TRIPS AND INDIA: THE TRANSFORMATION IN THE INDIAN PATENT REGIME

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ABSTRACT

The amendment act of 2005 in the Indian Patents Act was brought as a result of India ratifying the TRIPS agreement. Tremendous change in Indian Patent regime was done after the introduction of TRIPS Agreement. The author, in this article, has made efforts to bring forth such changes by comparing the pre and post trips era in the Indian Patent Regime and also discussed at length various provision brought by the TRIPS Agreement. At last, the author has tried to throw some light upon problems related to TRIPS agreement and also offered solutions.

Keywords**:** *Amendment, TRIPS Agreement, Indian Patent Regime.*

AN INTRODUCTION TO THE TRIPS AGREEMENT

Patent is a grant of exclusive rights by the government to the inventor to reap the benefits of his/her invention by excluding others to exploit his innovation by manufacturing, selling or using the patented product. The jurisprudence behind this form of intellectual property right is to encourage innovations and reward the inventor by giving him exclusive rights. The basic principle underlying the grant of patents is that the invention must be new and useful and capable of industrial application.[i]

The TRIPS agreement provided among other implications, norms and certain standards relating to seven broad categories of Intellectual Property Rights. They were copyrights, trademarks and product patents in all areas of technology.[ii] These provisions were to be complied by all the members of World Trade Organization (WTO) starting January 1, 1995.[iii] However, the same agreement provided for a transition period of 10 Years for its member developing countries, which meant the developing countries could incorporate Product Patent Protection by enacting a bill in their respective legislature by January 1, 2005.[iv] Accordingly, as per the provisions of TRIPS, the patent would provide the rights of production and marketing solely on the inventor in all the countries who are member of WTO for 20 years.[v]

INDIAN PATENTS ACT AND THE TRIPS AGREEMENT

As a matter of fact, India already used to grant Product patents for many of the products available.[vi] However, in regards to the pharmaceuticals and agro-chemicals, the Indian Patent Act 1970 only recognizes Process Patents while on the other hand, TRIPS Agreement required granting of Product as well as Process patents in all fields. Due to this requirement, India was required to change its Patent Laws to accommodate the TRIPS provisions. When the consequences were studied and looked at, it seemed politically very inappropriate and difficult to enact keeping in mind the effects of the same on Indian Consumers. This was then followed by a complaint that was filled by the United States to the WTO based on which the WTO asked India to take necessary steps to amend the existing Patent law in order to meet the WTO commitments till April 1999. Soon after that Rajya Sabha passed the bill relating to the amendment in December 1998 but even then the government could not bring it in force as there was many oppositions from the treasury as well as the opposition parties. However, in order to

fulfil the county's obligation towards WTO, the government, however, passed the Patents (Amendment) Ordinance in January 8, 1999 that changed the Indian Patent Act 1970 to comply with the standards of the WTO. The said Ordinance provided –

1. Application Filling for Product Patents in Agro-Chemicals and Pharmaceuticals
2. Granting of Exclusive Marketing Rights for applicant after fulfilling the conditions.

The major consequences of the TRIPS Agreement was the sharp price hike in the pharmaceutical sector for products produced after passing the amendment in 2005. However, this impact increased slowly and gradually as almost all drugs produced were patented using the product patent after passing of the amendment in 2005. In addition to this, all the old medicines and drugs would become ineffective by passing time as the bacteria that causes disease would develop resistance to the old drugs, thereby the people would be forced to shift to the new and more costly drugs that would be then available in the market.

Major Difference in Pre- and Post- TRIPS Patent Act

Category	***Pre- TRIPS***		***Post- TRIPS***	
	Patents Act, 1970	***Implication***	***Patents Act, 2005***	***Implications***
Product Patents	No	Able to Reverse Engineer & Reproduce	Yes	Reverse Engineering Disallowed
Process Patents	Patent granted on a single manufacturing process	Easy to follow up with new process	Multiple Process Patentable	Difficult to develop a non-infringing process
Patent Term	Seven years from the date of filling the application or Five years from the date patent is granted	Short Term	20 Years from the date of filling the application.	Longer Term for monopoly rights.

