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Access to Medicine and Patent Rights in the Globalized World

SHUBHI TRIVEDI [1]

ABSTRACT

The researcher in the present project aims to analyze the present position on the access to medicine after the introduction of product patent regime in TRIPS agreement, an outcome of globalization, especially in context with the situation in developing and least developed countries. The provisions of TRIPS agreement had changed the whole intellectual property regime by setting the minimum standards of IPR protection. Under the TRIPS agreement, it introduced the product patent regime which grants the monopoly right to the holder of IPR on the product itself which significantly affected and raised the price of medicines in the pharmaceutical industry. It created a big obstacle for the accessibility of medicine in developing and least developed countries. Although various flexibilities are mentioned under TRIPS agreement which can be used in case of non-working of patent or non-availability or accessibility of patented product in the market but there are still many developing and least developed countries which don't have access to essential medicines. Also, under Doha Declaration it obligates the member countries to take measures to ensure public health but the situation is still not pleasant in most of the developing and least developed countries. Some of these flexibilities are Compulsory licensing under Article 31, Article 31bis of TRIPS absorbed under Section 84-92A of the Patents Act, 1970 of India and Principle of Exhaustion under Article 6 of TRIPS allowing for parallel importation of medicines in case of regional and international exhaustion.

Under the light of the above discussion the researcher will study the implications of the issue of access to medicine and imparting of justice to not only the patent holder but also to the general public not having access to it despite of the entire world being a global village because of which transfer of knowhow and medicines from one jurisdiction to other has become immensely smooth and easy. The researcher will also try to propose how harmoniously a balance can be adopted to resolve this issue thus ensuring justice to all the stakeholders.

Key terms *– Patent, Access to medicine, TRIPS.*

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I. INTRODUCTION

The entire intellectual property regime was completely changed when the TRIPS agreement was introduced. The provisions of the agreement revised the whole regime by setting minimum standards for IPR protection. The product patent regime was introduced by the TRIPS agreement which aimed at granting exclusive monopoly rights to the IPR holder over the product itself. The product patent regime affected and increased the prices of the medicines significantly and hence built a big hindrance for the developing countries in accessing the medicines.

As per a study conducted by World Health Organization, a major chunk of the total population of the world even today after such scientific and technological advancement fails to have access to basic and essential medicines. The condition still persists even though multiple flexibilities are provided in the TRIPS agreement which can be utilized during non- working of patents or in case of unavailability of medicines and patented products in the market. Some of these flexibilities are compulsory licensing under Article 31, Article 31bis of TRIPS absorbed under Section 84-92A of the Patents Act, 1970 of India and Principle of Exhaustion under Article 6 of TRIPS allowing for parallel importation of medicines in case of regional and international exhaustion. Apart from this the Doha Declaration obligates it for the member nations to ensure public health by adopting efficient measures. However, the situation is still unpleasant in major developing and under developed countries and millions of people even today don't have access to basic medicines.

Therefore, at this juncture being a global family it becomes the moral responsibility of every member country to extend a helping hand by adopting such measures so as to be able to strengthen the conditions of people facing adverse conditions due to unavailability of essential medicines. This is generally done by issuing compulsory licenses against the patent holders of drugs and life saving medicines wherein they are compelled by the governments to provide essential medicines for such developing and least developed countries.

In this research, the researcher will study the implications of the issue of access to medicine and imparting of justice to not only the patent holder but also to the general public not having access to it despite of the entire world being a global village because of which transfer of knowhow and medicines from one jurisdiction to other has become immensely smooth and easy. Besides this the paper will also focus on the issues of product patent and the enormous monopoly rights relished by the pharmaceutical giants and its implications upon the

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accessibility of medicines in the least developed and developing nations. The researcher will also try to propose a harmonious way to resolve this issue thus ensuring justice to all the stakeholders.

II. PROBLEM OF ACCESS TO MEDICINE UNDER TRIPS

The TRIPS agreement has set minimum standards for the protection and enforcement of intellectual property rights. As per TRIPS the member nations are mandated to ensure patent protection to all types of technological inventions and innovations including the inventions made in the pharmaceutical sector. The protection is provided for a period of 20 years from the date of filing the application.[2] As per Article 28 of the TRIPS agreement, it is compulsory for the member nations to provide patent protection to the pharmaceutical industries for their products and grant exclusive rights to exploit their invention, prevent the third parties from making, using, selling or importing their products without authorization. Such rights are provided to the holder so as to prevent the rise in the prices of the drugs which lead to major health problems because of non affordability of essential medicines.

