

TRIPS AND INDIAN PHARMACEUTICAL INDUSTRY

Available online at www.ijdra.com

REVIEW ARTICLE

¹Tannan S.K.*, ²Badjatya J.K.

¹Senior Faculty, Raffles University, Neemrana, Rajasthan.

²NSN Biotech Pvt. Ltd., Noida (U.P.), India.

*Corresponding Author's E-mail: sktannan@rediffmail.com; sktannan@rafflesmanagement.com

ABSTRACT:

The TRIPs Agreement has led to a reinforcement of the protection of intellectual property, particularly in many developing countries. From the point of view of transfer of technology, the imitation of technologies from industrialized countries and the marketing of the resulting products will now be more difficult. The MNCs are also expanding vigorously in the generic segments. They are trying to grow not only organically, but through mergers and acquisitions and strategic alliance with Indian generic companies.

90% of the Indian Pharmaceutical Industry was dominated by the Global companies that imported most of the drugs. During the early 1970s, the Indian players gradually gained prominence as a result of the Indian Patent Act, 1970 which allowed Indian companies to reverse engineer Patented Molecules and launched them in the domestic markets.

Key words: TRIPs Agreement, GATT, NCE, NBEs, MNCs, compulsory licensing.

Introduction:

Until the late 1960s, public sector firms such as Hindustan Antibiotics Limited and Indian Drugs and Pharmaceuticals limited and a host of global companies dominated the Indian Pharmaceutical Industry. United States Senate Committee (The Kefauver Committee) found in the 1960s that India was among the highest priced nations in the world in pharmaceuticals. (1,2) 90% of the Indian Pharmaceutical Industry was dominated by the Global companies that imported most of the drugs. During the early 1970s, the Indian players gradually gained prominence as a result of the Indian Patent Act, 1970 which allowed Indian companies to reverse engineer Patented Molecules and launched them in the domestic markets. (3)

Indian Patent Authority allowed only Process Patent, and not product patent. So manufacturers could copy foreign patented drugs, and with a minor change in the process, they could make them available to the common man at an affordable price. As a result, by the end of mid of 1980, imports reduced drastically, and by the 1990s, exports gained prominence.

Globally, the Indian Pharmaceutical Industry has emerged as the 4th largest in terms of volumes and 13th largest in terms of value by the 2000s. It is having a worth of about \$ 5 billion, growing annually at about 10% and with over 20000 units in the organized sector. (4) The industry provides employment to about 3 million people, out of which about 5 lakh people are directly employed in the industry. In 2007, Medecins Sans Frontieres, the International Medical Aid Organization operating in more than 70 countries described India as the "Pharmacy for the Developing World". (1,2)

The major players in the industry are categorized into two types: Companies with Indian origin (Domestic) and MNCs. In 2001, Ranbaxy, Cipla, Dr Reddy's Laboratories and NPIL were the top four domestic companies in terms of gross sales, while Glaxo-Wellcome, Hoechst-Marian-Roussel, Novartis India Limited were the major MNC's operating in India.

The Indian Pharmaceutical Industry was in a state of transition with the implementation of TRIPs in 2005 being administered by WTO. The Agreement on Trade Related Aspects of

Intellectual Property Rights (TRIPS) set rules on Intellectual Property Rights/Patents and require Member Countries of WTO to reflect the same in their domestic laws.

Before the TRIPS Agreement, most of the developed countries granted patents on drugs, but many developing countries including India only granted patents for the process of producing an invention (For example, the method of producing a drug) but not for the product (the drug itself). As a result, generic copies of original drugs (generic drugs) were made or imported into these countries without getting permission from the patent holder. Hence, the prices of medicines were often lower because of generic competition against the patented drugs. The TRIPS Agreement attempted to end this practice by implementing the International Patent Law.

The high prices of medicines are the result of patents, which give their holders right to restrict their competition and therefore sell a certain drug in a monopolistic environment. TRIPS require many developing countries to enforce their patent protection which would restrain innovation and information flows. Moreover, prices of medicines would continue to rise, making access more difficult and adversely affecting the local pharmaceutical industry. Production of generic equivalents to expensive branded drugs will be limited because of 20 year patent protection for pharmaceutical products and processes.

