INDIAN INTELLECTUAL PROPERTY RIGHTS BARRIER TO PHARMACEUTICAL RESEARCH AND DEVELOPMENT INVESTMENT

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ABSTRACT

The development of Pharmaceutical sector is not only important for the betterment of the health of the citizen but also for the development of the nation's economy. In no other industry involving intellectual labor do patents play as vital a role as in the pharmaceutical industry, where reportedly the number of innovations is far less due to the absence of strong patent protection. The pharmaceutical sector has unusual importance in debates about IP policy, and has served as the salient agenda for national and international controversies about the relationship between IPRs, R&D incentives, pricing and access to drugs and knowledge. By conferring rights to the patents it provide incentives for inventors to invest in expensive and risky Research and Development. A major change in the patent laws in India was the enactment of the Patent (Amendment) Act, 2005, which made patent laws in India compliant with the TRIPS Agreement and which led to decline in innovation and research and development investment in the pharmaceutical sector. The section 3 of Indian Patent Act is considered as an obstruction for patenting invention by many global pharmaceutical industries. Compulsory Licensing have been viewed as a necessary evil, in a developing country they have also caused grave concerns in the industry due to the revenue loss that CLs tend to cause. This paper tends to observe various drawbacks in the current patent regime pertaining to pharmaceutical sector and tries to find necessary solutions for the same.

Keywords**:** Patent , Compulsory Licensing , Indian Pharmaceutical Industry , Research and Development , Clinical Trials .

INTRODUCTION

The Pharmaceutical sector contributes towards the health-care development of a nation which is one of the significant aspects for the betterment of their citizen and to strive for healthy and disease-free nation. But along with this Pharmaceutical sector also contributes towards a nation's economy. They have a significant impact in the *Gross Domestic Product* (GDP) of nation by increasing job opportunities, creating demand, incentive and boost to research and development in medical sciences.[1] One of the leading nation in pharmaceutical sector is India and it can be the best player if it improves current policies and laws which regulates present Pharmaceutical sector. Intellectual Property Rights play a significant role in the shaping, development and various economies related to present Pharmaceutical sector. Five IPR which influences Pharmaceutical sector such as *Patent, Copyright, Trademark, Trade-secret, Industrial designs*. But among these Patents plays a major role in this sector and have positive as well as negative impact on the research and development investment. Until the TRIPS Agreement in 1994 developing countries did not provide product patents in the field of Pharmaceutical sector. Before complying with the TRIPS Agreement and making an amendment in 2005 to the Patent Act of 1970 , India in the late 1980's achieved self-sufficiency and emerged as the largest drug exporter in the world by applying *reverse-engineering* or export drugs whose product patents are in effect.[2]

Patents are exclusive property rights in intangible creations of the human mind. They can only be enforced by an individual state and a patent granted in that state will only cover the territory of the state. The global standard of patent rights being 20 years from the date of application. The conditions for granting patent under Indian IPR is:-

- Newness
- Inventive step
- Industrial Applicability

[1] Pradeep Agrawal and P. Saibaba , TRIPS and India's Pharmaceuticals Industry , Economic and Political Weekly, Vol. 36, No. 39 (Sep. 29 - Oct. 5, 2001), pp. 3787- 3790 (July 24, 2018 , 16:35) , https://www.jstor.org/stable/4411175 .

[2] Murphy Halliburton , Pharmaceuticals in the New Intellectual Property Regime , India and the Patent Wars, (July 25,2018 , 17:25) , https://www.jstor.org/stable/10.7591/j.ctt1w1vkb4.10 .

The determinations if these conditions are fulfilled are made by comparing the new patent applications by the existent prior patents and the published literature in the field. Patents work differently in different industries, in pharmaceutical sector it covers the cost of the product and majorly the extensive investment which is required for research and development and clinical trials which goes before introducing the product in the market. The introduction of Pharmaceutical product patents have a negative impact on the industries because it hinders growth of research and development both at India and abroad and will restrict foreign investment by withholding the introduction of new products to the Indian market, or by refusing to create new high-paying jobs.[3]

