

# TRIPS AND ITS IMPACT ON THE INDIAN IP REGIME

Written by **Ivin George**

5th Year BBA LLB(Hons.) Student, NMIMS University, School of Law

---

## **Abstract:**

The post-colonial world in the late 20<sup>th</sup> century and early 21<sup>st</sup> century witnessed a change in the global economic setup, international trade and investment was on the rise and there was a need for its regulation. This led to the formation of General agreement on Trades and Tariffs in 1947, and it remained the regulatory agreement till 1995, in 1995 as a result of the Uruguay Round of negotiations, through the Marakesh agreement an international body to regulate the world trade was instituted, known as the World Trade organisation. Under its ambit, the agreement on the Trade Related aspects of Intellectual Property Rights was also adopted in 1995. This research paper tries to analyse the impact of TRIPS on the Indian laws on intellectual property, in the first part of this research paper the researcher analyses the circumstances which led to the adoption of TRIPS and how the ambit of the agreement has been broadened to encompass not only the trade related aspects of IPR but also the entire regulation of the IP laws. The researcher also analyses the method of implementation of the obligations laid upon India through this agreement, the researcher touches upon the concepts of Mail Box, and Exclusive marketing rights granted by the Indian IP regime during the transitional phase. The researcher also touches upon the proponents of the Doha Declaration and the impact on the pharmaceutical industry. Subsequently the researcher analyses the provisions of the TRIPS plus plus agreement, upon the IPR regime in place and in conclusion the researcher tries to determine the overall effect the TRIPS and the TRIPS Plus Plus would have on the Indian economy, which is the world's fastest growing economy with huge IP potential

**Keywords:** TRIPS, Implementation, world politics, impact, Doha Declaration.

**Introduction:**

At the turn of the 21<sup>st</sup> century, the global landscape saw a gradual change from a colonial setup, led by the power bloc of mostly European Nations, to a global setup, dubbed as an era of globalization. As the global economy boomed, capital and labour flowed across the national borders at a rapid pace and international bilateral trade prospered.<sup>i</sup> It was at this time that the global community felt a need for a global regulation of international trade, and this culminated in the General Agreement on Tariffs and Trades (GATT) in 1947.<sup>ii</sup>

However, in the period from 1980 till 1994 was one of international turbulence, the global economy was dominated by the world powers like USA. In 1980s, USA felt threatened by losing its competitive edge to countries like Mexico, Taiwan and Singapore because of their increasingly sophisticated industries and technical advancements.<sup>iii</sup>

In 1982, USA instituted a GATT ministerial meeting, this meeting led almost a decade of international controversies, first there was the ‘working program’ generated by the ministerial conference which tried to increase the ambit of the GATT by including Services within its ambit. The developing countries formed a bloc of 24 countries to resist this move, but to little avail. By 1986 this bloc was reduced to only 10 developing nations led by Brazil and India, who put up an unyielding opposition. This issue was referred to the ministerial meeting to be held in Punta Del Este (Uruguay) in September of 1986.<sup>iv</sup>

It was in this meeting that a compromise was met between the developed nations, led by US and “the group of ten”, led by India and Brazil. While it was agreed that ‘services’ was outside the ambit of GATT, and that a different negotiation stream was needed which respected the national laws and regulation of the developing nations, it was in the Punta Del Este Meeting that the issue of trade related intellectual property rights were tackled as being within the framework of GATT.

Soon after the launch of the Uruguay round a coalition of American, European and Japanese drugs and pharmaceutical companies launched an offensive to include the issues of regulation standards and norms under the ambit of the GATT negotiation, this was primarily done with an intention to compel the national regimes of developing countries like India, Brazil and South Korea to fall in line with a global regime doctored to their favour.<sup>v</sup> This was resisted

by the group of ten, as they emphasised that only the trade related aspects of Intellectual Property are under the ambit of the GATT.<sup>vi</sup>

However, in 1989 the negotiating group on TRIPS was given a full mandate thereby, including within the ambit of GATT not only the trade related aspects but also the mandate to, in general, negotiate rules on the Intellectual property laws, and is the basis of the current TRIPS agreement.<sup>vii</sup>

This research paper tries to analyse the impact of TRIPS on the Indian laws on intellectual property, in the first part of this research paper the researcher analyses the method of implementation of the obligations laid upon India through this agreement, the researcher touches upon the concepts of Mail Box, and Exclusive marketing rights granted by the Indian IPR regime during the transitional phase. The researcher also touches upon the proponents of the Doha Declaration and the impact on the pharmaceutical industry. Subsequently the researcher analyses the provisions of the TRIPS plus plus agreement, upon the IPR regime in place, in conclusion the researcher tries to determine the overall effect the TRIPS and the TRIPS Plus Plus would have on the Indian economy, which is the world's fastest growing economy with huge IP potential.

### **TRIPS and its impact:**

The nature and scope of the obligations under the TRIPS agreement, hereinafter referred to as the 'agreement', permits the implementations of more extensive provisions for the protection of Intellectual Property Rights, than the ones provided in the agreement.<sup>viii</sup> The agreement is meant as a framework for minimum level of protection which has to be granted for the protection of intellectual property.

