THE INTERNATIONAL JOURNAL OF HUMANITIES & SOCIAL STUDIES

Trips & the Pharmaceutical Industry in India

Megha Dua
Assistant Professor, Department of Economics, (UILS, PUSSGRC, Hoshiarpur), Punjab, India

Abstract:
One of the fastest growing industries in the world is Indian pharmaceutical industry. After 1947, the pharmaceutical industry in India was dominated by MNC's and the prices of drugs in India were very high. The government gave encouragement to the growth of drugs manufacturing by Indian companies in the early 1960's and this process got ignition with the passing of Patents Act 1970. The great process of economic reforms in 1990 transformed the shape of Indian pharmaceutical industry. This Act removed the composition patents from food and drugs and retained the process patents. It provided special status to medicines, food items and chemicals. With the establishment of WTO in 1995 and the adoption of TRIPS a revolutionary change took place in IPR's. India being a founder member of GATT and subsequently of WTO incurred an obligation to bring its IPR regime in tune with IPR obligations within 10 years. Being a developing country owing its commitments to WTO, India has been amending its IP laws. The Indian pharmaceutical industry has emerged technologically as the most dynamic manufacturing segment in the Indian economy. Since 1990's TRIPS played an important role to make Indian pharmaceutical as an important part of the knowledge industry. India happens to be having world's 6th largest pharma market. Indian patent law has been amended after 1970's in 1999,2002&further in 2005 to comply with the provisions of patent act. TRIPS have included within the scope of IPR's the rights of plant breeders, trade secrets, rights arising out of biodiversity and computer layout design. The present paper seeks to analyse the significance of patent amendment Act in 1999,2002 &2005 consequent to the adoption of TRIPS by India and the post TRIPS scenario of the pharmaceutical industry in India.

Keywords: *TRIPS, pharmaceutical industry, India, patents, intellectual property*

1. Introduction

The TRIPS agreement introduced intellectual property law into the international trading system for the first time and it is the most comprehensive international agreement on intellectual property. After the Uruguay round, the GATT became the basis for the establishment of the WTO. Ratification of TRIPS is a compulsory requirement of WTO membership, any country seeking to obtain the access to international markets must access the strict intellectual property laws mandated by TRIPS.TRIPS has a very powerful enforcement mechanism. The agreement on TRIPS came into force on Jan1,1995. It is one of the most comprehensive multilateral agreement on intellectual property. It has greatly influenced the existing patent law regime in most developing countries. The most important reforms which has been imposed limits on compulsory licences. IP plays an important role in trade. These differences became a tension in international trade. The Uruguay round achieved the target of settling the system of IPR's in a more systematic way. The WTO's TRIPS agreement is an attempt to benefit the society as it narrows the gaps between long term benefits and short term costs. Society gets benefitted in the long term when IP encourages creation and invention and if some dispute arises in trade over IPR's the WTO's dispute settlement system is available.

2. What Is a Patent

A patent is in the form of industrial property as we commonly known as intellectual property. A patent is a monopoly right which is granted to a person who has invented a new and useful article or an improvement of an existing article or a new process of making an article or a new process of making an article. Patent is different from copyright as copyright emerges automatically on the creation of a work whereas patents are granted only when the requirements of registration are fulfilled. The object of patent law is to encourage scientific research new technology and industrial progress. Reward of monopoly rights to inventor simulates him more and more in the field of research and technology development. Value of patent system has now been realised at global level. In India, the patent law has been suitably modified to bring it in tune with TRIPS requirements. A lot of technological information throughout the world has been possible to be exchanged only by the publication of patent specifications.

3. What Is Copyright

Copyright is an exclusive right which is exercised over a work which is exercised over a work which is done by the intellectual labour of a person. Copyright law has been developed to give legal protection to copyright. Copyright law prevents the reproduction sale or

any other act with respect to the work if it is done without the consent of the owner. The main objectives of copyright law are as follows:

1. Protection of individual commercial interest in an intellectual work.
2. Protection of social interest.

4. What Is Intellectual Property

It is an intellectual work produced by the intellect of human brain. No one can make use of IP without the consent of the owner. The law that protects intellectual property is known as intellectual property law. The significance of intellectual property right in the international trade had been realised as early as in 19th century, as in 1883, an international convention on the protection of industrial property was convened in Paris with the efforts of inventors and industrialists. This convention is known as Paris Industrial Property convention, 1883.

