PATENTS FOR PHARMACEUTICAL SECTOR & PEOPLE'S RIGHT TO ACCESS TO HEALTH IN INDIA - ISSUES AND CHALLENGES

Vishakha Nandini, BSc LLB, University of Petroleum and Energy Studies, Dehradun

ABSTRACT

Every person wants to gain monopoly over the things they invent themselves, or things they invest their time in. Monopoly rights like patents, give them this advantage which motivates them and helps in further developments in the field of inventions. There is a broad category over which patent rights can be claimed, but when it comes to the question of granting patent rights on medicines and other pharmaceutical products, the patent law becomes sceptical.

While the laws are made keeping in mind that the inventor gets their share of the profit and benefits, a conflict regarding the right to health systems for common public is also there in their mind. For that reason, laws have to be made ensuring the interests of both sections. There have been major developments in the patent laws with regard to pharmaceutical products. In India, the view of the lawmakers was different earlier, but now they have taken a completely different approach. The motive of patent, besides giving them due credit, is to provide reasonable incentives as pharmaceutical companies make revenue only because of patents, or else any other company can produce the same medicines at lower costs. TRIPS agreement plays a major role in shaping the future of pharmaceutical industries in India. There are many landmark judgments which helped in understanding the laws better.

This paper is going to focus on the development of patent laws in India in the pharmaceutical sector and try to find out the difference between product patent and process patent. This research paper will try to find answers to questions like- whether patent on medicines will affect the people's access to health? What are the challenges in ensuring that right to public health is not being violated?

Keywords: Pharmaceutical sector, patents, incentives, TRIPS agreement, right to public health

INTRODUCTION

The pharmaceutical industry is a technology based industry. It is a booming sector which has been witnessing consistent growth over the past decades even though the whole IPR sector is a newer concept for the world. Since science is expanding and there are new, unforeseen inventions every day, the need and demand of patent has increased like never before. In this paper we are going to focus on the aspect of- granting of patent in the field of pharmaceuticals.

With advancements in the medical field, diagnosis of diseases have become easy and quick, leading to newer diseases being discovered which means there is a requirement of medicines for each and every disease. But the fact can't be ignored that, making of medicine means investing a lot of effort, time, knowledge and money. Therefore any individual or company, or whoever is inventing any drug deserves and expects recognition for their work, incentives and other monopoly rights over it. For the reasons stated above, patenting in the pharmaceutical industry is an important legal right. If patent right is not granted, people will not feel encouraged to invest their time and money in making something for which they won't get any benefit.

When monopoly over a medicine is granted to its inventor, the state also needs to ensure its duty to provide access to free or affordable medicines to every citizen. It is the obligation of the state to ensure the right to access to health. Whenever there is a requirement to take measures in the interest of public, they should take appropriate measures to protect their right and provide affordable drugs and medicines for all.

After the change in concept from process patent to product patent for granting of patent in the Indian law, there has been major changes in the pharmaceutical industry in terms of patent protection. Process patent refers to patenting of the process used to manufacture a particular drug. A drug cannot be patented under this system. But with the introduction of the "product patent" regime, even the product could be patented.

This led to pharmaceutical companies taking benefit of the situation and rising the prices of their products and controlling everything. Since the pharmaceutical sector does not only comprise of government owned companies, but also comprise of privately owned companies, there was no control of government authorities on their actions.[1] The implication of these

[1] Angell M. The Pharmaceutical Industry.To Whom Is It Accountable? *N Engl J Med.* 2000;342:1902–4

changes were that the right of public to access to health was being violated. Even though these private companies have played a major role in expanding the pharmaceutical sector and making profits, the lives of common people were being effected and they were being deprived of crucial medicines due to economic reasons.

This paper focusses on the patent for pharmaceutical products which has undergone so many developments in recent times and the implications of changing the criteria of patenting from process patent to product patent. This paper is going to look at the threat caused to the people's right to health, what are the issues behind such threat and what can be done to ensure that there are no violations and every person gets the medicines at affordable costs and without any kind of struggle.