Before the birth of TRIPS many countries didn't recognize product patent protection especially to pharmaceutical inventions. Many countries including India didn't even provide product patent protection. The coming into existence of the TRIPS compelled many member nations to include product patents in their patent regime. The mandatory incorporation of the product patent system in the pharmaceutical sector earned a lot of controversy and was criticized a lot by the developing nations.[3]

The access to medicines and the low costs of the generic medicines was impeded by the product patent regime under TRIPS as the protection to the patent holders was uniformly extended regardless of their local conditions and circumstances after the coming into existence of the TRIPS.[4] This posed serious issues on the future of pharmaceutical industry more specifically in respect to access to medicine in developing countries. Taking into consideration the seriousness and gravity of the issue Mr. Thomas Pogge wrote in his book that the responsibility for avoidable deaths and massive spread of disease lies on TRIPS because it was caused due to the enormous monopoly given under the product patent regime. This led to the inflation in the

[2] See *Article 33, TRIPS Agreement*, Available at - https://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed on March 17, 2019).
[3] Janice M. Mueller, *In Depth Analysis of Indian Patents Law*, 68 UNIVERSITY OF PITTSBURGH LAW REVIEW 491, Available at - http://www.nalsarpro.org/CL/Articles/InDepthAnalysisofIndianPatentLaw.pdf (Accessed on March 18, 2019).
[4] FREDERICK M. ABBOTT& GRAHAM DUKES, *Global Pharmaceutical Policy: Ensuring Medicine for Tommorow's World* (Edward Elgar Publishing Limited, 2009), ISBN – 9781848440906.

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price of medicines making it unaffordable and beyond the reach of common man.[5]

There was a shift in the market control after the grant of product patent over medicines transferring the complete monopoly into the hands of the private pharmaceutical companies thus giving them the right to exclude others from making, using or selling the medicines patented by them. This shift of the market control into the hands of pharmaceutical industries had an adverse impact upon the affordability and accessibility of the medicines in the developing countries. The birth of the product patent system enabled the pharmaceutical companies to sell their drugs at a price very close to profit maximization. However, earlier when only process patent was granted over the technology and the process or mechanism to procure the product not on the products itself, in such cases the generic drug manufacturers were allowed to manufacture medicines through a different process or by reverse engineering. But due to product patent the holder now holds exclusive monopoly over the product itself, here the medicines. It is now impossible for the generic drug manufacturers to enter the market before the expiry of the patent of that drug because the patent holder has exclusive absolute monopoly over his invention which shall last till the expiry of patent.[6] This means absence of any competitor in the market till the expiry of the patent i.e 20 years because of which the patent holder can exploit his invention by pricing at any price which the market will bear.

In his famous article 'Patents and the Poor', Justice Bhagwati mentioned that "*grant of patent protection on pharmaceutical medicines can never be justified at the cost of the right to health of the people*"[7]. It should be seen that same patent protection cannot be fitted in all developing and least developed countries similarly as their situations are totally different which should be kept into consideration while granting patents on pharmaceutical products including essential medicines.[8]

The debate still continues on the relevancy of patent protection as one cannot deny the importance of patent rights which promote research and development in pharmaceutical sector because of the incentives which are a major compelling force for the innovations due to which new drugs are introduced in the market. However, the issue of high pricing of the medicines also cannot be sidelined due to the patent protection in many developing and least developed

[5] THOMAS POGGE et al., *Incentives For Global Public Health*, (Cambridge University Press, 2010) ISBN – 9780521116565.
[6] Himanshu Gupta ET AL., *Patent protection strategies*, JOURNAL ON PHARMA AND BIOALLIED SCIENCE, Jan-March 2010, Available at - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3146086/ (Accessed on March 18, 2019).
[7] Bhagwati J., Patents and the Poor, Financial Times, 16 September, 2002.
[8] Sigrid Sterckx, *Patents and Access To Drugs In Developing Countries: An Ethical Analysis*, DEVELOPING WORLD BIOETHICS JOURNAL, Volume 4, Number 1, 2004, ISSN - 1471-8731.

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countries. A large section of the population in such countries is below poverty line with no access to healthy food and in such wretched conditions purchasing high priced medicines is a far flung dream.[9] The high costs of the medicines acts as a hindrance for the treatment of these poor people thus leading to a clear cut violation of their fundamental right to health.