5. WTO & TRIPS

The TRIPS agreement is a significant international agreement on IPR's. It relates IP with the international trade. TRIPS constitute Annexure IC of the Marrakesh agreement which established WTO and came into force on Jan,1995. The creation of WTO is a landmark in the history of multilateral trading system. TRIPS is a mandatory agreement attached to WTO whose failure would entail penal provision of WTO. In the field of food, medicines, drugs and chemical products, the TRIPS agreement provides for the granting of product patents. Such product patents will be available for 20 years. And in case of copyrights and related rights the protection will be given for 50 years. The basic principles of TRIPS are:

- Member states to determine their own legal system.
- Equal treatment to the nationals of other member states.
- Most favoured nation Treatment to all members.
- Protection of public health, nutrition and public interest.
- TRIPS is divided into 7 parts containing 73 articles. The categories of intellectual property covered by TRIPS are referred in PartII as:
    1. Copyright and Related Rights.
    2. Trademarks
    3. Geographical indicators
    4. Patent
    5. Layout design and integrated circuits.
    6. Industrial design
    7. Protection of undisclosed information.

5.1. Trips and India

The greatest argument in favour of IPR's is that it encourages innovation by rewarding the inventors. But, however it is argued that it is going to favour only few developed countries the agreement is highly favoured for MNC's and developed countries. It has been pointed out that intellectual property rights amounts to legalising the monopoly of multinational corporations. The Patents Act of India, 1970 granted only process patents to drugs and medicines. It meant that an Indian company was only required to develop and patent its own process for producing a drug but it was not required by itself to invent the drug. Then the company could legally manufacture the drug even if it was under a product patent abroad. The effect of these laws has been positive for India. After the 1970 Act, the Indian pharmaceuticals have grown very rapidly. The introduction of product patents from Jan 1, 2005 to meet the requirements of TRIPS has changed the situation. The domestic pharmaceutical companies face a lot of competition through MNC's. In view of the TRIPS agreement, the Indian pharmaceutical industry has started a new business model which is based on research and development.

6. Pharmaceutical Industry in India

India is the pharmacy for the world. Domestic pharma market value is growing by about 14% annually. In the post independence period two PSU's were set , the Hindustan Antiboitics in 1954 and indian drugs & pharma Ltd (IDPL)in 1961.

The Indian pharmaceutical market is the third largest in volume and thirteenth largest in terms of value as per the reports of Equity Master. The pharmaceutical market in India is dominated by branded generics. India is the largest provider of generic drugs globally consolidation has become an important characteristic of the Indian pharmaceutical industry. India has a large pool of scientists and engineers who can take the industry to highest levels. As on march 2014, Indian pharmaceutical manufacturing facilities registered with the US Food and Drug Administration stood at 523, highest for any country outside the US. Most of the sectors in the world today are affected by the global market slowdown, the pharmaceutical industry showed a high rate of growth. This sector is expected to be one of the leading providers of employment in India. The first legislation in India related to patents was the Act 6 of 1856. The object of this legislation was to encourage the inventions of new and useful manufactures and to induce the inventors to disclose the secrets of their inventions. It was further consolidated into Indian Patents and Design Act, 1911. After independence, it was felt that the Act was not fulfilling its objective. It was basically due to the fact that there were many changes in the political and economic system of the country. The government of India appointed a committee under the chairmanship of Justice(Dr). Bakshi Tek Chand in 1949 and further Justice. N. Rajgopala Ayyanagar committee in law. After the recommendations of the committee of Patents Act 1970

was passed. Most of the provisions of the Act were brought into force on 20th April, 1972. Among many salient features of Patent Act ,1970 the most significant is the abolition of product patent for drugs and medicines. The Patents (Amendment)Act 1999 and now in 2002 which provides a new definition of "invention which means that a new product or process which involves inventive steps and which is capable of industrial application. The Drug Policy of 1978 was the first comprehensive drug policy enacted in India. The ability to develop the generic drugs was acquired and improved during the mid 1990's. Apart from these measures other measures such as FERA (1974) and the Drug Price Control order of 1970 (DPCO 1970) played an important role in the development of pharma industry in India.

