CHAPTER - IV
TRADE RELATED INTELLECTUAL PROPERTY RIGHTS
AND INDIAN PHARMA INDUSTRY

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the World Trade Organisation that sets down minimum standards for many forms of intellectual property regulation as applied to nationals of other WTO Members.

Ideas and knowledge are an increasingly important part of the trade. Most of the value of new medicines and other high technology products lie in the amount of invention, innovation, research, design and testing involved.

Creators can be given the right to prevent others from using their inventions, designs or other creations and to use that right to negotiate payment in return for others using them. These are “intellectual property rights”. They take a number of forms. For example books, paintings and films come under copyright; inventions can be patented; brand names and product logos can be registered as trademarks; and so on. Governments and Parliaments have given creators these rights as incentive to produce ideas that will benefit society as a whole.

The extent of protection and enforcement of these rights varied widely around the world and as intellectual property became more important
in trade, these differences became a source of tension in international economic relations. New internationally-agreed trade rules for intellectual property rights were seen as a way to introduce more order and predictability, and for disputes to be settled more systematically.

**GATT LEADING TO WTO AND IN TURN TO TRIPS**

The General Agreement on Tariffs and Trade (GATT) completed 8 rounds of Multilateral Trade Negotiations (MTNs). The Uruguay Round (the 8th round) was the first multilateral agreement dedicated to the sector. It was a significant first step towards order, fair competition and a less distorted sector. The WTO Agreements concluded with the signing of the Final Act on April 15, 1994, in Marrakesh, and produced the World Trade Agreement (WTO) and its annexes

As of January 2000, all developed and developing countries who are members of the World Trade Organization (WTO) were obligated to have domestic laws and enforcement mechanisms that comply with the international standards set forth under the Agreement on Trade-Related Aspects of Intellectual Property Rights (Trips), is the most comprehensive multilateral agreement on intellectual property.

With countries such as India, China and Brazil emerging as ‘advanced developing nations’ in a few fields, a dominant issue seriously exercising the advanced nations was to provide a legal framework to circumvent this process. These efforts were orchestrated secretly among themselves outside the United Nations Conference on Trade and
Development (UNCTAD) and other such UN mediated international trade bodies. The strategic aim was to define a set of regulations to be valid at a global level so as to prevent what they defined as ‘counterfeit goods and services’ entering into trade. The G-7 countries themselves worked them out over a roughly 15-year period and away from GATT/Uruguay Round negotiations. It led to a document almost ditto becoming the TRIPS Chapter of the WTO Treaty.

With India opting to become a member of WTO, implementation of TRIPS became sue motto obligatory services with uniform patent validity of 20 years.

**OVERVIEW OF TRIPS AGREEMENT**

The WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), negotiated in the 1986-94 Uruguay Round, introduced intellectual property rules into the multilateral trading system for the first time. Its inclusion was the culmination of a program of intense lobbying by the United States, supported by the European Union, Japan and other developed nations. Campaigns of unilateral economic encouragement under the Generalized system of preferences and coercion under Section 301 of the Trade Act played an important role in defeating competing policy positions that were favored by developing countries, most notably Korea and Brazil, but also including Thailand, India and Caribbean Basin States.

After the Uruguay round, the GATT became the basis for the establishment of the World Trade Organization. Because ratification of TRIPS is a compulsory requirement of World Trade Organization
membership, any country seeking to obtain easy access to the numerous international markets opened by the World Trade Organization must enact the strict intellectual property laws mandated by TRIPS.

The WTO’s TRIPS agreement is an attempt to narrow the gaps in the way and rights are protected around the world, and to bring them under common international rules. It establishes minimum levels of protection that each government has to give to the intellectual property of fellow WTO members. In doing so, it strikes a balance between the long-term benefits and possible short-term costs to society. Society benefits in the long term when intellectual property protection encourages creation and invention, especially when the period of protection expires and the creations and inventions enter the public domain.

TRIPS are the most comprehensive multilateral agreement on intellectual property to date. The TRIPS agreement was negotiated during the Uruguay Round trade negotiations and became effective on January 1, 1995. This agreement motivated WTO members to implement and enforce patent rights, including those for biopharmaceutical products and processes. Most WTO members were immediately bound by the standards stipulated by the TRIPS agreement, although the deadline for implementing its provisions was extended to 2000 for some developing countries, and was recently extended from 2006 to 2016 for least-developed nations.

The preamble of the agreement lays out its general goals as reducing distortions and impediments to international trade, promoting effective and
adequate protection of intellectual property rights, and ensuring that measures and procedures to enforce intellectual property rights do not themselves become barriers to international trade.

