Impact Of Pharmaceutical Patents On Public Health In India

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Abstract

Patents are most widely used form of Intellectual Property Rights in pharmaceutical industry. Major changes were observed in patent law after India signed the TRIPS Agreement which have provisions for product patent and term of patent for 20 years came into action which directly affected the financially weaker section of the society as prices for the essential medicines increased because of the product patent regime and India who was a leader for generic drug industry prior to 2005 regime, find it difficult to produce life saving drugs at affordable prices after its numerous drugs got patented. This paper deals with the impact on access to public health after 2005 patent regime.

KEYWORDS: Access to Healthcare, Pharmaceutical Patents, Product Patent Regime TRIPS Agreement.

Introduction

India, a developing country has been aiming to habituate pharmaceutical patents law to take charge of domestic needs, giving more emphasis on common man's health needs. In a developing country like India, a population of 73 million people still lives below the poverty line[i]and such people are unable to afford the expenses of health care needs and therefore, there is a serious health crisis for such people with respect to healthcare and its accessibility and affordability of the medicines in India.

- ***Importance of patent law in pharmaceutical industry***

The pharmaceutical industry is always a fresh and vital industry, be it in times of recession or in boom for any country. Medicines are always needed by each and every country. There are many forms of IPR (Intellectual Property Rights) which are associated in pharmaceutical industry. They are namely:

- Patents
- Industrial Designs
- Trade Secrets
- Copyright
- Trademarks

However, the importance of patent law is more significant than any other forms of IPR when talking about pharmaceutical industry. Following are some importance to better explain the fact stated above.

a. Safeguarding Invention:

When one develop a drug it needs to be protected before it could be poached from you. So, the inventor has two options to choose from. The first one is to protect under Trade Secrets, but the drawback of protecting under

trade secrets is, the other person can inverse your drug engineering and can be robbed. In comparison to trade secrets, patent law provides much better protection to such invention of drugs as well as their engineering[ii].

b. Safeguards interests of consumers and inventors

IPR's main aim is to protect interests of its consumers, so that safety of public remains the foremost priority while granting protection to any invention or discovery of drugs and medicines under patent law and consumers get an assured standard quality to choose from. IPR along with consumer's interest and safety also protects its inventor's interest and safety. Patent law awards monopoly rights to the inventors and ensures them with high profits without any division along with sole marketing rights to sell or to license the patented invention of drugs and medicines.

c. *Developing new drugs to meet world-wide demands*

There is a constant need for innovation and development of new drug formulas and medicines to meet the dynamic worldwide demands of vaccines as and when new diseases attack any country. In such situations, patent law does the job right by promoting innovation along with protecting it against being poached and also by funding the same to such inventors.

d. *Creating safe environment for inventors*

Patent law helps in creating a safe environment for its inventors to share their inventions with public in exchange; recognition for their work is awarded to them along with monopoly rights to sell or license their inventions. When an inventor feels safe to share their inventions, then only there shall be a rise in research and development sector of any country for innovation of new forms of drugs in the market.

Therefore, one can say that role of patent laws in advancement pharmaceutical industry is very symbolic.

1) ***Right to health and pharmaceutical patents***

- Introduction to right to health

Human rights are inherent to all human beings and are basic for living a life in dignity, without the right to health being ensured, the other rights becomes frivolous. The other rights that are closely related with right to health are right to life, food, housing, equality and many more such rights. Since all such rights are intertwined, inseparable and connected with each other, they all are labeled as an essential component of right to health.[iii]

US President Franklin Roosevelt mentioned right to health in a document that included 'the right to adequate medical care and the opportunity to achieve and enjoy good health'.[iv] This term was accurately first defined in WHO Constitution as a 'state of complete physical, mental and social well-being and not merely the absence of disease or infirmity'[v]. In addition to this, the Preamble of the Constitution mentions that; the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being' without any distinction whatsoever.

After Constitution, the document which first talked about right to health was in 1948 UDHR (Universal Declaration of Human Rights), which said that "everyone has the right to standard of living adequate for the health and well-being of himself and of his family, including medical care'[vi], although even this declaration is not legally binding. Still, many members of human rights community consider that this particular document has some legal effect to it.