The agreement further puts an obligation upon the nations to comply with the provisions of the Paris convention of 1967, the Berne Convention, the Rome Convention and The Treaty on Intellectual Property in respect of Integrated Circuit.<sup>ix</sup> The agreement also provides for the generally accepted principles of International Law such as those of National Treatment and Most Favoured nations.<sup>x</sup>

The agreement, brought about significant changes to the Indian Intellectual Property regime. The patents law was amended to include the product patents under the ambit of the

Indian patents law, furthermore inventions in the field of agriculture, pharmaceuticals and non-natural and genetically engineered life forms have been included under the ambit of patentable invention provided that the inventions demonstrate characteristics like novelty, inventive step, utility and written description. Lastly the term of patents was increased from 14 years to the now universally acknowledged 20 years.<sup>xi</sup>

India was given an exemption to from implementing pharmaceutical and agrochemical product patents till 2005, but during this period of transition India was required to implement a 'Mailbox' provision which aimed to assign each application filed during this transition period with a filing date. India was also under an obligation to grant Exclusive Marketing Rights (EMR) for these patent applications which were in the mailbox.

However India, was not able to comply with these obligations immediately, although it tried to implement the Mailbox provision and the Exclusive Marketing Rights through Presidential order, the failure to implement an amendment for these provisions, prompted the US to use the WTO dispute settlement process to get the Indian parliament to comply with the obligations. The Indian government ultimately implemented the Mailbox provision and EMR via an amendment in 1999, this amendment then became obsolete after the 2005 amendment and have been repealed since.<sup>xii</sup>

During India's ten-year TRIPS transition period, 8926 mailbox applications were filed in the four branches of the Indian Patent Office, there were then deposited in a 'black box' and were not examined until 2005.<sup>xiii</sup> Some applicants however did seek additional protection by way of the EMR for example, pharmaceutical companies like Novartis applied for the grant of EMR over their drugs, which was needed keeping in mind the highly competitive nature of the pharmaceutical industry.

EMR was however not granted without due process, the Indian law required that EMR could only be granted to applications which showed that:

- an examination by the Indian Patent Office had established that the invention did not fall within any of the categories of subject matter considered as non-patentable inventions like business methods, frivolous inventions, mere admixture, or within the scope of the prohibition on patenting inventions relating to atomic energy.<sup>xiv</sup>

- the mailbox/EMR applicant had filed a patent application for the same invention, claiming the “identical article or substance” in a “convention country” on or after January 1, 1995.<sup>xv</sup>
- the mailbox/EMR applicant had been granted a patent by the convention country on or after the date it filed its mailbox application in India.<sup>xvi</sup>
- the convention country had issued “approval to sell or distribute the article or substance” in the convention country, “on the basis of appropriate tests conducted” in the convention country on or after January 1, 1995.<sup>xvii</sup>
- an authority on behalf of the Indian government had given approval to sell or distribute the article in India.<sup>xviii</sup>

The Indian Patent amendment of 2005, was not however free from its controversy, it included provisions specifying certain subject matters as non-patentable, it also added a new definition for ‘inventive-step’ and also provided for procedures for pre- and post-grant opposition to the patent-application. The amendment also liberalised the framework for compulsory licencing of essential patents.<sup>xix</sup>

Under the copyright laws provisions were amended to include Computer programs under the ambit of the copyright laws per article 10 of the agreement, this was change was brought to bring the copyright laws to the digital era. It also made commercial rental of computer programs the proprietary right of the owner of the copyright owner, thereby recognizing that computer programs not only have copyrightability, but also a commercial aspect.<sup>xx</sup>

Under the trademark laws, well known trademarks, collective marks and service marks were included within its ambit, the scope of trademarks was enlarged to include figurative elements like shape, packing and combination of colours.<sup>xxi</sup>

### **The Doha Declaration:**

The TRIPS agreement had a huge impact on the world and the pharmaceutical industry, by adding pharmaceutical drugs under the category of patentable inventions, the big pharma companies rushed to file patents in the least developed and developing countries, these were the countries with the largest market for their products.

This was a matter of grave concern for the developing nations, the impact of the TRIPS agreement on the prices of the drugs, this was the age when diseases like typhoid, malaria and tuberculosis were rampant.<sup>xxii</sup> The pharma companies have always had a say in the matters of international and national politics, the work these pharma companies conduct are responsible increasing the average life expectancy of the entire world and are constantly trying to evolve and innovate to combat the mother nature and the pathogens that are responsible for diseases.

