PHARMACEUTICAL PATENTING IN INDIA- PROBLEM OF PUBLIC ACCESS TO HEALTH

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Abstract

Intellectual property rights assumed significance in the post TRIPS agreement era. Prior to the adoption of TRIPS Agreement, World Intellectual Property Organization (WIPO) was looking into the IPR matters by and large. It has adopted a large number of treaties on various types and various aspects of IPR. In advancing the improvement of its homegrown drug industry, India's involvement with the enactment and legal practice merits genuine consideration, for example, utilizing TRIPS' adaptability to work with admittance to medicine, carrying out necessary authorizing to make more possibilities for an intentional permitting exchange, and refreshing the rules for looking at drug applications to forestall evergreening of drug licenses. The Trips Agreement evolved minimum standards for copyright, patents, trademark, industrial design, layout design of integrated circuits and undisclosed information which includes trade secrets. There are a few laws that direct Patents, like patent protection, expanding the existence of a patent, lessening patentability principles, and stretching out patent insurance to bothersome items increment imposing business models. What's more, the patent proprietors embrace systems to broaden the extent of the patent to acquire extra licenses which secure the fundamental element of the medication. Medical services costs are quickly expanding in India. this nation, for this investigation, is considered as being a delegate of the non-industrial nation and created nation individually. The Patent Act, 1970 was amended several times to bring it in conformity with the provisions of TRIPS agreement. Hence, the study made under this paper calculates the possibilities of making and implementing to increase access to affordable medicine with certain legal obligations in India.

Keywords

Patent, Pharmaceutical industry, Generic drug, Compulsory license, public health.

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Introduction

India since quite a while ago has been a pioneer to adapt and adjust drug patent law to assess domestic health, underscoring more on the need of the average person. In India due to the high population, there have been significant health crises and the costs towards medical services cash-based which plainly shows that there is a critical wellbeing emergency regarding medical services and the openness, moderateness, and accessibility of the drugs in India. Many cases were raised to the notification of the Government wherein the compounding of prescriptions was being finished by people who were not educated in this field. Hence it was necessary to enact a law for the regulation of the profession of pharmacy. Section 3(d) is a provision under the Indian patent law 1970.

Pharmaceutical Patenting Meaning

A patent may be a sort of right that gives protection over any novel invention and conjointly, offers the prerequisite to sell, use, produce and/or manufacture the patented product. As new and improved medicine square measure being introduced per annum within the market, drug or pharmaceutical patents became notably vital as these medicines help to generate a significant quantity of revenue for commercial benefits. Pharmaceutical care means that the availability of drug medical aid and different patient care services meant to achieve outcomes associated with the care, elimination, or reduction of a patent's symptoms, or slowing of a disease process. A pharmaceutical Practitioner is an individual presently licensed, registered, or otherwise authorised beneath the Act to administer medicine or drugs within the course of professional practice. Under Pharmacy Regulation 2015, many terms are used in Section 2(h) of the Act. Such terms like "community pharmacist", "hospital pharmacist", "Drug information Pharmacist", "Clinical Pharmacist", "Registered Pharmacist" etc. The pharmaceutical sector is a part during which innovation impacts a very cheap line of drug makers. WHO targets analysis and development of a replacement drug and incurs vast prices in doing thus, wherever there's neither a guarantee nor an assurance that their analysis product shall survive varied testing stages and can commercially thrive if free within the market. The TRIPs Agreement makes it obligatory for the member states to protect bio- technological inventions however permits them to exclude plants and animals from patentability. However, it is essential to protect micro-organisms and biological processes for production. In India, after the amendment made in Patents Act 2002, micro-organisms were made patentable. This amendment was made to fulfil our obligations under the TRIPs Agreement.