The first 'legitimately' binding instrument providing high standard of health was in 1966 ICESCR (International Covenant on Economic, Social and Cultural Rights) which clearly defined right to health in its

Article 12, as 'a right of everyone for the enjoyment of the highest attainable standard of physical and mental health'.[vii]

But, later on many changes were made in the definition mentioned in WHO Constitution about health and at last, the drafters of Covenant recognized right to health mentioned in ICESCR as ' a right to the enjoyment of a variety of facilities, goods, and services and conditions necessary for the realization of the highest attainable standard of health'[viii] in General Comment No.14. After the acceptance of the Covenant, the first declaration ever to mention right to health is by Alma-Ata Declaration on Primary Health Care of 1978, which declares that 'health is a state of complete physical, mental and social well being and it is not entirely understood as absence of disease or infirmity, and is considered as a fundamental human right with highest attainable level of health as a social goal in entire world who also requires attention for other social and economic sectors in addition to just health sector'.[ix] While, Alma-Ata Declaration their part of the work, the other most authoritative document that accepted ICESCR was the General Comment (GC) No. 12 from 2000, drafted by CESCR. Mr. Paul Hunt was appointed as a Special Rapporteur by the Resolution of the UN Commission of Human Rights in 2002 and his work included report on the conditions and status of the realization of the health globally and to provide suggestions for the measures. He prepared a number of reports on all segments of the right to health such as essential medicines, less known diseases as well as engagement of pharmaceutical companies and has drafted the Human Rights Guidelines for Pharmaceutical Companies in relation to access to medicines[x]. Later on, Mr. Anand Grover took up the charge in 2008.[xi]

- How human rights differ from patent rights?

Many consider both rights as one, misconception originated in Articles 27(2) of UDHR and 15(1(c)) of ICESCR which in summarized form mentions that the authors of literary, scientific or artistic work have a human right to the protection of the moral and material interests resulting from it. The scopes however, are different from modern IP laws[xii]. These provisons do provide protection to their human rights but not to their patentable right[xiii]. Therefore, the Committee on Economic, Social and cultural rights (CESCR) in its General Comment No.17, made a descriptive distinction between the two rights.

- The GC declares that human rights are fundamental rights as they are inherent by all, whereas IP rights are to the greatest extent of States as they not only recognize the artist's innovative work but provide rewards to the same and promotes the innovation for development of the society as a whole along with the inventor[xiv].
- Human rights are 'timeless expressions of fundamental certificate of the human person' whereas, IP rights are 'perishable in nature, easily exchangeable and fluctuating' as well.[xv]

Therefore, the two Articles safeguards scientific production of authors as their basic interests which are needed by them to enjoy a particular standard of living and not their IPRs which go beyond these moral and material interests[xvi]. In addition to this, they safeguards only individuals and not group of individuals like pharmaceutical companies which are supreme holders of IP rights and significant investors to the Research and Development of the various inventions[xvii]. Therefore, both ICESCR and UDHR does not accommodate according to the modern day IP to a human right.

But, there are some regional instruments which consider IP rights as human rights, as they protect Intellectual Property rights as property rights of the inventor.[xviii] India has also recognized right to health as a fundamental right and along with India, TRIPS Agreement as well pinpoint the member's countries which may set aside patentability from certain inventions, exploitation of which is prime to protect health of humans, therefore the

right to health care and also access to such health care at affordable prices are admitted globally as human rights[xix].

- Status of Right to Health under Indian Constitution

Under Indian Constitution right to health has not been directly recognized but has considered it as a fundamental right of each individual irrespective of his caste, religion, race, and color, social and economic condition. The burden is on the States to ensure proper conditions regarding good health as under provisions contained in Articles 38,39 (e), 42, and 47 in Part iv of the Constitution of India.

a. Article 38

The state has to direct its policy towards securing that health and strength of workers, men and women, and tender age children shall not be abused and must not force to work unsuited for their age and health.

b. Article 39 (e)

The children must be given opportunities and facilities to develop in a healthy manner.

c. Article 42

This article talks about provisions for just and humane conditions of work which the State must ensure to comply with.

d. Article 47

This Article talks about duty of the State to raise the level of nutrition and standard of living and to improve public health.

e. Article 21

This Article of the Constitution guarantees protection of life and personal liberty to every citizen. The Supreme Court has held that the right to live with human dignity in Article 21 derives itself from directive principles of state policy and therefore includes protection to health.[xx]

The above articles act as guidelines to the State to ensure proper standard of living with proper nutrition and condition of work to its each citizen as being integral to health under Indian Constitution.

