PRODUCT PATENT AND ACCESS TO MEDICINES IN INDIA

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ABSTRACT

Trade Related Aspects of Intellectual Property Rights (TRIPS) provides a regime for the protection of the intellectual property rights and provides various mechanisms through which a country can ensure in providing protection to the owners of the property.

Patent protection provides the owner of the patent means to prevent the third party from using, making or from selling the patent protected products for a period of limited time. TRIPS provides protection of 20 years to a patented product, the protection can be either for a product or for a process of producing an ingredient or any other drug. TRIPS also provide a mechanism through which it ensures that the country is capable of providing access to medicines at affordable prices to its people. TRIPS protect the interest of pharmaceutical industries who invest in the production and manufacturing of the medicines, also the resource investment on R & D of medicines and drugs, and on the other hand, it provides for the protection and promotion of public health of the member countries that belong to the WTO in their states. It is basically trying to control the balance between the public rights and private rights.

Though TRIPS provides for the positive mechanism and obligation on the member countries, still there is a huge gap in its implementation by the member states. Developing and under developed states are most adversely affected by the protection given to the pharmaceutical products through a patent. Patented pharmaceuticals have increased the cost of life-saving drugs thus, making it out of the reach of the general public, which forms the majority of world's population. This has also lead to a problem where the TRIPS guidelines could not be implemented due to such high costs of medicines and drugs, hampering the ability in the framing of appropriate health policies and access to medicines to the people.

India is one of the major countries that have the flourishing generic pharmaceutical industry that has been successful in providing drugs and medicines at lowest prices all over the globe. This has been only possible through strict compliance with the TRIPS agreement and enactment of Indian Patent Act, which provides for the process as well as product patents and also the shortening in the life of patents being granted to the pharmaceutical industries.

This article will be focusing on the public rights and private rights of the patent holders. Also, will be discussing the effects of the protection granted to the pharmaceuticals on the accessibility of the medicines to the public in India. Unlawful profits and gains that the pharmaceuticals make through the rise in the prices of life-saving drugs and problems faced by the public due to such high prices of drugs in the light of Indian Patent Act, an amendment to Patent Act, 2005, along with the TRIPS agreement and the entire patenting system of the pharmaceuticals.

KEYWORDS: access to medicines, TRIPS agreement, WTO, product patent, pharmaceutical patent in India, patent (amendment) act, 2005.

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1. INTRODUCTION:

India has been very active in this developing era to make attempts in adapting Pharma patent laws to take care of domestic needs with more emphasis on common man needs of healthcare facilities. In India large part of the population is below the poverty line and healthcare expenses for poor people out of their pocket is very difficult. Indian patent act tries to strike balance between TRIPS and access to medicines to poor and common people. Section 3(d)[1] is an exclusive provision under the act. India has tried to address the patenting of pharmaceuticals with respect to current emerging issues of public health and access to medicines in India, as India is one of the largest supplier of low cost generic medicines throughout the world. India being the part of TRIPS and Doha Declaration has assumed dimensions since 2001. We have seen that patenting of pharmaceuticals restricts generic competition and increases prices of medicines, which act as a barrier for poor people to access the essential medicines in developing countries

LITERATURE REVIEW-

List of articles

1. *Pharmaceutical Patent in India: Access to medicines*

This article discusses the entire background of the patent rights in pharmaceutical industry and access to medicines under the TRIPS agreement. It also talks about impact of the latest amendment to the patent act in the country, whether it has been successful in proving the basic health care facilities to the poor for whom medicines are generally unaffordable due to its high costs.

2. *Intellectual Property Rights and The Challenges to Indian Pharmaceutical Industry*

This article touches upon the changes which the Indian Pharmaceutical industry has gone through during the decades. Amendment its implementation and effect of the same during the years. Also discusses on various regulatory framework in India, regulating prices of essential drugs and other cosmetics.

3. *Five years into the Product Patent Regime: India's Response*

This is a study conducted by UNDP, based article discussing on the impact of amendment (product Patent) in India. It also analyses the role of Pharmaceutical industry and the legal system in building post Trips scenario providing a source to affordable medicines in India.

[1]Amy Yee, "Novartis in Indian patent dispute," Financial Times, Dec. 22, 2006. "Novartis contests India's patent law," Chemistry World, Feb. 15, 2007

4. *The Trickle-Down effect of product patent in India and on the developing world*

This article throws light upon the Indian Patenting system, specific after amendment of 2005. Also India needs to provide sustainable and affordable drugs to the general public which is their basic right.