One big observation that can be seen here is that although product patent regime was introduced to increase the research and development of the country but the patent over the medicines led to the unavailability of the basic medicines to the needy thus failing to cater the health care needs of the people.[10] Therefore, this demands a strong need to stabilize the research and development and the health care requirements of the public under TRIPS.

Therefore, to address this issue much flexibility has been provided in the TRIPS to cater to the health care needs of the people. These flexibilities can be invoked by any member nation by incorporating it under its national laws without prejudicing the legitimate interest of the patent holder.

III. TRIPS FLEXIBILITIES

Multiple flexibilities have been provided by the TRIPS agreement to address and solve the problem of public health. Article 30 read with Article 7 and 8 of the TRIPS provides certain limited exceptions against the exclusive monopoly rights of the patent holder which can be invoked by the member country to avail the medicines to the people.[11] Also Article 31 of the agreement states "*Other use without authorization of the right holder*" thereby providing for the grant of compulsory licenses. The various flexibilities under TRIPS are:

Transition Period

Article 65 of the TRIPS agreement provides a transition period to the developing and least developed countries to implement the provisions of TRIPS by incorporating them in their domestic laws. Generally, a transition period of 1 year is provided to all member countries but for developing nations an additional period of 4 years is provided thus making it a total of 5 years transition period. The least developing countries were given a period of 10 years besides the general 1 year period thus making a total of 10 years.[12]

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[9] Shubhra Khanna, *TRIPS, Pharmaceutical Patents And Health Care For The Poor In India*, ILI LAW REVIEW, Summer Issue 2016, pg - 71, Available at - http://ili.ac.in/pdf/paper5.pdf (Accessed on March 18, 2019).

[10] William Greene, *The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market*, Available at - http://www.usitc.gov/publications/332/EC200705A.pdf (Accessed on March 18, 2019).

[11] Peter K. Yu, *The Objectives and Principles of the Trips Agreement*, Available at - http://www.peteryu.com/correa.pdf (Accessed on March 18, 2019).

[12] See *TRIPS transition period extensions for least-developed countries*, Available at -

Further the coming into existence of Doha Declaration on Public Health extended the transition period by 5 years for developing nations and 10 years for least developed countries therefore making it a total of 10 years for developing and 21 for least developed nations. This was done so as to cater to their needs and economic restraints and the strong requirement for an additional time frame so as to create a viable technological base.

The main purpose for providing this transition period was to ensure the pharmaceutical patent applications in developing and least developed countries don't get patent protection until a feasible technological base is created for the realization of the TRIPS provisions in their domestic laws thus permitting generic competition in the market.[13]

Evergreening of Patent

The patent protection is provided as per TRIPS to only those inventions which are novel, non-obvious and have industrial applicability.[14] Many countries including India don't recognize the concept of evergreening of patent calling it as s non-patentable subject matter. As per them, the mere discovery of a new form of a known substance or its new property or enhancement of its known efficacy will not be patented.[15] It is commonly observed that pharmaceutical companies tend to retake patents over the same drug by making slight modifications in the drug thus showing a new use of the same drug which in reality sees no enhancement in efficacy. The Apex Court of India in the famous Novartis case held that for the patentability of a drug enhanced therapeutic efficacy of the drug has to be shown.[16] Here, the court laid emphasis on the fact that to prevent misuse of patent rights in pharmaceutical industry, it is necessary to recognize evergreening especially from the perspective of developing countries which are already facing a lot of problems in accessing medicines because of the high cost of the medicines.

Exhaustion of Rights

Article 6 of TRIPS discusses about the exhaustion of rights and is also called as first sale doctrine. As per this doctrine the IPR holder's rights are considered to be exhausted after the

http://www.unaids.org/sites/default/files/media_asset/JC2474_TRIPS-transition-period-extensions_en_2.pdf (Accessed on March 18, 2019).

[13] See *WTO and TRIPS Agreement*, Available at - http://www.who.int/medicines/areas/policy/wto_trips/en/(Last visited on 12 Oct 2016).

[14] Antara Dutta, *From Free Entry to Patent Protection: Welfare Implications for the Indian Pharmaceutical Industry*, 93 REVIEW ON ECONOMICS& STATISTIC. 160, 162 (2011).

[15] William J. Bennett, *Indian Pharmaceutical Patent Law and the Effects of Novartis Ag v. Union of India*, 13 WASHINGTON UNIVERSITY GLOBAL STUDIES LAW REVIEW, (2014) 535, Available at - http://openscholarship.wustl.edu/law_global studies/vol13/iss3/12 (Accessed on March 18, 2019).

