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TRIPS AGREEMENT AND ITS EFFECT ON INDIAN PATENT LAW*

INTRODUCTION

Intellectual Property basically means those kinds of properties which has some intellect in it.[1] This means that the inventions/properties which are created by usage of human mind and intellect and the owner of these properties are those who create them by their own mind. There are various kind of Intellectual Properties such as Trademarks, Patents, Designs, Copyrights, Geographical Indications etc, and the rights which arise from these kinds of properties or which are associated with these properties are called Intellectual Property Rights (IPR).

IPRs have a brief history regarding its origin. It has continued to be developed and growing through the different ages, for e.g.; the history of patents and patent law is generally considered to have started with the Venetian Statute of 1474 and the 1624 English Statute of Monopolies.[2] Likewise the different IPRs were covered by Paris Convention of 1883, Berne Convention of 1886 followed by BIRPI, UCC and ultimately the WIPO.[3] But the most significant step taken towards the development of IPRs was the establishment of WTO (World Trade Organisation) and followed by the inclusion of TRIPS Agreement under it.

The TRIPs agreement, together with the 1968 Stockholm Conference that adopted the revised Berne and Paris Conventions and created the World Intellectual Property Organization (WIPO), is undoubtedly the most significant milestone in the development of intellectual property in the twentieth century. Its scope is in fact much broader than that of any previous international agreement, covering not only all areas already protected under extant agreements, but also giving new life to treaties that failed and protecting for the first time rights that did not benefit from any multilateral protection. In addition, the TRIPs agreement enshrined detailed rules on one of the most difficult and, for rights holders, painful aspects of intellectual property rights' enforcement.[4]

The Uruguay Round of multilateral trade negotiations resulted in the adoption of the Agreement Establishing the World Trade Organization (WTO Agreement) on April 15, 1994 in Marrakech. The TRIPs agreement was contained in the Annex to the WTO agreement, which entered into force on January 1, 1995. Built upon the foundations laid by the Paris Convention and the Berne Convention, the TRIPs agreement is an unprecedented international agreement in terms of its coverage, scope, specificities and enforceability.

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[1] Fisher, William, Theories of Intellectual Property available at http://www.law.harvard.edu/faculty/tfisher/iptheory.html accessed on 20th April, 2015

[2] Devaiah, Vishwas. History of Patents Law available at http://altlawforum.org/publications/a-history-of-patent-law/ accessed on 20th April 2015.

[3] Okediji, Ruth L, WIPO-WTO relations and the future of global Intellectual property norms. P-7-9 available at http://content.lib.utah.edu/utils/getfile/collection/utlawrev/id/6133/filename/20214.pdf accessed on 20th April 2015.

[4] Daniel Gravis, *The Trips Agreement: Drafting History and Analysis*, 2nd ed., (London: Sweet & Maxwell, 2003), p.3.

As regards geographic coverage, the TRIPs agreement is binding on all WTO members. Compliance with its provisions is a precondition of joining the WTO, which deals with the rules of trade between members at a global level. Although intellectual property rights (IPRs) and their effects on trade have been advocated for a long time, the TRIPs agreement is the first international instrument to focus on trade-related aspects of IPRs. In view of the different levels of 'preparedness' among members to implement the TRIPs agreement under national laws, the TRIPs agreement sets out certain periods of time after the entry into force of the WTO Agreement before members are obliged to implement the TRIPs agreement.[5]

Different periods were prescribed for developed countries (January 1, 1996), developing countries (five years from the date on which the TRIPs agreement becomes mandatory for developed countries) and least-developed countries (ten years from the date on which the TRIPs agreement becomes mandatory for developed countries). The targeted date for least-developed countries, which was January 1, 2006, has proved to be too ambitious, and was extended more to July 1, 2013.[6]

In a democratic country, like India, it is not easy to shift the policy against public interest. India was in the difficult situation of protecting people's interest on the one hand and fulfilling the WTO's agreement of TRIPs at the other. A successful patent policy of any developing country is one that strikes a clear balance between protecting the rights of innovators & services at affordable prices to the population. India's patent policy so long has been, infact, protecting the interest of public more than that of the monopoly rights. The question is that whether the amendment to the Indian Patents Act, 1970 has taken advantage of the provisions available under the TRIPs agreement.[7]

Intellectual Property rights have generated strong impact on the modern day life. Therefore, the impact of IPR is enormous and on the modern day life. These IPRs were promoted in an ever seen manner by the TRIPs agreement. The TRIPs agreement has mandated its members states to implement the provisions of the agreement in order to promote and protect IPRs. Members states are asked to provide protection to different IPRs by making necessary adjustments in their existing laws or enacting new laws. India, being a member state to the TRIPs agreement brought changes in its IPRs laws. The preceding fifteen years have seen many new IPR enactments. With globalization, liberalization and privatization, the ambit of IPR has grown multifold and its importance has amplified, having a profound impact on
commercial interests.

INTRODUCTION TO TRIPS

History

The TRIPS Agreement is one of the most significant developments in the field of IPR laws. The TRIPS Agreement traces its origin to the emergence of WTO Agreements and in the year 1995 it came into existence. The WTO Agreements was first discussed in the GATT rounds held in Uruguay in 1986. TRIPS is a multilateral trade agreement which is binding on all members of the WTO, the successor of GATT.

