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TRIPS AGREEMENT AND PRODUCT PATENT - SOME ISSUES

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Abstract: *Patent is for use and not for hoarding or exploitation. Patent rights give the owner the exclusive right to make the invention, use the invention, sell the invention and distribute the invention. Patent rights are granted only to new inventions capable of industrial applications. Many advocates for a global right to health believe that intellectual property rights protections have a negative effect on the realization of the right to health. The TRIPS Amendment allows developing countries with no or insufficient pharmaceutical manufacturing capacity to access alternative supplies of medicines in the event of a public health crisis. The Amendment includes safeguards to ensure that export compulsory licensing is used as originally intended for public health purposes and not to achieve industrial or commercial goals. (a) The term of a patent protection has been extended to twenty years compared to the seven years which was provided by the Act of 1970. This was made applicable to all the member countries and hence rules out all the differences with respect to patent protection which prevailed in different countries. A product patent system will make India dependent on the multinational companies for technology and for permission to produce the patented drug. Exorbitant prices will be charged and the Indian pharmaceutical industry will become subservient to the MNC's. They will lose the position that they had gained in the wake of the Act of 1970.*

Keywords: *Patent rights, Intellectual Property Rights, Amendment, compulsory licensing, Product patent and process patent, exorbitant prices, pharmaceuticals*

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INTRODUCTION

The word ***patent*** originates from the Latin ***patere*** which means 'to lay open' (i.e. to make available for public inspection). Patent is a form of industrial property. It is a statutory privilege granted by the Government to inventors and to others deriving their rights from the inventor, for a fixed period of years so as to exclude others from manufacturing, using or selling a patented product. Patent is a set of exclusive rights granted by a State to an inventor or his assignee for fixed period of time for a disclosure of an invention. Patent rights give the owner the exclusive right to make the invention, use the invention, sell the invention and distribute the invention. Examples of patents for inventions include biological patents, business method patents, chemical patents and software patents.

Many advocates for a global right to health believe that intellectual property rights protections have a negative effect on the realization of the right to health. This debate originates in the World Trade Organization (WTO) and the related Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement states that patent protection must be available for inventions for at least twenty years for both products and processes, in almost all fields of technology. Governments can refuse to issue a patent for an invention if its commercial exploitation is prohibited for reasons of public order or morality. They can also exclude diagnostic, therapeutic and surgical methods, plants and animals (other than microorganisms), and biological processes for the production of plants or animals (other than microbiological processes).

The TRIPS Agreement describes the minimum rights that a patent owner must enjoy, but it also allows certain exceptions. A patent owner could abuse his rights, for example, by failing to supply the product on the market. To deal with that possibility, the agreement says that governments can issue "compulsory licenses," allowing a competitor to produce the product or use the process under license. However, this can only be done under certain conditions aimed at safeguarding the legitimate interests of the patent-holder.

An issue that has arisen recently is how to ensure that patent protection for pharmaceutical products does not prevent people in poor countries from having access to medicines, while at the same time maintaining the patent system's role in providing incentives for research and development of new medicines. Flexibilities such as compulsory licensing are written

into the TRIPS Agreement, but some governments have been unsure of how these would be interpreted, and how far their right to use them would be respected.

SPECIAL DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

A large part of this was settled when WTO ministers issued a Special Declaration on the TRIPS Agreement and Public Health at the Doha Ministerial Conference in November 2001. In this Declaration, the WTO ministers agreed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. They underscored the ability of countries to use the flexibilities that are built into the TRIPS Agreement, and they agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016. On one remaining question, they assigned further work to the TRIPS Council, namely to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can import patented drugs made under compulsory licensing. A waiver providing this flexibility was agreed to on August 30, 2003.

On December 6, 2005, in an effort to make the waiver permanent, the WTO General Council adopted an Amendment of the TRIPS Agreement (the "Protocol") and submitted it to the Members for acceptance. Two-thirds of WTO members must ratify the Protocol, and it was decided that the Protocol would be open for acceptance by Members until December 1, 2007 or such later date as may be decided by the Ministerial Conference.

COMPULSORY LICENSING SYSTEM

Article 31(f) of the TRIPS Agreement says that production under compulsory licensing must be predominantly for the domestic market. There was a concern that this could limit the ability of countries that cannot make pharmaceutical products from importing cheaper generics from countries where pharmaceuticals are patented. As with the 2003 waiver, the permanent amendment allows any member country to export pharmaceutical products made under a compulsory license for this purpose. A separate statement by General Council chair Amina Mohamed, Kenya's ambassador, was designed to provide comfort to those who feared that the decision might be abused and undermine patent protection.