[16] Lucky George, *Patentability: Ever greening and Compulsory Licensing in Indian Context and Global threats*, Available at - http://tndalu.ac.in/pdf/SEMINAR%20BOOK_1Final.pdf (Accessed on March 18, 2019).

first sale of the products through the holder or by anyone else with his authorization. The member nations have the freedom to adopt any exhaustion policy subject to the principles of MFN and national treatment. The doctrine of exhaustion plays a very vital role in making cheap medicines accessible by various means like parallel import etc.

Parallel Import

The concept of parallel import arises from the doctrine of exhaustion. It basically means importing of the patented invention without the permission of the holder from a third country where the patented product is sold at a cheaper price than in the country where it is imported.[17] The TRIPS makes it open to the member nations to adopt any parallel importation policy and frame laws accordingly however it shouldn't be prejudicial to the interests of the patentee.

Since the principle of parallel importation works on the doctrine of first sale the patent holder despite owning the exclusive rights cannot stop the resale of the medicines sold by it. Here, an intermediary has the right to legitimately buy the drug in one country at lower price and resell it in other country at higher price.[18] This allows the availability of the drug at a cheaper price to the people than that charged by the patentee. Therefore, parallel importation is helpful in increasing the availability and accessibility of the medicines in developing countries.

Bolar Exception

The concept of bolar exception arose from the popular case of *Roche* v. *Bolar*.[19] This exception enables the generic drug producers to make, sell, use or import a patented invention for the development and submission of information needed under any law for receiving market approval.[20] This exception is adopted by many countries like Canada, India, Thailand etc in their domestic patent laws.

Bolar exception is extremely beneficial for the generic drug manufacturers in receiving market approvals in advance before the expiry of patent on the medicine thus enabling the generic manufacturers to hit the market with their products immediately after the expiry of the patent.[21] This ultimately benefits the general public by accomplishing their health care needs by making

[17] Dhruv Joshi, *A point of view on Parallel Imports, Global Policy Essay*, July 2012, Available at - http://www.globalpolicyjournal.com/sites/default/files/pdf/View%20Points%20on%20Imports%20-%20July%2012.pdf (Last visited on March 18, 2019).

[18] Ravi Duggal, *Operationalizing Right to Health care in India*, Available at - http://www.cehat.org/rthc/rthpaper.htm (last visited on March 19, 2019).

[19] Soumya Prakash Patra, *Critical Appraisal of Bolar Exemption with Respect to Indian Patent Act 1970* (September 3, 2008). Available at SSRN: http://ssrn.com/abstract=1262712 (Accessed on March 19, 2019).

[20] Manisha Singh, *Helping the generic market: the Bolar exemption*, Available at -https://www.lexorbis. com/wp-content /uploads/2015/06/Bolar-exemption-LexOrbis.pdf (Accessed on March 19, 2019).

[21] Prabhu Ram, *India's New* "*TRIPS Compliant" Patent Regime: Between Drug Patents and Right to Health*, 5 *Chicago* - KENT JOURNAL OF INTELLECTUAL PROPERTY 204 (2006).

the drugs accessible at low price via its generic version immediately after the patent expires.[22]

Compulsory License

Instead of using the term compulsory license "*Other use without authorization of the right holder*" has been used under Article 31 of TRIPS. This article is completely dedicated to compulsory license. Compulsory license is the most important flexibility provided in the TRIPS as it allows the generic manufacturers to get license after failing to obtain voluntary license due to unavailability of the product or due to its unaffordability at reasonable price.

All the flexibilities discussed above are permitted only in coherence with the preamble, objective and principles of TRIPS mentioned under Article 7 and 8 to protect public health.[23] Therefore, proper balance of above stated flexibilities is required while recognizing the rights of the patentee also.

IV. CONSTITUTIONAL VALIDITY OF TRIPS FLEXIBILITIES

The various flexibilities discussed in the previous chapter have been constitutionally challenged many times. It was held in the case of *Consumer Education Research* v. *Union of India*[24] by the Supreme Court of India that right to health and right to access to medicines at reasonable price is a fundamental right under Article 21 of the Constitution. Thus, the flexibilities provided under TRIPS and incorporated under Indian Patent law help in preventing any serious prejudice to the public health.[25]

Article 25 of UDHR states that "*every human being has a right to a standard living with adequate health care needs and well-being*".[26] The article further obligates the member countries to adopt appropriate measures to safeguard the life and health of people. Similarly, Article 12 of ICESCR (International Covenant on Economic, Social and Cultural Rights) also reinstated the right to health as a basic human right important for the sustenance.[27] Therefore, these provisions clearly validate the TRIPS flexibilities as reasonable requirement to promote public health care.