Government of India has launched various policies for poor and urban people in order to meet the obligations as specified under Constitution of India. Policies such as National Rural Health Mission and National Urban Health Mission which are reproductive and health care program to save women and new born from pregnancy deaths and also provide free drugs to the pregnant mothers and new born children. Many more schemes such as Universal Health Coverage Model, Polio Drop Scheme, and Mission Indradhanush implemented to focus on providing immunization to children who have been left out or missed from getting immunization.

- Judicial Approach to Right to Health

The Indian Judiciary has interpreted the right to health through public interest litigation as well as litigation arising out of claims that individuals have made on State in respect to health services.

1. ***Consumer Education and Research Centre v Union of India***[xxi]

The SC ruled that in this historic judgment the right to health and medical care to protect health in service or post retirement along with health insurance while in service or post retirement is a fundamental right of the worker under Art 21. Also, private industries do come under ambit of Art 21 for providing health insurance to its workman.

2. **Vincent Panikulangara v Union of India**[xxii]

The SC on right to health care observed in this case:

"Maintenance and improvement of public health have to rank as high as these are indispensable to the very physical existence of the community and on the betterment of these depends on building the society of which the Constitution makers envisaged. Therefore, public health in our opinion is our top priority."

3. **State of Punjab and others v Mohinder Singh Chawala**[xxiii]

The honorable court of India held that the right to health is integral to right to life and government has constitutional obligations to provide health facilities.

4. **Paschim Banga Khet Mazdoor Samity v State of West Bengal**[xxiv]

In this case, the question before the court was whether the non-availability of services in the government health centre amount to violation of Art 21? The honorable court answered the said question as Yes, it would be a violation of Art 21 and further directed primary health centre's to equip to deal with medical emergencies and the lack of financial resources shall not be a reason for the State to shy away from its constitutional obligations.

2) ***Criticism to right to health under pharmaceutical patents***

The developed countries and developing countries have their respective problems regarding healthcare in their country. In developed countries, people are very conscious about their health and so demand for quality healthcare in such countries is booming and government has still not succeeded in providing global access to quality health care. But in case of developing country like India, they have less access to health both in terms of factors providing access to healthcare and expenditure for the same. Also majority of population in India is below poverty line or is uneducated or not conscious about their right to health and proper health care facilities including the basic cleanliness and sanitation facilities.

In India, the access to healthcare faces various challenges and though judiciary has pronounced many cases supporting access to healthcare to the claimant but legislative implementation is what is lacking in India. India still needs to done a lot in administrative field along with its statutory role in this regard[xxv].

It is a debatable discussion on disagreements between countries about the justification of protection to be given to holders of IP, who are in favor of economic growth support the protection given and on the contrary, those who are concerned with the health are opposed to the views of protection. This problem arose when TRIPS agreement was signed by India.

- During the pre-TRIPS regime the patent protection granted was not that tough which was beneficial it increased the accessibility and availability of medicines. But, after TRIPS the scenario changed completely and now the medicines were priced beyond the reach of the poor giving a major loss to the poor population.
- Lack of reliable supply systems is also a major concern in a developing country as many a times the medicines rejected in the developed country either because they are unsafe or their expiry date has passed somehow finds their way to the developing country. This 'recycling' of medicines is unacceptable.
- Another major problem in developing countries is lack of insurance policies or bad health care systems as the majority of essential medicines are paid 'out of pocket' which creates a financial burden on a person itself.
- B.P Jeevan Reddy J felt that the TRIPS Agreement favors only the MNCs and he cites wide differences between the prices of medicines produced in India by Indian companies and those produced by foreign MNCs and warned that the exclusive marketing rights permitted by the 1999 amendment Act and the product patenting permitted from 2005 amendment Act would be adverse to the common man.
- However, product patenting of drugs and pharmaceuticals was bound to contribute to increase in the prices of life-saving drugs, which make it unfeasible and inaccessible for large number of people living in a developing country like India. Clearly, because of TRIPS regime there is a conflict of interests between health and welfare of the society with that of economic rights of the individual patent holders in developing country like India.

