International Journal of Law, Policy and Social Review
www.lawjournals.net
Online ISSN: 2664-6838, Print ISSN: 2664-682X
Received: 20-11-2022, Accepted: 07-12-2022, Published: 23-12-2022
Volume 4, Issue 4, 2022, Page No. 57-59

Impact of trips agreement on paramedical industry amid the commercialization of COVID 19 vaccine

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Abstract
Intellectual Property Rights (IPRs) have become omnipresent in the current society and have emerged as the key issue of global innovation policy. Patent, Trade mark, industrial design, geographical indication and copyright are the forms of IPRs available in India. The 'Trade Related Aspects of Intellectual Property Rights' (TRIPS) Agreement, signed in 1994 as a founding element of the World Trade Organisation, contains international provisions relating to IPR and represents the most important attempt to establish a global harmonization of Intellectual Property protection. WTO proposed TRIPS to provide a fair trade among its member countries. Patents are quite significant in pharmaceuticals. This review provides a brief overview of development of patent law in India as a consequence of the TRIPS agreement. The main aim of this paper is to study in detail about the impact of the TRIPS agreement on paramedical industry in relation with the Indian patent law, 1970. It also deals with the amendments made in the patent law with regard to patenting of Para medicine drugs and about compulsory licensing of patent, issues related to it and its impact on the developing countries and finally the patent waiver on covid vaccine is discussed briefly.

Keywords: IPR, TRIPS, global harmonization, pharmaceuticals, compulsory licensing

Introduction

The term property includes both animate and inanimate things belonging to a person. It includes legal rights and personal rights like a person's life, liberty, reputation, status etc., intellectual property is an intangible, incorporeal property. It cannot be seen or touched. It consists of a bunch of rights in relation to protection of certain untouchable objects created by the owner. Whatever is produced or originated by human skill, intelligence, labor and efforts are called the intellectual property. This law confers on the owner the proprietary right over his products and authorizes him to take action against third parties for their acts of infringement rights over the property. The justification for protection of intellectual property law is that a man should own what he produces, that is, what he brings into being'. So the main objective of this branch of law is the protection of the private person's rights over the intellectual property. It should be noted that although intellectual property rights are intangible, the material form of tangible intellectual property rights can only be protected through intellectual property rights. Like any other property, intellectual property is an asset, so it can be bought, sold, mortgaged, licensed, traded, or gifted to others. Intellectual property owners have exclusive rights to their intellectual property rights, which means that no one can legally use the intellectual property rights they create without permission. Out of all the types of IPR, patents are considered as the most valuable assets in the pharmaceutical industry.

Trade Related Aspects of Intellectual Property Rights (TRIPS)

TRIPS was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) between 1989 and 1990 and is managed by the WTO. Widespread differences in intellectual property standards and protections, and the lack of multilateral principles, rules, and disciplinary frameworks for managing international trade, have led to tensions in international economic relations. To resolve these tensions, an agreement was formulated, namely a trade-related aspect of intellectual property rights agreement, which addresses the basic principles of the General Agreement on Tariffs and Trade (GATT) and incorporates the principles of international intellectual property agreements in the WTO. Therefore, adequate intellectual property regulations, effective enforcement measures, multilateral dispute resolution, and transitional arrangements have been formulated. In 2001, developing countries were concerned that developed countries would insist on an overly narrow interpretation of TRIPS, launch a round of negotiations, and eventually arrive at the "Doha Declaration". The Doha Declaration is a WTO declaration that clarifies the scope of TRIPS.

There are certain standards of protection and obligations given by the member countries, the first one is that the main provisions of Berne convention, WIPO and Paris convention must be incorporated in the TRIPS agreement and this is given in article 2.1 and 9.1 of the agreement. The agreement also stipulates certain general principles applicable to all intellectual property enforcement procedures and provisions, involving internal procedures and remedies for intellectual property enforcement. It also resolves the dispute between countries in respect of intellectual properties. The obligations arising from the agreement will apply equally to all member states, but certain special transition agreements operate in circumstances where developing country's restrictions in patent protection for products in the field of pharmaceuticals.

