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SALIENT FEATURES OF TRIPS (TRADE RELATED INTELLECTUAL PROPERTY RIGHT) AGREEMENT

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ABSTRACT

The term intellectual property rights (IPRs) refers to those legal rules, norms and regulations that prevent the unauthorized use of intellectual products[1]. IPRs essentially consist of two domains: one deal with industrial products, which includes patents, The TRIPS Agreement which came into effect on 1 January 1995, is to date the most comprehensive multilateral agreement on intellectual property. The areas of intellectual property that it covers are: copyright and related rights (i.e. the rights of performers, producers of sound recordings and broadcasting organizations); trademarks; geographical indications; industrial designs; patents, including the protection of new varieties of plants; and undisclosed information including trade secrets. The modern pharmaceutical industry is of recent origin. With the introduction of sulpha drugs in the mid-1930s and penicillin in the early 1940s, the international pharmaceutical industry went through what is usually referred to as a therapeutic revolution. Before the 1930s, few drugs were capable of curing diseases[2]. While there are a large number of pharmaceutical manufacturers in the world, only a small number of MNCs dominate the industry. There is a clear distinction[3] between (i) a small number of big MNCs which do R & D for new drugs and get these patented and (ii) a large number of smaller companies that produce products for which parents have expired. The latter are known as generic companies. TRIPS agreement is regarded by developing countries as having been forced upon them by the United States. This is not entirely a fair claim in the case of India, where the government and some of the successful generic drug companies recognized in the early 1990s that an eventual transition to a regime allowing pharmaceutical patents might be in the nation's long-term interest.[4] The TRIPS agreement, informed by both the classical arguments for patent and the developing country – argument, made a distinction among three classes of the nation. Developed countries were required to bring patent regimes into immediate compliance with the agreement.[5] Developing countries, India and Brazil among them were given ten years, and the least developed countries, mostly those in Africa and the Middle East, were given more time. This differentiated timetable makes sense for both developing and the least developed countries, and, specifically, for India. Three factors may be suggested (1) India's growing size concerning markets (2) its increased capacity to innovate, and (3) the flexibility inherent in the TRIPS agreement that will allow India to avoid most of the adverse consequences envisioned by the opponents of reform.

Keywords: *Intellectual Property Rights, TRIP, Patent, Copyright, Pharmaceutical Industry, Drug.*

Introduction

TRIPS Agreement means the agreement on Trade Related Aspects of Intellectual Property Rights. This is most comprehensive multilateral agreement on intellectual property. This is most comprehensive multilateral agreement on IP. TRIPS are an international agreement administrated by WTO. It sets down minimum standards for many forms of Intellectual property regulations and will be applied to other WTO members. The TRIPS agreement came into force on 1995. It was negotiated at the

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1 Merrill and Elliott, 2004
2 (Calder 1962, p. 20).
3 Another category, the research-intensive small and medium biotechnology firms are gradually important (see Cockburn 2004).
4 G.B. Reddy, Intellectual Property Rights and the Laws, Gogia Law Agency, Hyderabad, at p. 73
5 Narayan P., Intellectual Property Law, Eastern Law House, Culcutta, at p. 331

end of the Uruguay round of GATT in 1994.The TRIPS Council is responsible for administering and monitoring the operation of the TRIPS Agreement. The TRIPS Agreement is also described as a "Berne and Paris-plus" Agreement. The Doha Declaration on the TRIPS Agreement and Public Health was adopted by the WTO Ministerial Conference of 2001 in Doha on November 14, 2001. Agrees that the TRIPS Agreement "Does Not and Should Not" prevent member countries taking measures to protect public health. It gave right to every WTO members to grant Compulsory Licences. TRIPS also specify enforcement procedures, remedies and disputes resolution procedures.

- **Meaning of Intellectual Property Rights:** Intellect means mind, creativity and Property means asset or bundle of rights. Intellectual Property is the property which is the creation of human intellect (mind).
- **Right:** A simple meaning of right is power to use, sell, mortgage, transfer, ex- change, destroy the object etc.
- Intellectual property rights means the rights given to persons over the creations of their minds. It is exclusive right to commercially exploit the property. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time. For example, Ram wrote a Book. He has right to Print, publish in market, sell, make new edition, make movie on book and author can also right to transfer his copyrights to publisher.