	(Whichever is earlier)			
Pre-Grant Opposition	Yes	Opportunity to object before patent is granted	Yes	Opportunity to object before patent is granted
Post-Grant Opposition	No	Not Applicable	Yes, within 12 months	Opportunity to raise concerns even after granting of patent
Compulsory Licensing	After 3 Years from grant of patent	Practically Unrestricted Applicability	After 3 Years from grant of patent, under certain conditions	Only for domestic market supply
Exports under Compulsory Licensing	Unrestricted	For Domestic or Exports	Under Sec 92A (1) conforming to 30th Aug decision of WTO	Under specific conditions including labelling to prevent re-export
Data Protection	Not Applicable	Not Applicable	Yes, against unfair commercial use. However, No Data Exclusivity	Possible disputes with delays to introducing generics
Patent Infringement Disputes	Burden on Patentee to prove the infringement	No for some disputes	Burden on the Alleged Infringer to prove non-infringement	Escalation of disputes. Small Companies likely to shy away from innovation

Source – Compiled from GOI Reports (1972, 1999, 2002b, 2005c)[vii]

POST-TRIPS PATENT REGIME: FIVE YEARS DOWN THE LINE IN INDIA

The TRIPS Agreement provided a multi stage framework for developing countries like India which were not granting Product Patent to Pharmaceutical products at the time when TRIPS was implemented on January 1, 1995. The frameworks were as follows:

Mailbox Provisions

Under the TRIPS Agreement, the countries that did not have implemented the TRIPS agreement in 1995 were asked to provide mailbox provisions. Mailbox is a mechanism in which a patent application is accepted until the product patent regime was actually came in place. Few experts in the pharmaceutical sector assumes that most of the applications in the Mailbox Provision would be of already famous and widely used medicines that are simply modified. When the Indian Patent Office started accepting application in the Mailbox, it received a total of 8,926 applications in total of which majority of applications, 7,520 applications, were from the foreign companies. Then after over a span of 10 years, just around 100 New Chemical Entries were identified, but, notwithstanding that approximately 9,000 patent application were accumulated in the Indian Mailbox.[viii]

On the other hand, Multi National Pharmaceutical Corporations were not behind filling the mailbox applications. The data regarding mailbox applications filed by MNCs as well as Indian Pharmaceutical Corporations are mentioned in the table below.

Indian Companies	**Number of Mailbox Application Filling**	**Pharmaceutical MNCs**	**Number of Mailbox Application Filling**
Ranbaxy	38	***El Dupont***	95
Cipla	45	***Glaxo Smith Kline***	115
Sun Pharma	46	***Merck***	156
Dabur India	56	***Procter & Gamble***	187
Panacea Biotech	75	***Johnson & Johnson***	262
Dr. Reddy's Labs	205	***Pfizer***	373

Total	**465 Applications**		**1188 Applications**

Source:- *Intellectual Property Rights, A Bulletin from TIFAC, Vol. 11, No. 1-3, January –March, 2005, 13 and Financial Express, March 21, 2005*

Compulsory Licensing

Article 31 of the TRIPS Agreement[ix] permitted Compulsory Licensing which was already brought in to force by the Indian Patent Act 1970 under Section 84(1)[x]. The Agreement although never limited the grounds on the compulsory licensing could be granted, but it stated the conditions before the granting of Compulsory Licensing. This included specification on grounds of compulsory licensing and the reasonable fees of licensing to the Patent Holder.[xi] Accordingly, members of the WTO were granted access to use the subject matter of a patent or permit the usage by any third party without the authorization of the actual patent holder, but only in some specific cases such as Extreme Medical Emergency or National Emergency with Public Non Commercial Use.[xii] Indian Patent Law that already allowed Compulsory Licensing, never used the flexibility that the TRIPS provided in terms of Compulsory Licensing under situations mentioned above.

Bolar Provisions

Under Article 30 of the TRIPS Agreement, it is allowed to member countries to provide Exclusive Rights (with limited exceptions) that is conferred by a Patent, which means to define an act which would not be termed as an infringement even when they are done without the authorization of the actual Patent Holder. These acts can include acts of reverse engineering and experimentation and subsequently applying for market approval of a drug before the original patent expires.[xiii] This is a TRIPS measure and numerous nations outside the European Union including the US, Canada and Israel take into account the early advancement and testing of generic version of medicine to upgrade fierce competition in the off-patent division instantly after basic patent of an originator product expires.[xiv]

Parallel Importation

Parallel Importation is one of the many flexibilities that were incorporated in Patent Laws of various countries to make available some drugs and medicines at a much lower price as compared to the amount charged to the original patent holder.[xv] Under the same agreement,

countries have an option to come over the high price issue of a patented drug by manufacturing a generic version or importing the same by way of issuing Compulsory Licensing or by way of importing a much cheaper version of the medicine from another country through provision of Parallel Importation.[xvi]

SUGGESTIONS AND CONCLUSION

There are some problems with the TRIPS Agreement that are likely to harm the interest of the developing nations like India. I would like to sum up one of the major problems with the new regime that is regarding the dispute over the domestic biodiversity legislation. There is a long felt need to recognize the need for establishing institutions that would recognize the rights of various communities on their own traditional knowledge; their biological recourses along with the traditional remedies, from which majority are not in a documented form. It would definitely be a major violation of rights if in any circumstances, the same traditional knowledge is granted a patent in some other country where that knowledge might not be well known.