History of Patenting in Pharmaceutical Industry

There were no provisions for patenting of pharmaceutical products in India before the year 2005. Patents for pharmaceutical products was allowed to merely follow India's obligation as they had signed the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The agreement required all countries party to the agreement to grant pharmaceutical patents and the deadline to do so was the year 2005 for countries which didn't have that provision.

India patent law contained provisions for process patent when the TRIPS agreement was being signed and had to reluctantly adopt the concept of product patent. Since the 1970's, when the India Patents Act came into existence, domestic companies were allowed to replicate the drugs patented by MNCs which led to booming of the generic pharmaceutical industry. The intention behind not adopting the product patent was for the benefit of the public, but MNC's started incurring losses and hence, started leaving India. They were having concerns over protection of their drugs as private pharmaceutical companies started selling generic medicines. These private companies were making a lot of profit without much investment whereas the inventor company were running in losses.[2] Since MNC's weren't there in the market anymore, the generic pharmaceutical industry of India was established and also became *one of the most prolific drug manufacturing industries in the world*.

[2] Shodhganga.inflibnet.ac.in. n.d. *Shodhganga : a reservoir of Indian theses @ INFLIBNET*. [online] Available at: <https://shodhganga.inflibnet.ac.in/bitstream/10603/128146/14/07_chapter%202.pdf>.

When in the 1990s, the Indian government decided to open India for foreign investments to boost up their economy, many new measures had to be taken. One of those measures involved becoming a member to agreements, including the TRIPS agreement.[3] After signing the TRIPS agreement they were obligated to follow the pattern of patenting followed all over the world and allow product patent instead of process patent.

India was resistant in taking this step, but eventually they had to comply with it. Section 3(d) of India's Patent Act was added to comply with the agreement which resulted in a lot of controversy. It says that mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process will not be allowed for patent.4 It tried to prevent any chance of extension of patent due to any small modifications in the product as patent protection will start to lose its value. Patent extension should only be allowed when there is a significant enhancement which can be demonstrated. Under this controversy related to section 3(d)'s constitutional validity, the decision given by the court in the case of Novartis AG vs. Union of India[5] has proved to be an exemplary judgment. The facts of the case are such that Novartis applied for an Indian patent on the beta crystalline form of imatinib mesylate. On which the Madras Patent Office rejected the patent application stating that imatinib mesylate was already known to the public and beta crystalline form was only one of the derivatives of imatinib mesylate.

Then Novartis appealed at the Intellectual Property Appellate Board (IPAB) regarding the decision. The decision of the Patent Office was modified by the IPAB by stating different grounds of rejection that for granting of patent, there is a requirement of novelty and non-obviousness in the beta crystalline but the application is rejected on the ground that the drug is not novel. It is just another form of the already present substance which has been modified a little from the already known compound.

Novartis, aggrieved, filed another case in the High Court of Madras but with the contention that that Section 3(d) of the Indian Patent Act, 1970 is violative of Article 14 of the Constitution of India stating that the meaning of the term 'enhanced efficacy' used in the clause was not defined properly and was also in violation of the TRIPS Agreement. But the High Court held

[3] Lehman, B., 2003. *The Pharmaceutical Industry and the Patent System*. [online] Available at: <https://users.wfu.edu/mcfallta/DIR0/pharma_patents.pdf>.
[4] Sec 3(d), Indian Patent Act, 1970.
[5] AIR 2013 SC 1311.

that the provision was not vague and was complying with the TRIPS agreement and that the provision under Section 3(d) was constitutional. This case of Novartis is important as it highlights that no one can deny the right to access to life-saving drugs to the public due to their monopoly in the market and high pricing.

The Supreme Court of India in the year 2013, finally shared their view on the judgment of the Novartis case that private pharma companies are booming in India and have almost captured the domestic pharmaceutical market due to favourable laws and government policies. Also the international competition is very less in India.