Patent law, Pharmacy Law in India and Public Heath

The word "*health*" according to Black's Law Dictionary State of being hale, sound, or whole in body, mind, or soul, well-being. Not synonymous with "*sanitation*." One of the absolute rights of a person is the right to the enjoyment of health which is also a subdivision of the right of personal security. It is a Law prescribing sanitary measures, designed to market or preserve the health of the community. The officer is charged with the execution and social control of health laws. The powers and duties of health officers are measures regulated by local laws. One of the objects of the police power of the state, the "public health" means that the prevailingly healthful or sanitary condition of the overall body of individuals or the community in mass, and therefore the absence of any general or widespread disease or cause for mortality. The Indian Pharmacy industry has a strong base with nearly 60,000 generic brands in 60 categories in the market which was then nurtured by the legal system concerning patents. This has resulted in the growth of the domestic pharmaceutical industry as one of the success legends of the Indian economy. This was attainable in light of the fact that, around then, no item patent framework for medications and drugs existed. There are certain people under *The Pharmacy Act,1948* where biotechnological work is taken care. Biotechnology plays an important role in the fields of medicine and the protection of the environment. Under Section 10-18 of the Pharmacy Act, 1948, The Pharmacy Council of India, with the approval of the Central Government exercises powers and makes regulations. Regulation 9 under Pharmacy Practice Regulation, 2015 talks regarding dispensing/ offer of medicine. A registered pharmacist shall undertake a pharmaceutical assessment of each prescription given for dispensing. For the aim of the act, pharmaceutical assessment is outlined because the purpose at that registered pharmacist applies his information to determine the protection, quality, effectuality, and rational use of medical treatments such by a prescriber. To promote rational use of drugs, the pharmacist shall involve himself in activities like preparation of formularies each at the hospital level and the state as well as national levels. Registered pharmacists pretty much as good voters, possessed of special coaching shall broadcast recommendations on public health problems. They should play their part in enforcing the laws of the community and in sustaining the institution that advances the interest of humanity. They shall particularly co-operate with the authorities in the administration of sanitary or public health laws and regulations.

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in the organization of sanitary/ public health laws and regulations. Enrolled specialists, particularly those occupied with general public work, will enlighten people in general concerning isolate guidelines and measures for the prevention of plague and transferable diseases. Consistently the enrolled drug specialist will inform the authorities of each instance of transmittable illness under his consideration, as per the laws, rules, and guidelines of the health specialists. At the point when an epidemic happens, a registered specialist will not forsake his obligation inspired by a paranoid fear of getting the sickness himself. After the TRIPs agreement, a 5year transition period was given to India and 5 years in addition to amending the existing patent laws on patent protection of pharmaceuticals. After this, there were several amendments made in Indian Patent Laws;

i. The Patents (Amendment) Act,1999 – Increased exclusive marketing rights in the transition period.

ii. The Patents (Amendment) Act, 2002 – Widespread changes to keep up the TRIPs standards.

iii. The Patents (Amendment) Act, 2005 – Wide ranging improvement before the expiration of the transition period.

However, the most recent amendment is of 2005. It brought significant changes to the Indian Patent laws. The most significant change introduced by the amendment is the omission of Section 5 of the Patents Act, 1970 which provided that no patent shall be granted in respect of claims for substances indented for use, or capable of being used, as food or as a medicine or drug or relating to materials prepared or produced by chemical processes.

Section 3(d) of the Indian Patent Act,1970 was brought into the limelight with the case of *Novartis AG and Ors. v. Union of India.* In this case, the Appellant i.e., Norvatis filed an application in accordance with the TRIPS agreement before the Chennai Indian Patent Office for a permit of the patent of drug name *"Glivec",* which is used to aid Chronic Myeloid Leukaemia and Gastrointestinal Stromal Tumours. In 2005 the Madras Patent Office rejected his patent application by stating that the drug is un-patentable under Section 3(d) of Patent Act,

1970. After this, the appellant filed two writ petitions under Article 226 of the Indian Constitution to Madras High Court, who transferred the case to IPAB (Intellectual Property Appellant Tribunal) in 2007 who heard and dismissed the petition. Therefore, Novartis filed a Special Leave Petition before the Supreme Court of India. However, the Supreme Court also rejected the appeal.

Drug Patents and Generic Pharmaceutical Drugs

At the point when a pharmaceutical company initially fosters a new drug, it is at first sold under a brand name by which the clinicians can embrace the medication for use by patients. The medication is covered under patent assurance, which implies that the drug organization that holds the patent is permitted to fabricate, market the medication, and in the long run make benefit from it. It is said that once the patent has lapsed, the medication can be produced and sold by different organizations. Therefore, a drug can be manufactured as a generic drug when the following applies;

a. Its patent has expired

b. The company that would manufacture the generic drug certifies that the patents held on the drug are either unenforceable, are invalid or would not be infringed upon.

c. There have never been any patents on the drug before.

d. In countries where the drug has no patent protection.

