IMPACT OF TRIPS OVER INDIAN PATENT REGIME VIS A VIS INDIAN PHARMACEUTICAL INDUSTRY*

ABSTRACT:

In the process of industrialization, pharmaceuticals have been a favourite sector for policy makers in the developed as well in many developing countries, including India. This special policy preference has been due to the criticality of the pharmaceutical products for the health security of the populace as well as for developing strategic advantages in the knowledge based economy. The Indian pharmaceutical industry, which had little technological capabilities to manufacture modern drugs locally in the 1950s, has emerged technologically as the most dynamic manufacturing segment in the Indian economy in the 1990s. It achieved a significant scale and level of technological capability for manufacturing modern drugs indigenously and cost - efficiently to emerge as a major developing country competitor in the world market.

The emergence of the world trade organisation makes a watershed in international law and its impact on the international trade and business. The WTO has set differential deadlines and continuous deliberation for the member states to comply with the agreements. A member joining WTO has to adhere to the 18 specific agreements establishing the WTO. Out of these TRIPS have the largest impact on the pharmaceutical sector. The WTO agreement is a treaty that creates in international obligations among its members. These obligations include refraining from taking actions that are inconsistent with the agreement. The various parts of the WTO agreement, including the TRIPS Agreement, require that such national legislation embodies certain specific standards.

* Saurabh Chandra, Assistant Professor, School of Law, Galgotias University

(1) Evolution of Indian Pharmaceutical Industry:

The pharmaceutical production in India began in 1910s when private initiatives established Bengal Chemical and Pharmaceutical Works in Calcutta and Alembic Chemicals in Baroda and setting up of pharmaceutical research institutes for tropical diseases like King Institute of Preventive Medicine, Chennai (in Tamil Nadu), Central Drug Research Institute, Kasauli (in Himachal Pradesh), Pastures Institute, Coonoor (in Tamil Nadu), etc. through British initiatives. The nascent industry, however, received setbacks in the post World War II period as a result of new therapeutic developments in the Western countries that triggered natural elimination of the older drugs from the market usage by newer drugs like sulpha, antibiotics, vitamins, hormones, antihistamine, tranquilizers, psycho pharmacological substances, etc. This culminated in the discontinuation of local production based on indigenous materials and forced the industry to import bulk drugs meant for processing them into formulations and for selling in the domestic market.

In the post - independence period, Indian pharmaceutical industry exhibited four stages of growth. In the first stage during 1950s–60s, the industry was largely dominated by foreign enterprises and it continued to rely on imported bulk drugs notwithstanding its inclusion in the list of 'basic industries' for plan targeting and monitoring. Foreign firms, enjoying a strong patent protection under the Patent and Design Act 1911, were averse to local production and mostly opted for imports from home country as working of the patent. Given the inadequate capabilities of the domestic sector to start local production of bulk drugs and hesitation of foreign firms to do so, the government decided to intervene through starting public sector enterprises. This led to the establishment of the Indian Drugs and Pharmaceuticals Ltd. (IDPL) plants at Rishikesh and Hyderabad in 1961 and the Hindustan Antibiotics at Pimpri, Pune, in 1954 to manufacture penicillin. The starting of the public sector enterprises has been an important feature in the evolution of the pharmaceutical industry as it assumed initiative roles in producing bulk drugs indigenously and led to significant knowledge spillovers on the private domestic sector.

The second growth stage of the industry took place in the 1970s. The enactment of the Indian Patent Act (IPA) 1970 and the New Drug Policy (NDP) 1978 during this stage are important milestones in the history of the pharmaceutical industry in India. The IPA 1970 brought in a number of radical changes in the patent regime by reducing the scope of