LIST OF BOOKS

1. *Impact of Patent Ever greening and Access to Medicine*

Ever greening of the patent product in pharmaceutical industry which is used to block the generic drug in the market. This in turn also blocks the affordability of drugs to the general public posing great threat of health to the public at large. This makes very difficult for developing countries to access their right to basic healthcare. The same is used as a reference in this paper.

2. *Pharmaceuticals in the New Intellectual Property Regime:*

Here in the book author discusses about the controversies related to pharmaceutical production and medicine knowledge that India is going through. Debates on price of medicines and restrictions on access under the patent law is very prominent in International forums.

3. *Indian Pharmaceutical Industry: impact of changes in IPR Regime:*

The study by the author shows the development of the Indian Pharmaceutical Industry after the amendment to the Patent act was brought.The study on insertion of section 3d to the act, playing a very important role in diminishing or preventing a negative impact from introduction of product patents. Also focuses on the model adopted by the Pharma industry in India. Adoption of compulsory licensing with respect to the NATCO- BAYER case.

STATEMENT OF PROBLEM-

Whether the patents on pharmaceutical products and process creates monopoly over the production and marketing of drugs and medicines thus increasing the prices of medicines to maximize profits, also its impact on the availability and affordability of these medicines to general public in developing country like India.

OBJECTIVES-

1. To study the impact of product patents on pharmaceutical industry
2. To understand the effect of patents and monopoly on the price of medicines.

3. To understand the Indian scenario with respect to affordability of medicines and patents

SCOPE AND LIMITATION-

this research article is limited to the statues, international agreements, policies of government on pharmacy, health concerns and pharmaceutical industry, patents rights and issues with special address to the patents rights in India.

HYPOTHESIS-

Patent law regime does not favor the rights to health care of citizens especially to poor when it comes to developing countries like India

RESEARCH QUESTIONS-

1. The amendment of 2005, Patents Act
2. What is the impact of TRIPS on pharmaceutical patents and health care in India?
3. Patent rights vs. right to health?
4. What are the limitations of the exclusive rights provided under the Patents Act
5. How compulsory licensing combat product patents in Europe, USA, India and Canada
6. What is National Pharmaceutical Pricing Policy, 2012?

RESEARCH METHODOLOGY-

Present study is based on the qualitative and quantitative method of research. The research has drawn help from various books, articles, newspapers, journals, gazettes, reports of commission and committees and judicial decisions. We have used both primary and secondary sources of data for the purpose of this research.

TENTATIVE CHAPTERISATION-

1. Introduction
2. Patents(amendment 2005) act
3. TRIPS on pharmaceutical and healthcare

i) Dependence of India on pharmaceutical industry.

ii) TRIPS impact on Pharma related inventions

iii) Challenges and concerns of developing countries of TRIPS

4. National pharmaceutical pricing policy and other regulators

5. Right to health and Patents

ii) Basic rights of health and Patent rights

iii) Scope of implementation of right to health under the Patent act

iv) Right to health under the constitution

6. Availability, accessibility and affordability of medicines in developing countries

7. Compulsory licensing

ii) Compulsory licensing under TRIPS in USA, Canada and Europe

iii) Compulsory licensing in India

iv) Cases related to compulsory licensing in India

8. Suggestions

9. Conclusion

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1. PATENT(AMENDMENT) ACT, 2005:

India has fully complied with the TRIPS agreement, which required amendment to its Patent's regime. India before the amendment of 2005[2] followed the process patent regime for pharmaceutical and agricultural chemical products, and from 2005[3] onwards it introduced product patent system as per the TRIPS agreement for the pharmaceuticals that were earlier covered by only process patents[4]. India adopted three amendments to the patents act with significant to the global developments. There was growing and urgent concerns for developing countries to provide their citizens with the medicine at affordable prices all among the members of WTO. This resulted in adoption of Ministerial Declaration at Doha Ministerial Conference, 2001- on TRIPS agreement and Public Health, also known as Doha Declaration.

2. TRIPS ON PHARMACEUTICAL AND HEALTHCARE:

I. DEPENDENCE OF INDIA ON PHARMACEUTICAL INDUSTRY:

India is one of the largest market or the generic manufacturing companies all over the world. Indian pharmaceutical industry has a strong base of generic drug covering a large area of Indian pharmaceutical market[5]. Indian economy is largely dependent on pharmaceutical industry for is evolution. India today is largest producer and exporter of low priced generic drugs known for its high quality. Patents act of 1970[6] provided a strong base which resulted in healthy growth and development of the pharmaceutical industry in India. This growth and development was possible only because earlier there was no product patenting of drugs and pharmaceuticals and made it possible for industries to come up with the generic version of the patented drugs though reverse engineering process. This resulted in creating big market for the Indian pharmaceutical industries for domestic as well as for export purpose.

