Pharmaceutical Patents and their Impact on Indian Pharmaceutical Industry

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ABSTRACT:

Drug discovery and access to generic drugs at affordable prices are so tightly inter woven that neither could exist without the other. Health has always been a concern in India since the time of Independence and even after the advent of the Trade Related aspects of Intellectual Property Rights it continues to act as a hindrance in the development of the economy.

The pharmaceutical sector in India plays an important role in the society and can have an adverse effect on the economy as well. This legal writing is accordingly geared towards gaining and understanding as to what exactly patents and its evolution are internationally and how the product patents gradually emerged in India, the focus will be on the patents in the pharmaceutical sector and its relevance in the society and the economy. India is a developing country and therefore, it has to balance the needs of its citizens of granting easy access to patented drugs especially the ones which are sold at exorbitant prices. The two major problems in the Indian Pharmaceutical sector which need to be critically analysed:

Firstly, there exists a tussle between concept of granting patents especially in the pharmaceutical sector and the right to health. Right to health, guaranteed under Article 21 of the Indian Constitution is considered to be one of the most essential and basic Fundamental Right and in the present scenario we hardly get to witness the justice being done to it, since monopoly is conferred on the lifesaving drugs as a result they became inaccessible to the common people due to the exorbitant prices at which they are sold and this fact always proves to be a major setback in accessing these drugs.

Secondly, the amount of money involved in Research & Development for inventing a drug is so high that there exists a dilemma of choosing between the protection of rights and interests of the public at large and the protection of rights and interest of the private sector and how the existing patent regime proves to be more fruitful in resolving the present dilemma in order to keep the public interest and the private interest at the same pedestal.

The question that remains is whether India should bring about a change in its Patent Policy for Pharma practices in the global market or it should continue with the same perspective that is favourable to a greater number of people who can have access to life saving drugs, at much reasonable and affordable price, which in my opinion is a much larger issue.

I. INTRODUCTION

Drug discovery and access to generic drugs at affordable prices are so tightly inter-woven that it would appear that neither could exist without the other. Public health has been a major concern in India since the time of Independence and even after the advent of the Trade Related aspects of Intellectual Property Rights (TRIPS), it continues to be one.

The pharmaceutical sector in India plays an important role in the society and can have an adverse effect on the economy as well. This research is accordingly geared towards gaining an understanding as to what exactly patents and its evolution are internationally and how the product patents have over the period impacted the Indian Pharmaceutical industry.

India is a developing country and therefore, it has to balance the needs of its citizens of granting easy access to patented drugs especially the ones which are sold at exorbitant prices. Following are the two major problems in

the Indian Pharmaceutical sector which need to be critically analysed:

Firstly, there exists a tussle between concept of granting patents especially in the pharmaceutical sector and the right to health. Right to health, guaranteed under Article 21 of the Indian Constitution is considered to be one of the most essential and basic Fundamental Right and in the present scenario we hardly witness justice being done to it. Since monopoly is conferred to life saving drugs, as a result they became inaccessible to the common people due to the exorbitant prices at which they are sold, and this fact always proves to be a major setback in accessing such drugs.

Secondly, the amount of money involved in Research & Development for inventing a drug is so high that there exists a dilemma of choosing between the protection of rights and interests of the public at large and the protection of rights and interest of the private sectorand how the existing patent regime proves to be more fruitful in resolving the present dilemma in order to keep the public interest and the private interest at the same pedestal.

The question that remains is whether India should bring about a change in its Patent Policy for Pharma practices in the global market or should it continue with the same perspective that is favourable to a greater number of people who can have access to life saving drugs, at much reasonable and affordable price, which in my opinion is a much larger issue.

II. INTERNATIONAL INSTRUMENTS GOVERNING PATENTS

a. Origin and Development of Patents at International Level

Globalization of trade and commerce has given an international character to intellectual property. Before the existence of any international convention, it was difficult to obtain protection in many countries due to diversity in international laws.