Origins/Background of Trips Agreement

The first agreement to regulate international monetary policy was made in 1944 at Bretton Woods by a number of nations. It established the International Bank for Reconstruction and Development (IBRD) in 1945 and the International Monetary Fund (IMF) in 1946, both of which are referred to as Bretton Woods Institutions. In order to unify global commerce, the General Agreement on Tariffs and Trades (GATT) was subsequently founded in 1947. GATT was the sole multilateral agreement regulating international commerce since 1948 until the World Trade Organization (WTO) was founded in 1995.

After continuous talks and difficult negotiations, the WTO was ultimately founded in 1994 and went into operation on January 1st, 1995. India was one of the 123 countries that took part in the Uruguay Round and joined the WTO. 153 countries currently make up the WTO, or about 90% of all countries in the world. New trade agreements must be negotiated and put into effect by the WTO.

The TRIPS Agreement is one of the most significant WTO agreements. The first day of 1995 saw the implementation of this Agreement. The TRIPS Agreement, sometimes known as "the Agreement," is a WTO-managed international agreement that establishes the basic requirements for various types of intellectual property laws. The Pact is now the most extensive multinational agreement on intellectual property.

TRIPS Agreement of Key Principles

- Common minimum standards: Article 1 (1)
- Language of balance, preamble: Article 7 and 8
- National Treatment: Article 3
- Most-favoured Nation: Article 4
- Relationship with pre TRIPS WIPO treaties: Article 2 and 5
- Exhaustion undefined: Article 6
- Non-violation excluded: Article 64
- TRIPS Plus
- Transition periods for implementation of TRIPS

Types of Intellectual Property Covered under the TRIPS Agreement

Following areas of Intellectual Property are covered under the Agreement.

- Copyrights and Related rights
- Trademarks (also service marks)
- Geographical Indications (including appellations of origin)
- Industrial Designs
- Patents (including protection of new variety of plants)
- Layout-designs of Integrated Circuits
- Undisclosed Information (Trade secrets and Test data)

Intellectual Property in India

- Copyright
- Patent
- Trademark
- Industrial design
- Geographical indication
- Layout design of integrated circuit
- Plant varieties
- Data protection
- Information technology & cyber crimes

The three Main Features of the TRIPS Agreement

Standards: In respect of each of the main areas of intellectual property covered by the TRIPS Agreement sets out the 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 convention for the protection of industrial property (Paris convention) and the Beme Convention for the protection of literary and Artistic Works (Beme Convention) in their most recent versions must be complied with. With the exception of the provisions of the Beme convention on moral rights, all the main substantive provisions of these conventions are incorporated by reference and thus become 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 Beme Convention. Secondly, the TRIPS Agreement adds a substantial number of additional obligations on matter where the pre-existing conventions are silent or were seen as being inadequate. The TRIPS Agreement is thus sometimes referred to as a Beme and Paris – Plus agreement.

The process establishing the ITO was launched in 1946 by a decision of the UN Council for Economic and Social Affairs (ECOSOC), which asked a committee, composed of representatives of 18 countries to draft the ITO charter "for the purpose of promoting the expansion of trade and production, exchange and consumption of goods".[1] A first draft was discussed at Church House, Westminster from October 15 to November 26, 1946 on the basis of a proposal by the United States.[2] No agreement was reached that conference on organizational aspects.

A second conference was convened in New York from April 10 to August 22, 1947.[3] A second version of the daft charter was then submitted to governments in early September. Meanwhile, the first round of tariff negotiations had begun. The results of discussions o the second draft and on tariff negotiations were combined in the Final Act adopted at the conclusion of the Second Session, including the text of GATT, which was signed at Geneva on October 30, 1947 by representatives of 25 governments. Provisional application of GATT, under the "Protocol of Provisional Application" included in the Final Act, began as of January 1, 1948.[4]

The full Untied Nations Conference on Trade and Employment was then held at Havana from November 21, 1947 to March 24, 1948. An interim committee of the ITO (ICITO) was formed by a resolution of this conference. The annex to this resolution provided from the membership and functions of the committee.[5] The conference adopted the ITO charter (known as the "Havana Charter").