Process patent and product patent

Process patent means that only the process used to manufacture a particular drug can be patented. The drug cannot be patented under this system. Process patent is a patent which only gives protection only to a certain extent. The reason behind granting process patent in India before 2005 was to reduce or limit the monopoly of the inventor so that every person can get the benefit of the produced drugs. It does not restrict or prevent other companies from manufacturing the same product, but the condition is that since the process of manufacturing has been patented, they need to find a different method to manufacture the same medicine. Therefore, it is possible that many process patents are being granted for just a product. The process patent makes sure that there is competition in the market so that the companies try to make the best products at the cheapest of prices to gain buyers. Process patent has given liberty to every pharmaceutical company to make the product due to which the MNC's felt threat to their companies as they will not get enough monetary benefits as well as complete monopoly for a product which they produced by investing a lot of time, money and knowledge. Therefore, there was a boom of generic medicines in the market, making sure that every citizen gets the medicines at affordable costs and their right to health is protected.

But with the introduction of the product patent, now since patent had to be given on the product itself which meant that there is complete monopoly given to the inventor. Now, no matter what process is used for manufacturing, however different it is, they will lead to infringement as they are not allowed to make that product. The patent is granted on the product.[6] Other companies do not have the right to manufacture the same drug once it has been patented. For introducing

[6] iPleaders. 2021. *Difference between product patent and process patent - iPleaders*. [online] Available at: <https://blog.ipleaders.in/difference-between-product-patent-and-process-patent/> [Accessed 14 November 2021].

this particular change in the Indian Patent law, after they were obligated to comply with the TRIPS agreement, the Indian government removed section 5 (1) from the Indian Patents Act, 1970 which contained the provision relating to process patent in the pharmaceutical sector. This raised concerns in the Indian market regarding the prices of drugs. Since the inventor company will get absolute monopoly over their product and taking advantage of the situation, they will raise the prices of the drugs according to their wish which will make it unaffordable for the common man and will lead to a violation of their right to access to health.

If we talk about who prefers what and why, the developed countries are bent towards following the product patent as they realise the usage, necessity and benefit of it. For the developed countries, patent product will bring a lot of advantages but for the developing countries, they don't believe in bringing the concept of product patent, they prefer the idea of process patent as it will bring in a lot of generic companies.[7] In developing countries, there is a wide gap among the rich and the poor, also a huge population cannot even afford 3 meals a day, then how will they be able to buy patented products which will be costly for them. That is why they do not find the product patents useful for them.

If we consider the take of TRIPS and WTO on this debate, they also considered product patent useful and necessity for the inventors.[8] To motivate and provide recognition to the inventors for their hard work, it is necessary to have powerful IP laws so that there is no insecurity in the mind of the inventor. For that reason, they made sure that every country, party to the agreement adopt the concept of product patent. So, there was a requirement mentioned in the TRIPS Agreement which stated that all countries that ratified the agreement must follow the Product Patent Regime.

The right to access to health

Right to life and health is a fundamental right which has been guaranteed by the constitution of India to every citizen of India, which cannot be ignored or violated in any circumstance. Even the courts have held in numerous cases that the right to life includes right to health as well. It is the duty of the Government to take every measure which helps in providing easy

[7] Collier, R., 2009. *Drug development cost estimates hard to swallow*. [online] PMS- US National Library of Medicine National Institutes of Health. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2630351/>.
[8] Core.ac.uk. 1998. *TRIPS and Pharmaceuticals: Implications for India*. [online] Available at: <https://core.ac.uk/download/pdf/224038539.pdf>.

access to life-saving drugs to its citizens. They should also ensure that these life-saving drugs are available to the common man at affordable prices. The government is responsible for taking care of these rights and ensure that there are no violations of the fundamental rights.[9] The laws and policies should be made in such a manner that it helps in maintaining the balance of the social and economic rights. For maintaining that balance, first the balance between public health and the economic interests of pharmaceutical industries has to be ensured.

A completely utilitarian patent framework would bring about a converse connection between the expense of such items and moderateness of access. This has driven some to propose that the worldwide licensed innovation framework might be confronting an emergency of public authenticity as licenses might be impeding the entrance of customary individuals to prescriptions and their right to wellbeing. Despite the fact that the crossing point among IP and drugs has a ton of importance, the global IP associations are battling to track down the best laws to keep away from any disarray or debate.