Earlier there was fear that patent protection in pharmaceutical sector would result in restricting the innovations that is essential for the general public. It was problem for the developing countries that could not come up with the new product using the alternate methods or process

[2] The amendment was notified in the Gazette of India on 5 April 2005 as the Patents (Amendment) Act, 2005. See Govt of India (2005a)
[3]Articles 65.2 and 65.4 of the TRIPS Agreement.
[4] India's new product patent law: challenges and opportunities for local drugmakers,Pharma Market Letter, Dec. 6, 2004
[5]Nidhi Joshi, "Data Protection for Pharmaceutical Products under TRIPS: Data Exclusivity Legislation a Necessary Evil for India" 1 Delhi law review 104 (2005).
[6] Amendments to the Patents Act, 1970: Background Note," Department of Industrial Policy and Promotion, Ministry of Commerce, New Delhi

of already patented products during the lifetime of their protection. Then with the protection under process patents, process could be protected, so far it is invented, as there can be various means to make a product. This resulted in India becoming self- sufficient in manufacturing drugs and formulations. Innovation in Indian pharmaceuticals highly depends on the pricing of the products and has been developed in such a way only.

i) IMPACT OF TRIPS ON PHARMA INDUSTRY:

Patent is a kind of social tool that promotes innovation, which resulted in reintroduction of product patent regime in India. Patent basically is being protected by the WTO: TRIPS agreement, which sets the minimum standards for the protection for protection of patents throughout its members. India which was largely dependent on other countries for the supply of pharmaceutical products earlier came out to be as one of the most dynamic manufacturer of pharmaceutical products, being cost efficient and technologically advanced competing in the global market. This made India eventually a strong market for generic drug available at low a price which is lowest among the other countries[7].

TRIPS agreement provides for the issue of compulsory licenses for the country who cannot afford medicines to be made available to them at very low prices, which as a result allows for the production or importation of generic version of the patented drug at very low price and affordable to the poor. Protection given to pharmaceutical invention provides them with the short term protection creating monopoly and loss to consumers, but it is benefit in long term for social welfare of people, complying with the guidelines of TRIPS India is attracting more FDI in pharmaceutical sector. Due to introduction of product patent system in India with the compliance of TRIPS agreement India is opening up for the generic market of pharmaceutical industry,[8] which manufactures generic versions of patented drug at low rate, thus affordable to public also at low rates, allowing access to medicines to poor unlike the patented drugs that are generally high priced.

ii) CHALLENGES AND CONCERNS OF DEVELOPING COUNTRIES:

As per the article 1[9] of TRIPS agreement member country is allowed to adopt any system for the protection of IPR in their country and TRIPS does not set any minimum universal standard for the protection. It is on the country how to set the standard for the betterment of public health

[7] Ashok Ram Kumar, "impact of TRIPS on Indian Pharma, pharmabiz, dec 2, 2004.
[8] Indian drug sector tackling new patent regime,"pahrmatechnologis.com,feb. 14, 2005
[9] Samira Guennif and N Lalitha, "TRIPS Plus Agreements and issues in Access to medicines in Developing Countries" 12 Journal of Intellectual Property Rights 471 (Sep. 2007).

in the country and legislate accordingly as per the needs of their country. Intention of the agreement is to assure the implementation of sufficient protection of IP and secure public health in developing countries and LDCs. Despite of the guidelines and laws developing countries unable to enforce the same in their country due to the pressure from the industrialized countries, resulting in non-securement of the public and health. The current patent regime also does not favor these developing nations in providing rights to the citizens of developing countries.

TRIPS has provided with some relaxations and flexibilities to the developing and LDCs to strike the balance between the protections provided under the IP and the rights of public to meet their social responsibilities. This challenge faced by the developing countries related to the pharmaceutical industry has been clarified by the DOHA declarations on TRIPS, 2001 and Public Health, 2003- that the countries who are not self-sufficient and poor to manufacture can import the medicines as per the compulsory licensing system[10]. DOHA declaration promotes both the availability of the present medicines as well as production of new medicines. It also restricts the TRIPS agreement from creating any barrier in taking measures for the protection of public health in the country. TRIPS has provided developing countries with various other flexibilities and relaxation apart from compulsory licensing system, i.e., freedom of exclusion of new form of already known drugs from being protected under patents, also parallel importation of drugs and to exhaust the international rights to make the medicines available in the countries needing as per article 6[11] of the agreement. Other flexibilities also includes research exception to the producers of generic versions[12], approval of generic drugs for market from the patented drugs.