The Havana Charter never entered into force as no acceptances were received by the UN Secretary-General which can be explained, at least in part, by the fact that on December 6, 1950 the United States Department of State issued a Policy statement indicating that the Havana Charter would

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1 The WTO *Guide to GATT Law and Practice* (Updated 6th ed., Geneva, 1995), pp. 3-4. This book is referred to hereinafter as the *GATT Analytical index.*

2 Suggested Charter for an International Trade organization of the United Nations, Washington DC, US Department of State Publication 2598, *Commercial Policy Series,* 93, 1946.

3 Actually, a Drafting Committee of technical experts met from January 20 to February 25, 1947 at Lake Success (New York). Report of the Drafting Committee of the Untied Nations Conference on Trade and Employment, UN document EPCT/34 March 5, 1947).

4 *GATT Analytical Index,* p. 5.

5 Havana conference Final Act and Related Documents (March 24, 1948), document ICITO/I/4, pp. 158-159.

not be resubmitted to congress.[1] It is not possible to fully explain here why the United States Congress rejected the ITO, but it is fair to say that a perceived loss of sovereignty was key element of the decision. When approving adhesion to the WTO, Congress sought and obtained the reassurance of the Executive Branch that WTO Membership would be reviewed should consecutive panel reports under the new WTO dispute settlement system be unfavorable to the Untied States.

- **Enforcement:** The second main set of provisions deals with domestic procedures 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 an administrative procedures and remedies, provisional measures, special requirements 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 right holders can effectively enforce their rights.
- **Dispute settlement:** The Agreement makes settlement procedures of disputes between WTO members about the respect of the TRIPS obligation subject to the WTO's dispute.

In addition the Agreement provides for certain basic principles, such as national and most-favored-nation treatment and some general rules to ensure that procedural difficulties in acquiring or maintaining IPR 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.

The TRIPS Agreement is a minimum standards agreement, which allows members to provide 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.[2]

WTO's Agreement: The WTO's Agreement on TRIPS makes it mandatory for all countries to establish standards for intellectual property protection. This Agreement came into effect on 1995 of all developing nations including India, needed to fulfill the above requirements by 2000. While the developed countries were to implement this requirement by 1996, the schedule for the least developed ones gave then time till 2005.

The TRIPS solution suggests a wonderful new market will open up for nations like India, South Africa, Brazil and china which have domestic manufacturing capacity in pharmaceuticals. There are so many safeguards that few compulsory licences will actually be used not to mention the delivery and government problems that will plague exporters from India. It could make India and other developing countries think a big victory has been wrested & thus deflect attention from more important issues like agriculture.

- **Implications of Trips Agreement**: To the new advantage of technology producers and users, the promotion and enforcement of intellectual property will help to advance technological innovation as well as the transfer and diffusion of technology. Member nations should base their domestic IP laws on TRIPS provisions. The 1970 Patent Act was significantly revised by the Indian government in 2005, and the 2010 copyright law reform went into effect in 2012.
- **Trips Agreement's Impact on Indian Laws**: India signed the TRIPS Deal in 1994, but it didn't go into effect until January 1, 1995, making it the most significant global agreement on intellectual property at the time. The Agreement promotes international trade and technology transfer by establishing baseline requirements for IP rights. The Agreement's Article 27 was broken by the Patent Act of 1970. India has to take the appropriate actions during the grace period in order to fully comply with the Agreement. In developing nations like India, which did not permit product patents in the fields of medicines and agricultural chemicals (for which patent applications are also known), the Agreement created a three-stage framework for enhancing the IP system. These stages are described as follows:

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[1] *GATT Analytical index,* p. 6. Also document GATT/CP/86 (December 7, 1950).

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- **Introduction of Mail-box Facility:** From 1st January, 1995 for product patents in the field of agrochemicals and pharmaceuticals. These mail-box applications were not examined until 2004 compliance with other obligations of the Agreement such as, rights of Patentee, term of protection, compulsory licensing, etc… from 1st January, 2000.Full implementation of product patents in al technological domains including mail-box applications w.e.f. 1st January, 2005.