It is very evident that few of the western corporations have been eyeing on the traditional knowledge of one country and have been trying hard to take advantage of the same, for example, the traditional knowledge regarding herbal medical products. There must be a set of stringent laws that would aim to prevent such kind of abuse. Regarding this, India has already suggested and proposed that the origin of biological substance utilized in any invention must necessarily be mentioned in the patent application. In addition to that, the country providing the corporation with such biological substance must get a share of the commercial benefits that arises from the patent. Similarly, products made by utilizing traditional knowledge of a community shall either not be patentable at any cost or alternatively, if patented, the commercial benefits arising from that product must be shared with the same community from where the traditional knowledge originated.

Ideally, the TRIPS Agreement should not have been a part of WTO. It is unreasonable to ask the developing nations to compromise and amend their Patent Laws in order to accommodate TRIPS provisions, which out rightly is seen favoring the MNCs and developed countries, at the cost of the public health of its own people.

Atleast, the developed nations should accommodate changes in the TRIPS provisions that would be helping the developing nations. I think, a more appropriate agreement should be drafted as soon as possible in order to accommodate the interest of the inventors as well as of poor developing nations and LDCs in order to gain access to cheap drugs.

My view is to reduce the patent life from 20 years to 10 years which would be much more reasonable and along with that a right should be granted to developing nations to enforce Price Controls and Compulsory Licensing after a gap of 5 years of its invention. If not for all drugs then at least this could be done for Life Saving Drugs and Drugs of Mass Consumption. This is what I think would be a very balanced approach to safeguard the commercial interest of the Pharmaceutical MNCs without unreasonably distressing the poor developing countries and LDCs.

Meanwhile, we must strive to take most of the advantages of the present TRIPS regime. As a matter of fact, India is comparatively in a very better position as compared to other developing countries because of the presence of a strong Pharmaceutical corporations. We can motivate the Indian Pharmaceutical Firms to undertake more R&D and to become more competitive in Drugs Exports. This goal can be easily achieved by facilitating the companies engaged in R&D by way of Tax Incentives for undertaking Research & Development, by allowing liberal imports of various raw materials required for manufacturing drugs and proceeding with R&D and also by levying minimum or no import duties on essential items.

ENDNOTES

[i] Suman Sahaí, *Indían Patents Act and TRÍPS*, Economíc and Polítícal Weekly Vol. 28 No. 29/30, 1495-1497 (1993).

[ii] Jayashree Watal, *Implementing the TRIPS Agreement: Policy Options Open to India*, available at www.jstor.org/stable/4405898 last visited on September 23, 2016

[iii] *Ibid*

[iv] Pradeep Agarwal & P Saibaba, *TRIPS and India's Pharmaceuticals Industry*, Economic and Political Weekly Vol. 36, No. 39, 3787 – 3790(2001).

[v] *Ibid*

[vi] *Ibid*

[vii] Prabodh Malhotra, GOI Reports, Pp 86-87, *Impact of TRIPS in India: An Access to Medicine Perspective*, Palgrave MacMillan (2010), New York

[viii] IDMA Bulletin, XXXVI, (12), March 30, 2005, 29

[ix] TRIPS Agreement, 1869 UNTS 299; 33 ILM 1197 (1994)

[x] Sec. 84(1) of Indian Patent Act, 1970: At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely:—

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

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

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

[xi] Nagesh Kumar, "Intellectual Property Rights, Technology and Economic development: Experiences of Asian countries", Study Paper 1b, Commission on Intellectual Property Rights, (accessed at http://www.iprcommission.org on Sept. 23, 2016)

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[xiii] Carlos M.Correa, Implications of the Doha Declaration on the TRIPS Agreement and Public Health, World Health Organization, June 2002.

[xiv] Ranjit Roy Chaudhury, Nirmal Kumar Gurbani, TRIPS safeguards, In: Enhancing access to quality medicines for the underserved, Anamaya Publishers, New Delhi, 2004, 88-89

[xv] Ellen 't Hoen, Patents, Prices and Patients, accessed at http://www.un.org/Pubs/chronicle/2003/issue2/0203p13 on Sept. 24, 2016

[xvi] *Ibid*. Ellen 't Hoen, Patents, Prices and Patients, accessed at http://www.un.org/Pubs/chronicle/2003/issue2/0203p13 on Sept. 24, 2016