

# TRIPs & PATENTS

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In 1899, Mr. Charles H. Duell, Director of US Patent office said “Everything that can be invented, has (already) been invented”.

The events thereafter proved that inventions are waiting for those who are willing to “think out of the box”. We have moved in to the era of ideas, creativity, inventions and intellectual properties, intensively and aggressively in the 21<sup>st</sup> century and the dawn of the new millennium.

Intellectual property (IP) has emerged as a key tool in value creation and innovative growth of communities and countries in the transition to the 21<sup>st</sup> century and the birth of the millennium. IP in knowledge industry such as pharmaceuticals has become more relevant in the post WTO-TRIPs era.

## GATT to WTO

For many years, international trade was governed by GATT (General Agreement on Trade and Tariff). In mid-80's, the Uruguay Round of GATT, proposed for the inclusion of Intellectual properties in the trade agenda. Long deliberations and complex negotiations later in 1994, WTO (World Trade Organisation) was born effective 1<sup>st</sup> January 1995, where India was also a founder signatory.

WTO brought in or activated many agreements, treaties and conventions as well as many new regulations. Important among all of them is, of course the TRIPs (Trade related aspects of Intellectual property rights) Agreement. TRIPs has emerged as the most widely impacting Agreement post WTO leading to harmonization of Intellectual properties among member states.

All the forms of the intellectual properties, Patents, Trademarks, Copyrights, Designs and Trade secrets are extensively created, protected and integrated with the Pharmaceutical profession, practice and industry. The Pharmaceutical industry has evolved with innovative research leading to new medicines for a wide range of diseases including emerging ones and

lifestyle diseases. Often breakthrough inventions or even “disruptive inventions” leading to “blockbuster” drugs have emerged primarily resulting intensive investigative research, which would not have been possible without the support of Intellectual property protection and the research funding made available from commercialization or licensing out of such new chemical or biological entities.

Pharmaceuticals, like information Technology and biotechnology is a knowledge based industry. As already seen, Pharmaceuticals is a research based industry and needs innovative and creative approach which is the key to generation of intellectual properties compared to other industries, the balance of rights and obligations are very delicate in Pharma, since the inventions need to serve the needs of health care and nutrition of the community making essential medicines affordable and accessible to the needy, world over. TRIPs (Trade Related Intellectual Property Rights) Agreement have special references to health and nutrition, microorganisms, test date protection etc which are relevant to the pharma industry, In this topic, we will look at the emergence of IP with the Pharmaceutical industry in India and globally in the 20<sup>th</sup> century and its emergence in the 21<sup>st</sup> century.

Significance of Patents in Pharmaceutical industry:

Innovation is the key to success of pharma industry. Inventing newer medicines and solutions to address unresolved healthcare issues and to fight emerging diseases as well as unconquered areas of Tuberculosis, malaria, cancer, HIV/AIDS as well as life style diseases continue to be of utmost urgency and importance.

Innovation can only be successful with the support of strong R&D facilities. R&D could lead to inventions only if strongly supported by prior art disclosures and access to information and data. To encourage disclosure of novel ideas and innovative technologies to be used for further research, the state grants “Patents” to the inventor as a “*quid pro quo*”, provided the invention is novel and inventive/non-obvious.

### **TRIPs and Pharma**

Following are the provisions in TRIPs relevant to Pharma sector incorporated through various Articles of TRIPs.

Pharmaceutical Product Patents: - The most significant obligation under TRIPs with respect to pharmaceuticals is that the member nations were to adopt the product patent provision for the pharmaceuticals, food products and agrochemicals. Through the 'Transitional Provision' the developing and least developed countries were given certain period of time to comply with the obligations of TRIPs. For developing countries, the general transition period provided was five years, i.e. until January 2000 and for least-developed countries, the transitional period provided is eleven years. Special transition rules apply in the situation where a developing country does not provide product patent protection in a given area of technology, especially to pharmaceutical or agricultural chemical inventions, on the general date of application of the Agreement for that member, i.e. in the year 2000. According to Article 65.4, such a developing country may delay the application of the TRIPs obligations on product patents to that area of technology for an additional five years i.e. up to the year 2005.

However, the Agreement includes additional transitional arrangements in the situation where a country does not provide, as of the date of entry into force of the WTO Agreement, patent protection for pharmaceutical and agricultural chemical products commensurate with the TRIPs provisions. In accordance with the "mail-box" provision contained in Article 70.8, the country concerned must provide, as from the date of entry into force of the WTO Agreement, a means by which patent applications for such inventions can be filed. These applications will not need to be examined for their patentability until the country starts applying product patent protection in that area, i.e. for a developing country, at the end of the ten-year transition period. If a product that has been the subject of such a patent application obtains marketing approval before the decision on the grant of the patent is taken, there is an obligation under Article 70.9 to grant exclusive marketing rights for a period of up to five years to tide over the gap.