patenting to only processes and not pharmaceutical products and also for a short period of seven years from the earlier period of 16 years. It also recognizes compulsory licensing After three years of the patent. The enactment of the process patent contributed significantly to the local technological development via adaptation, reverse engineering and new process development. As there exits several ways to produce a drug, domestic companies innovated cost–effective processes and flooded the domestic market with cheap but quality drugs. This led to the steady rise of the domestic firms in the market place. The NDP 1978 has increased the pressure on foreign firms to manufacture bulk drugs locally and from the basic stage possible. Foreign ownership up to 74 per cent under the Foreign Exchange Regulation Act (FERA) 1973 was permitted to only those firms producing high technology drugs. Foreign firms that are simply producing formulations based on imported bulk drugs were required to start local production from the basic stage within a two year period. Otherwise were required to reduce their foreign ownership holding to 40 per cent. New foreign investments were to be permitted only when the production involves high technology bulk drugs and formulations thereon. The outcomes of the strategic government interventions in the form of a soft patent policy and a regime of discrimination against foreign firms affected the industry with a time lag and provided strong growth impetus to the domestic sector during 1980s. In the third stage of its evolution, domestic enterprises based on large - scale reverse engineering and process innovation achieved near self - sufficiency in the technology and production of bulk drugs belonging to several major therapeutic groups and have developed modern manufacturing facilities for all dosage forms like tablets, capsules, liquids, orals and injectibles and so on. These had a lasting impact on the competitive position of the domestic firms in the national and international markets. In 1991, domestic firms have emerged as the main players in the market with about 70 and 80 per cent market shares in the case of bulk drugs and formulations respectively. The industry turns out to be one of the most export - oriented sectors in Indian manufacturing with more than 30 per cent of its production being exported to foreign markets. The trade deficits of the seventies have been replaced by trade surpluses during 1980s.

The growth momentum unleashed by the strategic policy initiatives continued in the fourth stage of the evolution of the industry during 1990s. The production of bulk drugs and formulations have grown at very high rates and the share of bulk drugs in total production

has gone up to 19 per cent in 1999–2000 from a low of 11 per cent in 1965–66.This stage has also witnessed dramatic changes in the policy regime governing the pharmaceutical industry. The licensing requirement for drugs has been abolished, 100 per cent foreign investment is permitted under automatic route, and the scope of price control has been significantly reduced. India has carried out three Amendments in March 1999, June 2002 and April 2005 on the Patent Act 1970 to bring Indian patent regime in harmony with the WTO agreement on Trade Related Intellectual Property Rights (TRIPs). Following the Second Amendment to the Patents Act (1970), parallel imports of products patented in India were allowed, subject to the condition that the foreign exporter was authorised by the patentee to sell and distribute. The Patents (Amendment) Act, 2002 had introduced the Bolar provision[1] to allow for using and selling the patented product during the term of the patent, for obtaining regulatory approvals. The amended Act 2005 has revised this to include the act of importing as well. The provision has been selectively transposed from the US law.

The third and the final one, known as the Patents (Amendment) Act, 2005 came into force on 4th April 2005 and introduced product patents in drugs, food and chemicals sectors. The term of patenting has been increased to a 20 year period. The Patent (Amendment) Ordinance, 2004 allowed for the possibility of patenting incremental innovations — new use or new property of a known substance, etc. Under the amended Act (2005), this flexibility has been substantially curtailed.

These changes in the policy regime in the 1990s, thus, started a new chapter in the history of Indian pharmaceutical sector where free imports, foreign investment and technological superiority would determine the trade patterns and industrial performance. The Indian pharmaceutical industry is looking at this era of globalization as both an opportunity and a challenge.

[1] In the US, under the Bolar provision (applicable only to pharmaceuticals), even as enabling measures are provided to ensure the entry of generics just at the time of expiration of the patent term, it also gives relief to the patent-holder by allowing a suitable increase in the patent term to compensate for the time lost in getting regulatory approval. That strikes a balance between the interest of the generics and those of the patentees.

(2) KEY REQUIREMENTS OF THE TRIPS:

On April 15, 1994, the signatory nations of the General Agreement on Tariffs and Trade (GATT) signed an Agreement of Trade Related Aspects of Intellectual Property (TRIPS). As the name suggests, this agreement is aimed at harmonizing national laws on protection of intellectual property and strengthening the overall IP regime for better protection and enforcement of intellectual property rights. However, the most contrasting feature of this agreement is that via this agreement, WTO introduced for the first time interlinking of trade and IP rights, which until now were being practiced on parallel plains. Before the WTO, the World Intellectual Property Organization (WIPO) was governing the IP rights. The world trade regime and intellectual property movement were so disconnected that in fact, the 1947 GATT mentioned intellectual property rights only in passing. However, as the WTO Agreement was being negotiated, the U.S. and other developed nations insisted that the new trade institution link IP rights to the terms of trade for goods and services. As a result, the WTO Final Act included the new TRIPS Agreement as part of a newly conceptualized trade regime.