> The negotiations of the TRIPS Agreement began with the Ministerial Conference of the General Agreement on Tariffs and Trade (GATT) in Punta del Este, Uruguay. Held in September 1986, the conference came at a critical point in time when the negotiations between developed and less developed countries over the revision of the Paris Convention for the

[5] TRIPs Agreement, Articles 65 and 66.
[6] Toshiko Takenaka (edr), *"Patent Law and Theory"*, (U.K: Edward Elgar Publishing, 2008), p.170.
[7] Chaudhuri Sudip,*TRIPS Agreement and Amendment of Patents Act in India*, EPW
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Protection of Industrial Property (Paris Convention) was deadlocked at WIPO.[8]

The TRIPS Agreement came about in recognition of the fact that widely differing standards of protection and enforcement of intellectual property rights and the absence of a multilateral framework of principles, rules and disciplines to deal with the international trade in counterfeit goods had become a serious tension in international trade relations.[9] The agreement addresses applicability of basic GATT principles and those of existing intellectual property conventions and agreements; the provision of adequate intellectual property rights; the provision of effective enforcement measures; multilateral dispute settlement; and transitional arrangements. A key feature of the TRIPS Agreement is the extension of the multilateral GATT dispute settlement procedures to intellectual property. This allows for the application of trade sanctions including, for example, the suspension of concessions or other obligations where a Member fails to meet its obligations under the agreement.[10]

General Arrangement and regulation.

The TRIPS Agreement addresses the availability, scope, use and minimum term of protection for intellectual property rights. The Agreement, in Part II, defines intellectual property to include, (1) copyright and related rights, (2) Trademarks, (3) Geographical indications, (4) Industrial designs, (5) Patents, (6) Layout-designs of integrated circuits, and (7) protection of undisclosed information. The Agreement also addresses the control of anti-competitive practices in contractual licences. Further, it also sets out the minimum standards of protection.

The minimum standards of protection are to be incorporated by the member states in their own domestic laws. The member countries have their own discretion to implement these minimum standards of protection in their domestic legislation and practice. The members are also free to implement in their laws more extensive protection than is required by the agreement.[11]

The TRIPS Agreement also follows the principle of national treatment and the most favoured nation treatment.

National treatment

The principle of national treatment underlies all international conventions on intellectual property. It is also contained in Article III of the GATT. Though similar in some aspects with the TRIPS provision, but the role played by the principle in these two categories are different. Under the GATT system, the main function of the national treatment is to ensure non-discrimination between foreign and national products. Unlike the GATT provisions and the different IP Conventions the TRIPS Agreement establishes common rules and standards concerning the availability, scope and use of IPRs as well as 'effective and appropriative' means for their

[8] Watal, Jayshree, Intellectual property rights in the WTO and the Developing Countries, *the Hague and Boston, Klewer International*, p-21 cited in Peter K Yu, Objectives of the TRIPS Agreement, p-2 available at http://www.peteryu.com/correa.pdf

[9] The preamble to the TRIPS Agreement states that it is the desire of members: "*to reduce distortions and impediments to International Trade, and taking into the need to promote effective and adequate protection of intellectual property rights, and to ensure that the measures and procedures to enforce intellectual property rights do not themselves become barriers to legislative trade*."

[10] Leesti, Mart, Historical Background, general provisions of the TRIPS Agreement and Transitional Arrangements, *Journal of Intellectual Property Rights*, Vol. 3 March 1998, pp 68-73, p-69 available at http://nopr.niscair.res.in/bitstream/123456789/19551/1/JIPR%203%282%29%2068-73.pdf

[11] **Article 1.1 of the TRIPS Agreement provides that**, "*Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice*."

enforcement. Thus the TRIPs Agreement's main purpose was to harmonise all the national legislations and thus to promote the idea of national treatment.[12]

Article 3 of the TRIPS Agreement provides that,

1. Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.
2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.[13]

Most Favoured Treatment

Article 4[14] of the TRIPS Agreement covers this aspect which basically talks about the prevention of a member from discrimination with regard to intellectual property among nationals of other members.

Apart from this TRIPS Agreement also talks about the exhaustion clause. Article 6 provides for the same which states that, "*For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights*."

Main features of TRIPs.

The main features of TRIPS are:

A. **STANDARD**: in respect of each of the main areas of intellectual property covered by TRIPS Agreement sets out minimum standards of protection to be provided by each Member. Each of the main elements of protection is defined, namely the subject matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection. The agreement sets these standards by requiring, first, that the substantive obligations of the main conventions of the WIPO, the Paris

[12] Correa, Carlos M., Yusuf, Abdulqawi A., Intellectual Property and International Trade, the TRIPS Agreement, *Kluwer Law International*, p-15

[13] Available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf

[14] **Article 4 of TRIPS Agreement**, "*With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member:*

(a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property;

(b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country;

(c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement;

(d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members. "

Convention for protection of Industrial Property (Paris Convention) and the Berne Convention for the protection of Literary and artistic works (Berne Convention) in their most recent versions, must be complied with. With the exception of the provisions of the Berne Convention on moral rights, all the main substantive provisions of these conventions are incorporated by reference and thus became obligations under the TRIPS Agreement between TRIPS member countries. The relevant provisions are to be found in Articles 2.1 and 9.1 of the TRIPS Agreement, which relate, respectively, to the Paris Convention and to the Berne Convention. Secondly, the TRIPS Agreement adds a substantial number of additional obligations on matters where the pre-existing conventions are silent or were seen as being inadequate. The TRIPS Agreement is thus sometimes referred to as Berne and Paris plus Agreement.[15]

B. **ENFORCEMENT**: the second main set of provisions with domestic procedure and remedies for the enforcement of Intellectual Property rights. The Agreement lays down certain general principles applicable to all IPR enforcement procedures. In addition, it contains provisions on civil and administrative procedures and remedies, provisional measures, special requirement related to border measures and criminal procedures, which specify in a certain amount of detail, the procedures and remedies that must be available so that the right holder can effectively enforce their rights.[16]

C. **DISPUTE SETTLEMENT**: The Agreement makes disputes between WTO members about the respect of the TRIPS obligations subject to the WTO's Dispute Settlement procedures. In addition the Agreement provides for certain basic principles, such as national and most-favoured –nation treatment, and some general rules to ensure that procedural difficulties in acquiring or maintaining IPRs do not nullify the substantive benefits that should flow from the Agreement. The obligations under the Agreement will apply equally to all member countries, but developing countries will have a longer period to phase them in. special transition arrangements operate in the situation where a developing country does not presently provide product patent protection in the area of pharmaceuticals.[17]

The TRIPS Agreement is a minimum standards Agreement, which allows members to allow more extensive protection of intellectual property if they so wish. Members are left free to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice.