The flip side to the TRIPS agreement is that while, it ensures the protection of the efforts of these pharmaceutical companies in ensuring increased efficacy of drugs and incentivises them for continued research and development. It also puts the least developed countries at a risk of having to pay exorbitant prices for such lifesaving drugs. This was the growing concern post the TRIPS agreement.<sup>xxiii</sup>

This concern was put to rest by the Doha Declaration where it was recognized that all the nations have the right to ensure public health by using procedures like compulsory licencing, the freedom to determine the grounds on which the licence would be granted and enhance access to medicine for poor countries. The Doha Declaration also extended the deadline for least developed countries to implement the TRIPS agreement from 2006 till 2016.<sup>xxiv</sup>

### **TRIPS plus provisions:**

While the developing countries were still coming to grips with the TRIPS agreement, the developed nations are already raising the bar for IPR protection by way of Free Trade Agreements. The frontrunner in this is none other than USA. These provisions which provide for more protection for intellectual property rights have been dubbed as the TRIPS plus provisions.

One aspect of TRIPS plus provisions are the increasing demand for protection by the developed nations for data exclusivity. Data exclusivity provision tries to protect the clinical test data submitted to a regulatory agency to prove the safety, quality and efficacy of a new drug. This would help prevent the generic drug manufacturers from relying on such data in their own application and subsequently relying on such data while applying for licences.<sup>xxv</sup>

The demand for protecting exclusive data that have high commercial value is a major demand from the developed world which doesn't usually come under TRIPs. This move

triggers a much larger debate between the inventor's proprietary rights and the fair use doctrine for public welfare. India has tried to resist the implementation of TRIPS plus standards, being a developing country, it has always emphasised on the need to maintain a balance between the proprietary right of the inventor and public welfare. Which is evident from India's FTA negotiations with countries like Japan etc.

### **Conclusion:**

It is evident that through the TRIPS agreement the US has successfully widened the ambit of the GATT and the WTO over Intellectual Property Rights. the current TRIPS agreement covers not only the trade related aspects of Intellectual Property but the entire regulation of the Intellectual Property regime. This move was initially resisted by India but to little avail and the US was successful in its efforts. However, the developing nations voiced their concerns through the Doha Declarations and were successful in ensuring the protection of the public health aspect for pharmaceutical patents.

The developing nations are now again under duress as the developed countries want higher standards of protection for intellectual property, than those enshrined in the TRIPS agreement. The developing nations like India, however have the opportunity to ensure that their interests are protected. Countries like India have huge man-power and also have equally huge base for intellectual development. It is the need of the hour for developing nations to invest substantially on increasing the knowledge economy of their country. TRIPS plus provisions are aimed to maintain the gap between the developed and the developing nations, they need to put a unified front in resisting this change.

### **REFERENCES**

---

<sup>i</sup> Jeffrey G. Williamson, "Globalization, Convergence and History", *Journal of Economic History*, vol. 56, no. 2 (June 1996): pp. 1.

<sup>ii</sup> S.P. Shukla, "From GATT to WTO and beyond", (UNU/World Institute for Development Economics Research, Paper no. 195) <https://www.wider.unu.edu/sites/default/files/wp195.pdf>.

<sup>iii</sup> *Ibid.*

<sup>iv</sup> Williamson, *supra* Note 1.

<sup>v</sup> Shukla *supra* note 2.

<sup>vi</sup> Williamson, *supra* note 1.

<sup>vii</sup> Unni, V.K., “Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health” (January 2, 2012). Pacific McGeorge Global Business & Development Law Journal, (2012) Vol. 25, No. 1, 323.

<sup>viii</sup> TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Article 1, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

<sup>ix</sup> TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Article 2, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)

<sup>x</sup> *Supra* Note 9, at Art 3,4.

<sup>xi</sup> P. Narayanan, Patent Law (4th ed. 2017).

<sup>xii</sup> Mart Leesti, “Historical Background, General Provisions and Basic Principles of the TRIPS Agreement and the Transitional Arrangement”, Journal of Intellectual Property Rights, Vol 3, Mar 1998. pp 66-73.

<sup>xiii</sup> Unni, *supra* note 7.

<sup>xiv</sup> The Patents (Amendment) Act, 2002, No. 38 sec. 24A(2), Acts of Parliament, 2002 (India)

<sup>xv</sup> *Id.*

<sup>xvi</sup> *Id* at sec. 24B(1)(a).

<sup>xvii</sup> *Id.*

<sup>xviii</sup> The Patents (Amendment) Act, 2002, No. 38 sec. 24A(2), Acts of Parliament, 2002 (India).

<sup>xix</sup> Narayanan *supra* note 8.

<sup>xx</sup> TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)

<sup>xxi</sup> *Id.*

<sup>xxii</sup> Carlos M. Correa, “Implications of the Doha Declaration on the TRIPS Agreement and Public Health”, WHO, [https://www.who.int/medicines/areas/policy/WHO\\_EDM\\_PAR\\_2002.3.pdf](https://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf).

<sup>xxiii</sup> Charles Clift, “A Guide to Assessing the Impact of TRIPS-Plus Provisions on Drug Prices in Developing Countries”, A Study Commissioned by the International Centre for Trade and Sustainable Development (ICTSD).

<sup>xxiv</sup> *Id.*

<sup>xxv</sup> Sandeep Mittal, “Effect of TRIPS plus provisions in International Trade Agreements upon access to medicines in Developing Countries”, JIPR, Vol 22 November 2017 pp 295-302.