IMPORTANCE OF PATENTS IN PHARMACEUTICAL INDUSTRIES, PARTICULARLY OVER COVID VACCINE

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ABSTRACT

Innovations created by mind are known as Intellect, and as these innovations have economic value, thus, are known as Intellectual property. A patent is the conferring of legal privileges for creating compelling technical and scientific knowledge. A patent protects intellectual properties from market competition for a limited-term, provided that invention must be a novel, unique, useful and non-obvious. For assuring fair trade amongst the nations, the World Trade Organization formulated TRIPS agreement and has been rectified by India. In the context of India, presently, it is regulated by the Indian patents Act (1970) which came into enforcement in 1972. Patent laws were initially enacted for mechanical, chemical and electrical invention. But the amendment act of 2005 extended it to all sectors of technology, pharmacy, electronics and biotech including microbial organism, microorganism, food, chemicals and drugs. This article highlights the development of Patents law in India and how it impacts the pharmaceutical industry as Article 47 of the Constitution of India declared that *the state must boost public health*. Also, Article 12 of the International Covenant on Economic, Social and Cultural Rights rectified by India states that *nations are under an obligation of facilitating Right to health.* As per Article 21 of the Constitution of India Right to health comes under the purview Right to life. Therefore, pharmaceutical industries play a very crucial role in countries like India, as it is known to all that many adverse advances in medical conditions of the nation have led to the introduction of many new drugs that are now becoming extremely important for surviving in today's world like drugs for the vaccine of COVID-19. Thus, this article puts light on how the development of patents helps in the development of the pharmaceutical industry.

INTRODUCTION

A patent is a sole right to use an invention/ process that is imparted by the Government to an inventor. Patents provide the inventor to prohibit others from making, using, or selling their innovations in the country where the patent was granted.

Patents are ordinarily issued to actual persons and not to corporations, but it's pretty obvious to find inventors assigning (transferring) their stake in their patent to their employer.

Patents typically preserve inventions, products, processes, or designs that meet specific requirements of novelty and utility.

1. MEANING

Modernly, patents in India last for 20 years from the filing date of the patent and are governed by the Indian Patents Act, 1970. Section 2(1)(m) of the Indian Patent Act, 1970 defines a patent as "a patent for any invention granted under this Act",[1] and section 2(j) of the act defines inventions as "a new product or process involving an inventive step and capable of industrial application."[2] Patents confer the right to manufacture, use, offer for sale, sell or import the invention for the prescribed period. Initially, the act provided the patent rights for short-term protection, but after the amendment act of 2005, the period extended to 20 years.

2. IMPORTANCE

Patents are essential because they help protect your invention by giving you the exclusive Right to stop others from copying, manufacturing, selling, or importing your invention without your permission. The objective of patents is to encourage innovations, researches and development, as enumerated in the case of *Bishwanath Prasad Radheysham v. Hindusthan Metal Industries*.[3]

Intellectual property rights mainly patents are the bedrock of the pharma industry as it entirely relies on the variation that can be monetized in the future. In simple words, patents are an elite right awarded for an invention which is unique and non-obvious to a person/entity proficient in the art to which the contraption relates. According to industry surveys, patents provide 70%-80% of the overall profits of pharma firms.

[1] Section 2(1)(m), the Indian Patent Act, 1970.
[2] Section 2(j), the Indian Patent Act, 1970.
[3] Bishwanath Prasad Radheysham v. Hindusthan Metal Industries, Air 1982, SC 1444.

DEVELOPMENT OF PATENTS

The patent law in India has experienced significant changes since it was first enacted in 1970 to comply with the international standards and meet India's obligation under the TRIPS Agreement. Patent rights were proposed in India for the first time in 1856 and, in 1970, the Patent Act 1970 ("the Patents Act") was enacted, revoking all former legislations. India has also signed the Paris Convention for the shelter of the Patent Cooperation Treaty, 1970, and industrial property, 1883. The Patents Act gives that any invention that meets the standards of newness, non-obviousness and utility can be the material of a patent. Some of the non-patentable innovations under the Patents Act include methods of agriculture or horticulture, processes for the surgical, curative, medicinal, prophylactic or other medication of human beings, animals or plants or substances acquired by a mere admixture, resulting only in the aggregation of the properties of the components, and more.

Concerning pharmaceuticals, in the case of materials intended for use or competent of being used as food, drugs or medications or materials produced by chemical processes, patents are granted only for the methods of manufacture of such chemicals and not for the bodies themselves. Hence, pharmaceutical products are currently not yielded patent assurance under Indian law.