Globalization necessitated harmonization in laws relating to intellectual property. The internal character of intellectual property is recognized in various international conventions like the Paris Convention, Berne Convention, Universal Copyright Convention, etc. The Paris Convention was the first international convention that talked about the protection of patents.

b. Paris Convention

The first foundational international Convention on the patent law was the Paris Convention of 1883[1]which provided inventors with a rational base for international protection. The nationals of a country belonging to the Convention must enjoy in other countries of the convention the same rights with regards to intellectual property

[1]*The Convention was adopted on 20th March, 1883 revised at Brussels on 14th December 1900, at Washington and at Stockholm on 14th July, 1967 and as amended on 28th September 1979.*

as their own nationals. [2] The Convention also provides for the application of the National Treatment Rule nationals of non-member countries, if they are domiciled or have an industrial or commercial establishment in a member country.[3]

The Paris Convention allows an applicant to obtain a priority date by filing a provisional specification, customarily in the inventor's home country. The Applicant may then file a patent application in any country bound by the Convention within 12 months and maintain an earlier priority date.[4] Thus, the later applications enjoy a priority status with respect to all applications relating to the same invention field after the date of the first application.

India is a member of the Paris Convention having acceded to it in 1998. The Paris Convention for protection of Industrial Property was signed in 1883 by 14 contracting States also called as the Convention countries and was the first major International Convention relation to the Industrial Property.[5]

c. Patent Cooperation Treaty

On a global basis, the system of international patent application under the PCT was put into effect from June 1st,1978, its central administration being provided by WIPO in Geneva.[6]

It is open to the State parties to the Paris Convention for the protection of Industrial Property.

The national patent system required the filing of an individual patent application for each country in which protection is sought. The PCT is an Agreement for international cooperation in the field of patents and to make economical the filing of patent application for a series of countries. It is a special Agreement under the Paris Convention and an agreement for international cooperation in the field of patents. To achieve its objects, the PCT enables the filing with the receiving office with a single application called the international application.

Since it is a worldwide treaty, the countries that have acceded to it are deemed to belong to the International Patent Cooperation Union. India having acceded to the PCT is also a member of the Union.

d. World Intellectual Property Organization

World Intellectual Property Organization has adopted an international harmonization treaty on patent formalities. The Patent Law Treaty was adopted in June 2000 to standardize divergent formal requirements applied in national and regional patent systems to patent applications and patents. Users of the patent system will, thus, be able to rely upon the predictable and simple procedures for filing national and regional patent

[2] *Ibid Article 2*
[3] *Ibid Article 3*
[4] *Ibid Article 4*
[5] *Paris Convention, Article 19*
[6] *1st Edition Dr. JK Das, Intellectual Property Right, 243*

applications and for maintaining of patents for all contracting parties. The Patent Law Treaty came into force after 10 States deposited their instruments of ratification or accession.

e. Trade Related Aspects of Intellectual Property Rights Agreement

The Agreement on Trade Related Aspects of Intellectual Property Rights, 1994 [7] was negotiated in order to reduce distortions and impediments of international trade and to promote adequate property measures for intellectual property. Part I[8] of the Agreement sets out general provisions and basic principles, notably a national- treatment commitment under which the nationals of other countries must be given treatment no less favorable than that accorded to a countries own national with regards to the protection of intellectual property.

It also contains a Most-Favored-Nation clause, a novelty in an international intellectual property agreement, under which any advantage a party gives to the nationals of other countries must be extended immediately and unconditionally to the nationals of all other countries, even if such treatment is more favorable than that which it gives to its own nationals.[9] As regards to patents, there is a general obligation to comply with the substantive provision of the Paris Convention.[10]

Articles 27-34 of the TRIPS Agreement recognizes the patentable subject matter[11], various rights over patent,[12] exceptions to the rights conferred[13],conditions of patent application,[14] process patents[15] etc. In addition, the agreement requires that 20 years patent protection be available for all conventions[16], whether of products or processes, in almost all fields of technology.

The TRIPS Agreement does not limit the members' rights to establish compulsory licenses on ground other than those explicitly mentioned therein. In cases of emergency and public non-commercial use, there is no need to make a prior request for a voluntary license, as required by Article 31(b) of the Agreement. In case of public non-commercialuse, the patent holder may be informed after the use of the invention has taken place, as soon as it is reasonably practicable[17].