The benefit of boosting advancement and giving admittance to it is perceived in the International Covenant on Economic, Social and Cultural Rights (ICESCR), perceives a people right to profit from the moral and material interests as creators of logical manifestations [Article 15(1)(c)], a right incorporated with the freedoms of people to get to the advantages of science [ICESCR Article 15(1)(b)]. Strains emerge when the right to wellbeing meets with IP freedoms (IPR); and ensuring the interests of the innovators of logical manifestations are adjusted against privileges to get to science and privileges to wellbeing. Prosperous nations are likewise obliged to help less prosperous nations to meet center least right to wellbeing guidelines including admittance to fundamental prescriptions. This is likewise a significant general medical problem. Right around 2 billion individuals don't approach essential prescriptions [19]. On the off chance that IPR raised costs making drugs exorbitant, this could have genuine ramifications for the right to soundness of people. Low wellbeing guidelines can affect other common liberties, like efficiency misfortunes and negative monetary outcomes [21]. In spite of the fact that there is no common liberty to efficiency, loss of usefulness is probably going to diminish greatest accessible assets that can be utilized to acknowledge monetary, social and social privileges.

[9] Sharma, D., n.d. *Pharmaceutical Patents And Healthcare: A Legal Conundrum | SCC Blog*. [online] SCC Blog. Available at: <https://www.scconline.com/blog/post/2019/09/03/pharmaceutical-patents-and-healthcare-a-legal-conundrum/> [Accessed 8 November 2021].

What really establishes a fundamental medication is apparently not entirely clear regardless of WHOs meaning of fundamental meds that incorporates those that fulfill the need medical services needs of the populace and are planned to be accessible inside the setting of a working wellbeing framework consistently. Notwithstanding, concentrates by Duong et al. found that partner chiefs, pioneers or consultants in fundamental prescriptions in Australia couldn't observe whether medications that were broadly repaid were fundamental drugs and didn't consider the EML idea in medication repayment choices or supply the executives.

Other relatively affluent nations have likewise set up measures to guarantee residents are not denied of admittance to drugs. A new model is the Serious Shortage Protocols (SSPs) that emerged from vulnerabilities around Brexit. The UK Government acquainted new laws with manage the chance of medication deficiencies in the UK market. SSPs, that work under The Human Medicines (Amendment) Regulations 2019, have permitted local area drug specialists in the UK to supplant drugs they can't access with substitute medications that may have diverse strength, amount or drug type of the solution just medication to that arranged by the prescriber.

Challenges to right to health and IPR regime

The high prices of the patented products and its access to every person around India has been one of the major concerns and challenges for the government. This concern came up since the Indian Patent Act came into existence and is still a concern, even after so many amendments in the act. The solution is still to be found, but one thing is for sure that pharmaceutical sector cannot be separated from IPR. The reason behind pharmaceutical sector's progress is dependent on IPR protection is the staggering cost of new chemical entity (NCE) development as a potential drug molecule and high attrition rate in the development cycle.

The inventors deserve patent protection for the amount of time, research and money which is spent on making these life-saving drugs for the common man. Making a drug is not an easy process as it involves years of research on the disease and its cure, numerous phases of trial and not to forget years of hard work with money. In a report, it is mentioned that only 1 out of every 5000 medicines synthesized during applied research, eventually reach the market. Of the 100 drugs that enter the clinical testing Phase I, about 70 complete Phase I, 33 complete Phase II, and 25-30 clear Phase III which can be marketed, rest all of them are rejected. With such

high rate of failure, companies cannot find good investment.[10] And without a good investment, they will not be able to go ahead with the drug invention and tests. To conduct this expensive, high-risk research, assurance and security is very much needed, which only patent protection can provide. Without strong patent protection, fewer drugs will be developed and the flow of medicines to the public drugs and pharmaceuticals.

Indian Patent Act 1970 incorporates arrangements for shielding the freedoms of the maker of generic medicines that make conventional medicines. The Act has tested the right of a great many individuals to wellbeing. It restricted just the well off, and well-off sections of society to approach life-saving medications and freed them up to the powerless and penniless in our general public. Indian patent law consolidates the interests of patentees with the necessities of the overall population. It has likewise found some kind of harmony between severe imperatives on protected innovation and the adaptability of the TRIPs. Nonetheless, the Indian court excused Novartis attestation and, subsequently, Indian nonexclusive organizations continued to sell the conventional form of Glivec at around one-10th of the first medication cost. This has widened the scope of the poor in our nation to purchase life-saving medications at a lower rate.