II. NATIONAL PHARMACEUTICAL PRICING POLICY AND OTHER REGULATORS:

(i) The National Pharmaceutical Pricing Authority (NPPA): NPPA is responsible for fixing the prices of bulk and formulation of drugs within the national list of essential medicines (NLEM) under the essential commodities act, to make the medicines available to people at reasonable prices.

[10]Compulsory license can be also granted under article 40 of TRIPS, in case if there is an adverse impact on competition.
[11]Article 6 TRIPS agreement
[12]Generic company can come with the regulatory approvals by the authorities but can start manufacturing only when the patent expires of the particular product.

(ii) Drugs and Cosmetics act: this act controls the import, manufacture, distribution and sale of bulk drugs and cosmetics in the country[13]. It keeps check on the quality of drugs being manufactured in India. Also imposes penalties on defaulters.

(iii) Drug Prices Control Order (DPCO): as per essential commodities act it fixes the prices of essential drugs and formulations. It also regulates the same. aim of the policy is equitable distribution, cheap availability of bulk drugs and sufficient supply to meet the needs of people on time.

III. RIGHT TO HEALTH AND PATENTS:

i) BASIC RIGHTS OF HEALTH AND PATENT RIGHTS:

Right to health is a human right which means it is inalienable in nature, something which cannot be taken away from a person, and the state is obligated to promote, respect and protect the right to health in the country and take appropriate and effective measures for the same. It is also onus of the country to refrain from taking any actions or indulging into any practices that would deprive its citizens from access to right to health and healthcare facilities[14]. There is always been issue of protection of right to health Vis a Vis patent rights, as it is a challenge for the states to provide facilities with the available resources and limited supply of the resources according to the demand of the healthcare sector. It is also important to note that the duty of government is not only to provide the healthcare facilities and right to health but also improvement of economically backward groups by striking a balance between the distributions of resources to reduce the financial burden of ill health from the marginal groups in the society. Right to health is of utmost important and is above every right for any country, so it is duty of the states to take corrct measures. Due to development in technology there has been improvement in healthcare ssector also which is very important part for right to health in any country. Under TRIPS agreement also it has provided various flexibilities to the developing countries excluding certain inventions from patenting which is necessary for these countries for protecting the health rights of their citizens as social welfare or to maintain public order. This has led to the universal recognition of right to health and healthcare as fundamental right not only in India but throughout the world. India believing in social welfare of its citizens and giving priority to the health rights has come up with healthcare policies, affordability of

[13] Ames gross and sunilpatel, indian Pharmaceutical industry: market, regulatory, import and investment regime, pacific bridge medical, inc. may 2002.

[14]India Healthcare: Ranbaxy ready to take on the world, financial times, oct. 11, 2006.

essential medicines at low rates and schemes to protect the rights of people especially poor people who cannot afford essential medicines at high prices.

ii) SCOPE OF IMPLEMENTATION OF RIGHT TO HEALTH UNDER THE PATENT ACT:

The foremost object of patent act is to provide protection to the IPR which gives rights to the owner of the product to commercialize the product for the period of 20 years from the date of application without any violation of his rights. Patent act also has provisions for remedies and alternate in case of emergency situations to take away the monopoly rights from the owner for the public welfare by the government. The rights must be exercised in such a way that it would balance the social and economic rights and obligations, also contributing towards technological advancements and innovations, as per article 7 of the TRIPS[15] under article 8[16] it says that a country must adopt the means and measure essential to protect the public health and also promote the public health in the interest of public for the social and economic development of the country in their legislation as per the agreement. This also requires for the state to look for any abuse of the rights given under the patent affecting the transfer of technology by the owners of the rights. Along with these rights to the government TRIPS also provides for the compulsory licensing of essential drugs under article 31.[17]

iii) RIGHT TO HEALTH UNDER THE CONSTITUTION:

Right to health is fundamental right of every human being on earth, Indian constitution though not recognizes right to health as fundamental right directly but under article 14[18] and 21[19] it has provided for right to life without being discriminated on the basis of caste, color, sex, religion, race etc. obligating states to provide for the basic healthcare facilities, promotion of healthcare, protection to people without any discrimination based on social or economic standards. Also under the Indian constitution provides for other rights under the Directive Principles of State Policies which indirectly protects the health rights of people and access to healthcare facilities and improving health of people in India, which includes articles 39[20], 41[21], 42[22], 43[23], 51[24] and

[15]Article 7 TRIPS agreement
[16]Article 8 TRIPS agreement
[17]Article 31 TRIPS agreement
[18]Article 14 of Constitution of India, 1949
[19]Article 21 of Constitution of India,1949
[20]Article 39 of Constitution of India, 1949
[21]Article 41 of Constitution of India, 1949
[22]Article 42 of Constitution of India, 1949
[23]Article 43 of Constitution of India, 1949
[24]Article 51 of Constitution of India, 1949

51A.[25]In addition to these rights states also have launched various schemes and national policies for the promotion of health and improvement of health in the country. Despite of these there are many challenges that are being faced by the state to provide the right to health in the country, which being high expenditure on healthcare facilities as people demand quality facilities, developing countries like India have problem to access the facilities provided by the government as it is not universally provided, illiteracy among the people as most of the population is below poverty line and are unaware about the hygiene, sanitation which makes difficult to implement the policies by the state.

IV. AVAILABLITY, ACCESSIBLITY AND AFFFORDABLITY OF MEDICINES IN DEVELOPING COUNTRIES:

In developing countries who cannot manufacture their own drugs and pharmaceutical products relies on other countries to meet the needs in their country. Patent rights creates monopoly over the patented products which makes them expensive for the people who cannot afford to buy them and which is essential for them, this is one of the problem faced by the developing countries. This has affected the people from the LDCs and developing countries where most of them belong to the poor background and cannot afford such high priced medicines, making the medicines non accessible to them at such high price. Also medicines are not available of the diseases which the poor are suffering from, which is not available to them as it is being never developed.

TRIPS agreement has provided for the remedies and development of medicines for the diseases that are mainly caused in poor countries.

Also it provides for the availability of medicines to developing and LDCs once the patent protection expires.

V. COMPULSORY LICENSING

i) COMPULSORY LICENSING UNDER TRIPS IN USA, CANADA AND EUROPE:

USA: in USA there is provision for the issue of compulsory license. Under section 1498 of U.S.C. it provides for compulsory license by the government to use patented inventions by others. It also provides for the grant of compulsory licensing in case of antitrust violations[26]. Compulsory licensing does not occur in general but only under circumstances like, judicial

[25]Article 51A of Constitution of India, 1949

[26]Dawson Chemical Co. v. Rohm and Haas Co., 448 U.S. 176 n.21 (1980)

pronouncements[27] in infringement of patents, antitrust enforcements[28], or as per the federal government.

CANADA: in Canada it allowed first compulsory licensing of HIV drug under the DOHA declaration to Rwanda, to a Canadian company called Apotex[29] to use the patented drugs for the manufacturing.

EUROPE: EU has provision of compulsory licensing of patented medicines to the countries that cannot produce and needs the medicines for people, as per the WTO ministerial meeting held in 2005, where council adopted this resolution of compulsory licensing. That allows companies to produce the generic version of the patented drug without consent of the right holders. This has been major contribution of EU[30] to the developing countries that are incapable of manufacturing medicines and making medicines available at affordable prices for the poor. This provides that countries in need applies directly to the WTO and it is upto the generic companies to apply for the license for the production of the generic version of the patented drug.

ii) COMPULSORY LICENSING IN INDIA:

India has different approach when it comes to granting of compulsory licensing of the patented drugs. Under the patent act, it says one can only apply for the compulsory license after the period of 3 years from the date of grant of the patent.[31] The grounds for license need to be justified, which includes national emergency or other unavoidable emergency where license could be granted earlier also. NEXAVAR was the first case where India granted its first compulsory license.[32]

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[27] Mark P. Gergen et al., "The Supreme Court's Accidental Revolution: The Test for Permanent Injunctions," 112
Columbia Law Review (2012), 203

[28] Colleen Chien, "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals
Hurt Innovation?," 18 Berkeley Technology Law Journal (2003), 853.

[29]Holger P. Hestermeyer, "Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines" 11 American Society of International Law (2007). 81(2013) 6 SCC 1.

[30]Ieurope has three major generic market for pharmaceutical products that is Germany, France and United Kingdom.