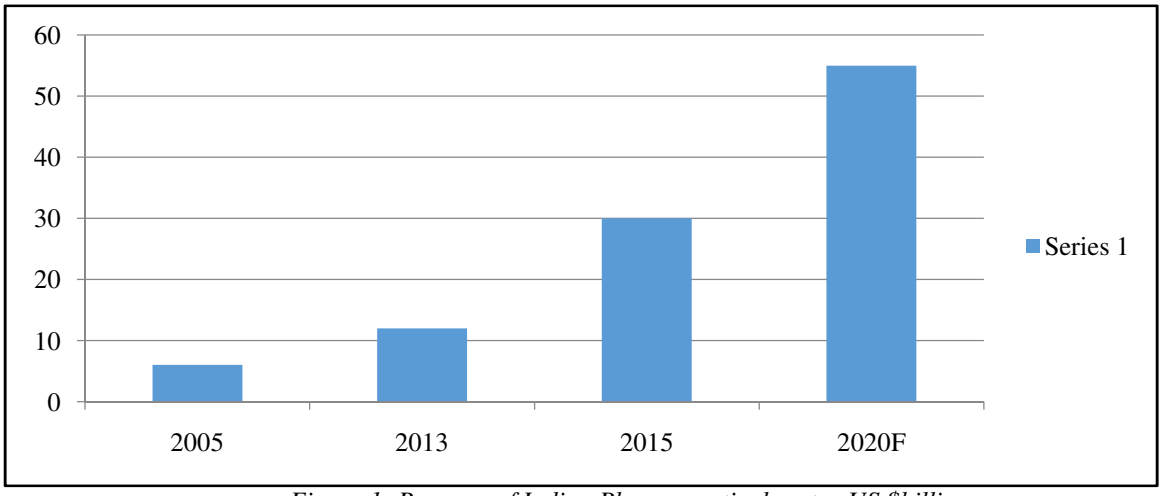

Figure 1: Revenue of Indian Pharmaceutical sector US $billion
Source: Dept of Pharmaceuticals PWC, Mckinsey Tehsci Research Notes F-Forecast, CAGR-Compound Annual growth Rate

7. Amendment of the Patent Law

The Patent Act of 1970 recognised only process patents. The life of the patent was also reduced from 16 to 5 years from the date of sealing or 7 years from the date of filing a complete application. Further in the amended act an MNC could patent only one process. The New Drug Policy of 1978 had reservation for the domestic manufacturers for the production of various categories of drugs. The Drug policy of 1978, was revised in 1986 also regularized the production of a large number of drugs that were earlier questionable on regulatory grounds.

7.1. Post Liberalisation Phase

The pharmaceutical industry witnessed a consistent growth from 1995 onwards. The Indian companies emerged to be major players in the domestic market. The Government of India abolished the licensing requirements for the entry and expansion firms under the policy of 1994 and 2002. Apart from changes in domestic policies the most controversial issue is related to the Patent Act of 1970. Under the WTO compulsion the patent law was amended in 2005. Thus, there has been a gradual shift in public policy form the regime of control to decontrol and product patents.

