The Influence of TRIPS Compliant Patent Laws on Indian Pharmaceutical Industry

Rupesh Rastogi
Assistant Prof., Dept. of Business Administration, Azad Technical Campus, Lucknow
Virendra Kumar
Assistant Professor, Azad Institute of Pharmacy & Research, Azad Technical Campus, Lucknow

Abstract

The first legislation in India relating to patents was the Act VI of 1856. The Indian Patents and Design Act, 1911 (Act II of 1911) replaced all the previous Acts. The Act brought patent administration under the management of Controller of Patents for the first time. After Independence, it was felt that the Indian Patents & Designs Act, 1911 was not fulfilling its objective. Various comities were constituted to recommend, framing a patent law which can fulfill the requirement of Indian Industry and people.

The Indian Patent Act of 1970 was enacted to achieve the above objectives. The major provisions of the act, provided for process, not the product patents in food, medicines, chemicals with a term of 14 years and 5-7 for chemicals and drugs. The Act enabled Indian citizens to access cheapest medicines in the world and paved a way for exponential growth of Indian Pharmaceutical Industry. TRIPS agreement, which is one of the important results of the Uruguay Round, mandated strong patent protection, especially for pharmaceutical products, thereby allowing the patenting of NCEs, compounds and processes. India is thereby required to meet the minimum standards under the TRIPS Agreement in relation to patents and the pharmaceutical industry.

India's patent legislation must now include provisions for availability of patents for both pharmaceutical products and processes inventions. The present paper examines the impact of change in Indian Patent law on Pharmaceutical Industry.

Key Words: Intellectual Property, Patents, TRIPS, NCEs

I. Introduction

The first legal provisions to protect works of human intellect can be traced back to 500 BCE in ancient Greece, where provisions were made to share profits on inventions, with the inventor for one year. Later on other countries also made laws for protection of human intellect. Modern intellectual protection laws include provision for protection of copyright, design, patent etc. Intellect protection is necessary and debatable for Pharmaceutical Industry because it is human intellect intensive industry. Foundation of the industry lies on finding new and efficient molecules which can cure diseases and can have least harm to other bodily organs and system. If protection of intellect for pharmaceutical industry becomes too tight it can harm the citizens of poor country because, it adversely impacts their access to new and effective molecules. And if patent control laws gets loose, then the incentive for developing new drug molecule will not be available which costs at least 4 billion dollar.

Patent Act in India is more than 150 years old. The Patent Act was first enacted in India in the year as Act VI of 1856 under the rule of British and it was subsequently amended several times. The objective of this legislation was to encourage inventions of new and useful objects and to induce inventors to disclose secrets of their inventions. In 1872 "The Patterns and Designs Protection Act" was introduced. This Act was further amended in 1883 (XVI of 1883) to introduce a provision, to protect novelty of invention, which may be disclosed prior of application for their protection. A grace period of 6

months was provided for filing such applications after the date of opening of such novels, was allowed under the Act. The Patents and Designs Act 1911 of India had provision of Product patent for drug molecules also.

After independence a committee under Chairmanship of Justice (Dr.) Bakshi Tek Chand, a retired Judge of Lahore High Court, in 1949 was constituted to review the patent law for suggesting suitable amendments in the patent system to protect national interest. The committee recommended that Patents Act should be amended to ensure that food, medicine, surgical and curative devices are made available to the public at the cheapest price by giving appropriate compensation to the patentee. Another committee headed by Justice N. Rajagopala Ayyangar was appointed in 1957 by Govt. of India to find ways to protect the National interest and also to examine and review the Patent law. The Patent Bill, 1965 was based mainly on his recommendations incorporating a few changes, in particular relating to Patents for food, drug, and medicines. The bill was passed by Parliament and then Patents Act 1970 came into force on 20th April 1972 along with Patent Rules 1972. The Patent Act 1970, made provision for process patents for pharmaceuticals and agro-chemical products and for a short period i.e. 7 years for pharmaceutical, agro chemical and food products and 16 years for other categories.