Different Standards of Protections of IPR under TRIPS.

The TRIPs Agreement provides different standards of protection for different types of IPR namely:

I. **COPYRIGHT:** during the Uruguay round negotiations, it was recognized that the Berne Convention already, for the most part, provided adequate basic standards of copyright protection. Thus, it was agreed that the point of departure should be the existing level of protection under the latest Act, the Paris Act of 1971, of that Convention. The point of departure is expressed in Art. 9.1[18].

The provisions of the Berne Convention referred to deal with questions such as subject-matter to be protected, minimum terms of protection, and rights to be conferred and permissible limitations to those rights. The Appendix allows developing countries, under

[15] Lokagnathan, E.T, Intellectual Property Rights, TRIPS Agreement and Indian Laws, New Century Publications, pp-7-9

[16] ibid

[17] ibid

[18] **Article 9.1 of TRIPS Agreement**: "*Members shall comply with Articles 1 through 21 of the Berne Convention (1971) and the Appendix thereto. However, Members shall not have rights or obligations under this Agreement in respect of the rights conferred under Article 6 bis of that Convention or of the rights derived there from*."

certain conditions, to make some limitations to the rights of translation and the right of reproduction.[19]

In addition to requiring compliance with the basic standards of the Berne Convention, the TRIPS Agreement clarifies and adds certain specific points. E.g.; Art.9.2[20], Art.10.1[21] etc.

The TRIPS Agreement also talks about the Related Rights: the provisions on protection of performers, producers of phonograms and broadcasting organizations are included in Article 14. According to Article 14.1, performers shall have the possibility of preventing the unauthorized fixation of their performance on a phonogram.

The fixation right covers only aural, not audio-visual fixations. Performers must also be in a position to prevent the reproduction of such fixations. They shall have the possibility of also preventing the unauthorised broadcasting by wireless means and communications to the public of their live performance.[22]

II. **TRADEMARKS:** The basic rule contained in Article 15 is that any sign, or any combination of signs, capable of distinguishing the goods and services of one undertaking from those of other undertakings, must be eligible for registration as a trademark, provided it is visually perceptible. Such signs in particular words including personal names, letters, numerals, figurative elements and combination of colours as well as any combination of such signs, must be eligible for registration as trademark.

Where signs are not inherently capable of distinguishing the relevant goods or services, member countries are allowed to require, as an additional condition for eligibility for registration as a trademark, that distinctiveness has been acquired through use. Members are free to determine whether to allow the registration of signs that is not visually perceptible (e.g. sound mark or smell mark).[23]

Members may make registrability depend on use. However, actual use of a trademark shall not be permitted as three years must have passed after that filing date before failure to realize an inherent to use is allowed as the ground for refusing the application (Art. 14.3[24])[25].

The provisions of the TRIPS Agreement which covers trademarks are mentioned under Articles 15-21.

III. **GEOGRAPHICAL INDICATION**: Geographical indications are defined, for the purposes of the agreement, as indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristics of the goods is essentially attributable to its geographical origin (Art. 22.1). Thus, this definition specifies the quality, reputation or other characteristics of a good can be a sufficient basis for eligibility as a geographical indication, where they are essentially attributable to the geographical origin of the good.[26]

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[19] Lokagnathan, E.T, Intellectual Property Rights, TRIPS Agreement and Indian Laws, New Century Publications, p 12

[20] **Article 9.2 of TRIPS Agreement,** "*Copyright protection shall extend to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such*."

[21] **Article 10.1 of TRIPS Agreement**, "*Computer programs, whether in source or object code, shall be protected as literary works under the Berne Convention (1971).*"

[22] Lokagnathan, E.T, Intellectual Property Rights, TRIPS Agreement and Indian Laws, New Century Publications, p 13-14

[23] Lokagnathan, E.T, Intellectual Property Rights, TRIPS Agreement and Indian Laws, New Century Publications, p 15

[24] **Article 15.3 of TRIPS Agreement**, "*Members may make registrability depend on use. However, actual use of a trademark shall not be a condition for filing an application for registration. An application shall not be refused solely on the ground that intended use has not taken place before the expiry of a period of three years from the date of application.*"

[25] Lokagnathan, E.T, Intellectual Property Rights, TRIPS Agreement and Indian Laws, New Century Publications, p 15

[26] Lokagnathan, E.T, Intellectual Property Rights, TRIPS Agreement and Indian Laws, New Century Publications, p 17

The provisions which cover the aspects of geographical indication are mentioned under Articles 22-24.

IV. **INDUSTRIAL DESIGNS**: Article 25.1 of the TRIPS Agreement obliges Members to provide for the protection of independently created industrial designs that are new or original. Members may provide that designs that are not new or original if they do not significantly differ from known designs or combinations of known design features. Members may provide that such protection shall not extend to designs dictated essentially by technical or functional considerations.[27]
Apart from this there are other provisions covered under Articles 25-26.

