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Compulsory Licensing of Pharmaceutical Products

ORIGINAL ARTICLE

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Abstract

Drug patents and their impact on prices have been at the centre of the international debate about inadequate access to life-saving HIV/AIDS drugs in developing countries for many years. Conflicts over the introduction of intellectual property systems in developing countries were resolved by following amendments to the TRIPS Agreement, which stipulated 20-year patent protection for drugs for these countries and resulted in high drug prices for patented drugs. Developing countries that already have patents try to reduce high drug prices through compulsory licensing, a protective measure that allows generic drugs to be produced or imported without the approval of the patent owner. Compulsory licensing is permitted under the TRIPS Agreement, but disagreement over the terms under which compulsory licences for "essential medicines" are available has restricted their use. There is no definition of the extent to which compulsory license holders can export generic drugs to developing countries that are unable to manufacture their own drugs. However, on August 30, 2003, the WTO announced that it had resolved this problem by removing the TRIPS Agreement's export restrictions and permits for the export of drugs manufactured under compulsory licences as an exception to the patent law. It is advisable to make further recommendations about which generic drug manufacturers and which places should receive compulsory license. In fact, the debate over compulsory licensing is part of a much broader structural issue in development policy. Addressing the inaccessibility problem requires a combination of steps, including a functioning compulsory licensing system. However, disagreements, such as how to fairly allocate the necessary funds to developed countries, can delay reaching pragmatic solutions.

Key Words

Compulsory Licence, Patent, Pharmaceutical, Intellectual Property Rights, Products.

Introduction

There is no precise statutory definition of term 'compulsory licence' but several attempts have been made to define the term compulsory licence under different perspectives as discussed below:

In intellectual property system a compulsory licence is the mandatory offer of a licence to the entire world on condition that parties who avail themselves of it make royalty payments to the relevant rights holder. The compulsory licence is a legal setting which plots a midway course between an exclusive right and a free

exception, so that within the scope of the licence an exclusive right is converted into a right to remuneration.

The compulsory licensing debate revolves around the balance of interests between the public at large at one hand and IP right holders on the other. Compulsory licensing refers to the grant of IP licences, particularly copyright or patent licence by a national Government without the owner's consent for the purpose of wide utilization of the protected right. The grant of such an IP licence tends to fulfil one of the three purposes: massive production of protected products (e.g. patented drugs to cure a disease), antitrust act to allow fair competition (e.g. between firms), and non-commercial use (e.g. by the Government) in the interest of the general public.

Pharmaceutical products mainly consist of two components, namely Active Pharmaceutical Ingredients (API) or bulk drugs and formulations. While the active ingredients are produced by chemical synthesis of plant, animal or biological origin and the formulation is suitable for the final dose. For the pharmaceutical industry, patents are very important for the manufacture and marketing of pharmaceutical products. Pharmaceutical companies may be granted patents for new drug molecules, for new drug delivery systems for existing products, or for new indications for existing molecules. The World Trade Organization has decided to set a product patent term of 20 years in all countries. This means drug development and FDA approval take 10 years from the initial discovery of the molecule, and one pharmaceutical company gets 10 years of exclusivity to commercialize the formulation. Exorbitant drug development costs force drug prices to remain high. Drug prices vary from country to country. People in developing countries cannot afford high drug prices. Therefore, multinational companies must sell their products at low prices in developing countries.

Pharmaceutical Patents Under the Indian Patents Act

Regarding drug patents, it makes more sense to start concretely with the recent amendment of India's patent law which implemented the TRIPS Agreement and granted patents for pharmaceutical products, as it has caused many advances and disputes in demonstrations finds that this amendment is in accordance with the provisions of the TRIPS Agreement and the WTO decision against India's refusal of a product patent. The revisions resulted in important improvements in areas such as patentable subject matter and patentability, and a different definition of the term "inventive step" was substituted by the 2005 amendment, which clarified the term as an element of innovation that includes technical progress as opposed to current knowledge. In this case, innovation is central financial and economic interest or both, so innovation is not as obvious to someone with talent or manual ability.

The meaning of imaginative (inventive) step alongside the 'pharmaceutical substance' which was characterized as any new element including at least one or may be more innovative steps, prompts numerous discussions. Another big change made by the amendment in regards to the pharmaceutical patent is the substitution of section 3(d) with another arrangement, which prohibits from patentability simple revelation of a known substance except if there is significant improvement in the efficacy or another utilization of a known substance.

Compulsory licensing was a fundamental element of Indian Patents Act and the 2005 amendment has made many changes in the arrangements of the compulsory authorizing. These progressions were made in light of the Doha declaration on public health.

Problems with Pharmaceutical Patent

Despite the fact that the terms of the TRIPS Agreement provide for the granting of a patent for any innovation in all areas of invention, patent laws around the world related to pharmaceutical patents as a unique branch that poses anomalous problems for many areas of innovation. Medicines are clearly seen as an important part of overall public health, leading many countries to provide them with unique policies. Like India, many countries indicated that they were initially reluctant to grant product patents for pharmaceuticals and therefore

only allowed product patents. This reluctance is one of the elements that has contributed to the development of the generic drug industry in India.