This provision was intended to help poor people of India who were not in a position to buy exorbitantly priced drugs produced by pharmaceutical giants. This also greatly helped the growth of a strong local generic drug industry, which produced the same drugs as the MNCs at relatively low prices. India, since 1970, had a Patent law that was proclaimed by many as a model for other developing countries. One of the important factors that contributed to growth of Indian pharmaceutical industry was that, 'the Patent

Act 1970 did not allowed monopoly rights in area of drugs and agro-chemicals'. [Sengupta Amit, "Jeopardising the lives of millions"]

India became a member country of WTO in 1994. With accession at WTO, India was compelled to honour TRIPS agreement, which was a part of WTO agreement. The TRIPS agreement was one of the important results of the Uruguay Round, mandated strong patent protection, especially for pharmaceutical products, thereby allowing the patenting of NCEs, compounds and processes. The purpose of TRIPS agreement was to establish a uniform set of rules across the globe that would provide adequate standards of protection for intellectual property and provide greater predictability and stability in international economic relations.

Patent reforms can affect the pharmaceutical industry in two ways by presenting barriers to imitation, thereby lowering performance or by stimulating licensing, thus enabling better performance. Moreover the changes in Indian pharmaceutical industry in past have closely mirrored the evolving intellectual property regime changes in India. Through this paper attempt has been made to examine the resultant changes of Indian pharmaceutical industry with 'new' patent law. Absence of strong patent protection for pharmaceuticals in country has discouraged the industry from conducting original drug discovery research. Developing countries like India, China, Brazil, etc., have traditionally provided weak patent and other IPR protection. (Sajeev Chandran et. al. 2005).

The Indian pharmaceutical industry is a successful, highly-technology-based industry that has witnessed consistent growth over past three decades, in spite of it operating under severe price competition and government price control. There are around 465 main bulk drugs used in India and out of which, around 425 bulk drugs are totally manufactured in

ISSN: 2249-1066, Vol. 4, No. 1, June, 2014

India and does not include any imports. Of the remaining 40 bulk drugs, 30 are totally imported, whereas around 10 are partially imported. Out of the total 425 bulk drugs manufactured in India, around 60 are also partially exported. (Nair 2002, & Jha 2003)

II. Comparison of India's Patent Act and TRIPs

Indian Patent Act of 1970	TRIPs
Only process not product patents in food, medicines and chemicals.	Process and product patents in almost all fields of technology
Term of patents 14 years and 5-7yrs in chemicals and drugs respectively.	Term of patent to be 20 years
Compulsory licensing and license of rights.	Limited compulsory licensing, no license of rights.
Method of agriculture, Process for medicinal, surgical or other treatment of human or similar treatment of animals and plants to render them free of disease or increase economic value of products were excluded from patent.	Almost all fields of technology were covered under patentable. Only plant varieties were excluded from patentability. Though debate regarding some areas in agriculture and biotechnology continued.
Government was allowed to use patented invention to prevent scarcity.	Very limited scope for governments to use patented inventions.

Source: Adapted from Patent Office Technical Society, Indian Patent Act, 1970 and Rules, 1991 and MVIRDC, GATT Agreements: Results of the Uruguay Round, World Trade Centre, January 1995

III. Research Objectives

1. Study of process patent regime.
2. Study of product patent regime.
3. Study of the Impact of Process Patent Regime to Product Patent Regime on Indian Pharmaceutical Industry.

Sub Objectives

1. Study of the growth and future business prospective of Indian Pharmaceutical Industry in product patent regime.
2. Study of the behavior of Pharmaceutical Industry in PPR.
3. Study of the effect of PPR on R&D/ Innovations.
4. Study of the effect of PPR on Business Model

IV. Indian Pharmaceutical Industry in Pre-TRIPS Era

The Patents and Designs Act 1911 of India had provisions for patenting all known and possible processes of manufacturing a drug, besides patenting the drug itself. Foreign multinational corporations (MNCs) took complete advantage of this provision. Western MNCs controlled between 80 and 90 percent of the market primarily through importation. Approximately 99 percent of all pharmaceutical products under patent in India at the time were held by foreign companies. And domestic Indian drug prices were among the highest in the world Multinational corporations imported bulk drugs, from their own home countries and produced formulations in India. They also patented heavily in the country. The indigenous firms were legally prevented from manufacturing, most of these new drugs introduced by the transnational corporations (TNCs) during the life of patents secured by the latter, i.e., for 16 years, which could be extended to a maximum of another 10 years if the working of the patent had not been sufficiently remunerative to the patentee. The domestic firms were also forbidden from processing a patented drug into formulations or importing it.