[31]Indian Patents Act 1970, s. 89 reads: The powers of the controller upon an application made under s. 84 shall be exercised with a view to securing the following general purpose, that is to say:
a. That patented inventions are worked on a commercial scale in the territory of India without undue
delay and to the fullest extent that is reasonably practicable;b. That the interest of any person for the time being working or developing an invention in the territory of
in India under the protection of a patent is not unfairly prejudiced

[32]Natco Pharma Limited v Bayer Corporation, Compulsory Licence Application No 1/2011 (March 9, 2012)

iii) CASES OF COMPULSORY LICENSING IN INDIA:

Natco vs. Bayer:

this was the first case of compulsory licensing in India. This was related to drug called sorafenib which was sold by Bayer, under the trademark called NEXAVAR. As per the controller bayer failed to meet the public demand and was not selling the drug at affordable and reasonable price. Also they did not manufacture the drug in India as required by the rules under the act, hence the controller granted the compulsory license to the Natco Pharma ltd.

Bayer Corporation vs. Cipla Union of India:

It is one of the important cases that were reported for attempt in patent linkage practice. Not allowing the grant of market approval to the third party before the expiration of the protection period unless consented by the owner of the right.[33] Bayer was the producer of a drug used for treatment of cancer which was sold at price of 2, 85,000 one month dosage, It filed a petition to restrict the grant of license to cipla regarding manufacturing, selling or distributing its drug. Here the court held that patent linkage could not be read into provisions of drugs act, and patents act as such.

VI. CONCLUSION:

TRIPS has been trying to strike the balance between the rights of the owners of the IPR vis a vis others. It has provided with various flexibilities to the developing countries that do not have sufficient resources to meet their needs, we have seen that pharmaceutical industries invest much in R & D, to get the protection over their product and create monopoly during the protection duration to recover the price of their investment. After expiration of the term of protection the government of the countries goes for the generic versions of the patented medicines to provide people with medicines at affordable price. We know that whatever innovation is done in the field of pharmaceutical industry, the ultimate aim is to save lives of people and not just making profit out of the invention. Keeping in mind this very important principle a better understanding towards health in the modern world is to be achieved, which includes effectively ensuring safety of people throughout the world.

India has amended its patent act to comply with its obligations under the TRIPS agreement. It has reintroduced product patent regime after the process patent. This included no patent

[33]2009 (41) PTC 642 (Del); 2010 SCC Del 541.

protection to the drug already known and inventor is coming up with mere modification. India has been always working towards the welfare of its people by providing them with the best possible measure it can[34]. Providing people who are below poverty line and cannot afford expensive medicines are being provided with low cost medicines. This has been made possible with the generic drug production within India of patented drugs, to meet the local needs of people. Indian regulatory framework of pharmaceutical industry is a remedy for its survival. Setting standard, quality of drugs manufactured, price control of essential drugs, compliance by industries is addressed by the regulators. There are some policies that affect the industry like healthcare policy, safety policy, and industrial policy. These policies address the issues like price control of drugs, availability of drugs at low prices, strengthening the development of the generic industry, transfer of technology etc.

Other countries including India have opted for compulsory licensing system to provide the developing countries with the medicines that cannot produce the medicines on their own due to incapacity and non-availability of resources. Health right has to be enforced against any other right, as it is of utmost importance. It is one of the fundamental right of people which has to be effectively enforced and understood across the globe.

VII. SUGGESTION:

Throughout the paper we have been seeing that India has gone through various amendments to comply with its obligations under the TRIPS agreement to provide the owners of the invention rights. Also it has provided with flexibilities to the developing countries where without the consent of the right holder one can produce the drugs during emergency under compulsory license. Compulsory license is a tool in patents which balances the rights of owners and others.

It is the ultimate duty of the government to take appropriate measure to ensure good health and provide sufficient healthcare facilities to the people in need at affordable prices which should include the people below poverty line who are more prone towards deadly diseases.

State should also encourage research and development in the pharmaceutical sector at university also among students who have more potential and provide them with sufficient fund and investment, also ways and means to come up with more economically priced drugs and medicines which could be affordable to people who belong to marginalized groups.

[34] DP Dubey, "globalization and its impact on the indian pharmaceutical industry"

If government is investing in the research of the drug under Open Source Drug Discovery then no one can claim monopoly rights under the act, as government is the owner of the drug which cannot be patented in the name of a person, thus making drug affordable for the poor people.

Policy framework by the government should not only be on papers but should be efficiently enforced to provide people with maximum benefit.

Regulatory bodies should work effectively while approving any drug before letting it enter the market.

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