Thus, the Agreement came into force in India in January, 2005. TRIPS changed the face of IP in the world as many developing countries, including India, which had weak IPR mechanisms had to extensively revise, amend and create their patent laws, or where there were no IPR regimes (the most important examples being plant variety protection, lay-out design and geographical indications) had to put in place an entirely new IPR regime. However, implication of the Agreement and the regime so incorporated has its own pros and cons. The revision of Patent laws brought into existence a stronger patent protection mechanism which is at par with the international standards or the standards set out in the Agreement. The result of this has been positive for India as foreign investors were encouraged to invest in India. It can be expected that the domestic investment might not respond to the stronger patent regime but Foreign Direct Investment (FDI) might. Further, the research and development (R&D) expenditures of the domestic players tremendously increased in post Agreement period as compared to the pre-agreement period.

Another positive implication is more technological in nature. The availability of products ought to be better with stronger IPR protection. However, the prices of these better and patented products may not be affordable for majority of the population.

Investments from domestic as well as foreign sector have risen in the field of seeds and agriculture. That is, post the Agreement, stronger protection regimes have encouraged domestic private sector as well as foreign firms to invest in R&D for the development of better seeds. Many Geographical Indications and methods in Traditional Knowledge which are of importance to the domestic industry of India have got protection and have encouraged investment in these sectors, for example: Darjeeling Tea.

When the Indian parliament passed the new patent law in 2005, it not only brought back product patents, but also granted all patents a term of 20 years. Moreover, the new law paved way for the formation of the Intellectual Property Appellate Board, a specialized judiciary to hear the IP cases.

- **Modifications in the Patent Act, 1970:** The patent (Amendment) Act, 2005 is presently in force. Subsequently, the central Government amended the patent Rules, 2003 and the rules were called the patent (Amendment) Rules, 2005. By a publication dated June, 2005 in the gazette of India, further amendments to the rules were published, called the patent (Second Amendment) Rules, 2005.

With regard to the examination of the application and time for placing the application in order, section 11B of the patent (Amendment) Act, 2005 stipulates that the application will e examined only after filling the request for examination. Rule 24B prescribes various time limits for making the request. The Rule 24B (1)(i) also stipulates that the request for examination can be filed only after the publication of the application but within 36 months from the date of priority or the dale of filing of the application, whichever is earlier.

On the request for examination, according to the proposed amendment to Rule 24B (1) (v), in the cases of applications filed before January 1, ’05, the time limit for filing a request for examination shall be the period specified under section 11B before the commencement of the patent (Amendment) Act, 2005.While appreciating the amendments proposed, It would be appropriate if the extract period was stipulated in the rule itself, instead of making a reference as proposed. Rule 24B (4) is not clear as to the applications in respect of the period specified therein. It is presumed the applications are those which have been examined after the coming into force of the patent (Amendment) Act, 2005 and not those examined earlier. So, an order for a grant under section 21 in respect of the application, which is examined after the amended act, shall be 9 months from the date on which the first statement of objection is issued to the applicant to comply with requirements.

These provisions are intended to expedite the grant of patent and in principle, are a good provision and are appreciated. It is seen that after meeting the official requirements, the applicant has to wait for a considerable length of Time to receive another official action if any, for a considerable period of time. In other words, many a time, the patent office takes away majority of the period available. In the case of inspection and supply of published documents, in rule 27, there is a mention of “payment of fees” but the schedule does not prescribed any such fees. Hence, if any fees are to be paid, it has to be

stipulated in the schedule of fees. On the other hand, if no fees are to be paid, then the above words have to be deleted. When it comes to opposition by representation against the grant of patent, in the proposed amendment to rule 55(1), no time period has been specified, though from the new Rule 55(1) a, it can be presumed that the period is six months from the date publication under section 11A in order to make the rule clear and precise and not leave anything to presumption, the time limit may be specified in rule 55 (1) itself.[1]

The patent (Amendment) act, 2005 also provides the constitution of an opposition Board, which will provide inputs to the controller. The Board will consist of three examiners, one of them acting as the chairman. When it comes to inspection of documents for the grant of patent, Rule 74 A though specifies that for this, a written request has to be made along with the prescribed fees, though no fees have been prescribed. Therefore, in the schedule of fees, the prescribed fees have to be indicated. Section 153 deals with the request of information. In rule 134 (k), the words "official Gazette" should be substituted with the words" patent office journal". This amendment is required consequent to the discontinuance of the gazette of India with effect from January 1, 2005 and the publication of the patent office journal instead.