The TRIPS Amendment allows developing countries with no or insufficient pharmaceutical manufacturing capacity to access alternative supplies of medicines in the event of a public health crisis. The Amendment includes safeguards to ensure that export compulsory

licensing is used as originally intended for public health purposes and not to achieve industrial or commercial goals. WTO Members also commit to preventing the diversion of products away from the intended recipient country, so that poor populations are not deprived of the medicines intended for them. The goal of the amendment is to ensure that only countries truly lacking in pharmaceutical manufacturing capacity will be able to use export compulsory licensing.

THAILAND'S DECISION TO CIRCUMVENT PHARMACEUTICAL PATENTS

In September 2007, according to an article by David Cronin for Intellectual Property Watch , a dispute erupted between two of the European Union's most powerful institutions over Thailand's decision to circumvent pharmaceutical patents in order to boost its supply of cheap medicines. As the article explains, Peter Mandelson, the then-European Commissioner for Trade, wrote to several Thai ministers after Bangkok decided to overrule patents on three medicines by issuing compulsory licenses. Mandelson expressed concern over reports that Bangkok "may be taking a new approach to access to medicines" by stating that drug companies who wished to do business in Thailand should "offer their drugs for no more than 5 percent above" the cost of generic versions of the products in question. According to Mandelson, "this approach would be detrimental to the patent system and so to innovation and the development of new medicines" and risked "forcing more drug companies to abandon their patents.

"Members of the European Parliament (MEPs), however, took exception to Mandelson's letter, which was dated July 10, 2007 and made public in late August 2007. Many MEPs believed that Mandelson should not be seeking to exert pressure over developing countries that overrule drug patents in order to address public health needs. They also felt that Mandelson was insensitive to questions raised by the Parliament over the relationship between global intellectual property rules and access to medicines.

The EU debate followed on the heels of a debate over Thailand's actions that was held at a March 16, 2007 Capitol Hill briefing in Washington, D.C. In an article written by Martin Vaughan of Intellectual Property Watch, Ron Cass, former chairman of the Federalist Society's Practice Group on International and National Security Law, said the circumstances of the Thai case do not fall within narrow exceptions in the TRIPS Agreement on when a government may use a patented technology without first negotiating with the patent

holder. Cass also defended the March 14, 2007 announcement by Abbott Laboratories that it had withdrawn requests to register in Thailand seven new medicines, including a new heat-stable version of the AIDS drug lopinavir/ritonavir, marketed by Abbott as Kaletra.[1]

PRODUCT AND PROCESS PATENTS

Product patents and process patents are two categories of patents.

Product Patent

The distinction between a product patent and process patent that existed prior to the 1995 TRIPS agreement helped India develop a huge generic drug industry which had its basis on reverse engineering of brand name drugs through slightly modified processes.[2]

Here, product patent is granted when a new product has been invented by the person. The product so invented may either be more or less useful product than an already known product, or a new product altogether.[3] A product patent provides benefits to an inventor of a tangible object. For example, if a person creates a new computer chip, computer companies that use that chip in their products must pay the inventor for every product sold. Patent is the most potent form of protection. The international treaties governing patents include the Paris Convention and the Patent Convention Treaty. Process patents protect the protocol or methodology employed in a certain technology.

For instance, the method by which a new gene is inserted into a mircro-organism. The basic rationale behind processs patents is that the same product can be manufactured by different processes. Whereas, process patents are only granted to man-made processes. Natural processes that are discovered, such as the laws of motion or physics, cannot be patented. A

process can be patented if it is a newly invented way of doing something. The definition from the Supreme Court is "a mode of treatment of certain materials to produce a given result." Patent rights are not unlimited. While a patent is in place, the inventor has exclusive rights to his product or process. However, the patent expires after 20 years.[4]

Indian Pharmaceutical industry

The Indian Pharmaceutical industry is one of the largest in the developing world and is ranked as the fourth largest in terms of production and 13th largest in terms of domestic consumption value. Over the past 30 years Indian drug industry has emerged from almost non-existent to a world leader in the production of generic drugs. With the changes brought about by the patents act of 1970, Indian drug manufactures became experts in the field of reverse engineering and increased its supply of less expensive copies of the world's best-selling patent protected drugs. This could only be possible because there was no product patents system for drugs and medicines. While the Patent Act of 1970 in its original form does provide a distinction between product patents and process patents, the exception provided in section 5 of the act of 1970 (which has been omitted by the amendment of 2005) offered only a process patent for food, medicine or drug substances and specifically excluded product patents for the same. Thus India was able to copy foreign patented drugs without paying a license fee and was able to make it available to the masses at one-tenth of the original price. Moreover the Drug Price control Order, 1970 put a cap on the maximum price that could be charged and ensured that the life saving drugs are available at reasonable prices.