[7] *15 April 1994. See, WTO Ministerial Conference, 4th Session, Declaration of the TRIPS Agreement and Public Health WT/MIN(01) DEC/2*
[8] *Articles 1-8 of the TRIPS Agreement*
[9] *1st Edition Dr. JK Das, Intellectual Property Right, 245)*
[10] *TRIPS Agreement, Article 1(3)*
[11] *Ibid Article 27*
[12] *Ibid Article 28*
[13] *Ibid Article 30*
[14] *Ibid Article 29*
[15] *Ibid Article 34*
[16] *Ibid Article 33*
[17] *Ibid Article 31(b)*

A compulsory license cannot be given without the patent owner being heard by the competent authority. A compulsory license is also subject to judicial review[18].

The TRIPS Council on 13th August 2003 reached an agreement, titled "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health".[19] The decision constitutes waiver of the provisions of paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to Pharmaceutical products only. Safeguards are inserted in the provision to prevent the drug manufactured and supplied under this agreement from being delivered as parallel imports into other countries.

f. Transition Period

A one-year transition period for the implementation of the agreement was provided for developed countries to bring their legislation into conformity. Developing countries and countries in the process of transformation from a centrally planned into a market economy would have a five-year period, and least developed countries a period of 11 years. However, in the case of pharmaceutical and agricultural and chemical products, they must accept the filing of patent applications from the beginning of the transition period. This is known as the Swiss version of "pipeline protection", which covers applications field after 1 January1995. Though the patent needs to be granted until the end of this period, the developing country concerned must offer an exclusive marketing right for the product for five years, or until a patent is granted, whichever is shorter.

In respect of pharmaceutical and agrochemical products alone, the TRIPS Agreement required that application for product patents must be accepted as from the date of the Agreement itself. If those products are granted patents and marketing approval in any other country, and the patent owner desires to introduce those products in the Indian market, he should be given exclusive marketing rights for five years of till his pending patent application in India is approved or rejected, whichever is earlier.[20]

g. Doha Declaration

The TRIPS Agreement provides for an in-built mechanism for review through the biennial Ministerial Conference.The fourth WTO Ministerial Conference in Doha, Qatar on November 14, 2001, adopted the Doha Declaration on TRIPS and Public Health.

Paragraph 4 of the Doha Declaration not only confirmed the rights but also the obligations of the WTO members to interpret and implement the TRIPS Agreement in a manner supporting the protection of public health through access to needed drugs. In addition, it recommended the provision to export patented products to

[18] *TRIPS Agreement, Article 31(i)*
[19] *See, Mohammed Hussain K.S "WTO and The Right to Health: An Overview" 43 Indian Journal of International Law 279-313(2003)*
[20] *1st Edition Elizabeth Verkey, Intellectual Property, 303*

countries which lack technical strengths to utilize their compulsory licenses. While it is true that the patent system under the TRIPS embodies monopoly, even TRIPS mandates that such a monopoly should never be used to create anti-competitive practices. It affirms governments' rights to enforce the flexibilities afforded by TRIPS in the form of compulsory licenses, parallel imports and through national inventions including control on price of drugs through appropriate legislations.[21]

III. EVOLUTION OF PATENT REGIME IN INDIA

a. History & Development of Indian Patent Legislations

The first ever legislation enacted for the protection of inventions was introduced by the British India Government in the year 1856 and was known as the Indian Patents Act, 1856. It was based on the British Patent Law of 1852 which granted certain exclusive rights and privileges to the inventors for a period of fourteen years.

The Pattern and Design Protection Act of 1872 further granted protection to new and original patterns or designs and also to the application of any such pattern to any substance which would remain within the definition of a "new manufacture". This was later amended in the year 1883 by the Protection of Inventions Act, 1883 which added a clause protecting the novelty of an inventor's invention if the same had been disclosed with respect to making the application for such protection.

In 1888, a consolidated legislation by the name of Invention and Designs Act, 1888 was passed as the 1872 and 1883 were considered to be more or less the similar in their approach. It was a mere amalgamation of the protections provided in the previous two legislations.

Further, in 1911,the need for a comprehensive legislation on patents was realized and the Government enacted, the Indian Patent and Designs Act, 1911 which was introduced to eliminate all previous enacted legislations on patents and designs. Under this Act, for the first time the Patent Administrative System was brought under the direct control of the Controller of Patents in India. It was a turning point with respect to patent laws in India. The 1911 Act was further amended in 1930 to inculcate certain provisions relating to secret patents, patent of addition and for the use of patented inventions by the Government. It also made certain changes which enhanced the powers of the Controller and extended the patent term from fourteen to sixteen years.