V. **PATENTS:** The TRIPS Agreement requires countries to make patents available for any inventions, whether products or process, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability. It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced. (Article 27.1).[28] Article 27 of the Agreement deals with patentable subject matter. The patentable subject matter according to the Agreement constitutes any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. However, the member nations may exclude from patentability, diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Further, plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes may also be excluded from patentability. Under the provisions of the Agreement the member nations have to provide protection for plant varieties either by patents or by an effective sui generis system or by any combination thereof. The term of protection available is usually twenty years counted from the filing date of the patent application.[29] Other proviso's dealing with the patents law are contained under Articles 27-34.

VI. **LAYOUT-DESIGNS OF INTEGRATED CIRCUITS:** Under the provisions of the agreement, member nations are obliged to provide protection to the layout-designs (topographies) of integrated circuits in accordance with the Treaty on Intellectual Property in Respect of Integrated Circuits. The member nations have to provide for protection of not less than 10 years from the date of filing of application for lay-out designs, however, member nations may limit the duration of protection up to fifteen years from the date of creation of the lay-out design.[30]

VII. **PROTECTION OF UNDISCLOSED INFORMATION:** Undisclosed information discussed herein is also called Trade Secret. The member nations are obliged to offer protection for trade secrets as per the provisions of the Agreement. The undisclosed information is considered as trade secret, if:

- It is secret in the sense that it is not generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
- It has commercial value because it is secret; and
- It has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.[31]

[27] Lokagnathan, E.T, Intellectual Property Rights, TRIPS Agreement and Indian Laws, New Century Publications, p 18
[28] Lokagnathan, E.T, Intellectual Property Rights, TRIPS Agreement and Indian Laws, New Century Publications, p 19
[29] TRIPS Agreement: An Overview, IPpro services (India) Pvt ltd., pp-9-10 available at http://www.ipproinc.com/admin/files/upload/5638424eba1ffe6d201d715e91034b8b.pdf
[30] TRIPS Agreement: An Overview, IPpro services (India) Pvt ltd., p 11 available at http://www.ipproinc.com/admin/files/upload/5638424eba1ffe6d201d715e91034b8b.pdf
[31] Ibid.

IMPLICATION OF TRIPS ON INDIAN PATENT LAWS

The regime of Intellectual property rights in India has seen a lot of development starting from the Britisher's era to the entry of India in the TRIPS Agreement in 1995.[32] The IPR laws so dealt with have been in arena of the changing globalisation era. The major focus of IPR was the induction of patents law and the famous case of *Novartis v UOI*[33], wherein India's existing patent law was amended according to the TRIPS Agreement. Indian IPR laws are of vast importance when it comes to global scenario. The Indian laws are almost at par with the global IPR regime itself.

India, along with several other developing countries, signed the TRIPs agreement in 1994, and became obligated to amend its domestic IPR laws within ten years. The signing of TRIPs remained deeply controversial in India for much of the 1990s, even as the country's patent regime began to be gradually modified to comply with the stronger IPR requirements stipulated in the agreement. On January 1, 2005, India became fully TRIPs-compliant by bringing into effect its most important requirement of enforcing product patents in all fields of technology. Given the large number of theoretically valid conjectures on both sides of the TRIPs debate, empirical evidence on its actual consequences in India would shed some important light on the relevance of stronger IPR protection for developing countries.[34]

The law of IPR is very vast and India has recently only seen such developments. Though the Indian legislators has enacted these laws almost decades ago but its development has been seen recently only. Even though the IPR laws are not a new concept but it still lacks the popularity among common masses. The main scenario for tackling such issues will be to look into the means by which the common masses can be informed or enlightened.

India's approach towards the TRIPS agreement may be cited to exemplify how the coordinates of India's WTO stance might have changed, but not the underlying neorealist policy paradigm. India's vehement opposition to TRIPS pre-1989 is perfectly understood in the light of the interests of its pharmaceutical industry, still at a nascent stage of technological maturity, which required a weak patent regime to prosper and develop. India's sudden turn around on TRIPS in 1989 has often been linked to economic threats from the US. India perhaps changed its course of action to accommodate the interests of the economic superpower (US), to obtain favours in other dimensions in India's best interest, vindicating our argument of a consistent neorealist position adopted by India.[35]

At the time of independence in 1947, India's IPR system was defined by the Indian Patents and Designs Act, 1911, which itself was based on the British Patent Act 1852. Under this regime, firms with patents were allowed exclusive rights to make, sell and use inventions in India, as well as give authorization to others, for 14 years from the date of filing.[36]

By the beginning of 1960, when the industrialization's first phase was complete then only Indian Government ventured into the development of its patent law. Till the middle of the 20th century, most countries followed the Paris Convention of 1883, the oldest international IPR convention of

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[32] Dutta, Antara, Sharma, Siddharth, Intellectual Property Rights and Innovation in Developing Countries: Evidence from India, October 2008, p-2 available at http://www.enterprisesurveys.org/~/media/GIAWB/EnterpriseSurveys/Documents/ResearchPapers/Intellectual_Property_Rights_India.pdf accessed on 7th April, 2015

[33] available at http://indiankanoon.org/doc/165776436/ accessed on April 1, 2015

[34] Dutta, Antara, Sharma, Siddharth, Intellectual Property Rights and Innovation in Developing Countries: Evidence from India, October 2008, p-4-5 available at http://www.enterprisesurveys.org/~/media/GIAWB/EnterpriseSurveys/Documents/ResearchPapers/Intellectual_Property_Rights_India.pdf