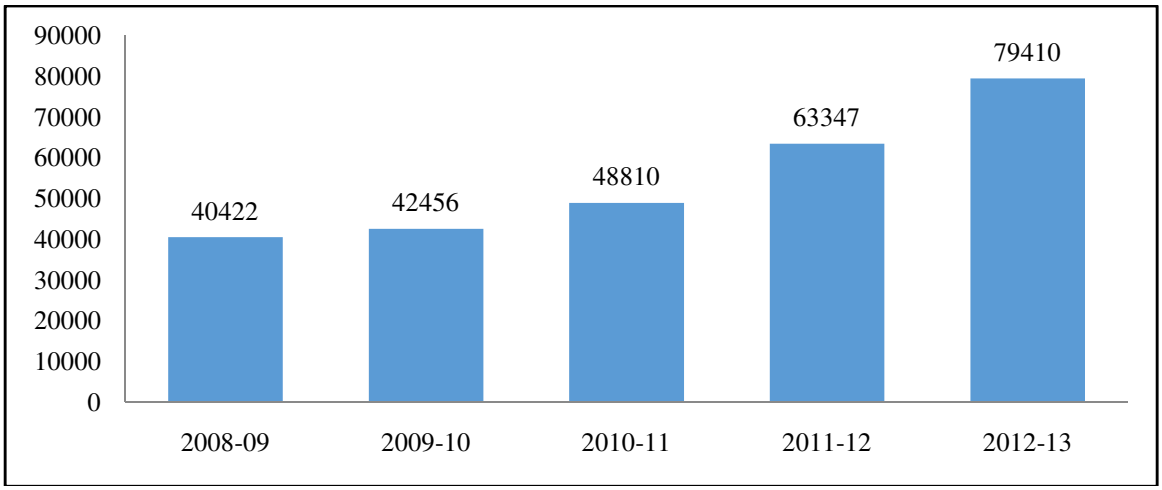

Figure 2: Pharmaceutical Exports of India
Source: Pharmaexcil, www.tandfonline.com

7.2. R&D in Indian Pharmaceutical Industry

The future of the pharma industry in India lies in research and development. A considerable increase is being seen in the public health and life expectancy over the years and all this is attributed to R&D. Initially, the Indian pharma industry spent very little on innovation. However, trends are not the same today as a lot of changes are taking place in the intellectual property system in various countries. In addition to R&D in industry substantial pharma related research and development is carried out in publicity funded research organisations, mainly by the council of scientific &industrial research(CSIR)Indian council of Medical Research , around 25 universities and a few pharmacy colleges. A few new drugs which make use of traditional screening techniques have emerged from the Indian R&D but none of them are much successful. The new R&D for generic products focus on the four aspects:

1. New drug delivery system
2. R&D for generic products for the regulated market
3. Non – infringing process.
4. New drug development research.

7.3. Issue of Access to Medicenes

Health is a fundamental human right which is a basic requirement for the exercise of many other rights. But for millions of people around the world the full enjoyment of the right to health remains a dream. One major factor is lack of good quality medicines and affordability. The 1994 TRIPS agreement represented the single greatest expansion of intellectual property protection in history, but it also includes a range of public health safeguards and flexibilities, which were reinforced by 2001 Doha declaration on the TRIPS agreement and public health. The US trade agreement over the past decade have tried to redefine and even undermine the Doha declaration. There are certain provisions which delay the onset of generic competition, keeping medicine prices high. An agreement was reached between congress and leadership and the Bush administration on May 10,2007 and it recognised the fact the fact that the higher levels of IP protection can run counter to public health interests. Under this agreement three key TRIPS plus some provisions were rolled back namely PATENT LINKAGE and PATENT TERM EXTENSIONS were made voluntary.

PATENT LINKAGE: It prohibits a country drug regulatory authority from approving a medicine if there is any patent.

PATENT EXTENSIONS PROVISIONS: It allows the companies to seek extensions of the 20 year patent term to compensate for administrative delays by patent offices and drug regulatory authorities.

DATA EXCLUSIVITY: It creates a monopoly that is separate from patents by prohibiting a country's drug regulatory authority from approving a generic medicine.

8. FDI and Pharmaceutical Industry

The entry of foreign companies in India in the pharmaceutical sector has increased due to FDI regulation in the pharma sector which allows FDI upto 100% under the automatic route. FDI was one of the main reason for making India as a leader in global exports to regulated market. The Indian government while concerning its rise in prices has established an inter-ministerial committee to review India's FDI in pharma sector.