The TRIPS Agreement is unlike other agreements in WTO because it establishes a minimum degree of protection for IP rights. Under the TRIPS Agreement, WTO members may enact more stringent IP standards than the WTO stipulates, but they cannot fall below the required floor[2]. On the face of it, the Agreement deals with different forms of IP, including the patents. The agreement provides for in a separate chapter (chapter-V), patent protections for innovations in all fields of technologies[3]. Article 27-34 are the most pertinent parts of the agreement in terms of patent protection. Those Articles require Members to provide a minimal standard of protection for inventions for twenty years from the patent application filing date. Importantly, they also require Members to make patent protection available for inventions, whether products or processes. Pharmaceutical products and processes being one such field of technology, therefore, qualify for patent protections under the agreement and all the patent related privileges and protections also extend to these products and process[4]. In this scheme of patent protection, Article 28 of the agreement confers a

[2] TRIPS Agreement art. 1.1

[3] Article 27(1)

[4] The term pharmaceutical has not been defined any where in the TRIPs agreement, only Article 27.3 allows signatories to exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals".

pharmaceutical patentee with certain exclusive rights in relation to his/her patented inventions which, includes the right to exclude others from the use of patented product or process[5]. Therefore, barring exceptional situations as expressly recognized by the agreement, no one can exercise those rights, related to a patented invention without the permission of patentee. Further, in relation to pharmaceutical patents, in addition to general protections and privileges conferred on all categories of patentees, all WTO members are required to maintain the confidentiality of clinical drug test data submitted in order to gain marketing approval ("marketing approval data") under certain conditions defined in Article 39.3 of the TRIPs Agreement[6]. The effect of this provision is that even though the patent has not been granted applicants are given protections for intermediate phase through the secrecy maintenance. Under the mandate of Article 39.3, the competitor drug manufacturer, who can otherwise relay on different trial data submitted by the applicant are excluded from such use and therefore the applicant maintains his edge in terms of time. Further, under article 70.8 and 70.9, all WTO Members were required to implement the so-called mailbox system and the exclusive marketing rights (EMR) provision embodied in the above two articles starting as of the date of entry into force of the TRIPS Agreement (1 January 1995).This means establishing systems for receiving and filing pharmaceutical and agricultural chemical product patent applications for later review (mail-box rule) as well as providing exclusive marketing rights for those products that are the subject of the mailbox rule. EMRs appear to be very similar to patent rights under the obligation of the TRIPS Agreement and are possibly even stronger than patent rights. Article 7 of the agreement provides that the protection and enforcement of intellectual property rights should contribute not only to the promotion of technological innovation but also to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare and which balances rights and obligations. Further, Article 8(1) provides that, when Members implement the TRIPS Agreement, they may adopt measures necessary to protect public health and nutrition and to promote the

[5] In relation to a patented product, exclusive right of making, using, offering for sale, selling, or importing the patented product for any of these purposes. In relation to patented process, exclusive right of using the patented process, offering for sale, selling, or importing for these purposes.

[6] The implication of such data protection is that for the specified year of protection, no other drugs manufacturer can compete with the applicant for approval of marketing rights, unless they independently conduct the same tests, which is a time consuming process. In a sense this protection confers a kind of absolute monopoly in favour of applicant.

public interest in sectors of vital importance to their socio-economic and technological development, provided such measures are consistent with the provisions of the Agreement. Still further, Article 27.2 [7] recognizes the conflict between intellectual property and public health when it ambiguously states that a patent is not required for an invention, product, or process which is necessary to protect public health. It has been argued that under this Article such medicines as drugs for AIDS should not be subject to TRIPS at all since these products are necessary to protect public health, however, rejoinders have been voiced arguing that 27(2) simply means that dangerous products should be excluded from patentability.