With regard to patents, *Section 5 Part II (Article 27–34 of TRIPS)* regulates the availability, scope, and use of patents. *Article 31* read along with *Article 27.1* of the agreement is quite ambiguous and they are quite contradicting in nature. *Article 31* is about compulsory licensing it is an authorization by a government to non-patentees to use the subject matter of a patent without or against the consent of the patentee and it is one of the major drawback why industries fear in investing a large sum of money in research and developing of a new drug . The restrictive interpretation of *Section 3(d)* of Patent (Amendment) Act, 2005 also works against the Indian pharmaceutical companies and India does not grant patent for incremental innovation of a drug. Incremental Innovations are minor improvements or simple adjustments on the existing drug. Thus improvement of an existing medicine also requires huge investment on research and development which includes conduction of clinical trials and also approval from the authorities before the new product is introduced in the market.

Conduction of Clinical trials are important before the introduction of a drug in the market because then its therapeutic accuracy can be checked and all risk and benefits can be identified. India is a developing country so there is a lack of investment for conducting clinical trials. Government incentives are less and private institution fear from incurring such huge expenses due to lack of appropriate policy framework. Foreign Industries are keen to invest in clinical trials in India because it is very favorable due to low cost and a diverse pool of patients. Thus Clinical Trials should be recognized as a new form of intellectual property because then it will

[3] Taylor & Francis, Ltd. , Effect of IPRS on foreign investment , The Interplay of Foreign Investment and Intellectual Property, (July 30, 2018 , 19:24) https://www.jstor.org/stable/3993115 .

encourage sponsor investment in clinical trials, minimize duplicative studies, increase the flow of information to the public, and increase competition within the industry.

JURISPRUDENTIAL ANALYSIS

A moral quandary is created by granting patents for innovation in pharmaceutical sector. In a libertarian society, the state shall grant importance to right to health care of individuals or right to individual's right over their property. ***John Rawls*** and ***Robert Nozick*** elaborated on the two distinct theories of justice within the society. [4]

According to Nozick, an idea is an intangible property and no physical labor can directly change its property. He gives more importance to an individual's right to property just like John Locke, *"every man has Property in his own Person"*.[5] Due to an individual's effort and labor an idea is channelized into a product and he should have full right over it. A mere idea does not have any value so once a product is created by incurring huge investment then the producer shall have full rights to determine the price of the product and restrict others from using it . The state while granting product patent to an individual should exercise little or no intervention because in his theory which is backed by lockean's theory on property rights more priority is given to the right of an individual over his property. The state shall not exercise certain actions such as redistribution of wealth which is acquired by the patent owner by having monopoly rights over the product. [6] Thus, when a state grants compulsory licensing over a patented drug it is highly immoral, unjust and biased. It infringes an individual's right over his property and pharmaceutical companies are under no obligation to provide medication to those in need. *Ever-greening of drugs* should also be allowed because a second inventor's property right is getting violated if the state is not granting him property right over his product because just like the first inventor he has also undergone a research procedure and investment to make the product better and increase its therapeutic level so the second inventor who contributed for the improvement of an existing drug should also be granted a protection over his property.

[4] Nevin M. Gewertz and Rivka Amado , Intellectual Property and the Pharmaceutical Industry: A Moral Crossroads between Health and Property , (July 25 , 2018 , 15:25) , https://www.jstor.org/stable/25123392 .
[5] Locke, J.: 1690, in P. Laslett (ed.), Two Treatises of Government. (2nd Edition ,Cambridge University Press, Cambridge, 1967).
[6] Nozick, R.: 1974, Anarchy, State, and Utopia (Basic Books, Inc., Cambridge, Mass)

Rawl's Theory of Justice focuses on two principles which are ***Liberty Principle*** and the ***Difference Principle***.[7] The first principle suggests that each individual shall have an equal basic rights like *"Freedom of Person and (health and security) and the Freedom of speech"*. As the name suggest Difference Principle, it concludes that social and economic disparities in a society is only valid if it provides maximum amount of benefit to the poor and underprivileged people of the society. This two principles of justice propounded by Rawls are placed in serial order which means that an infringement of basic equal liberties would not be justified by strengthening or intensifying social or economic advantages. According to Rawls companies in developing and under-developing would pursue treatment and formulation of drugs for diseases such as malaria etc. and they will be forced to market below and sell their products much lower than the cost price of the drug. If this goes on for a long time then the companies will invest less in their research for a better drug and it will take them away from cure of fatal illness towards palliative care. Thus, in this manner the first justice as propounded by Rawls that is basic liberties is being violated. Regulation and subsidization should be of only those medicines which treats potentially fatal diseases and not of medication such as pain-reliever because it does not violate basic liberties. The risk taken by Pharmaceutical companies by investing on research and development will decrease if they incentivize on their production and manufacturing returns rather than adhering to the regulatory schemes of the government.