Post-Independence, the National Government felt an urgency to change the Colonial Patent Act due to the sudden change in the Political and Economic scenario of India and as the previous legislations weren't adequate in resolving the emerging issues of patenting. To formulate the changes the Government of India formed an enquiry committee in 1948 known as the Justice (Dr) Bakshi Tek Chand Committee, aka, Patent Enquiry

[21] *MD Nair," TRIPS and Access to Affordable Drugs", Journal of IPR, Volume No. 17 , July 2012, 305*

Committee, 1948 to review the working of patent laws in India. Patent Bill, 1953 was formulated and introduced in the Lok Sabha as per the recommendations of the Patent Enquiry Committee but the same unfortunately lapsed and could not become an Act due to the dissolution of the First Lok Sabha.

The Government then set up the Justice Raja Gopala Ayyangar Committee in 1957 to examine and review the question of revision of patent law in India. The Committee gave its recommendations in 1959 which stated that India must stick to process patent and not adopt product patent and also to include the provisions of Compulsory Licensing. These recommendations led to the review of the existing patent laws and with the suggested changes and additions the Patents Act, 1970 was enacted which came into effect in 1972. It was in true sense an all-pervasive act and also had specific provisions to protect and give boost to the domestic industries.

The 1970 Act has thereafter been amended in the years 1999, 2000, and 2005. Once India became a member of the World Trade Organisation it was mandatory for it to become a member of the agreement on TRIPS which needed the domestic laws to be amended in compliance with the provisions of the agreement. And so, product patenting was established in India, amendments with respect to the same were made in the 2005 Amendment Act. This gave India an opportunity to become a part of the Global Patent System, although over the years from 1995-2015, India faced serious competition globally, the amendment enabled it to keep up with the global Intellectual Property regime.

IV. PHARMACEUTICAL PATENTS AND THEIR IMPACT

a. Development of pharmaceutical industry in India

The Central Government of British India first introduced allopathy in the country. However, there were no production units in India, instead the foreign companies exported raw materials from India, transformed into finished goods, and imported back to India.

Concerned about the lack of domestic manufacturing facilities few scientists like Praful Chandra Roy, IK Gujral and AS Bhasker laid the foundation of Bengal Chemicals and Pharmaceuticals Works in 1901. In spite oftheir sincere efforts, the drug production was quite low and met only 13% of the total medicinal requirements of the county.

Indigenous industry gained impetus during the second World War as there was a fall in the supply of drugs from foreign companies. Many more companies like Chemo Pharmaceuticals, Zandu Pharmaceuticals, CIPLA were established during this period. With the entry of these new companies, the production of drugs increased rapidly and the country's 70% medicinal requirements were being satisfied. But these companies were inclined towards production only and no research and development work took place.

Post-Independence there was a major change in the prevailing scenario, a major breakthrough known as the therapeutic revolution marked the beginning of this phase. There was a noteworthy achievement of shift in the drug therapy, that is, from treating the symptoms to treating the disease itself. There was increase in the sphere of Research and Development as huge investments with respect to the same were being made.

In 1950, foreign multinationals made the entire drug supply in India. They controlled more than 90% of the Indian pharmaceuticals market and hence determined the supply and availability of the drugs. The drugs were manufactured outside India and imported for much higher costs.

Around the same time, the Government of India made the first 5-year plan to carve India's development path. Income from pharma industries at that time was a mere 6.6% of the total National Income. Epidemic diseases accounted for 5% of the total mortality. India was the largest reservoir of epidemic diseases. Around 50% of the population was below poverty line and was unable to afford the cost of the drugs as poverty was at its peak. Consequently, the life expectancy was very low and mortality rate due to diseases was high. It was also observed that foreign companies didn't establish any production units in India as importing was more profitable.

To overcome this, the government, in its industrial licensing policy of 1986, made it mandatory for foreign companies to establish their production units in the country and producing drugs from the basic stge. In order to fulfil these regulatory requirements many foreign companies started production in India and gradually the pharmaceutical industry expanded.