Eventually the developing countries were to adopt the Pharmaceutical product patent obligation by 2005 and the least developed countries are to adopt it by 2016.

Term of Patent: Term of patent has become 20 years uniformly for all fields of the invention, thereby substantially increasing the patent term for pharmaceuticals.

Reversal of burden of proof: In pharmaceutical process patent infringement suits, the burden of proof has been reversed. Onus now lies on the infringer, who has to prove that his process is not the same as that of patentee's process and that he is not infringing the patentee's rights. The reversal of the burden of proof is stipulated for process patents in order to strengthen the patentee's position in civil cases of infringement. This would also encourage more and more research in the field of pharmaceuticals, to equip oneself with process patents for offensive as well as defensive use.

TRIPs Art. 27(3)(b) makes it obligatory to grant patents to microorganisms and biological processes.

Compulsory licensing: Specific provisions of compulsory licensing are incorporated having significance for Pharma industry, though not directly, but through third party rights in Art.30 and Art.31 of TRIPs. These have been elucidated in subsequent paragraphs on Doha Round.

Data Exclusivity/Protection of Data submitted to Government: TRIPs provided for protection of the data submitted to governments in order to obtain approval of pharmaceutical and agrochemical products. This is known as the "Data exclusivity". Article 39.3 of the TRIPs Agreement is interpreted to mean that such tests and data must be protected against unauthorized disclosure and unfair commercial use. Once a company submits the original data to the regulatory authority then others are excluded from referring to this submitted data for a fixed period of time. The regulatory authorities can rely on this data for the registration of generic substitutes after the exclusivity period expires. This interpretation of multinational companies and developed countries is however disputed widely by NGOs and developing countries.

### **Doha Round**

The importance of public health vis-à-vis TRIPs was first recognized at the DOHA WTO MINISTERIAL 2001. On 14<sup>th</sup> November 2001, declaration of the Fourth Ministerial Conference took place in Doha, Qatar. Public health problems faced by various developing and least-developed countries like tuberculosis, malaria, HIV/AIDS, cancer and other epidemics were brought to light. The agreement was interpreted and implemented so as to be supportive of WTO members' right to protect public health and, in particular, to promote affordability and accessibility of essential medicines for even the poor. They also outlined the

countries ability to use the flexibilities that are covered by the TRIPs agreement which included the provisions of compulsory licensing. On 27<sup>th</sup> June 2002, the TRIPs council approved the decision on delaying pharmaceutical product patent on LDCs (Least Developed Countries) till 2016.

Eventually the decision of removing the patent obstacles for export/import of the cheaper generic version of the patented molecules was made through the TRIPs council of the 30<sup>th</sup> August 2003 followed by 6<sup>th</sup> December 2005.

Para VI of the Doha declaration is contemplated in the TRIPs provisions as Article 31. It brings about flexibility whereby countries which do not have the adequate facility to produce essential pharmaceuticals can import the patented drugs from other countries which have adequate facilities and can manufacture and sell it at an affordable price. Government of the member nations were given the right to grant compulsory license and also the freedom to determine the grounds on which the compulsory license would be granted. Subsequent to this various countries amended their national laws to include this aspect of public health covered in the Doha declaration. Thus through the Doha declaration it was agreed to extend the exemptions on pharmaceutical patent protection for least developed countries until 2016.

The general council of WTO has come out with a decision on amendment of TRIPs agreement on 6<sup>th</sup> December 2005. As per WTO chairman's statement this decision will now be formally built into the TRIPs Agreement when two thirds of the WTO members have ratified the change. They have set themselves until 1 December 2007 to do this. The waiver remains in force until then.

'Compulsory Licence' is granted when the requirements of the public with respect to the patented inventions are not met and the patented invention is not available to the public at a reasonable and affordable price. Any interested person having the adequate facility to manufacture the product (patented invention) and can sell the product at an affordable price can apply for compulsory licence. If the prerequisites for compulsory licensing are fulfilled, the government [the controller] has the power to allow any third person to manufacture the patented product without the consent of the patent owner.

Compulsory licensing is one of the flexibilities covered by Article 31 of the TRIPs agreement. This provision was incorporated mainly for the interest of the least developed and the developing countries. Many of these countries do not have the facilities to manufacture the life saving drugs required to face various emerging health problems. On the other side various pioneering inventions are made in these fields. New medicines are emerging day after day which can cure these dreadful diseases. So it becomes necessary to import these medicines from those nations who have the manufacturing facility to manufacture and sell the patented product at affordable price for protecting the national interest and public health initiatives. Provisions of 'Compulsory licensing' will be a boon to meet these public health issues for the least developed countries and developing countries.