It is argued that patent protection in pharmaceutical sector balances the interest of both private and public goods but it also imposes barriers on Pharmaceutical sector by giving limited rights to the patent owners and subsequent innovator and it also does not take into account the requirements of price-sensitive consumers, who would have otherwise been benefitted from the availability of these new drugs are conveniently priced out of the market. The conclusion by the theories of Rawls and Nozick it can be concluded that pharmaceutical companies are under no obligation to provide medication to those in need.[8]

[7] Rawls, J.: 1971, A Theory of Justice (Harvard University Press, Cambridge, Mass)
[8] Id at 4.

INCREMENTAL INNOVATION: IN LIGHT OF NOVARTIS CASE

Novartis is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients worldwide. Novartis's struggle with Indian patent regime started when it applied for patenting around the world for synthesis of the molecule ***imatinib***. The same drug is patented in forty countries as Glivec. After India become a signatory of TRIPS Agreement, Novartis applied for a patent application for Glivec in India according to the "mailbox requirement". But Madras Patent Office rejected the application on the grounds of *"an unpatentable modification of an existing substance, imatinib"*. They also stated that according to Section 3(d) of the Patent (Amendment) Act, 2005, Glivec failed to adhere to the condition specified therein of novelty, inventiveness and improved efficacy. To this the Novartis contented that Section 3(d) is not compliant with the TRIPS Agreement and also that it is vague and ambiguous and also petitioned that it is violative of *Art. 14* of Constitution of India as it was being discriminatory towards them. To the first contention Madras High court said that it was beyond their contention and the proper forum of appeal would be WTO and secondly they rejected the plea and did not grant patent to Novartis. [9]

Novartis appealed before the Supreme of Court of India, but still the judgment delivered was not in favor of Novartis. Supreme Court in this judgment also failed to establish the meaning of enhanced efficacy but it also stated the Novartis judgment should not be read as general prohibitions for incremental innovation of molecules or drugs in pharmaceutical sector.[10] But this decision may seem beneficial in short run but it will tremendously harm innovation and growth and development of pharmaceutical Industry in India.

India does not have sufficient funds to carry out research and development programs for introduction and production of new drug. To cut cost they can solely rely on methods such as "incremental innovation" which will be beneficial for both producers and consumers of those drugs. Producers can be benefitted because they have to incur less investment comparatively and consumer can have a drug at a much cheaper rate. Thus, Indian policy maker and Judiciaries should have a liberal approach towards incremental policy and patents should be granted to them. It also argued that Indian scientist does not enough funds to carry out research

[9] Novartis Ag v. Union of India (2013) 6 SCC 1.
[10] Helen Pidd, Indian Court to Hear Crucial Novartis Patent Case on Cut-Price Generic Drugs, GUARDIAN (July29, 2018, 10:27 AM), http://www.guardian.co.uk/business/2012/aug/21/novartiscourt-battle-glivec-patent .

and development and also to invest in clinical trials so they are better in making improvement to an existing drug rather than producing a new drug overall .

It can be concluded that patenting for incremental innovation will not do harm to the Indian society or its growth but in return it will help in growth and development both at home and abroad. After this many MNC's will be in favor of investing in the drugs which are pertaining to the diseases of particularly India. FDI can also help many pharmaceutical industries to invest in their research and development and they can introduce various drugs which will be beneficial to the society and also help in the nation's development.