In the case of *Bristol- Myers Squibb and Co.v Canada (Attorney General)*[xxvi] the court focused upon striking balance which has to be made in protecting IPR of pharmaceutical drugs industry and health care costs as the main motive is to control price so that essentials medicines can be affordable and accessible to all, but on the other hand, the human efforts in discovery or inventing some new drug which results in saving a lot of lives is being invented by some then their work should be recognized and awarded. Therefore, a balance between the two is crucial

3) ***Suggestions***

The most probable solution for the above discussed problems are to have a compulsory license as they interlink to achieve balance between the interests of IP holders and public health in a country like India which is still developing and have a mass population is being affected by the product patent amendment Act 2005 because of the hike in prices of the medicines. Compulsory Licensing shall intensify the interest of the public and shall not hamper the incentive benefits for new innovations at the same time. Similarly, OSDD (Open Source Drug Discovery) is a network where pharmaceutical companies would not invest, in such scenario, Indian Government should invest as the medicines researched under OSDD would not be patented as Government itself is providing the investment to conduct such a research and the researched medicines could help a million of population in India.

4) **Conclusion**

Because of TRIPS Agreement, many opposed patent protection which ultimately postponed the accessibility of essential medicines to the much needed people in a country like India. In addition to this, pharmaceutical companies shall boost the research and development of new drugs when they will know that their invention shall be patented and for a term period they can demand monopoly price for their invention from government as well as needy patients, but the other side of the same coin shall commence once the term of patent protection is over and after that a large number of people could be benefited by it at affordable prices. This shall benefit

surely in a large number of populations in the long run, but even in today's time, the population shall be under a patent protection after all.

This extension of the IPRs shall benefit the people in the future because of a decision taken by people for their future in today's scenario. Last but not the least, Pharmaceutical companies must ensure that the goal of their existence is to serve the people of the country by saving their lives and not just earning profit. Pharmaceutical companies are not just any profitable business rather they have a major social responsibility to cover for the welfare of the needy people in the country.

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[i] https://timesofindia.indiatimes.com/india/india-no-longer-home-to-the-largest-no-of-poor-study/articleshow/64754988.cms (Visited on 5th March, 2019).
[ii] https://www.iipta.com/role-of-ipr-in-the-pharmaceutical-industry/(Visited on 5th March, 2019)
[iii] http://lup.lub.lu.se/luur/download?func=downloadFile&recordOId=3955219&fileOId=3955220 (visited on 6th March, 2019
[iv] F. D. Roosevelt, 'State of the Union Address to Congress (1944), quoted in Helfer and Austin (n14), p. 105 available at http://lup.lub.lu.se/luur/download?func=downloadFile&recordOId=3955219&fileOId=3955220 (accessed on 6th March, 2019).
[v] WHO, Constitution of the World Health Organization, adopted by the International Health Conference, New York, 19 June-22 July 1946, available at: http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf, Preamble
[vi] UDHR, 1948 Art. 25 (1).
[vii] Supra 3.
[viii] CESCR GC No. 14, para 9.
[ix] Declaration of Alma-Ata, International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978, Geneva: WHO, para 1.
[x] United Nations Human Rights: Office of the High Commissioner for Human Rights available at http://ap.ohchr.org/documents/dpage_e.aspx?m=100
[xi] UN HRC, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover, A/HRC/11/12, 31 March 2009, p. 2
[xii] Hestermeyer (n1), p. 153; CESCR, General Comment No. 17: 'The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author' (2005) (article 15, paragraph 1 (c) of the ICESCR), E/C.12/GC/17, 12 January 2006 [CESCR GC No. 17], para 3
[xiii] Hestermeyer (n1), p. 154
[xiv] CESCR GC No. 17, para. 1.
[xv] Id, para. 6.
[xvi] Id, para. 2.
[xvii] Hestermeyer (n1), pp. 155 and 157.
[xviii] Supra 3 pg 20
[xix] Art. 27(2) TRIPS Agreement, 1995
[xx] Bandhua Mukti Morcha v. Union of India (AIR 1984 SC 802) (source: manupatra)
[xxi] AIR 1995 SC 922 (source: manupatra)
[xxii] AIR 1987 SC 990: 995 (source: manupatra)
[xxiii] State of Punjab v Ram Lubhaya Bagga. (1998) 4 SCC 117 (source: manupatra)
[xxiv] Agarwal SC (J), Nanawati GT (J). Paschim Banga Khet Mazdoor Samity of Ors. vs. State of West Bengal & Anr. 1996 (source: manupatra)
[xxv] http://indiatoday.intoday.in/education/story/union-government-launched-health-mission--mission-indradhanush/1/408944.html (accessed on 6th March, 2019).
[xxvi] 2005 SCC 26 (Canada)