[35] Ray, Shovon Amit, Saha, Sabyasachi, Inida's stage at the WTO: Shifting Coordinates, Unaltered Paradigm, Centre for International Trade and Development, January 2009, p-12 available at http://www.jnu.ac.in/SIS/CITD/DiscussionPapers/WTO.pdf

[36] Ramani, Shyama V and others, The Biotech Segment of the Indian Pharmaceutical Industry in the Brave New Post-TRIPs World, Veena, IPR Protection and TRIPS Compliance, Issues and Implications, p-181

the time. Same was the case with India. Indian Govt. changed its patent laws in 1970 in a policy experiment to see whether such a change could induce private investment in market-based and market-led knowledge intensive sectors.[37]

The impact of the IPR policy experiment was tremendous in the pharmaceutical sector. The Indian legislators narrowed down its patent law to such an extent that it became easy for the Pharmaceutical firms to produce essential drugs like antibiotics with significant price reduction.[38]

Indian Patent Act, 1970

The umbrella legislation relating to patents is the Patents Act, 1970. The term 'Patent' is defined as a monopoly right which is granted to a person who has invented a new and useful article, or an improvement of existing article, or a new process of making an article. It consists of an exclusive right to manufacture the new invented article or manufacture an article according to the invented process for a limited period. Inventions that consist of products or new alloy are called product patent. Inventions that consist of process or processes of making a known or new alloy is a process invention and the patent for this is called process patent. The Indian Patents Act, 1970 only provides for process patent and for product like food, pharmaceuticals and chemicals, the inventors were granted only EMR (Exclusive Marketing Rights).[39]

The Patents Act, 1970 recognized two kinds of Patent i.e., product and process patents. A product patent is one where the patent holder has the absolute right to produce and market the product. A process patent is where the exact process of the product is patented. Similarly, a product patentee has the right a make, use, and exercise, sell or distribute such article or in India, while a process patentee has the right to use or exercise the method or process in India.

TRIPs Agreement has brought in a significant change in the Indian Patent law. It has been both a vice and a fortune for the Indian patent law as TRIPs is concerned.

Patent first amendment Act, 1999

The ordinance to change IPA was first promulgated by the President of India in December 1994. But due to the objections from the Pharmaceutical industries and the civil society of India the Patent Amendment Act was passed on December 1999. Due to this the US lodged complaint against India in the WTO for India's non-compliance to the TRIPS Agreement. Because of this the Patent Amendment Act, 1994 came into effect on May 20, 2003.[40]

The patents (Amendment) Act, 1999 added a new chapter i.e., Chapter IV-A consisting of Sections 24-A to 24-F, with retrospective effect from 01.01.1995, which deals with the Exclusive Marketing Rights (EMRs) to sell or distribute an article or substance in India. A claim for patent of an invention for a substance itself intended for use, or capable of being used, as medicine or drug,

Except (i) all medicines for internal or external use of human beings or animals,

(ii) all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of diseases in human beings or animals

[37] Ramani, Shyama V and others, The Biotech Segment of the Indian Pharmaceutical Industry in the Brave New Post-TRIPs World, Veena, IPR Protection and TRIPS Compliance, Issues and Implications, p-181

[38] Venkat Ramani, 2001 cited in Ramani, Shyama V and others, The Biotech Segment of the Indian Pharmaceutical Industry in the Brave New Post-TRIPs World, Veena, IPR Protection and TRIPS Compliance, Issues and Implications, p-182

[39] Lokagnathan, E.T, Intellectual Property Rights, TRIPS Agreement and Indian Laws, New Century Publications, p 144

[40] Venkat Ramani, 2001 cited in Ramani, Shyama V and others, The Biotech Segment of the Indian Pharmaceutical Industry in the Brave New Post-TRIPs World, Veena, IPR Protection and TRIPS Compliance, Issues and Implications, p-186

(iii) all substances intended to be used for or in the maintenance of public health, or the prevention or control of any epidemic disease among human beings or animals and

(iv) Insecticides, germicides, fungicides, weedicides and all other substances intended to be used for the protection or preservation of plants etc., can be made before the controller and the controller shall not refer such an application to the examiner for making a report till the 31st day of December, 2004. Where such application for EMR has been made in the prescribed form, the controller may directly refer it to an examiner. These provisions have been made with a view it to an examiner. These provisions have been made with a view to give effect to the treaty obligations of WTO and TRIPS agreements.[41]

With the signing of the TRIPS Agreement developing member countries are committed to making their IPR regimes TRIPS-compliant in the near future. For India, with respect to pharmaceuticals, this implies, inter alia, shifting from a patent regime that granted only process patents of seven years' duration (Indian Patents Act, 1970) to one that, by January 2005, must provide for product patents of twenty years' duration.[42]

The Patent (Amendment) Act 2002

The second of the three amending Acts in the evolution of India's patent law towards TRIPs compliance was the Patent (Amendment) Act, 2002, effectual from 20 May 2003.The 2002 Act implemented a number of key changes, but main significant was the extension of patent term to twenty years. Uniform term of patent safeguard of 20 years for all categories of invention as per Article 33 of the TRIPs agreement has been prescribed. The 2002 Act amended the principal Act to provide that the term of all Indian patents would henceforth expire twenty years after their application filing date. Prior to this amendment, Indian process patents last merely for the shorter of 5 years from sealing or 7 years from the date of the patent, while the term of all other types of patents (e.g., mechanical devices) was 14 years from the date of the patent.