COMPULSORY LICENSING: AN UNREASONABLE SOLUTION TO AN UNFORTUNATE PROBLEM

The disparity between large Multinational companies and developing countries who have less means to undertake or incur huge investment cost on manufacture of a drug gave rise to an unfortunate solution such as Compulsory Licensing. Compulsory Licensing means that when a government allows someone to produce a drug or a product without the consent of patent owner and it is explained in *Art.31* of TRIPS Agreement.[11] Compulsory License can only be issued when a person or company applying for license must have attempted and have failed or in case of ***national emergencies***, other circumstances of ***extreme urgency*** and ***anti-competitive practices***. It is also mentioned in Article 31 that the patent-owner will be granted a just remuneration but what will "just" include is not explained and is quite unclear. *Section 84* of Patent (Amendment) Act, 2005 mentions various ground when a company or a person can be granted compulsory license to manufacture patented drug. The grounds are that when the reasonable requirement of public at large with respect to the patented drug is not being fulfilled or when it is not available at affordable prices or when it did not work in the territory of India.

[11] Patent requirements of TRIPS can be found in Arts. 27–34, which form a comprehensive code for all aspects of patent regimes, including provisions for compulsory licensing. Getachew Mengistie , World Intellectual Property Organization, The Impact of the International Patent System on Developing Countries: A Study by Getachew Mengistie,. (Last visited on July 27, 2018 , 17:25), http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=17555

India was the first ever country to grant Compulsory Licensing of a Patented drug to a company post TRIPS Agreement. The infamous case ***Natco v. Bayer***[12] which become the first case ever which was contrary to the exclusive rights of a patent owner over his product. ***Nexavar*** was a Patented drug of Bayer and they received a license to import and market the drug in India on August 2007. In this case Natco was granted compulsory license for manufacturing Nexavar which was used for the treatment of advanced stages of kidney and liver cancer. This judgment was criticized by western countries and they challenged that this will discourage new investments.[13]

Compulsory Licensing of Pharmaceutical Patents is undesirable in long-term for a country like India. The economic analysis demonstrated by cost-benefit ratio states that to satisfy the need of today's suffering patient, long term societal goals by progressive research is being curtailed and hampered.[14] As we know patent protection only exist for a few period and then it is freely available in the public domain so it won't be feasible to grant compulsory licenses. Because it can be said that needs of few can be curtailed for few years so that there can be place for innovation and research in the field of pharmaceutical sector. Companies who undertake huge research and development to introduce new drug which have better therapeutic value need some protection towards the risk they undertake. The Government should always encourage such firms to undertake investment for innovation and provide those subsidies or tax-concession which will help in lowering the price of a drug. Due to curtailment in granting compulsory licensing there will be a healthy competition in the market because each firm will try to capture enough share in market by making their product better than other. So, demand will be equated to supply and also one more impact can be created there will be no monopoly in the market.

The argument against compulsory licensing does not state that the government cannot look into other solutions.[15] Firstly, prices of drugs can be lowered by reducing the cost which the

[12] Bayer Corporation v. Natco Pharma *Ltd* , Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), (July 30, 2018 , 20:27) http://www.ipab.tn.nic.in/045-2013.htm .

[13] Mansi Sood , NATCO PHARMA LTD. V. BAYER CORPORATION AND THE COMPULSORY LICENSING REGIME IN INDIA , (July 28 , 2016, 20:40) , http://nujslawreview.org/wp-content/uploads/2016/12/mansi.pdf .

[14] Antara Dutta , FROM FREE ENTRY TO PATENT PROTECTION: WELFARE IMPLICATIONS FOR THE INDIAN PHARMACEUTICAL INDUSTRY , (July 22 , 2018 , 19:27) , https://www.jstor.org/stable/23015926 .

[15] Bruce Lehman , The Pharmaceutical Industry and the Patent System , (July 30, 2018 , 18:30) , https://users.wfu.edu/mcfallta/DIR0/pharma_patents.pdf .

pharmaceutical companies face by curtailing tort awards. Secondly, Joint research programs can be undertaken by few companies together or with the help of government. Thirdly , subsidies can be provided to patients who are unable to incur expenses on such expensive drugs. Thus every government should also look into the rights of these pharmaceutical companies and help them recoup the investment which they have incurred while formulating a new drug which will in turn help citizen of world at large and also in improvement of country's growth and development. Innovation in pharmaceutical sector is beneficial for both public at large and world-wide economy.