In a pre-TRIPS period, many developing countries including India did not grant product patents, but process patents for pharmaceuticals, enabling domestic researchers to develop similar products through a process called "Reverse Engineering". The implementation of TRIPS put an end to this practice. (5)

(I) TRIPS and Affordability and Accessibility of Pharmaceutical Products:

A TRIP is being implemented at a time when the developing countries are going through a severe health crisis. About one third of the world's population lacks regular access to essential drugs. The situation is worse in Africa

and India. In Africa, almost half and in India, 50 to 65% of the population does not have regular access to essential drugs.

The infectious diseases that are treatable (from a scientific point of view) account for 14 million deaths each year-most of them in developing countries. A number of factors worsen the situation in these countries, e.g., poverty and lacking access to health services. Efficient and affordable medicines could cut down the death toll if people had access to essential medicines. In developed countries, lives saving drugs have raised life expectancy of HIV-infected people dramatically, but this treatment is unaffordable for people in developing countries. (6)

In the pre-1972 period, when India had a product patent regime in drugs, MNC's took full advantage of the product patent provisions and prevented the indigenous firms from producing new drugs. They charged prices as high as in the developed countries. Most poor people in developing countries pay for their own medicines- public health provisions and insurance facilities are low.

If product patent protection results in high prices, it is possible for the Government to intervene. TRIPS provide for some flexibility to member countries of WTO to take action to face the negative consequences of product patent protection. Within the scope of TRIPS, the following are the main flexibilities which developing countries can use:

- (1) Provide exemptions from grant of patents in certain cases.
- (2) Provide exemptions to product patent rights in certain cases.
- (3) Limit data protection
- (4) Provide for government use
- (5) Provide compulsory licenses to non-patentees. (3,7)

(1) Exemptions from Grant of Patents:

Under Article 27(1) of TRIPS, patents will have to be provided for inventions, which are 'new, involve an inventive step and are capable of industrial application. The agreement, however, does not define these terms. This provides some flexibility. A developing

country can interpret these terms so as to restrict the number of patents. (7)

(2) Exceptions to Exclusive Rights:

Patents basically confer on the patentee the right to prevent others from using the invention. But such rights are not absolute. All patent laws generally provide for some qualifications to such exclusive rights. Article 30 of TRIPS permits member countries to 'provide limited exceptions to the exclusive rights conferred by a patent. This Act does not list the specific Acts for which exceptions can be provided. The following are the most significant and common exceptions which the national laws in many countries provided when TRIPS came into effect. (7)

(i) **Early Working:** The 'early working' provision is popularly referred to as the 'Bolar' provision or exception as it is known in USA. The Bolar provision is very important for generic entry. It permits generic entry soon after the patents expire, and, hence, allows the customers to benefit from competition and lower prices without delay.

(ii) Parallel Imports:

Under Article 28 of TRIPS, the patent owner has the exclusive right to prevent others from not only from making, using or selling the invented product or process in the country, but also importing from other countries. This is, however, subject to Article 6 on 'exhaustion'. What it basically means that the patent holder in a country cannot legally stop imports of patented products offered for sale in another country. Such imports are known as parallel imports.

(iii) Research and Experiment Use:

Section 47 of the Patents Act, 1970, which has not been deleted in the recent amendments, provides other exceptions. The patented product/process may be made or used by any person for the purpose merely of experiment or research including the parting of instructions to the pupils. However, it is also possible to exempt acts of experimentation even if made with commercial purposes.

(3) Limiting Data Protection:

To get marketing Approval for a new drug developed, innovator companies are required to submit test and clinical data relating to safety and efficacy to national health authorities. India's Drugs and Cosmetics Act, 1940, which regulates the marketing approvals of new drugs, as well as the Patents Act 1970, the three amendments including the Ordinance of 2004 carried out to comply with TRIPS does not contain any provisions relating to test data protection. (7)

(4) Compulsory Licensing:

A proper compulsory licensing system is of vital importance to deal with the negative implications of product patent protection on prices. If generic companies are given licenses to produce a patented drug on payment of royalty, then competition among manufacturers would drive down prices, but the royalty paid to the innovators would continue to provide funds and the incentive for R&D. Both WHO and WHO have pointed out that compulsory licensing is one of the ways to strike a balance between promoting access to existing drugs and promoting R&D into new drugs.