Indian Patent Act of 1970 changed the scenario. It enabled Indian drug producers to become experts in 'reverse engineering' and increased its supply of less expensive copies of the world's best-selling patent protected drugs. India's pharmaceutical industry grew

ISSN: 2249-1066, Vol. 4, No. 1, June, 2014

and prospered in a highly regulated environment with government's price control on a significant number of formulations and bulk drugs. Over last 30 years, India's pharmaceutical industry had evolved from almost nonexistent to a world leader in production of high quality generic drugs. India has garnered a worldwide reputation for producing high quality, low cost generic drugs. Because of the changed law, Indian Pharmaceutical companies were able to supply cheapest generic medicines to both domestic and international market. Today Indian pharmaceutical industry is one of the developing world's largest and most developed, 4th ranked in terms of production volume and 13th in domestic consumption value.(National Pharmaceutical Policy, 2006, Department of Chemicals 2 and Petrochemicals, Government of India, Dec. 28, 2005.)

V. Indian Pharmaceutical Industry in Post TRIPS Era

The World Trade Organization (WTO) came into effect in 1995. Being a founder member of WTO, India automatically became a signatory of TRIPS agreement. The main elements of change in Indian patent system were:

- Enforcement of product patent protection in all branches of technology, including drugs.
- 20 years of protection instead of 14 or 7 in the case of Indian patent Act.
- No discrimination between imported and domestic products.
- Accommodate compulsory licensing.

TRIPS agreement opened up the prospects of re-introduction of product patent in many countries. However India was given ten years (till end 2004) of transition period to make their patent policies, TRIPS compliant. This window enabled leading Indian pharmaceutical majors to shift their focus from reverse engineering to discovery of new chemical entities. Other avenues exploited for survival and growth were contract manufacturing, contract research, inorganic growth through mergers and alliances. In

addition, as levels of disposable income rose, demand for new "lifestyle" pharmaceutical products and preventative medicines also grew in India. India also became one of the hotspots of healthcare tourism. All these factors encouraged local - based companies including , Glenmark, GVK Bio, Nicholas, Sun, Suven, Torrent and Wockhardt, amongst others, to increase focus on research, which industry leaders such as Dr. Reddy's and Ranbaxy were doing from long time.

Table 1: India's Pharmaceutical Industry in 2005

Share of global sales	Value 1%, Volume 8%
Global ranking	4th in volume, 13th in value
Domestic market	$5.3 billion
Exports	$3.7 billion
Imports	$985 million
Bulk drug production	$2.1 billion
Employment	5 million direct, 24 million indirect
Capital investment	$1.2 billion
Production costs	Among the lowest in the world, estimated to be 70% less than the west.

Source: OPPI

VI. Present Status

Indian pharmaceutical industry became one of the fastest growing segment of Indian manufacturing sector. The pharmaceutical industry has experienced a growth rate of

ISSN: 2249-1066, Vol. 4, No. 1, June, 2014

12%, with the annual turnover of sector crossing US$ 11 billion, in 2005-0614. Globally, Indian pharmaceutical industry ranks 4th in terms of volume with a share of 8% in world pharmaceuticals market. In terms of value, Indian pharmaceuticals industry ranks 14th.(Indian pharmaceutical industry :Surging globally Occasional paper no. 119 Export-Import Bank of India)

The Indian pharmaceutical industry is growing at about 8 to 9 percent annually according to "A Brief Report Pharmaceutical Industry in India," published in January 2011. The Pharmaceutical industry in India meets around 70% of country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectables. There are approximately 250 large units and about 8000 Small Scale Units, which form the core of pharmaceutical industry in India (including 5 Central Public Sector Units). The annual turnover of the Indian Pharmaceutical Industry is estimated to be about Rs. 1, 04,944.351 Crores during the year 2010-11.

McKinsey & Company's report, "India Pharma 2020: Propelling access and acceptance, realizing true potential," predicted that Indian pharmaceuticals market will grow to US$55 billion in 2020; and if aggressive growth strategies are implemented, it has further potential to reach US$70 billion by 2020. Market Research firm Cygnus' report forecasts that the Indian bulk drug industry will expand at an annual growth rate of 21 percent to reach $16.91 billion by 2014. The report also noted that India ranks third in terms of volume among the top 15 drug manufacturing countries.