Patents in Relation with Trips

The patent is beneficial to the inventor, as it gives him the right to use his invention to the exclusion of all others. Before the enforcement of TRIPS the Indian patent law

granted patent for a period of time, that is, if the product or process is related to food or drugs, a fixed period of five years, or in other cases 14 years. The objective of patent law is to promote scientific research and industrial progress. The basic principle is that patents are granted only to inventions that must be novel and useful.

TRIPS has given provisions for patents from article 27- 34. After the TRIPS agreement, provisions of the Paris convention were added to Indian patent law, that 20 year patent protection be available for all inventions irrespective of the field. In order to protect the public order certain inventions can be excluded from the patentability as they may be easily exploited. The diagnostic, therapeutic, surgical methods, biological process for production of plants and animals are also excluded from patentability. The conditions for grant of compulsory licensing or governmental use of patents without the consent of the owner are also prescribed in this agreement. If this act is infringed then the burden of proof falls upon the defendant to prove that he has not used that specific patented process.

Patenting in Paramedical Industry in India

The main law of the Indian patent system is the Patent Law of 1970. Initially, according to the provisions of the law, inventions related to food, drugs and chemicals could not get product patents, only process patents. However, since 2005, India has allowed product patent applications. As a member of the World Trade Organization (WTO), India signed the TRIPS (Trade Related Intellectual Property Rights) agreement in 1995. TRIPS prescribed certain laws to be followed by its members so India has to amend its patent law to fulfill its obligation, since 1995 Indian patent law is amended 3 times;

- In the first patent (amendment) act, 1999, the country gave protection until the product patent is provided; it added guidelines for filing an application for product patent, exclusive marketing rights (EMR) is granted for patent.
- In the second patent (amendment) act, 2002, a 20 years uniform term of patent for all categories of invention was introduced, the definition of 'invention' was also amended and the reversal of burden of proof in infringement proceedings was added.
- In the third patent (amendment) act, 2005, product patenting was introduced, Only by discovering new forms, new properties or new uses of known substances, patents can be granted under certain conditions, the provisions on pre- and post-grant objections have been revised, and the provisions on the granting of compulsory export licenses for patented drugs in certain conditions was introduced.

According to the Indian patent act, the main criteria for patentability is given under its definition of invention, "a new product or process involving an inventive step and capable of industrial application".

Compulsory Licensing of Patent

The compulsory license is a statutory license that the controller may grant to a third party under certain conditions. Compulsory license under the patent system is an involuntary contract between a voluntary buyer and an involuntary seller and is executed by the government. Under compulsory license, the government allows others to produce patented products or processes without the consent of the owner of the patent. It can be granted for the following reasons mentioned in Section 84 of the Indian Patent Law of 1970,

1. The reasonable request from the public for the patented invention has not been fulfilled,
2. The patented invention cannot be made available to the public at a reasonable price,
3. The patented invention does not work in India. However, a compulsory license can only be granted after it has expired after three years from the date of grant of the patent.

Compulsory licensing relating to Paramedicine

The section 92A of the Patents Act of 1970 stipulates that any country that does not have sufficient or no manufacturing capacity in the pharmaceutical industry to solve public health problems may obtain a compulsory license for the manufacture and export of patented drugs, provided that the country has granted compulsory licenses. The controller, after receiving the request in the prescribed form, will grant a compulsory license only for the manufacture and export of the relevant drugs to the country in accordance with the prescribed terms and conditions.

According to the TRIPS Agreement and paragraph 6 of the Doha Declaration on Public Health, compulsory licenses only apply to

a. Patented drugs
b. Manufacture and export to any country that does not have sufficient or no manufacturing capacity in the pharmaceutical field, and
c. Products/ drugs that could solve the public health problems in a country.