The Patents (Amendment) Act, 2002, implemented a myriad of other changes intended to bring India's patent law into accord with the TRIPs agreement, include new definitions of 'invention' and 'inventive step',[43] and new exclusion from patentable subject –matter like business methods,[44] algorithms[45] and traditional knowledge.[46] The amendment also reversed the burden of proof provision involving cases of process patent infringement[47] and rationalized the compulsory licensing framework.[48] The 2002 amendment also paved the way for patentability of microorganisms.[49]

The 2002 amendments are considerably different from the 1999 draft with regard to compulsory licensing. Section 83, which provides a general framework to guide the issuance of compulsory licences, is particularly noteworthy. It constitutes a broader endeavour to incorporate some of TRIPs in-built flexibility in to the Patents Act. Interestingly, Section 83 specifically mentions that patents granted should not "impede protection of public health", should not prohibit the central government from taking measures to protect public health and the patents should be granted to

[41] Available at http://indiacode.nic.in/incodis/whatsnew/newacts/PATENT.HTM accessed on 23rd April 2015.
[42] Article 27 of the TRIPS Agreement
[43] The Patents (Amendment) Act, 2002, (amending Section 2 (1), (j) and adding Sections 2 (1), (ja)
[44] The Patents (Amendment) Act, Section 4 (adding Section 3 (k))
[45] Ibid
[46] The Patents (Amendment) Act, Section 4 (adding Section 3 (p))
[47] The Patents (Amendment) Act, Section 43 (adding Section 104 (A))
[48] The Patents (Amendment) Act, Section 39 (substituting the previous provisions with a whole new chapter dealing with Compulsory Licensing, Chapter XVI)
[49] The Patents (Amendment) Act, Section 4 (adding new Section 3(j) dealing with plant varieties. India drafted a new law called Protection of Plant Varieties and Farmer's Rights 2001 to give effective protection to plant varieties)

make the benefits of the patented invention available to the public at reasonably affordable prices.[50]

The Patent (Amendment) Act 2005

The 2005 Amendment amended many provisions of the Act; these amendments were absolutely necessary for India to meet its obligation under TRIPS Agreement. Some of important amendments are discussed below –

- **Extension of product patent protection to all fields of technology**

The most prominent and controversial change of the 2005 Amendment has been the deletion of section 5 of the Act, thereby paving the way for product patents in the area of pharmaceutical and other chemical inventions. India moved from a process patent system to a product patent system in 2005. The patent law is one of the seven intellectual property laws protected under this agreement. Section 5 of the TRIPs agreement deals with Patents. Article 27 says that "patents shall be available for any inventions, whether products or processes in all fields of technology provided that they are new, involve an inventive step and are capable of industrial application"

Section 5 of the Act (as it stood after the 2002 amendments) had provided that, in the case of inventions being claimed relating to food, medicine, drugs or chemical substances, only patents relating to the methods or processes of manufacture of such substances could be obtained[51]. Before this Amendment in the Act, Product Patent was not granted on the inventions related to drugs, foods and chemicals and only process patents were granted on these inventions. It means if a company invented a medicine to cure a disease using a certain process. That company can't claim a patent on that medicine while the company can claim a patent on the process which it has used to manufacture that medicine. In the other words that company can't stop other competitors from manufacturing the end product but can stop others from producing the end product using their patented process or method. This resulted in a situation in which reverse engineering mechanism was highly used to develop the same medicine and drugs with slightly or substantially different process. This copycat business helped a few pharmacy companies, to grow into global players and made medications cheaper. The pharmacy MNCs were forced to watch Indian companies eat into their market share as Indian companies developed same medicine at much lower cost because of relatively lower investment in R&D. The Process Patent regime left no scope for absolute monopoly in the market; this resulted in increased competition in market and consequently leads to further drop in medicine prices.

- **Software Patentability**

Section 3(k) of the Patents Act, 1970 excluded "a computer programme per se" from the scope of patentability. This exclusion met with conflicting interpretations at the patent office, with some examiners granting patents to software combined with hardware or software with a demonstrable technical application of some sort. The 2004 Ordinance therefore qualified this exclusion by stating that software with a "technical application" to industry or when "combined with hardware" would be patentable. Owing to vigorous opposition from the free software movement[52], this provision was removed from the 2005 Act. The earlier position under the Patents Act, 1970 that a computer programme per se is not patentable now prevails.

- **Deletion of the provisions relating to Exclusive Marketing Rights (EMRs)**

Section 21 of 2005 Amendment deleted the Chapter IVA of the Act. The 1999 Amendment inserted this chapter in the Act to provide that applications claiming pharmaceutical inventions would be accepted and put away in a mailbox, to be examined in 2005. These applications are commonly referred to as 'mailbox applications'. This amendment was in pursuance of a TRIPS

[50] World Trade org. understanding the WTO: The Organistion, least developed countries, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7-e.htm. Accessed on 22nd April 2015

[51] Shamnad Basheer INDIA'S TRYST WITH TRIPS: THE PATENTS (AMENDMENT) ACT, 2005 THE INDIAN JOURNAL OF LAW AND TECHNOLOGY Volume 1, 2005

[52] See Free Software Foundation, Representation Made by the Free Software Foundation of India to the Government of India to Immediately Withdraw the Patents (Amendment) Ordinance, 2004, at http://fsf.org.in/representation/representation.html accessed on 23rd April 2015

obligation aimed at preserving the novelty of pharmaceutical inventions in those developing and least developed country (LDC) members that did not grant product patents for pharmaceutical inventions in 1995[53]. By virtue of this 'mailbox facility', applications would be judged for 'novelty' on the basis of the filing date and not with reference to 2005, the year in which product patents were first incorporated into the patent regime.