The Patent Act of 1970 could be considered to be one of the most progressive statutes which safeguards both the interest of the inventor and the consumer in a balanced manner. The Act has been promulgated keeping Directive Principles of State Policy contained in Article 39 of the Constitution in mind. Hence with a regulatory system focusing on process patents and being in the grip of a rigid price control framework, the Indian pharmaceutical industry has emerged from a import dependent industry to in the 1950's to having achieved world wide recognition as a low cost producer of high quality pharmaceutical products with an annual export turnover of more than $ 1.5 billion dollars.

The most important amendment which had to be introduced by the amendment of 2005 in order to make the existing patent regime in India TRIPS compliant was the introduction of pharmaceutical product patents. The amendment of 2005 extends full TRIPS coverage to food, drugs and medicines. It requires patents to be provided to products as well, while the patent regime provided by the Act of 1970 required patents only to be granted for chemical processes which resulted in the production of a particular drug. The other implications for the pharmaceutical sector under the new Act are as follows:

(a) The term of a patent protection has been extended to twenty years compared to the seven years which was provided by the Act of 1970. This was made applicable to all the member countries and hence rules out all the differences with respect to patent protection which prevailed in different countries.

(b) If the law of the country provides so, then the use of the subject matter of the patent shall be permitted without the authorization of the patent holder, including use by the government or any other third party authorized by the government. However such use shall be permitted only if prior to such use, the user has made efforts to obtain the authorization of the patent holder and such efforts have not been successful within a reasonable period of time. This requirement can be waived in case of a national emergency after notifying the patent holder.

© The burden of proof with respect to infringement matters have been reversed under the new Act. The onus of proving on a legal complaint that the process used by one enterprise is totally different from that which has been used by another would lie on the defendant. Prior to the amendment the responsibility was on the patent holder to establish patent infringement.

The new amendment was not to affect the drugs which were in the market prior to 1995. As far as those drugs which were produced between 1995 and 2005, they will have the right to continue to produce them in return for the payment of a fixed royalty to the patent holder. The main problem arises for those drugs which are now being manufactured and patented. The only way by which such drugs can be manufactured in India is by way of compulsory licenses. Such compulsory licenses are granted by the government on grounds such as non availability, high prices, public interest etc. The process ought to be simple and easy but the problem lies in the fact that the procedure has been left very ambiguous by the new Act. The deletion of the section 5 in the amendment of the Patent Act of 2005 and the recognition of the product patent therefore appear to be unfavorable for the Indian generic pharmaceutical companies, which have flourished by imitating the patented product of the foreign companies. But in spite of its adversities, the amended patent law of 2005 has also opened up some opportunities

IMPLICATIONS OF TRIPS COMPLIANCE WITH RESPECT TO HEALTH SECTOR

The immediate and the most drastic effect that TRIPS compliance and introduction of the new Act of 2005 will be with respect to the health sector in India. The patients are the ultimate beneficiaries of the pharmaceutical research and development. By denying product patents India will be able to encourage bulk generic drug production at cheap prices. However generics are not the only solution to counter the problem of access to medicines. Generic production of drugs will not necessarily result in the innovation of new and more effective drugs and by not acknowledging innovation India will run the risk of not having access to future medicines which will in turn affect public health. Denying patents and allowing the generic companies to freely copy the new drugs cannot be the solution to deliver medication to the patients too poor to buy them, be it rural or urban India. The actual problem lies in the fact that the product patents not only increase the cost of the drugs and medicines, but that most of them fail to introduce research and development in the neglected diseases.

Lack of access to affordable medicines was a reason for the vast majority of deaths that took place due to HIV/AIDS in the developing countries. Hence while on one side the introduction of product patents will help in development of new and more effective drugs, the problem still remains that the research and development undertaken by the drug manufactures evade the neglected diseases and the diseases which are region specific such as medicines for malaria and tuberculosis which are found prevailing in developing countries like India.

CONCLUSION

Unlike in the developed countries, the lack of the penetration of medical insurance makes the people directly affected by the increase in the prices and hence decreases the affordability. The patent system makes the lives of the people outside the sphere of social security, which forms majority in the developing countries, impossible. A product patent system will make India dependent on the multinational companies for technology and for permission to produce the patented drug. Exorbitant prices will be charged and the Indian pharmaceutical industry will become subservient to the MNC's. They will lose the position that they had gained in the wake of the Act of 1970.

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