Intellectual Property Protection Waiver on COVID Vaccine

All countries should be given the right to make their own vaccine during a pandemic. This is the basic principle of the movement, to support that the intellectual property (IP) protection for the coronavirus vaccine was temporarily waived. The campaign was initiated by India and South Africa, and was supported by more than 100 countries and international organizations, including the World Health Organization and UNAIDS. The goal is to reduce barriers for countries to produce their own vaccines, especially for lower-income countries. The pharmaceutical industry, as well as most high-income countries, is now opposed to the concept. Instead, these governments have committed to sharing more of their own vaccines with low-income countries and to increasing funding for charitable vaccine distribution programmes like COVAX.

Issues in suspension of IP protection

1. IP waiver gave the competitors a shortcut to expensive technologies.
2. Companies claim that IP relief will not speed up vaccine production because materials are in low supply and building capacity from scratch may take many years.
3. The countries which are opposing the waiver argue that the WTO already allow other countries to apply for 'compulsory licensing' to overrule IP during emergencies.
4. The vaccine production, research, and development are focused heavily in small communities of high- and middle-income countries.

5. The developing countries argue that they don't need charity, but the right to produce their own vaccine.

Related Case Laws

Natco Pharma Ltd., India vs Bayer Corporation, USA

In this landmark case mr. P. H. Kurian, the then controller of patents issued the order for grant of first and only compulsory license for patents in India on 9th march 2012. The license was issued to Natco pharma ltd and is issued by Bayer Corporation, USA. This patent is related to the drug Sorafenib tosylate sold under Nexavar as its brand name by Bayer. This drug Nexavar is used for treating Renal Cell Carcinoma- RCC (kidney cancer) and Hepatocellular Carcinoma- HCC (liver cancer). After getting the license Natco is permitted to manufacture and sell a generic version of Nexavar. But there are certain conditions vested on Natco, they are,

- It should pay a 6% royalty on the net sales at the end of the quarter to Bayer.
- It cannot charge more than Rs. 8800 for 120 tablets for a month's dose of drugs.
- It has committed to donate free supplies of medicine for 600 needy patients each year.

The decision given by the controller is based on the section 84 of the patents act, 1970 grant of compulsory license. The controller found that there is a reasonable requirement as only 2% of the public were able to access Bayer's drug and they were really expensive as Bayer charges about rs 2.8 lakhs for a month of drug therapy. The invention was not working or manufactured in India but only imported from other countries. So the controller found the need for providing compulsory license for the public welfare and granted it.

Suggestions

- Indian pharmaceutical companies should focus more on research and development instead of reverse engineering and copying existing foreign drugs.
- The developing countries must be given more opportunities through compulsory licensing.
- The countries that do not have sufficient or no manufacturing capacity in the pharmaceutical field must be encouraged with proper patent and funding.
- Import of drugs must be reduced while the export and manufacture must be increased.
- India instead of patenting and producing generic drugs, should try to invest more time and money in inventing new drugs.

Conclusion

The Indian patent law is a typical patent legislation designed to balance the interests of ordinary people and inventors. After introducing the product patent system, India can apply for patents for a wide range of pharmaceutical products. Before applying for a patent, researchers must carefully consider the criteria for patentability, and patent experts' advice in this regard is very much in demand. Once obtained, the patent right can be transferred to other individuals or companies through assignment or license. The overview of the relationship between development and IP shows that the TRIPS agreement is part of the broader question of the role of technology in the development and cannot be resolved in strict terms related to compliance. The public interest clause of the TRIPS agreement should provide guidance for future negotiations and provide opportunities for multilateral and bilateral technical cooperation agreements. To uplift the social health status of the developing countries TRIPS must be adapted and drug licenses must be provided to them. Though the TRIPS agreement is accepted and followed by its member countries during emergencies or pandemics it must be terminated and the public interest must be the only consent of the international organs.

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