DATA EXCLUSIVITY IN LIGHT OF CLINICAL TRIALS

Data Exclusivity is not an extension of right which are granted under patent protection and they both are mutually exclusive of each other. Both are different forms of protection, in Data exclusivity the clinical data which is submitted to the authority is protected and in Patent the product as a whole is protected. Thus, Data exclusivity means protection is granted by the state to the pharmaceutical companies on their clinical data which is generated by innovation. Article 39(3) of the TRIPS Agreement demands the member states to protect confidential information against unfair commercial use.[16] This article is ambiguous and can be interpreted in any manner by a member states and it does not speak exclusively about data protection. India does not have any provisions related data exclusivity in the Drugs and Cosmetic Act, of 1940 and Rules, of 1945. Indian Government is making changes in their policy-framework and regulatory environment to comply with the TRIPS Agreement and to promote Clinical trials.

Clinical Trials is an important stage which every pharmaceutical company conducts before introducing a new drug in the market. It is a fact that due to dosage of a wrong drug it can have side-effects on the patient and there are chances that he may die. So, it is compulsory to conduct clinical trials before prescribing that to patient. India is looked upon by other countries as one of the favorable place to conduct clinical trials because of its large pool of patients and volunteers, lower cost and also timely completion of clinical trials and also huge market opportunities. When clinical trials are conducted on human subject utmost safety have to be

[16] Vishva V. Ramlall, "The Pharmaceutical Industry in the Great White North and Land of the Rising Sun: A Comparison of Regulatory Data Protection in Canada and Japan," IIP Bulletin (2004), pp. 93-94. (July 30, 2018 , 21:06) , https://vdocuments.site/7-the-trips-agreement-and-the-pharmaceutical-industry-the-indian.html .

undertaken and strict guidelines should be followed. To conduct a clinical trial huge investment is required and it's quite expensive process and India being a developing country does not have enough funds and experts to conduct it. If Indian companies invest in clinical trials then they have to opt for licensing out their molecules.

Clinical trials comprise of 4 phases:-

I. **Phase I** inspects the safety of the drug .This stage takes months and includes few healthy volunteers. This phase helps in studying the effects which the drug will have on a human body such as how it is absorbed, metabolized and excreted. This phase also inspects the various side-effects that drug can have if the dosages are increased.
II. In **Phase II** the proposed drug is tested on a large pool of patients and new combinations of the drug are tested. Patients are held under scrutiny and are closely watched.
III. In **Phase III** the proposed drug is also compared with the standard-of-care drug which is used. It is to assess the various side-effects of the drug and which drug is better and have higher therapeutic value. This stage is often needed for the approval of FDA and will they allow the launch of the new drug in the market
IV. In **Phase IV** is conducted after the drug is launched into the market. It also helps in studying of side-effects which only a particular set of people might have. It also assists doctor in studying whether this drug can used for other treatments.

However, Indian Clinical trials only concentrates upon Phase III which is considered only with examine and determining the therapeutic dose of medicines.[17]

Innovator companies are required to submit the data which they have collected by conducting clinical trials and submit it to the authorities for getting approval to market the product. Companies which are engaged in formulating generic drugs are need not required to conduct clinical trial and they are not obliged to take permission of the regulatory bodies to market their products. So, it is necessary that data exclusivity be provided to innovator companies because if it is not provided then generic drug companies will use the data submitted by innovator companies and produce their drugs with that data.

[17] Swadhin Mondal & Dinesh Abrol, CLINICAL TRIALS INDUSTRY IN INDIA: A Systematic Review ,(July 30, 2018, 22:30) , http://isid.org.in/pdf/WP179.pdf .

Data exclusivity provided for Clinical trial data is essential because it facilitates innovation. Conducting a clinical trial is an expensive process and this step only determines the cost of the drug. A lot of investment in research and development is spent on clinical trial which helps in producing a new drug or new formulation of an existing drug or modification in existing drug which have enhanced efficacy.[18] In Indian patent regime the criteria for grant of patent is very strict and what amounts to a new drug or the qualification to get a drug patented is still a mystery. Thus, when in a society without data exclusivity and an uncertain situation whether they will be granted patent over their produced drug, there is no point a company will undertake such huge losses to introduce a new product and they will be at risk if they incur expenditure in clinical trials. There is no incentive for pharmaceutical companies to invest and due to this there will be no innovation which will lead to a stagnant market were no new drug is being introduced and this is detrimental to public health and growth of the nation as a whole.