The interests of drug firms to create a gain and their obligation regarding the powerless in the public arena ought to get reasonable consideration from TRIPS. Its point ought not be to forestall yet to support the accessibility of prescriptions that meet public general wellbeing prerequisites, at reasonable costs. A few more suggestion which can help in solving the issues and concerns of the state as well as the IP organisations are-

- Every nation should frame its patent law under its financial requirements and needs, including general wellbeing while at the same time regarding its global commitments.
- Fundamental general wellbeing needs incorporate trim patent standards to expand admittance to drugs especially for poor people.
- Legislatures ought to have the option to work rapidly, even in instances of infection emergency, under a wellbeing responsive lawful system.
- The public authority will set up a drug patent framework that expressly administers life-saving medication openness.

[10] Vicky, R., 2015. *Right to Health vis-à-vis Patent Protection: The Indian Scenario - Academike*. [online] Academike. Available at: <https://www.lawctopus.com/academike/right-health-vis-vis-patent-protection-indian-scenario/>.

- In the creating and least-created countries, the adaptability of required permitting ought to be polished. For the issuance of necessary licenses, a straightforward methodology should be formulated.
- Equal import ought to be took into consideration such fundamental life-saving medications.

With these changes, we can hopefully envision a picture where individuals leave the shadow of the serious sickness into the daylight, sing with their eyes, on the lush fields, in new forests, and on the sea shores.

Since the duration of exclusivity is gradually decreasing due to introduction of newer congeners of the molecule, the companies indulge in litigation and compromising marketing strategies to prolong their exclusive rights. It would slow the detriment of patients, public health and economic development throughout the world. Access to pharmaceuticals is part of the obligation of each ICESCR party to fulfil the right to health under CESCR General Comment No. 14. This provision not only covers essential medicines, but also covers other medicines because it forms part of progressive realization of the obligation for states to provide individuals with the highest attainable standard of physical and mental health.[11] This approach of progressive realization recognizes different economic capabilities between states. However, states are obligated not to regress from measures to protect economic, social and cultural rights, including the right to health once they are provided.

Drugs can be delisted in circumstances of failure or inability to supply where the supplier and the government cannot agree on price. Providing additional treatments means the health budget expands, governments can reduce other social services that could restrict the realization of other economic, social and cultural rights. These are opportunity costs, where decisions are made between competing alternatives. Consequently, cost considerations could limit human rights incentives to improve health through expanded access to cancer treatment.

Are there other ways to reduce the financial impact of providing new cutting-edge treatments? 'Access' is used as a proxy for affordability. It should also be acknowledged that access, from a health systems perspective, can also refer to barriers in both demand and supply, and be identified as geographic and financial accessibility, quality, acceptability and availability. Non-

[11] Salazar, S., n.d. *INTELLECTUAL PROPERTY AND THE RIGHT TO HEALTH*. [online] Wipo.int. Available at: <https://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_3.pdf>.

governmental organizations recognized that in less prosperous countries patent protection can increase pharmaceutical prices. Moreover, the 17-year extension to the transition period (to 2033) for least developed countries to enforce global trade rules could be even further extended under Article 66.1 of the TRIPS Agreement.

Courts in non-industrial nations ought to similarly know that courts are currently discussions for moulding and reshaping worldwide wellbeing tact. While worldwide drug organizations can effectively campaign for more grounded patent security in global exchange discussions, helpless patients and common society bunches ordinarily depend on generic courts to guarantee that their advantages are ensured at the nearby level.[12] Thusly, in a circumstance where more courts in emerging nations are embracing a right to wellbeing point of view in drug patent cases, it will support defendants in other non-industrial nations to look for the help of nearby courts to ensure their right to wellbeing. These nearby courts may likewise choose to follow the case of different nations by fusing a right to wellbeing viewpoint in drug patent cases.