Unable to control the expenditure on drugs the Government of India took two significant steps to remedy this situation:

1. The Government signed an agreement with UNICEF to setup a factory for manufacturing of penicillin and other antibiotics. This resulted in establishment of Hindustan Antibiotics Ltd in 1954 and Indian Drugs and Pharmaceuticals Ltd in 1961 to manufacture the drugs at a cheaper rate for the public.
2. The Government appointed Justice Raja Gopala Ayyangar Committee to recommend the revision of the existing Patent Law to suit the industrial needs. The object was to ensure that India develops a locally sustainable pharmaceutical market. The committee submitted the report in 1959.

The reforms given by the committee were that of sticking to process patenting and not include product patenting as that way generic drugs could be manufactured through reverse engineering. The Committee also advised to introduce Compulsory Licensing.

The Patent Policy of India in 1970s drastically changed India's condition. It enabled India to become a major international player in the generic drug market as India did not provide product patents for pharma drugs. This

gave rise to a thriving generic drug wherein practically every foreign drug was reverse engineered without the fear of any sanction.

Further decontrol with respect to the production of certain drugs also permitted many new domestic players to enter pharma sector. Liberalisation policy and eco reform of1981 opened the door for world players to invest. Largely, it resulted into the growth and development of Indian pharma industry. Further in 1986 it was debated whether to join the Paris Convention. Indian drug manufacturers association was at the forefront of highlighting the risk of joining the Convention.

India has also emerged as a reliable source and exporter of Generic Drugs in the South African AIDS crisis in 1982 and also in the USA Anthrax scare in 2001.

In 1995, India became a part of WTO due to political scenario and as a result, India was subsequently forced into becoming a member of TRIPS agreement. The TRIPS agreement tried to create a strong IP regime and at the same time offered flexibilities for developing countries.

It introduced the system of product patents and exclusive marketing rights. Being a developing country, India was given a transaction period of 10 yearsi.e., up to 2005 for complying with the TRIPS agreement. During this phase, "Mail Box Application" system was practiced. The company which filed an application for grant of product patent, which at the time wasn't provided by the government due to the lack of implementation of product patent regime, such applications were considered to be mail box applications. Such companies were given exclusive marketing rights for the said products. India introduced the system of product patent but excluded pharma, chemical and food products initially.

In the year 1990, pharmaceutical companies started to develop due to infrastructure creation and export initiation by the government. The Indian pharmaceutical market is dominated by branded drugs market. The share of branded and generic market is approximately 86 percent and 14 percent.

The Patents Amendment Act, 2005, introduced "Product Patent" in India. The product patent was granted for the new product for a period of twenty years. Earlier, due to absence of product patent, only process patents are granted for a new process of manufacturing an already known product or for manufacturing a new product. This has helped Indian pharmaceutical industry to develop generic versions of the new medical drugs without being afraid of infringement of patent. This has also helped in achieving a key-objective of policymakers in the developing world to ensure the availability of new medical treatments to save millions of lives by production of cheap generic versions of on-patent drugs. The introduction of product patents is considered as a major incentive for developing new medicines, especially for tropical diseases, not focused upon by the developed nations; it has a snowball effect on the generic industries with only one saving clause.

V. CONSEQUENCES OF PRODUCT PATENTING

a. Effect On R&D And Innovation

The justification behind the product patenting in the pharmaceutical sector is the cost which is incurred in the research and development behind every new invention. It is very risky and expensive. But the question remains whether the strong patent regime would be an answer to the heavy instruments leading to more of research and development.

In the postWTO era, the pharmaceutical countries have increased tremendously in the R&D activities and are moving towards the development of the advanced level process and product R&D capabilities.

The firms that developed knowledge and capabilities in reverse engineering-based R&D in the past have had to reorient themselves for R&D based on innovation to survive and compete in regulated and open market. [22]

The study conducted by the UN development programme (UNDP)[23] has found that not much has changed to dispute the traditional understanding that developing countries should not allow product patent protection in the field of pharmaceuticals.

They are already shelling out the cost of soaring prices of patent safeguarded products without having seen the expected connective technological benefits. While the R&D activities are expanded, endeavour in the full development of NSE's are still to succeed and are concentrated on rewarding developed country markets: there have been a number of setbacks and the partnership model has not worked properly at all times.