India had a commodity patent regime for all innovations under the Patents and Designs Act 1911. Yet, in 1970, the Government presented the new Patents Act, which eliminated pharmaceuticals and agrochemical outputs from eligibility for patents. This suspension was introduced to break away India's dependence on imports for bulk drugs and formulations and provide for the growth of a self-reliant domestic pharmaceutical industry.

"Thus, under our existing patent laws, molecules, which are products of chemical reactions, areas such as non-patentable in India. This restriction, coupled with the restriction on mere admixtures resulting in aggregation of properties in which the components do not exhibit any synergistic behaviour, severely limit the items, which can be patented in India. "Actives" prepared by chemical synthesis areas such as non-patentable in India even if they exhibit functional properties. Likewise, standard drug formulations in which the ingredients behave as mere admixtures also do not qualify for patents in India. In such cases, only the process, i.e.

the method of making the product is patentable. "[4]

The lack of security for product patents in pharmaceuticals and agrochemicals had a notable impact on the Indian pharmaceutical industry. It resulted in the development of considerable expertise in reverse engineering of drugs that are patentable as products throughout the industrialized world but unprotectable in India.

As a consequence of this, the Indian pharmaceutical industry proliferated by developing cheaper versions of several medications patented for the domestic market and eventually moved aggressively into the international market with generic drugs once the international patents expired. Besides, the Patents Act provides several safeguards to prevent abuse of patent rights and provide better access to medicines.

The Indian Government is progressing towards installing a patent regime that is favourable to technological advances and is in conformity with its global commitments.

The term of patents in case of processes/methods regarding the manufacture of a substance intended to be used/capable of being used as food or a medicine/drug is for seven years from the date of filing or five years from the date of sealing the patent, whichever is less. Patents associating to all other inventions are awarded for a term of 14 years from the date of filing the patent except shown to be invalid.

The Patents Act also has terms relating to compulsory licensing. On the conclusion of three years from the date of sealing the patent, any person involved in working the patented invention may ask for a mandatory licence concerning the invention. The controller of patents may advise the patent holder to award such a licence upon the terms as may be considered fit, only if he or she is convinced that the reasonable requirements of the public concerning the patented invention have not been satisfied or that the patented invention is not open to the public at an affordable cost.

In extension to compulsory licensing, the Patents Act incorporates a provision for "licences of right" where, in some instances, the central Government can, after the expiration of three years from the date of sealing of patent, apply for an order that the patent may be endorsed with the words "licences of right". It is because the reasonable requirements of the public for the

[4] Pradubuddha Ganguli, Gearing up for patents: The Indian scenario, p. 47.

patented invention have not been completed or that the patented invention is not accessible to the public at an affordable price.

Patents for some substances that are not food articles/ drugs but that are competent of being utilized as food items or drugs are considered to be authorized with the words "licence of right" quickly on the conclusion of three years from the date of the sealing of the patent. The effect of supporting a patent with the words "licences of right" is that any person who is involved in working the patented invention in India may request the patentee to grant a licence. Granting of licence would be on terms that have jointly agreed upon, even if he/she is previously the holder of a licence under the act. In case the parties are unable to decide on the terms of the licence, they can appeal to the controller of patents to settle on terms.

3. THE IMPACT OF THE WORLD TRADE ORGANIZATION OVER PHARMACEUTICAL PATENTS

The endowment of the World Trade Organization (WTO) has led to a massive paradigm shift in world trade. The contract on Trade-Related (Aspects of) Intellectual Property Rights (TRIPS) was adjusted during the Uruguay round trade negotiations of the General Agreement on Tariffs and Trade (GATT) and "one of the principal reasons for including intellectual property matters into the GATT framework was the pharmaceutical industry".[5] India confirmed the GATT on 15 April 1994, thereby creating it necessary to comply with the provisions of GATT, including the agreement on TRIPS.

India is thereby expected to meet the minimum standards under the TRIPS Agreement about patents and the pharmaceutical industry. India's patent act must now include provisions for the accessibility of patents for both pharmaceutical products and processes inventions. Patents are to be awarded for a minimum term of 20 years to any invention of a pharmaceutical product or method that fulfils established criteria. India has determined to avail itself of the full development period for developing countries and has until 1 January 2005 to increase patent security to pharmaceutical products. In keeping with the TRIPS commitments[6], India has commenced on a process of altering the Patents Act by implementing exclusive marketing rights (EMRs) and creating a mailbox system for patent requests for a term of five years or till

[5] Zafar Mirza, WTO/TRIPs, Pharmaceuticals and Health: Impacts and strategies, The Society for International Development, SAGE Publications.
[6] Article 70 (8), read with Article 65 (2) and (4) of TRIPS, obligates developing countries to provide for a mailbox mechanism for depositing applications and an exclusive marketing rights regime.

the patent is imparted or rejected, whichever is quicker. This provision was interjected in the Patents (Amendment) Act 1999, which imparts the inventors what is known as "pipeline protection". If the applicant has filed an application for his/her invention in any convention country and patent/ EMR has granted in that country on/after 1 January 1995, he would be eligible to file for a patent to pharmaceutical and agrochemical products in India. These patent requests will be kept pending. When India improves its patent law as per WTO proposals, the pending patent application will be suitable for product patent.