- **Compulsory Licensing Regime**

India's compulsory licensing provisions are the broadest and most comprehensive of all the world's patent systems. Section 92 of the India Patents Act, 1970 (2005) allows the grant of compulsory licenses on notification of the Indian government "in circumstances of national emergency or […] extreme urgency or in case of public noncommercial use." Moreover, Section 92A of the Act creates a new avenue for compulsory licensing that permits the manufacture and export of patented pharmaceutical goods to any country having insufficient or no manufacturing capacity to address public health problems. However, the grounds upon which compulsory licenses may be granted go far beyond state emergency, extreme urgent situations, and public health crises. For example, non-availability of the patented invention "at a reasonably affordable price" and the malfunction to work the invention in the territory of India can also be invoked to justify a compulsory license (Section 84).[54] This is one area where there have been main changes, both substantive and procedural. In respect to the 2005 Amendment following amendments have been made in respect of compulsory licencening regime -

a) Automatic Compulsory Licences for Mailbox Applications

The 2005 Amendment provides that in the case of those mailbox applications that result in the grant of a patent, an automatic compulsory licence would issue to those generic companies that made a 'significant investment' and were 'producing and marketing' a drug covered by the mailbox application prior to 2005.[55] Such licence is subject to a payment of a 'reasonable royalty'. However, no specific yardstick is provided to determine 'reasonableness' and this term is likely to lead to disputes in coming years.[56]

b) Compulsory Licences for Exports

In order to incorporate what is commonly referred to as the Paragraph 6 Decision[57], the Ordinance introduced section 92A, which provides for compulsory licences to enable exports of pharmaceutical products to those countries with no manufacturing capacity of their own. Unfortunately, this suffered from a handicap - the provision required that the exporter obtain a compulsory licence from the importing country as well. In the process, the provision failed to cater to those situations where there was no patent in such importing country and no requirement for obtaining a compulsory licence there. The 2005 Amenment therefore seeks to rectify this by adding that an exporter can resort to section 92A where the importing country "has by notification or otherwise allowed importation of the patented pharmaceutical products from India".

c) Procedural Changes

The general compulsory licensing procedure under Chapter XVI states that in most cases, a compulsory licensing application can be entertained only if negotiations towards a voluntary licence have not borne fruit within a reasonable time period. In order to prevent patentees from dragging on voluntary negotiations to the detriment of applicants, the Act caps a 'reasonable' period of negotiations at six months.

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[53] http://docsonline.wto.org/GEN_highLightParent.asp?qu=&doc=D%3A%2FDDFDOCUMENTS%2FT%2FWT%2FDS%2F50ABR%2EWPF%2EHTM accessed on 21st April 2015

[54] Fanny Masson, "Patenting Pharmaceutical Substances in India", http://e-collection.library.ethz.ch.pdf Accessed on 23rd April2015

[55] Patents Act, 1970, Section 11A, proviso, amended by Patents (Amendment) Act, 2005.

[56] http://164.100.24.230/Webdata/datalshom001/dailydeb/22032005.htm. accessed on 21st April 2015

[57] Patents Act, 1970, Section 87, omitted by Patents (Amendment) Act, 2002. Since the 1970 regime provided only 'process patents' in the case of pharmaceutical inventions, it was not too surprising that this compulsory licensing provision was hardly ever invoked by generic manufacturers.

The TRIPS Agreement has brought in many new provisions which were earlier not accustomed to the Indian legal regime. As rightly pointed out by Jayshree Watal in her Article, "Implementing TRIPs Agreement Policy options open in India."

> "The most fundamental change required to be made to Indian patent law is on patentable subject matter. Article 27 of TRIPS makes mandatory the availability of patents for any invention, irrespective whether this relates to a process or a product, in all fields of technology, with only some limited exceptions. In complying with TRIPS many of the exclusions to patenting now permitted under the 1970 law will have to go. India allows only process patents in inventions relating to food, pharmaceuticals, agricultural chemicals and chemicals. No patents. Either for products or processes is allowed in the field of atomic energy".[58]

A new section 2(1) (ja) substituted the existing definition of 'inventive step' to mean *"feature of an invention that involves technical advances as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art"*.

This is an interesting attempt to 'redefine' one of the cardinal patentability criteria. 'Inventive Step' was originally defined in the Act to mean 'a feature that makes the invention not obvious to a person skilled in the art'. An Explanatory note to Art. 27 (1) of the TRIPS Agreement states that 'inventive step' is synonymous with 'non-obviousness'. There exists a plethora of judicial pronouncements on what constitute 'non-obviousness' as a criterion of patentability. Further, many national patent offices have practice guidelines explaining the fundamental propositions concerning what is not obvious to a 'person of ordinary skill' in a given technological art – so as to make an invention patentable.[59]

Novartis Ag v. Union of India

Another significant development in the Indian Patent regime was the Novartis case, When pharmaceutical company Novartis challenge the rejection of its patent application for the leukemia drug Gleevec in Novartis AG v. Union of India,[60] it became the first main legal challenge to India's newly amended patent law. In 2005, India allegedly made the final changes required to bring its intellectual property laws in compliance with the Trade-Related Aspects of Intellectual Property Rights (TRIPs), the World Trade Organization's (WTO) minimum standards for intellectual property protection, but its patent law is still filled with a number of controversial provisions. The ability of pharmaceutical companies such as Novartis to secure patent protection in India not only is important in creating incentives for pharmaceutical research, but also greatly affects the Indian generic drug industry, and therefore the cost of medicine available to patients. India is the world's second most populous country and the second fastest growing major economy, but has 70% of its population living on less than Rs. 120 per day, making Novartis AG of paramount importance.