Another suggestion is that as the effect of non-transmittable infections, for example, malignancy keeps on expanding in agricultural nations, clearly more patients will expect admittance to costly however fundamental medications to support a solid way of life. A right to wellbeing point of view will accordingly guarantee that courts are aware of the significance of the accessibility of less expensive conventional medications on the lookout. We need to note that, not at all like the circumstance in industrialized nations where there are modern instruments, for example, antitrust laws that can be utilized to check the abundances of drug organizations, in a few agricultural nations the lawful structure to control against serious exercises is either lacking, underutilized, or non-existent.[13] In a few emerging nations, the right to wellbeing is the main strong weapon that can be adequately used to guarantee that drug organizations don't mishandle their patent privileges.

Consolidating a right to wellbeing point of view into drug patent cases empowers a court to appropriately understand and apply the adaptabilities previously contained in the generic patent law like arrangements on mandatory licenses and equal importation.[14]

[12] Khor, M., 2015. *Access to medicines and the right to health and life*. [online] Available at: <https://www.alainet.org/en/articulo/168961>.
[13] Anurag, A., 2019. *Pharmaceutical Patents And Healthcare: A Legal Conundrum | SCC Blog*. [online] SCC Blog. Available at: <https://www.scconline.com/blog/post/2019/09/03/pharmaceutical-patents-and-healthcare-a-legal-conundrum/>.
[14] Supra 10.

The courts must be more watchful while examining enactment pointed toward allowing more grounded security to licenses. A few respective and territorial economic alliance as of now pressure agricultural nations to take on enactment giving more grounded patent assurance, however potentially fundamentally obstructing admittance to medicines.74 Courts ought to be watchful and cautious when deciphering such laws to guarantee that the right to soundness of helpless patients isn't stomped all over.

During the pre-TRIPS system the patent insurance allowed was less severe or likely none which was in a manner better as the openness and accessibility of drugs was not an issue however presently the happening to the TRIPS the post-TRIPS situation the meds being estimated past the range of the poor are working to their impairment and causing a genuine misfortune to the poor as presently they can't get the new medications that they could have in the pre-TRIPS time.

The current circumstance is desirable over the number of inhabitants in the well-off nations who get entrance to extra meds that would not have existed without the additional market interest for licensed drugs, presently expected from less created nations. With the TRIPS the less-created, creating and underdeveloped nations are benefitting as for the accessibility issue that is those new prescriptions would not have existed and been dealt with had the TRIPS understanding not appear.[15] One of the benefits of the item licenses is that the more grounded licenses will give admittance to the most recent innovations in drugs, which the created world won't avoid presenting in India. Then again as to the openness issue they have become more awful off since while they can manage the cost of high syndication costs, they are presently not ready to advantage from the low costs of conventional medications. The destitute individuals would not have the option to bear the cost of new meds however they might profit from buys made for their sake by help offices and legislatures. The absence of admittance to life-saving medications (drugs) remove the lives of poor people and individuals of the growing, least created or the third world nations are the ones who are impacted

Conclusion

The states and the IP organisations like the TRIPS and WTO are struggling to balance the IP laws for the pharmaceutical sector. The situation in the developed countries is still better as there they don’t have to take measures as the gap between the rich and poor is not much and

[15] ili.ac.in. 2016. *Indian Law Institute*. [online] Available at: <https://www.ili.ac.in/pdf/paper5.pdf>.

medicines are accessible to everyone easily, but the situation is not the same in developing countries. In developing countries like India, there has been time and again violation of fundamental rights as patented products are not affordable for the common man and moreover the population of economically weaker people is far more and hence they have no access to the medicines and health services. There are pros and cons of both the concepts- process patent and product patent and therefore it is necessary that the state makes provision such that it benefits the inventors and also does not violate the fundamental right of the citizens.

They need to make some changes to benefit everyone and the future of public health is developing and not degrading. The incentives, protection and other benefits of the companies making those drugs should not be under threat as they have earned it by years of hard work and which is only for the world's benefit. They should have a sense of security only then the pharmaceutical industry will be able to boom. Therefore patenting is necessary as it gives the ultimate sense of security to any company. Innovations in the pharmaceutical sector should be majorly focussed on serving humanity and not just getting a patent and taking huge amounts of profit out of it. High pricing of the patented products does not show good intention of the inventor. In order to survive in the extremely competitive market companies need to innovate or improving the existing ones. Therefore high pricing in the name of further innovation does not hold the ground.