Table 2: Growth in Indian Pharmaceutical Industry: Export & Domestic Growth (Rs. in cr)

Year	**Exports**	**Growth%**	**Domestic**	**Growth%**	**Total**	**Growth%%**
Mar 2006	21230	23.23	39989	17.17	61219	19.21

Mar 2007	25666	20.89	45367	13.45	71033	16.03
Mar 2008	29354	14.37	50946	12.30	80300	13.04
Mar 2009	39821	35.66	55454	8.85	95275	18.65
Mar 2010	42154*	5.86	62055	11.90	104209	9.38

Source: Annual Report 2011-12, Government of India, Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals

Table 3: Indian Pharma – Domestic Growth Expectations

Company	FY12 Domestic Growth	Earlier Growth Estimates
Cadila	12%	15%
Cipla	10%	15%
Dr. Reddy's	10%	15%
Glenmark	16%	16%
IPCA	10%	17%
Lupin	19%	19%
Ranbaxy	12%	12%
Sun Pharma	15%	18%
Torrent	12%	12%
Unichem	5%	9%
GSK	13%	13%
Pfizer	14%	14%

Source: Emkay Research

Table 4: International sales on consolidated basis

Pharma Industries	Consolidated Net Sales	International Sales	Exports as % of Net Sales 2010-11
Ranbaxy Labs	8960.77	6771.74	75.6

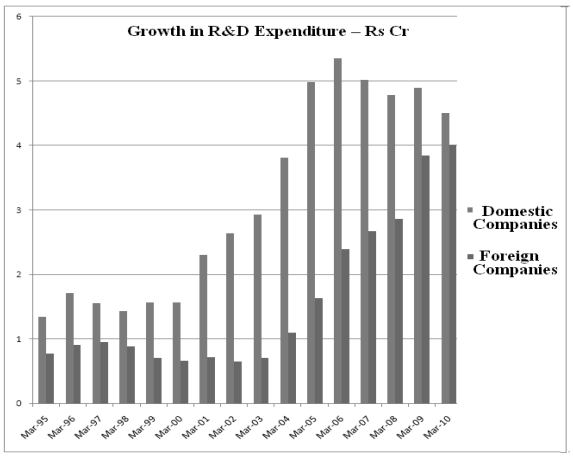
ISSN: 2249-1066, Vol. 4, No. 1, June, 2014

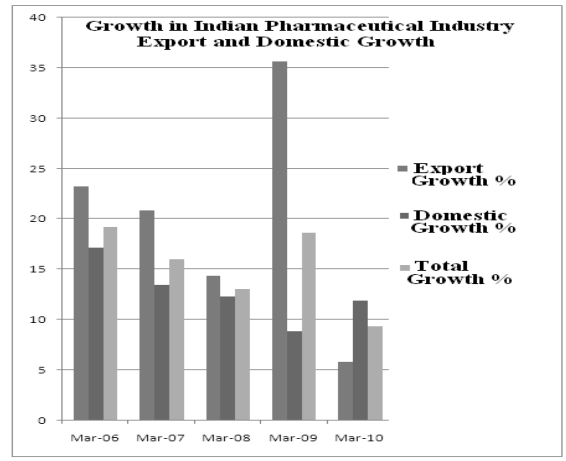
Dr Reddy's Labs	7236.80	5940.70	82.1
Lupin	5706.82	3983.08	69.8
Cipla	6130.31	3361.49	54.8
Sun Pharma	5721.43	2898.20	50.7
Wockhardt	3751.24	2709.91	72.2
Jubilant Lifescience	3433.40	2369.11	69.0
Cadila Healthcare	4464.70	2288.70	51.3
Biocon	2300.52	1956.79	85.1
Glenmark Pharma	3089.59	1955.83	63.3
Stride Arcolab	1695.84	1637.67	96.6
Plethico Pharma	1535.20	1367.22	89.1
Piramal Healthcare	2509.86	1280.58	51.0
Divi's Labs	1307.11	1204.95	92.2
Aurobindo Pharma	4381.48	1112.06	25.4
Torrent Pharma	2121.97	1101.57	51.9
Ipca Laboratories	1882.54	1025.18	54.5
Dishman Pharma	990.84	911.56	92.0
Orchid Chemicals	1781.79	725.85	40.7
Shasun Chemicals	799.42	676.78	84.7