The organization holding the underlying patent may, in any case, renew the patent by framing another form of the medication that is altogether changed contrasted with the first compound. Moreover, the new compound may need to compete with the first conventional molecule available, except if the medication controllers discover blames and eliminate it.

HOW PHARMACEUTICAL PATENTINGS CAUSING PROBLEMS IN PUBLIC ACCESS TO HEALTH?

Drug companies often abuse the monopoly of patents and also unreasonably high prices for patented medicines. The introduction of item patent has diminished the openness of medications. All in all, the improvement of new medications requires hefty ventures and long-haul research, combined with costly clinical preliminaries and administrative endorsement systems. The exclusive right presented by a patent is one of the incentives for developers of new drugs to make the necessary interests into that research. Countless nonexclusive prescriptions are being protected in India, including vaccines making it difficult for the industry to produce life-saving drugs.

There have been a lot of initiatives taken by the Indian Government to protect this situation such as compulsory licensing and parallel trade policies as alternative ways that can help non-industrial nation governments to make fundamental medications more reasonable to their residents. Compulsory licensing reduces prices to consumers by creating competition in the market for the patented good. Exorbitant pricing of the drugs blocks access for ordinary people to the medication runs counter to the expectation of the Government to protect the health of its citizens. Especially in a country like India, where a large-scale population is living in BPL (Below Poverty Line), and the healthcare costs are high, which unmistakably shows that there is a critical- care emergency with insufficiency concerning healthcare and the affordability, availability, and accessibility of drug system gives a reward for those who innovate by granting a patent monopoly. A patent brings along many benefits, especially the exclusive right to exploit the patent, thereby bringing a high profit. Another suggestion is that a reform of the patent system may be a way forward.

Patents covering minor improvement will be granted is become a subject of controversy for patent protection. This will reduce the incentive to invest money in incremental innovation focused on improvements. Instead by creating a favourable that for neglected medicine money will be invested into R &D that the society needs. In the field of pharmaceuticals, there is a large financial incentive for originator drug companies to push the boundaries of the protection system. For these companies, a patent is another business tool to be exploited as part of their duty to maximize shareholder returns. Whether through innovation in technology, innovation in the use of legal mechanisms, or both, we can expect to see the originator sector working hard

to expand the protection security of its protected innovation resources in the best manner it can. Evergreening patent promotes development in the pharmaceutical industry is an unfair means of patent abuse. It is simply bringing a small change or trivial modification and then claiming a patent right for another twenty years just to roadblock the generic competitors which are trying to provide safe and efficacious medicines to the masses at cost-effective prices. The provisions interpreted in the Novartis and the related provision of Section 3(d) of the Patent Act if adopted or becomes a model for another developing world, might help to encourage companies to spend maximum on innovation rather than trying hard for patenting by way of minor modifications. The Novartis decision will help poor people around the world to provide better access to affordable drugs whatever its implications for future innovation in pharma industries.

Conclusion

To bring the hypothesis to its end edge, I would like to draw a certain conclusion, where the inception of its very project began with an aim to highlight pharmaceutical patenting in India-problem of public access to health. It is pertinent to say that with time, inventions and technology are also at a high pace, and with such a pace it can be seen as an efficiency-enhancing law, tackling a discrete problem in accordance with the purposes of flexibility.

In the case of India, it includes both large patient's need for lower-cost medicine and the needs of the local drug industry. The government should step in to take proactive measures to ensure accessible healthcare for all, insurance schemes where health coverage extends to the poorest of the poor. Further, the government should invest in the form of research and development at the university level and come up with more economically priced drugs, and that the government should encourage the public sector to undertake the necessary research. The country, as well as the government, must achieve a meaningful balance between the utilisation of patenting law to motivate medicine co. to develop new medications for diseases that cannot be treated today and at the opposite hand, the requirement of patients to profit from those drugs without bankrupting either themselves or state budgets.

Reference

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