sup>, the plaintiff failed to prove the efficacy of Beta crystalline form of Imatinib Mesylate as compared to the therapeutic efficacy of Imatinib Mesylate. The Supreme Court rejected the appeal to provide for a patent for the former composition. The *ratio* behind this judgment was that it wants to prevent ever greening of patents to protect the interest of the citizens and make life saving drugs accessible for all. It also stated that selling such drugs at an affordable rate is essential for a developing country like India.

India became a member of WTO in 1995 making it essential to sign the TRIPS agreement. However, the rigid protection of IPR was challenged in the *Doha Declaration of 2001* highlighting the concerns of less developed countries allowing certain flexibilities.

Although *the Patents (Amendment) Act, 2005* is still very creator oriented as it protects patent holders for a term of 20 years according to Article 32 of the agreement, however, the sovereign nature of India and its socio-capital financial structure allows a fair amount of principles which protect the economically weaker section. The judgment in the Novartis case (2013) also represents the supremacy given to human rights and India's goal of all-round socio-economic development irrespective of the discrimination caused by the profit favouring provision of patents by regulating the benefits and avoiding its misuse.

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<sup>10</sup>Rituparna Maiti, Vikas Bhatia, Biswa Mohan Padhy, & Debasish Hota, Essential Medicines: An Indian Perspective, Indian Journal of Community Medicine(2015) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4581141/>.

<sup>11</sup>Uday S. Racherla, Innovation, Economic Development, and Intellectual Property in India and China272 (2019).

<sup>12</sup>*Novartis vs. Union of India* 2013 6 SCC 1