In the amended Patent Act of 1970, an application for a compulsory license can be made under two sets of circumstances

(i) **Under section 84**, three years after sealing of the patent. An application under this section can be made on the following grounds:

- (a) That the reasonable requirements of the public have not been satisfied or
- (b) That the product is not available at a reasonably affordable price or
- (c) That the patented invention is not worked in the territory of India.

Thus, under the Indian Law, if a patentee does not exploit locally the patented inventions, then compulsory licenses can be asked for.

(ii) **Section 92**, anytime after the sealing of the patent with respect to a patent notified by the Government as eligible for a compulsory license. The General principles in the amended Act sound very impressive.

The general principles note that patents are granted to encourage inventions and to make the benefit of patented invention available at reasonably affordable prices to the public, to secure that these are worked in India, and not to enable patentees to enjoy monopoly power by importing. (8)

(5) Government Use:

Article 31 of TRIPS dealing with compulsory licensing provides for special provisions in the case a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use 'Public use of patents' or 'Government use' is a standard feature of patent laws in many countries. Under section 92, the central Government can notify in the official Gazette, the issue of compulsory licenses under special provisions as per article 31 of TRIPS.

Trips provides a three stage frame for countries such as India which did not grant product patents rights in pharmaceuticals when TRIPS came into force on Jan 1, 1995.

(i) Introduction of a facility ('mail box') from Jan 1, 1995 to receive and hold product patent applications in the fields of pharmaceuticals and agricultural chemicals. Such applications will not be processed for the grant of the patent until the end of 2004. But, Exclusive Marketing Rights (EMR's) can be obtained for that application if a patent has been granted in some other WTO member country and the application has not been rejected in the country as not being an invention.

(ii) Compliance, from Jan 1, 2000, with other obligations of TRIPS such as the rights of the patentee, term of patent protection, compulsory licensing and so on.

(iii) Introduction of full product patent protection in all fields including pharmaceuticals from January 1, 2005. All the product patent applications held in the mail box are also required to be taken up for examination from Jan 1, 2005. Compliance with the TRIPS requirements has taken substantial time in India.

The Patents (Amendment) Act, 1999 amended the Patents Act 1970 with retrospective effect from Jan 1, 1995 to implement the mail box facilities EMR's. A fully fledged product patent regime has been introduced in India from Jan 1, 2005 through a presidential decree, the Patents (Amendment) Ordinance 2004 dated Dec 26, 2004. The Ordinance, introducing product patent protection in Pharmaceuticals has been widely opposed both in India and abroad.

The Multilateral organizations such as WHO has urged the Government to enjoy the rights enjoyed under WTO to protect public health. When the Ordinance was followed up with necessary legislation and the Patents (Amendment) Act 2005 was passed by the Parliament in March 2005. (9)

(II) The Role of Multinationals in the Pharmaceutical Industry in India after TRIPS:

(1) Rising MNCs Dominance:

Indian generic companies are no longer permitted to manufacture new patented drugs. These can now be manufactured only by the patentees and their licensees. Thus depending on the rate of introduction of the new patented drugs, the market share of MNCs is expected to go up. The MNCs are not only interested in patented markets, they are also trying to enter aggressively into generic segments as well.

Traditionally, MNCs have relied for their growth in patented drugs and focused mainly on developed country markets. The high monopoly prices of patented drugs yielded high returns. But recent years have witnessed a sharp fall in the number of new drugs introduced in the market. The MNCs are finding it increasingly difficult to fill the product gap as the patents of their blockbuster drugs are expiring and they are facing constraints on further profitable growth in the developed markets. For example, Pfizer is set to lose a \$ 10 billion dollars a year revenue stream as the patent on its blockbuster drug Lipitor expires.

The net profit of the top 15 MNCs declined sharply by 20% in 2010 with a major setback

for companies such as Merck, Bristol-Myers and GlaxoSmithKline. On the other hand, some developing country markets are experiencing rapid growth. The seven emerging markets of China, Brazil, India, Russia, South Korea, Mexico, and Turkey contributed to more than half of the growth of the pharmaceutical market of the world in 2009 compared to only 16% of contribution by the developed country markets of North America, Western Europe and Japan. Therefore, the MNCs are targeting the generic industry in the emerging markets.