Until such patent is ceded or rejected or for a term of five years (whichever is less), the applicant will be awarded EMRs in India if the application is found eligible. The amended Patents Act also provides for a compulsory licence for the EMR on the corresponding lines as patents. Also, it eliminates a provision that prohibited Indian inventors from applying for patents outside India without the approval of the Indian Government. The new authoritative measures to meet India's TRIPS obligations are currently in the process of being finalized. The Patents (Second Amendment) Bill 1999, which includes product patents for pharmaceuticals and agrochemicals in India's patent law, is still to be enacted, and recent press reports have intimated that the Bill is short to be tabled before the Indian parliament.

ROLE OF PATENTS IN PHARMACEUTICAL INDUSTRIES

Patents in the pharma industry are usually treated commensurate to their commodity portfolio and are one of the efficient ways to guard the innovation and create a return on investment. They play an essential role in the pharmaceutical industry to protect the inventions of the company, thus assist in producing drugs that meet patient requirements in developing and developed countries. Patents are also crucial for the industry as they aid in recouping investments incurred during research and development, and marketing of the drug.

A strong patent assurance can ensure the invention from the possible infringers and cannot be used, made, or diffused without patentee's permission. They are independent property rights of the patentee that has been achieved against the innovation for a term of 20 years. Patent operates differently athwart industries, but are essential in the pharma industry as the production opponents can efficiently duplicate a drug. Strong patent security is required to meet the demand for pharmaceutical inventions.

The absence of patent assurance in the developed countries stifles the development of the industry concentrated on producing drugs at affordable costs. Besides this, healthy and efficient

patent protection can lead to the growth of research-intensive pharmaceutical industries that develop profitably. It also guarantees breakthrough inventions and evolution of new life-saving drugs. Pharma companies preserve their drugs by acquiring patents and aid them in procuring market solely as generic companies invade the market and hinder the sales and profits. As these companies already face the burden of increased costs in connection to the growth of new drugs, plunging sales at the border of product lifecycle can direct to depressing innovations in the pharma area.

In the current months, pharma companies have been suffering patent difficulties, thus posing a warning to pharmaceutical inventions and increasing ambiguity about market exclusivity and lawsuit cost for commercially flourishing drugs. For instance, Novartis AG filed a patent dispute against Torrent Pharmaceuticals in the U.S. upon the drug Gilenya, which stood to be one of the high profits creating drugs. These patent conflicts can be inscribed by adopting adequate patent manoeuvring by imprinted pharma companies over acquiring patents for processes of production and active components.

As the cost associated with the R&D is too huge, majority of the pharma firms rely on patents and demand for patent assurance right from the research stage, i.e. former to clinical trials, thus compressing the time to market the drug and improve return on investments.

Moreover, acquiring patents for new methods of application for known syntheses can assist the firms to improve the commercial life of the merchandise and maximize their profits.

The pharma companies possess a brief span of the patent exclusivity contrasted to other sectors as the period between the patent filing and installing a product in the market is longspun. , pharma companies settle the patent term by PTA (patent term adjustment) that manages provisions for the settlement of patent term in circulating the patent rights. In the advanced countries, the patent time can only be stretched for half the period and also limits the independent Right of use, thereby permitting generic opponents to test and promote the option and can market the merchandise once the patent lapses.

To sum up, patents are essential to promote variation and economic growth. They aid in gaining a competing edge in the market and develop revenues and market portion. Satisfactory patent assurance can provide pharma companies with a stage for future extension and design new drugs. Also, defending new inventions aid pharma companies recover skyrocketing expenses incited in R&D and maximize the commercial merchandise lifecycle. Accordingly, it is

essential to devise an efficient I.P. strategy to maximize the returns and recognize the truth of intellectual property.

If we talk of the current situation, the whole world is suffering from a dangerous virus names COVID19, which is not just a common disease, but a pandemic crisis affecting not only the healths and lives of people but also affecting economies and growth of countries. For tackling this situation, there is a need for the development of a drug which can fight with this virus to protect people. Scientists all over the world are operating on this serious issue and are trying to prepare a vaccine.

THE REQUIREMENT OF PATENTS ON COVID VACCINE

As the world expects for a vaccine to become accessible, measures need to be necessitated to guarantee that when that vaccine arrives, it is accessible to all. And this necessitates looking strictly at the matter of patents. There are two aspects of this concern.