Similarly, Article 30 provides for granting members the right to legislate for limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. Some commentators assert that considering the administrative compliances involved in application of Article 31, even with the Article 31(f) solution implemented, compulsory licensing of pharmaceuticals for export to needy developing countries will rarely, if ever, occur. It would have been more feasible therefore, to have exporting countries make the one-off amendments to their domestic patent laws to enable the implementation of an Article 30 exception than to grant compulsory licence under Article31. However, it is not apparent how an Article 30 exception, consistently invoked with respect to pharmaceuticals, is to be reconciled with the Article 27.1 requirement that "patents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology" of the invention.

Above all and most importantly, TRIPS Article 31 permits Members to grant compulsory licenses for patented products and processes under limited circumstances and upon satisfying certain conditions. Under a compulsory license, a government is empowered to allow the production of a patented product without the necessary permission from the patent holder. In terms of pharmaceutical products and public health, the aim of the practice is to allow countries to produce low-cost generic equivalents of the patented product in certain circumstances and under certain guidelines.

---

[7]Jessica J. Fayerman, The Spirit Of Trips And The Importation Of Medicines Made Under Compulsory License After The August 2003 Trips Council Agreement, 25 Nw. J. Int'l L. & Bus. 257 (2004)

Before the enactment of the TRIPs Agreement, virtually there being no international agreement[8] providing for harmonization of patent laws, as such countries were free to decide whether or not they want to protect a particular product or process under patent under their domestic legislation. This flexibility came in handy for the developing and least developed countries for addressing their public health needs in so far as the patent protection[9] for pharmaceutical products was virtually nonexistent in many poor, developing countries. In pre-WTO membership era, developing countries were able to avoid paying the exorbitant prices charged by multinational pharmaceutical companies by purchasing or manufacturing comparable generic products for a small percentage of the market price[10].

The TRIPS agreement introduced global minimum standards for protecting and enforcing nearly all forms of intellectual property rights, including those for pharmaceuticals. The agreement covers basic principles, standards and use of patents, enforcements. Members must provide patent protection minimum for 20 years from the filing date of a patent application, for any invention, including of a pharmaceutical product or process[11]

Transitional agreements: All WTO members were generally given one year time that is up to January 1996, to phase in these changes into their intellectual property rights or other laws and regulations. Developing and other countries in transition were given an additional four years, i.e. up to January 2000 and least developed countries ten years that is up to 2006, to do so. A further period of five years up to 2005 was given too developing countries to introduce product patent in field of technology excluded thus far in their patent laws.

TRIPS provides transitional period during which countries are required to bring their national legislation and practices into conformity with its provisions. TRIPS specifically recognize the economic, financial, administrative and technological constraints of the least developing countries. It therefore provides the possibility for further extension of the transitional period.

[8] Paris convention was there in place but unlike TRIPs it did not provide for common minimum standard of protection in all the member countries. The area was largely left to the discretion of member countries.
[9] An exclusive privilege granted by government to the patentee for a limited period of time for commercial gains in consideration of full disclosure of his invention.
[10] Karl Vick, African AIDS Victims Losers of a Drug War, Wash. Post, Dec. 4, 1999, at A1.
[11] http://commerce.nic.in/trade/international_trade_ip_trips4.asp

(3) INDIA'S TRIPS COMPLIANCE AND PATENT LAW:

India signed the WTO in 1995 and automatically became a signatory of the Agreement on trade related aspects of intellectual property rights (TRIPS) in 1995. Under its requirements India needed to amend its patent law subject to transitional allowances provided for developing countries under article 65, i.e., it needed to amend the law by 1st January 2005[12]. In order to make the Indian patent law, trips compliant, the following amendments were required:

- Extended patent to microorganisms
- Introduce TRIPS compliant compulsory licensing provisions
- Introduce product patents.
- Bring all inventions under patent coverage and extend the term of protection to 20 years.
- Remove discrimination between local production and importation.
- Shift the burden of proof in process patent related infringement proceedings to the defendant.

In 1999, the first amendment was made in the patents act 1970,introducing the requirements under the transitional arrangements through section5(2) of the act of 1970, which allowed product patent applications to be filed, while chapter IVA provided for the grant of Exclusive Marketing Rights(EMRs).

The patent act 1970 under went a second amendment through the patent (Amendment) Act2002. The Act of 2002 was introduced for bringing in conformity with all the substantive provisions of the trips agreement, barring those related to the introduction of product patents. The key issues included in the second amendment were, redefining patentable subject matter, extension of the term of the patent protection to 20 years and amending the compulsory licensing system.