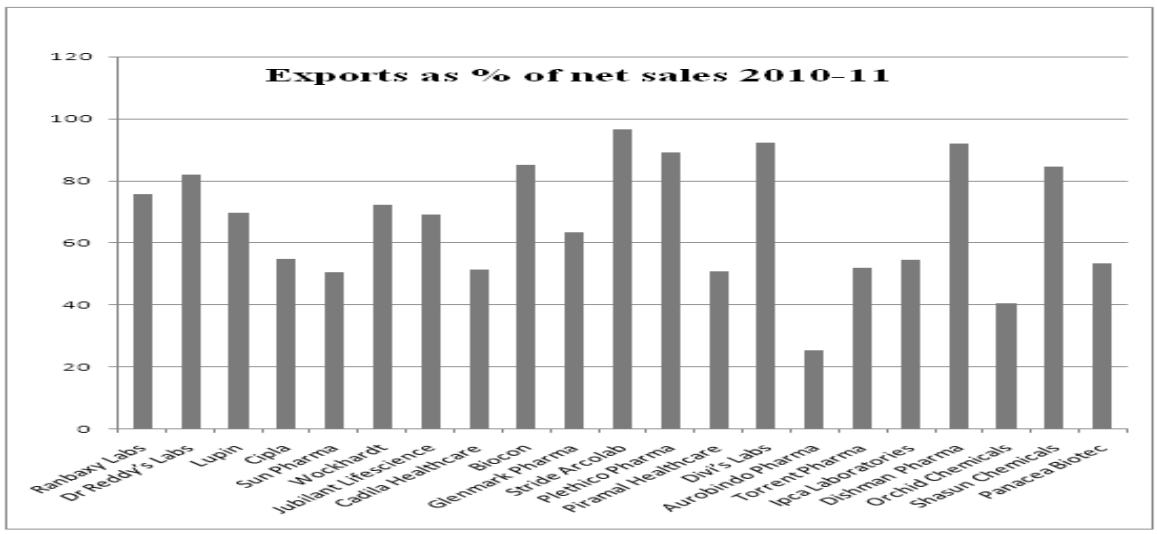
Panacea Biotec	1143.78	610.44	53.4

Source: Annual Report 2011-12, Government of India, Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals

VII. Data Analysis and Discussion







ISSN: 2249-1066, Vol. 4, No. 1, June, 2014

Analysis of data reveals following facts:

1. Since March 1995 Indian Pharmaceutical companies have continuously increased their expenditure on research and development activities and are spending more as compared to foreign companies and multinational companies.
2. After the implementation of TRIPS compliant patent laws, growth rate of export has fallen from March 2006 to March 2008.
3. The domestic growth rate of Indian Pharmaceutical Industry has declined from March 2006 to March 2008.
4. The total growth rate of Indian Pharmaceutical Industry has declined from March 2006 to March 2008.

VIII. Conclusion

The negative impact of TRIPS Agreement on Indian pharmaceutical industry does not seem to be too deplorable in the short run. Due to the provision of transitional period of 10 years, there was only a minimal effect until 2005. There had been challenges before Indian pharmaceutical industry started investing in basic R&D from the execrable level of less than 2% of total revenue to the world level of 8-10%. The results indicate that, larger companies had initiated activities, to increase investment in R & D and applications for process and product patents.

Small or medium scale units had started improving the quality of production to meet international standards and face competition in the generic market and also to enhance exports of their products. Indian pharmaceutical companies has also benefitted from the availability of cheap and abundant skilled work force which has resulted in lower cost of drug discovery and R&D in India. India can also become hub of R&D for multinational pharmaceutical companies due to the availability of cost-effective and skilled manpower.

Indian companies have also been benefitted from TRIPS provision which provides for non retrospective patenting of drugs in India that are already in the market or covered by existing patent applications elsewhere.

References

[1] Agrawal Pradeep & P. Saibaba (2001), 'TRIPS and India's Pharmaceutical Industry', Economic and Political Weekly, 36 (39).