Involvement of MNCs in the generic market is not new in India. When product patents were abolished in 1972, all the major MNCs decide to stay back. GSK (Earlier Glaxo), in fact, remained the largest seller in the domestic formulations market till recently. But MNCs in general maintained a low profile. They were hesitant to introduce their latest products in the Indian market. Some of them continued to compete but created new local brands rather than promoting their international brands. Others stop selling their products they thought were priced too low. (1)

In the post TRIPS era, MNCs are vigorously trying to expand not only in the patented markets, but also in the generic market of India. MNCs such as Pfizer, GSK and Merck have introduced some of their blockbuster drugs in India. Examples are azithromycin and quinapril by Pfizer, simvastatin by Merck and carvedilol by GSK. In fact, MNCs are marketing the products of other MNCs in the Indian market. Pfizer, for example, is marketing telmisartan developed by Boehringer Ingelheim.

MNCs are now forming strategic alliances with Indian companies. Indian companies such as Dr Reddy's Laboratories, Aurobindo, Cadila Healthcare and Torrent have entered into supply agreements with MNCs such as GSK, Astrazeneca and Abbott. Dr Reddys, for example will supply about 100 branded formulations to GSK for marketing in various emerging markets across Latin America, Africa, West Asia and Asia-Pacific including India. Dr Reddys will get a predetermined share of the revenue earned by GSK for these products. In some markets where Dr Reddys

have a presence, the formulations will be marketed jointly.

Another example is Aurobindo-Pfizer deal. Aurobindo will supply more than 100 formulations to Pfizer for the regulated markets of US and the European Union (EU) and more than 50 products for about 70 non-US/EU Markets. Apart from the revenue sharing, the deal involves the payment of upfront license fees by Pfizer to Aurobindo. Such deals enable the MNCs to get access to low-cost reliable products without undergoing the lengthy process of getting regulatory approvals in different markets and without incurring any additional expenditure for setting up manufacturing plants. The Indian companies gain by having access to formidable marketing resources of MNCs. (1)

(2) Rising Imports of Finished Formulations:

The new drug policy, 1978 (revised in 1986) imposed restrictions on FERA companies (i.e. those with more than 40% equity) which were not applicable to Indian companies. One of the most important policies that were implemented was that the MNCs were not allowed to market formulations unless they themselves produced the bulk drugs in specified ratio. This compelled the MNCs to undertake manufacturing investments from the basic stages. In fact, together with the Indian companies, the manufacturing activities of MNCs too expanded after 1970'.

But after the mid-1990 with the withdrawal of such restrictions, the MNCs started disinvesting in manufacturing operations. They have sold a number of plants which they had set up under Government pressure. Thanks to the development of the bulk drug industry in India after 1970' onwards, most of the bulk drugs are now produced by a number of Indian producers and are available at very low competitive prices.

In 1994, the investments in plant and machinery of the top MNCs was Rs 455 crores, accounting for about 70% of that of the top 10 Indian companies. However, by 2010, MNCs investments accounted for only 5% of the investment of Indian companies of Rs 13765

crores. Thus, the manufacturing activities of MNCs after economic liberalization are reminiscent of the 1950s and 1960s when the official policy was quite liberal but the MNCs were reluctant to undertake manufacturing.

What has attracted widespread attention is India's success as a pharmaceutical exporter. What is less noticed is that in recent years, imports of formulations have been rising sharply. Exports exceed imports, but between 1995 and 2010, imports were grown at a faster rate than exports leading to a decrease in trade surplus in formulations. (1)

(3) Market Structure and Prices of Patented Products:

The reintroduction of product patent protection since 2005 has crucial significance. Though product patent have been introduced since January 1, 2005, earlier from January 1, 1995, a mail box facility was put in place to receive and hold patent applications. As per the TRIPS Agreement, these applications are being processed since January 1, 2005 for the grant of patents.

Indian generic companies are no longer permitted to manufacture and market new drugs for which patents have been granted in India. But not all new drugs are patentable in India. Under article 70(3) of TRIPS, a WTO member country has no obligation to provide protection for any subject matter which has fallen into the "public domain" before the WTO came into being i.e. before January 1, 1995. Thus any drug product patented abroad before 1995 can continue to be manufactured and sold in India after 1995 even though these may be under patent protection in other countries.