- **Patents:** pharmaceutical: Insofar as patentability of chemical molecules is concerned, it has been clarified that mere discovery of a new form of a known substance which does not result in the enhancement of the known efficiency of that substance is not patentable. For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, isomers, mixtures of isomers and other derivatives of known substances are to be considered to be the same substances, unless they differ significantly in properties with regard to efficacy, (amendment to section 3(d) This amendment would alleviate fears amongst the Indian pharmaceutical industry and consumers with regard to the scope of product patent. What is not novel is now made clearer. A new form of a substance is patentable only if it results in enhancement of the know efficacy of such substance.
- **Compulsory License:** Relaxing the TRIPS rules would make it easier for developing and underdeveloped countries to access vaccines. It is unethical and immoral for pharmaceutical companies to be looking to make profits out of the vaccines. Life-saving drugs and vaccines should be made available to everyone. With regard to the current pandemic situation, it is said that no one is safe unless everyone is safe. Therefore, it is crucial that vaccines are made available to everyone in affected countries since it can easily spread to all countries as was seen in the first wave.

Section 92A, which was inserted by the ordinance in pursuance of paragraph 6 of the Doha Declaration on TRIPS, has been further amended. Now, compulsory license to manufacture and export the patented product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector can also be granted if such country has allowed importation of the patented pharmaceutical products from India.[2]

The amended provision will allow Indian companies to produce and export AIDS drugs to African and South East Asian countries. The Amendment has greatly broadened the scope of opposition to the patent by introducing two changes; that is after its publication but before its grant and after the grant, within one year.

Suggestions

- It is suggested that the pharmaceutical companies considerably raise their investments in R &D due to the introduction of product patents.
- Pharmaceutical companies should create a sound infrastructure for undertaking or enhancing the research activities owing to the introduction of product patents.
- it is suggested that small and medium pharmaceutical companies ensure good quality research, make sizeable investment in research, exports and up- gradation.
- It is duty of the Government and the pharmaceutical companies to allay the fears of the common man regarding hike in drug prices.

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[1] Peoples' Commission on Patent Laws for India (2003), Report of the Peoples' Commission on Patent Laws for India, New Delhi: Centre for Study of Global Trade System and Development

[2] It was the 11th in the list and thus all documents issued (officially) for the Group bore numbers starting with MTN.CNG/NG11/MTN stands for Multilateral Trade Negotiations and GNG for Group of Negotiation on goods.

- It is suggested that the Government protects the interest of not only the common man but also the pharmaceutical companies in regard to product patents.
- An important suggestion is that the Indian pharmaceutical companies take all out efforts possible to capture the drug market through good quality drugs at affordable prices through quality research work.
- Product patent procedures and practices should be simplified and transparent to attract more companies to produce quality drugs at reasonable prices.
- Network between the drugs controller General of India (DCGI) and the patent office must be a balanced one so that the position regarding issue, renewal and registration of patent can be known earlier.

Conclusion

The TRIPS agreement was negotiated in 1995 at the WTO, it requires all its signatory countries to enact domestic law.It guarantees minimum standards of IP protection. This provision, commonly referred to as "compulsory licensing", was already built into the TRIPS Agreement and the Doha declaration only clarified its usage. While the discussion in this study is confined to the above three issues that the Indian pharmaceutical companies face in the anvil of the new TRIPS compliant regime, the transition from a limited term process patent regime to the product patent regime can have several other far reaching implications. Under Section 92 of the 1970 Indian Patents Act, the central government has the power to allow compulsory licenses to be issued at any time in case of a national emergency or circumstances of extreme urgency. Intellectual property rights are the rights given to persons over the creations of their minds. Intellectual property rights (IPRS) are legal rights that protect these creations. IP rights give their owners rights to exclude others from making use of their creations only for a limited period. IP rights entitle the owners to receive a royalty or any sort of financial compensation or payment when another person uses their creations Trademarks, Patents, Copyrights, Industrial designs, Layout designs, Trade secrets, Geographical Indications.

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