This innovation raises several problems when deciding a pharmaceutical patent. Pharmaceutical substances are simply synthetic chemicals that are used to treat diseases. This section of the discussion relates to the legal provisions of the Patents Act regarding drug product patents. The constitutionality of Section 3(d) of the Patents Act is examined mainly on the ground that the provision is not in accordance with the TRIPS Agreement.

Pharmaceutical Industry- A Global Perspective

The emergence of the pharmaceutical industry dates back to the chemical industry in the late 19th century in Switzerland's Upper Rhine Valley. This industry produces dye-stuffs. They found antiseptic properties in the dye. As a result, a number of industries have developed into the pharmaceutical industry. As far the pharmacy, history records that the first pharmacy known to the public was opened by an Arab pharmacist in Baghdad in 754 AD. After that, many other similar pharmacies soon began operating in medieval and eventually medieval Europe. In the 19th century, many pharmacies in Europe and North America eventually developed into larger pharmaceutical companies.

Most of the major pharmaceutical companies were founded in the late 19th and early 20th centuries. Important drugs such as insulin and penicillin were discovered in the 1920s and 1930s. These drugs are mass produced and widely available. During this time a strong pharmaceutical industry developed in Switzerland, Germany and Italy. Great Britain, US, Belgium and the Netherlands followed this path of development. The Governments of these countries have enacted laws to test and approve these drugs and require proper labelling. As the pharmaceutical industry grew, the Government enacted laws that differentiated between prescription and over-the-counter drugs. The pharmaceutical industry gained momentum in the early 1950s thanks to the development of a systematic scientific approach, understanding of human biology and advanced manufacturing techniques. New drugs were developed in the 1950s, and mass production and marketing began in the 1960s. During this period, drugs such as oral contraceptives, cortisone, blood pressure medications, and other heart medications were mass-produced and sold.

Pharmaceutical Industry – An Indian Perspective

India got freedom from Britain in 1947. In the first few years immediately after independence, multinational companies were allowed to export pharmaceuticals. When the Indian Government put pressure on companies to prevent imports, these companies set up a formulation unit in India and only export drugs to the country in large quantities. In the 1960s, the Indian Government encouraged domestic manufacturers to mass-produce drugs. But India has a rich heritage of different types of medical care. Medical treatments like Ayurveda, Unani etc. The medical and pharmaceutical systems were developed by the Indians.

Compulsory Licence for Export of Patented Pharmaceutical Products

Section 92A of the Patents Act,1970 facilitates the manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems by granting compulsory licence for that patented pharmaceutical products.

Advantages in India for Pharmaceutical Sector

Indian Pharmaceutical Industry has been particularly the leader in the wide range of complex pharmaceutical manufacturing and technological development. Since it is the highly organized sector, it is receiving the advantage of organized structure. It has currently the revenue earning of around $ 21 Billion and it is growing at a rate of around 7-8% annually. India has more than 20,000 pharmaceutical manufacturing units scattered across the country.

Following are the advantages in India for the pharmaceutical sector:

- **Competent Workforce:** India has a large pool of human resource having managerial and technical expertise. India has increasing population with higher level of education. The skill of English language and professional competence is easily available for pharmaceutical companies in India.
- **Cost-effective Chemical Synthesis:** As a result of development, particularly in the area of technology and research and development, the chemical synthesis for various drugs is available at a very cheap rate. With the help of it, India can produce and export a wide range of bulk drugs.
- **Information Technology:** India has a well-established structure of the colleges and educational institutions imparting education in the field of information technology. The availability of world class system of information technology attracts the foreign companies to India.
- **Globalization:** After the economic reforms in 1991, India has boldly adopted the path of globalization. India is ready to welcome MNCs to operate here. A large market of around 70 million of middle -class consumers is available for these companies. As result the pharmaceutical market of India is constantly growing.
- **Increasing Sales:** India is gaining the advantage of pharmaceutical manufacturer in the world. Because of low-cost production and availability of a wide range of pharmaceutical products, India's sale is booming in the pharmaceutical market. The sale in pharmaceutical market of India is growing at a rate of around 9% per annum.

Conclusion

India's approach is based on a patent-centric system. The pharmaceutical industry in India is growing rapidly but the health status in India is not as good as it should be. More frequent use of patent restrictions in India could dampen the morale of the pharmaceutical industry. In this context, the Government can increase spending on health insurance for all is also a way to ensure public health. With a large population, making medicines affordable is a difficult task, but having insurance makes it much easier and more convenient to empower each individual to evaluate life-saving and expensive medicines.

Suppose the Government increases its investment in pharmaceutical research, it will obtain patents for new and increasingly successful pharmaceutical products or processes. This will benefit in two different ways: first, affordability will be ensured, and second, accessibility will be ensured as a Government would likely set the price. In addition, in this way there will be no negative impact on developments and innovations in the pharmaceutical field. Above all, it must be noted that the purpose of granting a patent is unfavourable to the provision of necessary or compulsory licensing. The string of this reason can be found in protection of patent under the labour theory.

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