India is a favorable ground to conduct clinical trials but the country lacks financial backing and experts to conduct proper clinical trials which are done on humanitarian grounds and are not violative of human rights of an individual. Many foreign countries are conducting clinical trials on Indian patients but those drugs are not beneficial for India and are exclusively for diseases pertaining in developed countries. So to increase investment on clinical trials for those drugs which are pertaining to the diseases of the country and also have a provision of at least 5 years of Data Protection from the date of marketing approval in India so it will be beneficial for all the key players of this sector such as companies, government, consumers and research and developers.

The success of Hatch-Waxman Act, which led to increase in innovation and research and development in pharmaceutical sector.[19] This led to introduction of new drugs in the market. On the same grounds if India also grants minimum 5 years of data protection from the date of marketing the product it will boost research and development investment in the Pharmaceutical sector.

[18] Bhavik Narsana , Souμyadri Chattopadhyaya , Yashashree Mahajan, Clinical Trials and Data Exclusivity: In Search of a Fine Balance, (25th July , 2018 , 22:10) , https://www.khaitanco.com/PublicationsDocs/Khaitan&Co-PharmaBioWorldMarch17.pdf .
[19] Ibid

CONCLUSION

The objective of this paper was to give an insight into the current IPR regime in India and how it has been proved that it is incapable of catering to the needs of the consumers and growth and development of the nation. In developed countries it has been observed that the IPR regime is very fruitful and is paving way for innovation in the field of pharmaceutical sector. Due to appropriate protection granted to the newly formulated drugs, pharmaceuticals companies have an incentive to invest in research and development. When same IPR regime was introduced in India it did not become as successful as it was in the developed countries because Indian Government had restrictive approach in granting patent to the drugs and no patent was granted in case of incremental innovation . It has also been illustrated in this paper how compulsory licensing might seem favorable in short run but is very detrimental in long-run and it will have adverse effect in the field of research and development because no company will be in favor to invest in a drug were protection won't be granted to the drug and they might incur huge loss.

Due to India's weak patent regime and globalization, Indian Pharmaceuticals company are investing more on production of drugs for diseases which are prevalent globally rather than drugs for those diseases which are prevalent in India . [20]Their main target is global consumers rather than domestic. One reason for this might be that India's current policies and laws pertaining to pharmaceuticals industry are not fulfilling the demands of those companies and little or no incentives are provided to them. So less private companies are getting engaged in development of new drugs and due to this public health is at stake. Indian Government have two: Firstly, they can adopt re-engineering of patented drugs which was quite prevalent before complying to the TRIPS Agreement. The process of re-engineering of patented drugs proved to be very successful in India and it made India one of the largest producer and supplier of drugs world-wide. Less investment was required in this process and due to this drugs were produced at lower rates which decreased the cost of the drug. Due to this cheap drugs were available in the market and accessible by all consumers.

[20] Reji K Josep , The R&D Scenario in Indian Pharmaceutical Industry, (July 30, 2018 , 23:09) , http://ris.org.in/images/RIS_images/pdf/dp176_pap.pdf .

Secondly, alternatives either to adopt a strong patent regime which is been found in the developed countries.[21] Incentives should be provided to foreign companies or private companies to invest in research and development of the product because in pharmaceutical sector price of the product totally depends on the cost incurred in research and development and conduction of clinical trials. Due to this research can only be concentrated on those diseases which are prevalent in India. India does not have sufficient funds to carry out high level research which is required in this field so there is a need of foreign assistance. In a strong patent regime only this could be possible. Public-private partnership should be encouraged in this field. Pharmaceutical sector is dynamic in nature and Indian Government also should adopt a policy which is appropriate for current scenario then huge opportunities will be awaiting for Indian companies in international market.

[21] Shyama V. Ramani and Augustin Maria, TRIPS: Its Possible Impact on Biotech Segment of the Indian Pharmaceutical Industry, (July 29 , 2018 , 17:25) , https://www.jstor.org/stable/4416206 .