The third amendment was brought by January1, 2005 to introduce product patent regime in areas, including pharmaceuticals that were hitherto covered by process patents.

[12] Article 65 of the trips agreement allow a grace period of five years to developing countries to implement the trips provisions in to their domestic laws and five more years to introduce product patents.

Compulsory licensing: Another protectionist aspect of the Indian law is the compulsory licensing system[13]. This is a system where the nation selects a firm to make the drugs and sell them at low cost. The patent holder is given a small royalty for the losses that he incurs. Compulsory licensing is allowed by TRIPS under Article 31, subject to twelve conditions that are put forth in the same Article.[14] Most importantly, before compulsory licensing is used, voluntary licensing must be sought for, and also, to impose compulsory licensing on a particular drug, there must be an established independent or judicial review. The Indian Patent Act provides that an application for the grant of compulsory licensing can be made only after three years from the date grant of the patent unless exceptional circumstances like national emergency or extreme emergency can be used to justify the grant of a license on a earlier date. Three broad grounds for the grant of the compulsory licensing have been spelt out thus:

(a) Reasonable requirements of the public with respect to the patented inventions have not been satisfied:

(b) The patented invention is not available to the public at a reasonably affordable price, and

(c) The patented invention is not worked in the territory of India.

---

[13] Compulsory licensing enables a government to license to a company, government agency or other party the right to use a patent without the title holder's consent. A compulsory license must be granted by a competent authority to a designated person, who should generally compensate the title-holder through payment of a remuneration. Compulsory licenses do not deny patent holders the right to act against non-licensed parties

[14] "Article 31 contains the following requirements:

(a) authorization for compulsory licensing must be considered on the merits;

(b) the licensee must have attempted to obtain authorization from the patent holder on reasonable commercial terms and that such efforts remained unsuccessful after a reasonable period of time had passed;

(c) the scope and duration of the compulsory license shall be limited to the purpose for which it was originally authorized;

(d) the use of the compulsory license shall not be exclusive;

(e) the use shall not be assignable;

(f) the compulsory license shall be authorized predominantly for the use of the domestic market of the Member authorizing the compulsory license;

(g) authorization for the compulsory license shall cease when the circumstances that necessitated its implementation no longer exist;

(h) the patent holder shall receive appropriate compensation for the use of the patent and such compensation shall be determined by taking into account the economic value of the license;

(i) the legal validity of any compulsory license scheme shall be subject to judicial review;

(j) the determination of appropriate compensation to be paid to the patent holder shall be subject to judicial review;

(k) anti-competitive practices by the patent holder shall be taken into consideration; and

(l) additional conditions shall apply where use is authorized to exploit the second patent which cannot be exploited without infringing another patent."

The Patent Act also sets out the circumstances under which "reasonable requirements of the public" would not have been met. Such circumstances would arise if the patent holder refuses to grant a license on reasonable terms, and which in turn, affects:

(i) development of new trade or industry in the country, and

(ii) establishment or development of commercial activities in India, and

(iii) development of the export market for a patented article manufactured in India

The provision under sec 84(7) clause (a) (iii) of the patent act relating to "a market for export of the patented article manufactured in India is not being supplied or developed" is adapted from the Doha round, which now allows the drugs manufactured under the compulsory licensing to be exported to countries which are unable to produce at a cheaper price. This provision is aimed at ensuring that India has the option to export the products that have been produced using the licenses from the patent holders. However, the act also stipulates that the relevant authority have to take into consideration four additional factors before the license can be granted.Royalty payment is a critical issue for the implementation of the compulsory licensing system as in provided in the patent act[15]Therefore, the TRIPS agreement, through the amendments of the patent act 1970 has changed the conditions which gave helped the in Indian pharmacy industry take into its roots.