[2] Arora Kishan (2007), the Patent Act, 1970 (39 of 1970) 1-4 (New Delhi: Professional Book Publishers Pg 39.

[3] Barton, John H. (2001), 'Differentiated Pricing of Patented Products', WHO Commission on Macroeconomics and Health, at http://cmhealth.org/cmh-papersandreports.htm.

[4] Bhusnurmath, Mythili (2003), 'Doha to Cancun, Fingers Crossed', The Economic Times, July 21, Ahmadabad Edition, p.8.

[5] Ghai Damanjeet (2010), Patent Protection and Indian Pharmaceutical Industry. Int. Jour. of Pharma. Sci. Review and Res., Vol- 3, Issue 2, pp- 43

[6] Ghai Damanjeet (2010), Patent Protection and Indian Pharmaceutical Industry, International Journal of Pharmaceutical Sciences Review and Research Vol-3, Issue 2, p.p. 43-48.

[7] Jha S K (2003), Intellectual property rights and globalization of the pharmaceutical industry, Pharma Times, 35(5), pp.13-22

[8] Keayla, B.K. (1998), Conquest by Patents: TRIPs Agreement on Patent Laws, Impact on Pharmaceuticals and Health for All, Centre for Study of Global Trade System and Development, New Delhi. Financial Times, 4 January, p18

[9] Nair Gopikumar G. (2008), Impact of TRIPS on Indian pharmaceutical industries. Jour. of Intellectual Property Rights. Vol-13, pp 432-441

[10] Nair M D (2002), An industry in transition: The Indian pharmaceutical industry, Journal of Intellectual Property Rights, 7(5), pp. 405-415

[11] Nirmal.B. C. (2007), "Indian Pharmaceutical Industry and the New Patent Regime", the Pharma Review, pp 63.

[12] Prasad G C (2005), Move to block patent holder from charging differential premiums, The Economic Times. 2 February. 2005

[13] Sajeev Chandran, Archna Roy and Lokesh Jain (2005), Implications of New Patent Regime on Indian Pharmaceutical Industry: Challenges and Opportunities. Journal of Intellectual Property Rights: Vol. 10, pp. 269-280

[14] Sengupta Amit, "Jeopardising the lives of millions". Financial Express, March 21, 2005

[15] www.cci.gov.in/images/media/.../NaveenDahiyaROUGHDRAFT.pdf.(Indian Patent Act, 1970 and Rules, 1991 and MVIRDC, GATT Agreements: Results of the Uruguay Round, World Trade Centre, January 1995)

[16] pharmaceuticals.gov.in/annualreport2012.pdf. (Annual Report 2011-12, Government of India, Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals)

[17] www.niperahm.edu.in/faculty-cv/dr-sheetal-anandjiwala.html. (Shrivastava Anshu, 2011). Report on India's Pharmaceutical Industry)

[18] www.igidr.ac.in/pdf/publication/WP-2003-006 (Das Keshab (2003), The Domestic Politics of TRIPs: Pharmaceutical Interests, Public Health, and NGO Influence in India Gujarat Institute of Development Research Ahmadabad ,India)

[19] www.ictsd.org/downloads/2008/06/cs_lall.pdf (Lall Sanjaya, (2003) Indicators of the relative importance of IPRs in developing countries, Forthcoming in Research Policy)

[20] www.ipo.org/wp-content/.../Whitepaper-PatentprocurementinIndia.pdf (Patent Act 1970, supra note 3, section 135)

[21] www.nber.org/reporter/spring03/patents.html (Lanjouw J. O. (2002), Intellectual Property and the availability of pharmaceuticals in poor countries, Center for Global Development Working.)

[22] www.shodhganga.inflibnet.ac.in/bit stream/10603/9145/.../11_chapter%205.pd. (Joshi Hemant N. (2005)"Analysis of the Indian pharmaceutical company with Emphasis on Opportunities in 2005")

[23] www.usitc.gov/publications/332/working papers/EC200705A.pdf (National Pharmaceutical Policy, 2006, Department of Chemicals 2 and Petrochemicals, Government of India, Dec. 28, 2005).

ISSN: 2249-1066, Vol. 4, No. 1, June, 2014