Indian companies are developing generics, but its capabilities have been attained and got better during the pre-TRIPS period and there is nothing to credit the product patent regime. Industry profits are obvious in the new connections with the MNCs. But from a public health perspective these can barely be a good reason enough for a country such as India to allow such patent protection.

The study finds that in the pre-TRIPS era, because there was a competition in the patented drugs in India, the Indian producers and consumers were able to profit from the policy of the existing strategy environment. But, after the TRIPS agreement, the new policy environment has led to partnership between the Indian companies and the MNC's that are limiting the competition and both of them are actually profiting at the cost of the consumers. Also, there is affright that this domination so as to gain more and more by the pharmaceutical companies will determine the prices, which will endanger the accessibility and the capacity to afford the essential drugs in India.

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[22] *Government of India Annual Report for the year 2014-15 (Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers 2015) available at http://pharmaceuticals.gov.in/annualreport2015.pdf.*

[23] *Sudeep Choudhary Chan Park, et.al.,"5 years into product patent regime: India's Response", UNDP 2010, available at: http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/five-years-into-the-product-patent-regime.html.*

The study also specifically discovers the contention that strong patent protection will be advantageous for India. The TRIPS negotiations were motivated by specific claims, which includes that a TRIPS-compliant patent protection would induce the developing country companies to carry out greater R&D for the development of new drugs more suitable to the local needs. The study finds that amongst a sample of 166 companies only 37 were mainly spending on R&D, while the others continued their R&D expenditure around 1 percent.

On one hand, granting patents acts as an incentive factor for the innovation of new products; whereas on the other hand there exists the issue of affordability . . The journey of pharmaceutical companies in India started during the British rule , though ups and downs could be seen according to the legislations in force. The significance of the sector can be attributed to the fact that the sector attracts very high R&D costs, time duration leading to a demand of a patent protection. The Indian law has tried to meet up with the societal expectations and the pharmaceutical industry demands which is reflected in the existing patent structure. The impact of TRIPS can also be seen as far as access and affordability of patented drugs or on the R&D and innovation are concerned.

b. Effect on Accessibility and Affordability of Patented Drugs

When the product patent was introduced in the Indian patent regime, it was feared that with the introduction of product patent, there will be a steep rise in the drug prices and an adverse impact on access to important drugs. A national health disaster was anticipated by the Indian Drugs Manufacturers Association as a result of the implementation of the TRIPS.[24] Whereas, the MNCs argued that such patents are essential to encourage innovation and help in transition of domestic pharmaceutical companies from copycat generics to innovative R&D.[25]

They further argued that it will serve India's interest better in the long run and there are adequate safeguards in the patent regime and other law to curb a sharp rise in drug prices. The inclusion of the product patent in the Indian Patent Regime did not have the deleterious effect as it was expected.[26] Few corporate giants undertook the Drug Discovery program in order to face the challenge of product patents, the few others undertook to set up research facilities and innovative research programs.[27]

The Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government 0f India, by its Annual Report for the year 2014-15,provided that the impact of product patents would not be too much. It said that only 5 to 10 percent of medicines globally would be under a patent protection at any given time. In the same therapeutic group, the price competition among different drugs is under control. Very high price of drugs in

[24]*Peter Darhos and Ruth Mayne (eds.), Global Intellectual Property Rights 97 (Palgrave Macmillan, Mew York, 2002)*
[25]*Peter Darhos and Ruth Mayne (eds.), Global Intellectual Property Rights 103 (Palgrave Macmillan, Mew York, 2002)*
[26]*Ibid*
[27]*Peter Darhos and Ruth Mayne (eds.), Global Intellectual Property Rights 60 (Palgrave Macmillan, Mew York, 2002)*

India would act as a deterrent to the patients since they pay from their own pockets. The medicine prices are under the control of the Government.[28] The safeguards like compulsory licensing and parallel importation exist. The Essential Medicines would be available at reasonable prices as they are less likely to be covered under patents.[29]

c. Issue of Evergreening

"Evergreening is a term used to label practices that have developed in certain jurisdictions wherein a trifling change is made to an existing product and claimed as a new invention. The coverage/protection afforded by the alleged new invention is then used to extend the patentee's exclusive rights over the product, preventing competition"[30]

The problem of evergreening persists as coming up with something new and unique to be termed as an invention can be tough but tweaking and modifying something old and calling it new just to continue enjoying monopoly is easy. In the pharmaceutical industry, brand companies patent "new inventions" and then right before the expiry of the patent make some slight modifications and apply for grant of patent as a new invention just to enjoy certain economic benefits.