In May 2006, Novartis petitioned the Madras High Court, oppose by the Indian Government, the Patent Office, numerous Indian generic drug manufacturers and an Indian public interest group. Novartis claimed that the Patent Controller erred in rejecting the Gleevec patent application, that Section 3(d) was not compliant with TRIPs, and that Section 3(d) was unclear, vague and in violation of Article 14 of the Constitution of India because it was discriminatory against Novartis. The case was bifurcated between the Madras High Court and the Intellectual Property Appellate

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[58] Watal, Jayshree. Implementing the TRIPs Agreement Policy Option Open in India, *Economic and Political Weekly*, Vol. 32, No. 39 (Sep. 27 - Oct. 3, 1997), pp. 2462

[59] Available at http://www.mondaq.com/india/x/31717/IT+internet/Indias+Patents+Bill+2005+Is+It+TRIPS+Compliant accessed on 24th April 2015.

[60] Novartis AG v. Union of India, (2007) 4 MADRAS L.J. 1153, http://www.scribd.com/doc/456550/HighCourt-order-Novartis-Union-of-India. Accessed on 23rd April 2015.

Board (IPAB). The challenges on TRIPs compliance and constitutionality of Section 3(d) were heard by the Madras High Court

As part of a series of amendments to the India Patents Act that took effect on January 1, 2005, the Parliament of India adopted Section 3(d). This statutory provision has been in force for more than seven years. A challenge brought by Novartis to the constitutionality of the provision and to its compatibility with the WTO TRIPS Agreement (World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights) was rejected by the High Court at Madras in 2007. That judgment was not appealed. On 1 April 2013, the Supreme Court of India rendered judgment on an appeal by Novartis against rejection by the India Patent Office of a product patent application for a specific compound, the beta crystalline form of imatinib mesylate. Imatinib mesylate is used to treat chronic myeloid leukaemia and is marketed by Novartis as "Glivec" or "Gleevec". Affirming the rejection, the Supreme Court confirmed that the beta crystalline form of imatinib mesylate failed the test of Section 3(d). The Court clarified that efficacy as contemplated under Section 3(d) is therapeutic efficacy.[61]

This judgment has attracted worldwide press coverage. It has received severe criticism from a number of originator pharmaceutical companies, including Novartis, and from the US Chamber of Commerce, to the effect the judgment of the Indian Supreme Court has dealt a harsh blow against the future of innovation, particularly in India.

The major problem with the compliance of TRIPs Agreement and the Indian laws is the idea of product and process patents.

For 'global' diseases, product patents will imply higher prices for new drugs in developing countries, with little or no offsetting dynamic gain, in the form of higher rates of medical research and innovation. In the case of 'poor country' diseases such as malaria id TB, on the other hand, stronger intellectual property protection, while necessary , may not, by itself, be sufficient to induce new, improved and affordable medical treatments for these ailments. Faced with this prognosis, participants in the international debate on patents and pharmaceuticals have begun exploring two distinct sets of TRIPS-compliant options/mechanisms that would enable patients in the developing world to access new treatments at affordable costs.[62]

CONCLUSION

Keeping in mind the end goal to administer the issue relating to Intellectual property, number of laws instituted however Indian involvement with IP has not been agreeable. The lawful administration of IP in India has been nomination of the British laws and a large portion of the Indian laws are virtual duplicates of the British enactment which have been passed from time to time.

The TRIPs Agreement has gotten a basic change in the Indian enactment. India being a party to the GATT Agreement held at Uruguay in 1986 which drove the establishment of WTO. In 1995 critical improvement occurred as TRIPS Agreement. India has formed its national enactments by numerous alterations in its IPR laws to follow the TRIPs Agreement.

The provision of the TRIPS Agreement however viable have numerous indecencies. A percentage of the provision are produced using the starting which looks like the thought of the developed nations and their financial components. The situation is distinctive in the developing and LDCs. The financial situation of Developed and developing countries is very diverse. There are a few procurements in the TRIPS agreement which does not suit to the Socio-economic situation of the developing countries like India, yet under pressure of developed countries, the developing countries need to execute the procurements of outings understanding, regardless of the possibility

[61] Abbot, M Freidreich, Inside views, the Judgement in Novartis v India: What the SC of India said, Intellectual Property watch available at http://www.ip-watch.org/2013/04/04/the-judgment-in-novartis-v-india-what-the-supreme-court-of-india-said/

[62] Mishra, Veena, Product Patents and Pharmaceuticals, *Economic and Political Weekly*, Vol. 26, no. 48, p-4464-4465

that it doesn't exactly measure up for to their financial situation. As can be seen in the circumstance of patent in India. The economically accessible medications in India like that of CIPLA pharmaceuticals are in presence however in the event that the item patent is incorporated then the inferable from the white collar class and the poor family of Indian culture they will be denied of the medications due to its cost variables.

The major changes introduced in the Indian Patent Act that were required to meet India's obligations to international agreements and treaties. The Patents Act 2005 has formed a strong patent system in India. Overall the present Act has increased the scope of patenting and provides stringent safeguards to the patentee. The new Act would play a major role in creating a technology determined market. Firms would ever more try to create monopoly based on their patented technology. Indian firms primarily those that are in high technology areas would face increasing pressure, as patented products would enter the market.

The amendment now gives the option of exporting drugs to a nation, which ask for a generic drug. The only circumstance would be that the nation where it can be exported should have no or insufficient manufacturing facility. The key changes made in the Indian Patent Act would have significant impact. The market would increasingly become technology driven.

Finally, the extent of the flexibility that is built into the TRIPs agreement is not plainly defined. Numerous provisions in the new patents regime are likely to be challenged in the near future since their compliance with TRIPs remains an open issue. This lack of clarity has to be resolve and, therefore, the system can promote from the judicial analysis by unraveling the meaning of its new patent law.