DOHA ROUND: In November 2001, the member nations of the WTO met at Doha, Qatar to discuss certain ambiguities that existed in the TRIPS agreement and to reach a conclusion some of the more contentious issues such as compulsory licensing, public health and parallel trading. Many countries claimed that they were uncertain about the scope of these exceptions and that many of them had not implemented them because they were worried about the trade sanctions that might be imposed on them in case they interpreted the scope of these provisions wrong.[16] The Doha Conference reaffirmed the 'public health' exception, especially to further free access of medicines to all. Further, with respect to compulsory licensing, the Declaration said that the member nations are allowed to decide on their own as to what a 'national emergency' is or what constitutes 'circumstances of extreme urgency'.[17]

[15] Sec 90 of the patent act terms and conditions of compulsory licensing

[16] Nuno Pires de Carvalho, *The TRIPS Regime of Rights*, (London: Kluwer Law international, 2002), p. 257.

[17] Paragraph 5(c) of the Declaration reads:

(4) WTO TRIPS INDIAN CONTEXT;

India as a signatory to the WTO was given the mandate to change its legislations relating to intellectual property related legislation in compliance with TRIPS. In respect of patent Law, the TRIPS agreement provides a three stage time frame for developing countries to comply with the obligations. This provides:

(i) Introduction of a facility[18] ("*mail box*") from January 01, 1995 to receive and hold product patent application in the fields of pharmaceuticals and agricultural chemicals till January 01, 2005[19]. Further, on fulfilment of certain conditions, to grant exclusive marketing rights (EMR) for a period of five years or till the product patent is granted or patent application is rejected, whichever is earlier.

(ii)Compliance, from January 01,2000, with other obligations of the trips agreement, namely, those related to rights of patentee, term of patent protection, compulsory licensing, reversal of burden of proof, etc.; and

(iii) introduction of product patent in all fields of technology from January 01,2005.at this stage, the application for product patents filed and held in mail box from January 01,1995 area also to be taken up for examination. India has complied with the obligations in respect of the above in the following manner –

(a) in respect of obligations effective from January 01, 1995, India has amended the Patents Act 1970 through the patents (Amendment) Act, 1999 effective respectively from January 01, 1995.This act provides for a "mail box" to

---

"Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."

[18] the Mail-Box (mostly for agrochemicals and pharmaceuticals) created under the first amendment to the Indian Patent Act in 1999, effective from January 1, 1995. With product patent law in place under the amended Act of 2005, the Patent Office has opened the Mail-Box and taken up scrutiny of applications filed before January 1, 2005. However, it has decided not to process those applications on which the word "WTO" is not marked.

[19] The developing countries like India which was not providing product patent will process the patent applications that have collected in their "mailbox" since January 1, 1995. The drugs that are the subject of "approved" mailbox applications will be patented for the remainder of the twenty-year term from the filing of their mailbox application. The effect of this change perhaps would be that those medicines which were considered generic earlier in these countries may no longer be the same as the "mailbox" applications would certainly cover a large number of such drugs which were earlier not patented. As per the 1999 amendment to the Patent Act, the applications for new patents were accepted and put away in a mailbox, to be examined in 2005. these applications are known as "mail box applications'.

receive and hold product patent applications in the field of pharmaceuticals and agricultural chemicals and also on fulfilment of certain conditions specified in the law, for grant of exclusive marketing rights (EMRs). It has also been provided in the law that product patent applications received shall not be referred for examination till december31, 2004.

(b) In respect of obligations from January 01, 2000 India has further amended the patent act through the patents amendment act 2002, passed by parliament in may2002 and notified in June 2002. The act has been effective from May 20, 2003.

(c) The third amendment to the patent act was promulgated as ordinance in December 2004 and later tabled in both the houses which was passed as patent amendment act 2005 in March 2005.

(5) IMPACT ON INDIAN PAHRMACEUTICAL INDUSTRY:

The pharmaceutical industry is one of the most profitable industries in the world, accounting profit margin in tune of 32% of sale. The Indian pharmaceutical industry comprises of two groups: the multinational corporations (MNCs) and domestic (entirely Indian owned), the second category has command over the share in the market. The wholly Indian owned domestic pharmaceutical sector is itself highly fragmented. A number of large indigenous companies engage in some original research and development along with generic drug manufacture. Majority of the Indian pharmaceutical companies are uniquely positioning itself as a leader in low cost research and development.