The main issue with evergreening remains that there is generally no therapeutic development involved and no benefit or improvement to the people's health occurs, it remains to be mere economic advantage of the company.

Big pharmaceuticals involved in the practice of evergreening claim that the same is done so as to recoup the research and development and innovation costs involved. This still does not overpower the fact that these modified drugs don't offer enough of advantage over generic versions of the original molecules.

VI. CONCLUSION AND SUGGESTIONS

The Indian patent system was originally designed with the objective to reward the individual inventor and thereby stimulate invention by promoting the progress of scientific research and technology for public good[31]. Today its objective has entirely changed to monopolize the industries. It achieves this objective by conferring an artificial monopoly upon the person applying for the 'invention' by granting a title.[32]

[28] *The Drug Price Control and the National Pharmaceutical Pricing Authority are some of the ways to keep the drug prices under control on the part of the Government.*
[29] *Government of India Annual Report for the year 2014-15 (Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers 2015) available at http://pharmaceuticals.gov.in/annualreport2015.pdf.*
[30] *Novartis Ag v. Union of India (2013) 6 SCC 1*
[31] *Biswanath Prasad Radheyshyam v. Hindustan Metal Industries, AIR 1982 SC 1444*
[32] *WIPO, FAQs, available at http://www.wipo.int?patentscope/en/patents-faq.html*

In 2005, India enacted a fundamental change to its patent system for pharmaceutical products. This represents one of the first attempts to apply an entirely new patent system to an existing market of this size and scope. Prior to the new patent system, there were many products being sold containing molecules that were patented outside of India but were domestically manufactured and sold by a large number of firms.

A patent is viewed as a noteworthy motivating force for mechanical improvement, both for being an official archive that awards lawful assurance to the development and for being the best wellspring of data on mechanical advancement on the planet. Since pharmaceutical industry in light of items and procedures, have now expected an expanding significance in the worldwide economy, there is an unequivocal need to all-inclusive fit approaches and strategy in regard of security of intellectual property rights in perspective of the way that ventures occupied with research will make speculation just if solid legitimate assurance is accessible for the consequence of their examination. India has started to see some positive outcomes as familiarity with the requirement for more prominent IP security has expanded. Teaching all the pharma experts from maker to pioneers to industry players is imperative for accomplishing the advantages of IP administration and in addition for remaining steadfast among worldwide contending players.

The Indian pharmaceutical industry is, by a wide margin, a standout amongst the most differing, information driven, innovation concentrated development region, where quick track headways can without a doubt produce huge resources. When TRIPS was marked, many thoughtthat it would be negative for the Indian pharmaceutical industry. Be that as it may, PatentsAct, 1970,was noticeably critical if India needed to expand its pharmaceutical industry by urging huge remote organizations to put resources into India. It takes a great deal of consumption before another medication is presented in advertise, and the organization which produces it goes for getting benefit. In the event that the patent demonstration of any nation doesn't give it enough help to that, it will never put resources into that nation. This will stagnate the development of pharmaceuticals industry on the grounds that, as specified above, it is an information concentrated part. It requires gigantic funding to put resources into R&D and afterward in additionally stages to create more improved pharmaceutical. Be that as it may, to ensure that the overall population of a nation can get simple access to medications, it is essential to have enough shields too. Fortunately, India has made its patent law very productive in such manner. By presenting, necessary permitting and arrangements to handle consistently evergreening techniques, it can stop restraining infrastructure which will enable India to develop its pharmaceutical industry.

Thus, it is safe to say that although the shift from process to product patenting in the pharmaceutical sector has been a tough journey for India, it still has to overcome the obstacles and stay in compliance with the TRIPs agreement provided for the benefit of public health along with the protection of rights of inventors. There is a balance created so as to not hamper the affordability and accessibility of essential lifesaving drugs to the public

and also to stay a global player in the international pharmaceuticals market by providing adequate protection to the inventors.