Drugs patented after January 1, 1995 can be classified into the following categories:

(i) Those involving new chemical entities (NCEs) also known as new molecular entities (NMEs) and new biological entities (NBEs) patented after 1995

(ii) Those involving NCEs/NBEs developed before 1995 but with patents after 1995 for:

(a) New formulations and compositions,

(b) New combinations

(iii) New chemical derivatives (Salts, esters etc)

According to article 27(1) of TRIPS, Patents are required to be provided for inventions, which are "new, involve an inventive step and are capable of industrial application". This agreement, however, does not define these terms. This provides some flexibility. India has taken advantage of this flexibility by enacting Section 3 (d) in the amended Patents Act and restricting product patents to some extent. Under Section 3 (d) India is not obliged to provide protection to any secondary patents (of new formulations/combinations/chemical derivatives) after 1995 involving NCEs developed before 1995 unless they differ significantly in properties with regard to efficacy. (1)

Conclusion:

The TRIPS negotiations of GATT Uruguay Round have altered the international system of Intellectual Property. The linkage of Intellectual Property issues to those of international trade led to the bilateral measures on the part of the industrialized countries and to the multilateral approach adopted within GATT. Developing countries opted to include intellectual property protection in the Uruguay Round because they cannot remain isolated in the age of market globalization, and their economic development depends on access to the markets of the industrialized countries.

The TRIPS Agreement has led to a reinforcement of the protection of intellectual property, particularly in many developing countries. From the point of view of transfer of technology, the imitation of technologies from industrialized countries and the marketing of the resulting products will now be more difficult.

The days of product monopolies and high prices are back in India. The MNCs have started marketing new patented drugs at exorbitant prices particularly for life threatening diseases like cancer. The

manufacturing and importing behavior since 1999s bears a close resemblance to that before the 1970s. Imports of high priced finished formulations are rising rapidly, with manufacturing investments are lagging far behind.

The MNCs are also expanding vigorously in the generic segments. They are trying to grow not only organically, but through mergers and

acquisitions and strategic alliance with Indian generic companies. The aggregate market share in the formulations market has gone up substantially with the taking over of some Indian companies by the MNCs. The MNCs are on the way to dominating the industry again.

References

1. Chaudhuri S. Multinationals and Monopolies Pharmaceutical Industry in India after TRIPS. Working Paper series [Internet]. 2011;[cited 2013 Nov 03]. Available from: http://facultylive.iimcal.ac.in/sites/facultylive.iimcal.ac.in/files/WPS%20685_0.pdf.
2. Chaudhuri S, Chan P, Gopakumar KM. *Five Years into the Product Patent Regime: India's Response*. New York: United Nations Development Programme, 2010.
3. Chaudhuri S. *TRIPS Agreement and Amendment of Patents Act in India* [Internet]. [updated 2002 Aug 16; cited 2013 Sept 27]; <http://www.scribd.com/doc/68993504/TRIPS-AND-AMENDMENT-IN-INDIAN-PATENT-ACT>.
4. Pharmaceuticals. *Connaught International Consulting*. [Internet]. [updated 2013; cited 2013 Sept 29]; Available from: <http://connaughtinternational.com/industry.php>
5. Medicines. WTO and the Trips agreement. WHO [Internet]. [updated 2013; cited 2013 Sept 21]; Available from: http://www.who.int/medicines/areas/policy/wto_trips/en/
6. Access to Medicines. Medecins Sans Frontieres [Internet]. [updated 2013; cited 2013 Oct 4]; Available from: <http://www.doctorswithoutborders.org/news/allcontent.cfm?id=84>
7. Chaudhuri S. TRIPS and Changes in Pharmaceutical Patent Regime in India [Internet]. [updated 2005 Jan; cited 2013 Oct 23]; http://www.who.int/hiv/amds/IDA_India-Patent-amendments-Sudip.pdf.
8. Chaudhuri S. Compulsory Licensing under India's Amended Patent Act Technology Policy Briefs. Maastricht: United Nations University Institute for New Technologies. 2002 (a); 1(3).
9. Love J. Compulsory Licensing: Models for State Practice in Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord. Jan 21,2001.