9. Impact of Post Trips Scenario on Indian Pharmaceutical Industry

The advent of WTO&TRIPS has done wonders in the Indian pharma industry. It was only after the emergence of TRIPS that the Indian pharmaceutical industry took the challenge of new IP regime. The real action of the pharma sector started after 1990's. A large number of corporations have set up research facilities of global standard for New Drug Delivery System. The Bio diversity Act 2002, was enacted which is also a post trips development. India has enacted Plant Variety Protection Act in 2001. India has been facing many hurdles in the research and development of herbal products even though it has great potential to do so. The Indian pharmaceutical industry has emerged a global player during post-trips. India has always been abounded of technically qualified people. More and more technically qualified people have been encouraged in pharmaceutical industry during the post TRIPS scenario. There is also an increasing trend in IP training and education. Most of the universities, institutions and law campuses have started graduate degree and diploma courses in IPR. India pharma was against IP's in general in 70's and 80's. Patent practice by Indian National Sector has started post TRIPS.

10. India's New Patent Regime

The major stress of the patent of all countries is to strike a balance between rights of innovations and ensuring access at reasonable prices. The basic idea behind the Patent Act, 1970 was to give preference to public rather than of encouraging monopolies. Thus, it provided for the availability of world class medicines to the people on one hand and the development of pharmaceutical industry on the other. Under pressure from MNC's IPR'S were included in the Uruguay round of negotiations. Initially India was against this inclusion but later on it signed the draft. By signing the treaty India committed itself to reform the patent law. As far as the evolution of India's patent regime is concerned it was the granting of EMR's (Exclusive Marketing Rights) in the field of pharmaceuticals and agricultural chemical products in the market. EMR's were granted for a period of five years. Then, was made the third amendment to the Patent Act, to bring it in line with TRIPS. The main features of the Amendment Act 2005 are as follows:

Scope of patentability: Patent rights are to be granted to inventions which represent the advances in technology. A common practice being found in the pharmaceutical sector is to file patent applications for already known molecules by claiming trivial improvements. As a result of this the patent holders can extend their monopoly even after the expiry of the original patent which is known as

evergreening. The patents Amendment act 2005 says that a pharma patent will have to be a new entity involving one or more inventive steps. The Act introduces three new inventions- inventive steps, new invention and pharmaceutical science.
Protecting rights of generic producers: The third amendment to the patents act had to address many complicated issues and one of them was to address the problems of generic producers in India. The interest of the generic producers in India are required to be protected in section 11 where it is provided that the patent holder shall only be given reasonable royalty.
Compulsory licensing: The Doha declaration clearly provided the right of countries who grant patents to use the compulsory licensing system when it stated that every WTO member has the right to grant compulsory licenses and the freedom to determine the grounds on which licences are granted.
Exports to poor countries: The Patent Ordinance issued in December 2004 had required that a poor country having no or insufficient manufacturing capacity required that a generic drug from India then it should issue a compulsory licence. The Indian firms that are producing under compulsory licence for the domestic market can also export their product to poor nations.
Pre-Grant opposition: Another issue of considerable significance is that with the Amendment Act of 2005 is the issue of the opposition to the grant of patents.

10.1. Trips and the New Firms
The introduction of product patenting affected the Indian pharmaceutical firms to a great extent. They have been prevented to take a route to growth by the adoption of process patents. However, many of them aimed to expand their business. For this purpose the following options have been adopted:

10.2. Development of New Drugs
Production of off Patent
Production of patented drugs under licence
Marketing of Imported drugs

11. Conclusions
The IP practices which include patent laws are undergoing major changes, the Indian patent law s are getting amended. People are getting aware, public participation is increasing.
The patent Act of 1970 and the DPCO have increased the development of the Indian pharma industry, along with it has also improved the health and welfare in India. But, the country has been facing challenges. Since the introduction of TRIPS it was considered to have a negative effect on the Indian pharma industry but the country has made progress in the post TRIPS period. The budget 2016 enables the pharma companies to benefit from push to patents but criticism is received due to cut in tax sops. According to a report India has replaced China as top destination for FDI by attracting 63$billion worth FDI projects in 2015.Indian pharma exports will touch 270000 crores by 2020, according to a major study by global management and consulting firm.

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