The advent of product patent regime in the field of pharmaceutical has brought in new challenges for the booming Indian pharmaceutical industry. These developments have affected India's status as a leading exporter of cheap, generic drugs in the world. Indian pharmaceutical company Cipla's role in exporting cheap AIDS drugs to Africa causing a major price war is well known.[20] However, with the coming of the TRIPS arrangement, there

[20] Cipla, one of India's largest pharmaceutical companies started selling primary AIDS drugs to Africa at the price of $600 per year, as opposed to American companies that sold these same drugs for approximately $10,000-$15,000 per year. Many other companies slashed their prices to compete with Cipla, leading to an all-round price decrease in AIDS drugs in Africa. (Gathered from the researcher from his interview with Mr. Ravi Vishwanath, General Manager, Orchids Pharmaceuticals.

was a need for India to amend its laws to keep up its international obligations. This move by India to enact its 2005 amendment to the Patents Act has been a reluctant one, taken not by the force of economic logic, but by the fear of trade sanctions imposed by the West.

The Amendment changes India's position on TRIPS with respect to one main Issue. In keeping with its obligations under TRIPS, India will allow product patents for pharmaceuticals, unlike earlier when only process patents for the same were allowed.[21] This is a huge blow for the generic drug manufacturers, as there are many Indian pharmaceutical companies that have thrived on the manufacture of cheaper versions of existing drugs.[22] However, the bigger issue in this case is of access to essential medicines for the common man in India – the problem of public health

The Indian pharmaceutical industry is highly fragmented with numerous small players. The small to medium sized companies, which have been making copies of generic formulations fear that they will not have sufficient capital or technology to invent new drugs that can be patented. The access to local firms to patented technology will become more difficult because of the enforcement of the patent holders bargaining position through investment in research and development. The larger firms, barring a few, on the other side are in full support of patents, which they hope will attract foreign investment, and thereby stimulate joint ventures and research.

Introduction to the product patent system replacing the existing process patent system will create impediments to develop and introduce new patented product. One danger in compulsory licensing is that it will discourage further the commercial R & D necessary to new drugs to fight global epidemics. Another danger is that compulsory licensing can be used to seek price levels below what a given national market is capable of supporting, further concentrating the burden of financing pharmaceutical innovation on developed country consumers and discouraging development of drugs targeted at the disease burdens of countries using compulsory licenses..

[21] S. 5 of the Patents Act that dealt with inventions for which only process was patentable was specifically deleted by the 2005 Amendment Act.

[22] Research has shown that Indian Pharmaceutical companies spend 1% of their profits on research and development as compared to foreign companies that spend an average of 15-18% of their profits.

(6) NOVARTIS CASE[23]:

New patent law under section 3(d) prohibited the patent of derivatives of known substances, unless such derivatives display significantly enhanced efficacy. This provision reflects a strong resentment towards ever-greening[24] of pharmaceutical patents. This section permits the patenting of a derivative that provides an enhancement of the known efficacy of a known substance. But it was not clear as to what kind of data will be required to establish efficacy. The ambiguity given in the section gave the Indian patent office a great deal of discretion.

Novartis had challenged the validity of Section 3(d) [25]of Patent Act, 1970 in Chennai High Court, which is intended to prevent ever greening of existing drugs, after its patent plea for a new use for its cancer drug, Gleevec was rejected by the Indian patents office in January last year. The section states that patents would not be given for new forms, uses or minor modifications of existing drugs unless they differ significantly with regard to efficacy. Two Writ Petitions were filed by Novartis in High Court of Madras praying to issue a writ of declaration that section 3(d) of the Patents Act, 1970 as substitute by the Patents (Amendment) Act, 2005 is non-compliant with the TRIPS Agreement and/or is unconstitutional being vague, arbitrary and violative of Article 14 of the Constitution of India and consequently to direct the Patent Office, Chennai to allow the patent application filed by the petitioner.

The Division Bench of the Madras High Court held that s. 3(d) is TRIPS compliant. It said that when TRIPS mandates such a comprehensive dispute settlement mechanism, then the court may not go into the validity. The court also held that the provision was added to curb ever greening. Art. 14 may be invoked only when it is shown that in the exercise of a

---

[23] *AG represented by it's Power of Attorney Ranjna Mehta Dutt vs. Union of India*(UOI) through the Secretary, Department of Industry, Ministry of Industry and Commerce,(2007) 4 MLJ 1153.