4. POSITIVE ASPECT

A patent is a two-sided pact. In return for acquiring a time-limited corner, the inventor must reveal the invention so that others apprehend how to invent it. Where there is no patent right, there may be no exposure, and the inventor can preferably keep significant information intrigue.

Even where the vital information *is* accessible, not every country will have the technological capability to produce the vaccine. And even whither they do, a vaccine costs capital to initiate.

So countries that can produce the vaccine will have to do so for the countries that can't produce, and they have to supply that at a financed price.

Sadly, sometimes corrupt distributors or contaminated governments in weaker countries take hold of the enthusiasm of citizens in wealthier countries to pay a tremendous price for drugs.

The threat is that a subsidized vaccine furnished to a weak country may finish up being transshipped to more prosperous countries for advantage, instead of being delivered to its residents.

A patent can aid prevent this. The patent possessor can stop such 'leakage' by practising their preferential Right of importation.

Patents require to be regarded as part of the solution for COVID-19 vaccine for all, not a piece of difficulty.

The international community is wide-awake to the problem of discriminatory access to medications. For a decade, the UN-backed Medicines Patent Pool (MPP) has established for patent holders to store their patents into a pool from which spontaneous licences are awarded to producers in poorer countries.

The MPP expands access to and promotes the development of, life-saving drugs for low and middle-income nations. To date, it has arrangements for HIV antiretroviral vaccinations and hepatitis C and tuberculosis medications. The WHO has recently declared that it would use this guide to ensure passage to COVID-19 vaccine protection. But clearly, a patent pool only operates when there are patents to deposit into it.

No-one objects that a COVID-19 vaccine must be accessible to all who need it - not just to those who can bear it. But in tackling that matter, patents need to be seen as part of the solution, not of the problem.

5. NEGATIVE ASPECT

Economics tells us that the sole rights provided by a patent make the patent holder a monopolist over the design. Monopolists reap patent profits. They sell at artificially raised prices by limiting production.

And where production is regulated, the invention will be accessible only to those people who can bear it.

In the matter of a patented vaccine, this indicates that only people in prosperous countries will get access and so relish immunity from a virus responsible for more than 890,000 deaths worldwide as of 8 September 2020.

Countries that can produce the vaccine will do so for the countries that can't, and they will supply the vaccine at a subsidized price.

According to this logic, to guarantee availability to all, we must *not* grant patents on COVID-19 vaccines. Kenya has formally requested the World Trade Organization to suspend certain intellectual property rights for Covid-19 medications.

The request attempts to avoid the HIV tragedy 20 years ago when thousands of people in developing countries died from Aids because they could not afford the patented HIV medication. It was placed forward by India and South Africa and sponsored by Kenya in October.

But the problem with this aspect is that it only represents part of the story.

The missing element is the understanding that by providing an inventor with exclusive rights, a patent can make it easier – not harder – to ensure the most comprehensive availability of the invention.

Patents are not absolute. All countries can 'break' the patent monopoly by compulsorily taking a licence to the innovation. For example, Australia has a Crown use terms in its patent legislation that enables a government to make, manage and market a patented invention "for the services of the Commonwealth or the State".

A government can revoke a COVID-19 vaccine patent to assure that Australians have passage to the vaccine. But such a provision can only implement where there is a patent to revoke.

We might believe that where there is no patent, there is zero to stop a government, or anyone else, from smoothly making the vaccine. But this presumes that they have the required information to be able to do so. In the struggle to provide immunity from COVID-19, those who would ban *patents* on vaccines may prove more dangerous than those who would refuse *vaccinations*.

CONCLUSION AND SUGGESTION

Concludingly, we can say that patents play a crucial role in the development of pharmaceutical industries as this industry always demands innovations and inventions to cure different kinds of diseases developing in the market. Even if we talk of our current scenario, there is a need for developing a need drug or vaccine to protect people as well as countries. This development demands patent rights over such inventions. As everything has two aspects, the same is with patents as well. People have their different aspects regarding patents. Some believe that patents must be granted upon the vaccine of COVID as it can aid the threat that a subsidized vaccine furnished to a weak country may finish up being trans-shipped to more prosperous countries for advantage, instead of being delivered to its residents. Whereas, some believes that it should

not be granted as the patent holder a monopolist over the invention. Monopolists derive monopoly interests. They sell at artificially raised prices by limiting production. And where production is limited, the invention will be available only to those people most able to afford it.

But this logic is not satisfactory, as it misses the element that a patent is a dual pact. Therefore, keeping all these arguments in mind, patents should be granted upon vaccine as it is more helpful than being harmful, as the significant control regarding patent always remains with the Government, that can mould the provision as the need of the situation and people.