The Doha round of WTO through Para VI had deliberated these areas relative to Article 7, 8 and 31 of TRIPs which led to introduction of Sec 92A in the Indian Patent [3<sup>rd</sup> Amendment] Act 1970.

After the 1970 amendment of the Patent Act, the pharmaceutical industry in India developed swiftly both in the field of raw materials (API's or bulk drugs) and also in the formulations (dosage forms). While the share of Indian domestic Industry was 30% in 1970, by 2000, the market share of the national sector of pharma industry grew to 70%.

The three consecutive amendments of the Indian Patent Act 1970 brought about several TRIPs-complying changes to Indian Patent Act, 1970. Some of those which are relevant to pharmaceuticals are mentioned below.

To accomplish India's commitment to WTO and TRIPs of which India had become a founder member, the first amendment to Patent Act 1970 was notified on 1.01.1995 to usher in the transitional alternative to product patents in EMR's (Exclusive Marketing Rights). As mentioned earlier, India had abolished product patents on pharmaceuticals, foods and chemicals in 1970 because of which an additional (optional) 5 years transition period was available to India (over and above the five years available to a developing country) to comply with TRIPs provisions. India had to implement the transitional provisions of TRIPs (Article 70.8 & 70.9). However, the Bill introduced in parliament based on the notification of 01.01.1995 did not get ratified. Since India did not comply the TRIPs agreement (Article 70.8 & 70.9) the US and European Union dragged India to the WTO, wherein the matter came up

before the Dispute settlement body. The judgment compelled India to become TRIPs compliant on transitional arrangements. Consequently mailbox was opened effective from 01.01.1995 to receive product patent applications and also to grant transitional alternative of EMR for qualifying products. Even though the 1995 notification could not be ratified in the parliament, a new amendment brought in 1999 was passed as the patent (1st amendment) Act, 1999 incorporating these provisions in sec 5 (2) and chapter IV A (Sec 24 A TO 24 F).

Term of patent has been made unanimously applicable to all fields including pharmaceuticals to 20 years to comply with Article 27(1) of the TRIPs.

The controversial “licence of right” provisions were deleted thereby bringing in new value and respect for patents granted for pharmaceuticals in India.

Definition of ‘invention’ has been amended.

‘invention’ reads as follows,

*“invention” means a new product or process involving an inventive step and capable of industrial application.*

Definition of ‘inventive step’ has been amended. [Sec2 (1)(ja)]

‘inventive step’ reads as follows,

*“inventive step” means a feature of an invention that involves technical advance 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”.*

The full fledged product patent regime was introduced effective from 01.01.2005. The examination of mail box applications commenced thereafter. The alternative transitional provisions of EMR were deleted simultaneously.

Section 3(d) of Patent Act, 1970 has been amended to put a check on the “Evergreening”.

‘Evergreening’ occurs when patent owners make an attempt to extend the patent monopoly by obtaining a new patent that “updates” the first one before its expiration. Some of the means by which the ‘Evergreening’ is done by providing a new use to the existing patented drug, by providing method of treatment, method for administering the pharmaceutical compound covered by the original patent, dosing regimen, delivery profiles, metabolite produced by the drug of the original product, therapeutic concentration achieved by the drug

of the original product, and so on. For pharmaceutical products this 'Evergreening' enlarges the market monopoly by preventing the entry of the generics.

Sec 3(g) was deleted from the list of inventions which are not patentable.

New testing methods and processes can now be patented. This will encourage research in pharmaceutical analysis and bring about new, efficient methods for testing of pharmaceuticals.

Sec 11A(7) has been incorporated: No patent infringement action can be initiated for any NCE molecules or product, for which product patents will be granted after 1.1.2005, if any manufacturer has introduced that product already in India. However, the inventor (product patent holder) can receive 'reasonable royalty' from the manufacturer. This facility is not available to applications filed after 1.1.2005. This may be the single-most favourable transitional provision for Indian manufacturers.

Sec92A, which was incorporated in the 3<sup>rd</sup> Amendment, provides for manufacture and export of patented products against compulsory licences issued by third world countries (LDCs) having no manufacturing facilities of their own (Doha Para VI compliance).

Sec84 to Sec94 of Indian Patent Act [as amended up to 2005] covers provisions of Compulsory Licence. Various scenarios and conditions for issue of Compulsory licences are covered in these sections.

Sec 107 A (a) covering the 'Research Exemption' similar to the Hatch Waxman (Bolar exemption) has been incorporated.

Sec 47(3): Use of the patented inventions for experimental or research purpose including imparting of instructions to pupils have been exempted from infringement.

The relevant Rules are yet to be incorporated in the Patent Rules, 2006. The procedures for export against Compulsory licences need to be specified in the Rules. However, the proposed TRIPs amendment appears cumbersome and impractical. India may need to draft its own workable procedures in the Rules.