[24] Ever greening refers to the attempts by the owners of the pharmaceutical patents to effectively extend the terms of those patents by obtaining related patents on modified forms of same drug.

[25] "(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation.-For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;".

discretionary power there is a possibility of a real and substantial discrimination and such exercise interferes with the fundamental right guaranteed by the Constitution8.

The High Court said that it was not the proper forum to decide whether Section 3 (d) is in conformity with India's WTO obligation. I must ask why it thought so. It is the duty of the High Court to make the Government of India conform to the law. The law is not only law made by Indian legislatures. It also includes international law that India has accepted. Such law is part of the law to which Indians must conform, and that includes the government. I believe the High Court was mistaken in refusing to enforce such law.

CONCLUSION:

The pharmaceutical industry is one of the most profitable industries in the world. The Indian Pharmaceutical Market (IPM) is growing at a CAGR of 13% over the last four years. The value of Indian Domestic Retail Pharmaceutical Market now stands around Rs.31, 038crores with annual growth of 13% excluding hospital sales and exports. In the last few years market of pharmaceutical industry achieved a turnover of around Rs. 31038 Cr. with a growth of 13%.Today Indian Pharmaceutical Market has around 27,000 registered brands, 33% brands of which are launched before 2000, which contributes to 62% value. Nowhere in the world, has such a scenario existed where contribution of old products is so high

During the early 1990s, markets were opened by removing restrictions on imports and in 1994 licensing was abolished for producing bulk drugs and formulations. Other than this FDI restrictions into this sector have been modified to allow 74% foreign equity through the automatic route. More favourable conditions are to follow in future particularly for MNCs as soon as 'Product Patents' and 'Exclusive Marketing Rights' (EMRs) are permitted. The advent of product patent regime in the field of the pharmaceutical industry (as per compliance of TRIPS) has brought in new challenges for the booming Indian Pharmaceutical Industry.

The Indian pharmaceutical industry is highly fragmented with numerous small players. The small to medium sized companies, which have been making copies of generic formulations fear that they will not have sufficient capital or technology to invent new drugs that can be patented. The access to local firms to patented technology will become more difficult because of the enforcement of the patent holders bargaining position through investment in Research and Development. In a situation like this, there is a lot of speculation that the

indigenous companies that have been the mainstay of the Indian pharmaceutical industry over the past couple of decades finally becoming a formidable part of Indian economy and a major source of foreign income might be facing uncertain market conditions in the future. It may also come down to a state where most of the small scale companies have to close down, with the multinational companies dominating and monopolizing the industry once again.

The larger firms barring few, on the other side are in full support of the patents, which they hope will attract foreign investment, and there by stimulate joint ventures and research. The Indian major pharmaceutical have already started investing in research and development.

Introduction to the product patent system replacing the existing process patent system will create impediments to develop and introduce new patented products in the market. In present era, R and D initiative, cost control and Market efficiencies will assume more importance along with partnership and along with partnership and alliances in the area of research marketing licensing and production.

The cost of drugs is going to increase when MNC's and research based Indian companies start launching their patented molecules. The drugs used in the treatment of diseases like cancer and the AIDS pandemic may become expensive.

Indian companies need to attain the right product-mix for sustained future growth. Core competencies will play an important role in determining the future of many Indian pharmaceutical companies in the post product-patent regime after 2005.

The Indian pharmaceutical industry also needs to take advantage of the recent advances in biotechnology and information technology. The future of the industry will be determined by how well it markets its products to several regions and distributes risks, its forward and backward integration capabilities, its R&D, its consolidation through mergers and acquisitions, co-marketing and licensing agreements.

It is frequently argued by proponents of the TRIPs accord that India, once new, WTOconsistent, intellectual property laws are in place, will be very attractive as a location for R&D because, by locating in India, firms can take advantage of a sizable pool of low-cost and technically skilled labour to escape part of the great expense of drug discovery and development.

One danger in compulsory licensing is that it will discourage further the commercial R & D necessary to new drugs to fight global epidemics. Another danger is that compulsory licensing can be used to seek price levels below what a given national market is capable of

supporting, further concentrating the burden of financing pharmaceutical innovation on developed country consumers and discouraging development of drugs targeted at the disease burdens of countries using compulsory licenses.