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[22] Emmanuel Kolawole Oke, *Expanding the Reach of India's 'Bolar' Exemption*, QUEEN MARY JOURNAL OF INTELLECTUAL PROPERTY, (2015) Volume 5 Issue 4, pp. 509-515.
[23] Shubhra Khanna, *TRIPS, Pharmaceutical Patents And Health Care For The Poor In India*, ILI LAW REVIEW, Summer Issue 2016, pg - 71, Available at - http://ili.ac.in/pdf/paper5.pdf (Accessed on March 19, 2019).
[24] 1995 AIR 922.
[25] S.B.Puranik, Mamata Sangamesh and Mona Golshan.S, *Patent Laws In India And Its Impact On Pharmaceutical Industry*, INTERNATIONAL JOURNAL OF PHARMA aND BIO SCIENCES, Vol. 2, Sept 2010.
[26]The Universal Declaration of Human Rights, Available at - http://www.un.org/en/universal-declaration-human-rights/ (Accessed on March 19, 2019).
[27]See *International Covenant on Economic, Social and Cultural Rights*, Available at - http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx (Accessed on March 19, 2019).

The apex court in the case of *Chameli Singh* v. *State of UP*[28] while interpreting Article 21 of the Indian Constitution stated that Article 21 includes "*the right to food, water, shelter, environment and medical care in its ambit*". Here, access to medicines is taken as a part of right to health. Even in the famous Novartis case[29] court upheld the invalidity of evergreening under Article 14 of the Constitution.

Similarly Article 41 of the Constitution imposes a duty on the state "*to provide assistance to sick and poor".*[30] Article 47 states that it is the duty of the state to raise the level of nutrition and improve the public health and standard of living. It is to be complied by the state under the mandates of Article 21. In the case of *Paschim Banga Khet Mazdoor Samity & Ors* v. *State of West Bengal & ors*[31] the court while widening the ambit of Article 21 imposed an obligation on the state to protect the right to health and being a welfare state it is the duty of the government to make medical facility accessible to every person.

Therefore, the flexibilities provided under TRIPS incorporated under The Patents Act, 1970 are also an obligation on the state to ensure accessibility to medicines to all people during unavailability. Through these flexibilities the government discharges its function of safeguarding right to health and right to life of its people.

The government in such a condition seems to ensure justice between the stakeholders i.e the patent holder and the beneficiaries. The patent rights being exclusive monopoly rights are negative rights thus being in conflict with the fundamental right of people i.e right to access to medicine under right to health. Here, the government by invoking the flexibilities provided in the patent law reinstates the right of health of the public and also ensures that the legitimate interest of the patent holder is not prejudiced by providing him monopoly rights to exploit his invention for 20 years.

V. CONCLUSION

The grant of product patent over the pharmaceutical products had significantly increased the price of medicines thus making it out of the reach of the common man hence violating their right to health a fundamental right under Article 21 of the Constitution. To resolve the issues related to right to health various flexibilities have been provided in TRIPS and the same have been incorporated in the patent laws of the developing and least developed countries. These flexibilities read in light of Article 7 and 8 of TRIPS balance the rights of the patentee and the

[28] (1996) 2 SCC 549.
[29] Novartis v. Union of India, (2013) 6 SCC 1.
[30] Article 41 of the Indian Constitution.
[31](1996) 4 SCC 37.

right of health of the people to promote public interest. Though these flexibilities have been challenged by the patent holders as a violation of their exclusive rights but the same have been held valid as the only resort to fulfill the public interest without prejudicing the legitimate interests of the patentee.

Thus, it is seen that justice is catered by the member states by ensuring that there is a balance between the rights of all the stakeholders and that the ultimate aim of giving monopoly rights to the patentee i.e. furthering public interest and public benefit by making the invention available to all public is fulfilled. Apart from this, by providing remuneration to the patentee in case of compulsory licenses the government not only caters to the interests of the deprived section whether inside or outside the country but also ensures that the patent holder gets a share of his incentive. However, generally it is seen that in case of compulsory license wherein the license is granted against the consent of the holder the remuneration provided is not adequate. Therefore, the researcher suggests that such injustice should be done away by providing royalty to the holder at a standard rate, that which is applicable in cases of voluntary licenses so that justice is done to all the parties.

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