The TRIPS agreement consists of 7 Parts and 73 Articles, which are shown, in Annexure – III.

GENERAL PROVISIONS

Certain general provisions of the agreement apply to all forms of intellectual property rights, from copyrights to patents. These include the fundamental rules of international trade on nationals, and on most-favored-nation treatment of foreign nationals, contained in Articles 3 and 4, respectively. The national-treatment clause generally forbids discrimination between a member's own nationals and the nationals of other TRIPS members, with respect to the protection and enforcement of intellectual property rights. The most-favored-nation clause forbids discrimination between nationals of other TRIPS members, thereby affording all foreign nationals operating in a member state the same level of protection. An additional important general provision, Article 6, makes it clear that exhaustion of intellectual property rights is outside the scope of the TRIPS agreement.

SPECIFIC PROVISIONS

The substantive patent provisions of the TRIPS agreement first and foremost require member countries to make patents available for any inventions, whether product or process, in all fields of technology, provided that the inventions are new, involve an inventive step, and are capable of
industrial application. As stipulated in Article 27, patents must also be available without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced. This important core provision presented a major step forward in international patent protection for the pharmaceutical industry in particular, as many nations had excluded pharmaceuticals and biopharmaceuticals from all patent protection prior to binding themselves to the standards of the TRIPS agreement. Countries where patent protection for pharmaceuticals was only recently introduced as a result of the TRIPS agreement include Argentina, Brazil, Guatemala, India, Morocco, and Turkey.¹

TRIPS allows for three important exceptions to the rule of patentability:

(1) TRIPS exclude inventions contrary to order public or morality.

(2) TRIPS excludes diagnostic, therapeutic, and surgical methods for the treatment of humans and animals, and

(3) TRIPS members may exclude plants and animals other than microorganisms, as well as essentially biological processes for the production of plants, other than non-biological and microbiological processes. If members decide to exempt plant varieties from patentability, they must provide an alternative effective system of protection.

The exclusive patent product rights conferred by TRIPS include the rights to make, use, and offer for sale, sell, and import the product. Process patent rights must give exclusive rights not only over the process but also

over products obtained directly by the process. Patent owners may also assign patent rights and conclude licensing contracts. The term of protection for patents is 20 years, originating from the filing date.

With respect to the limitations of patent rights, TRIPS allows member states to provide for limited exceptions to the exclusive rights conferred by a patent, provided these do not unreasonably conflict with the normal exploitation of the patent or prejudice the interests of the patent owner. In addition, the TRIPS agreement does allow for compulsory licensing and government use without authorization of the patent holder, subject to certain conditions listed in Article 31. The extent to which compulsory licensing of life-saving patented medicines is permitted and considered acceptable under Article 31 of the TRIPS agreement has been the subject of much controversy among WTO members. The TRIPS agreement further contains general principles regarding the procedure to enforce intellectual property rights, including provisions on civil and administrative procedures and remedies. Disputes among WTO members with respect to their obligations under the agreement are subject to the WTO dispute-settlement procedures.

**TRIPS CONTROVERSY: ACCESS TO MEDICINES**

Striking the right balance between protecting patents and providing patients in the developing countries with access to life-saving medicines has been a great challenge in the face of the worldwide AIDS pandemic and other devastating diseases such as malaria and tuberculosis. Biopharmaceutical companies are at the center of this debate. As global
trade negotiations increasingly focused on the relationship between trade and development, the issue of providing access to medicines through the use of compulsory licensing came to the forefront at the 2001 WTO Ministerial Meeting in Doha, Qatar, where WTO members adopted the "Declaration on the TRIPS Agreement and Public Health." This declaration recognized the right of member states to grant compulsory licenses in cases of national emergency, or other circumstances of extreme urgency, such as public health crises relating to HIV/AIDS, malaria, tuberculosis, and similar pandemics.

BILATERAL AND REGIONAL TRADE AGREEMENTS

The protection of intellectual property rights has also played a key role in bilateral trade negotiations between the US Government and its trading partners. The US Government has consistently used bilateral and regional negotiations to improve intellectual property standards worldwide, and has pursued a policy of ensuring that bilateral trade agreements contain strong and effective patent protections. Patents for biopharmaceutical products are often at the center of these negotiations.

The North American Free Trade Agreement (NAFTA) provides strong intellectual property protections in its Chapter 17. In recent years, the US has also concluded bilateral Free Trade Agreements (FTAs) containing strong intellectual property protections with Australia, Chile, Jordan, Morocco, and Singapore. An agreement with five Central American nations and the Dominican Republic has been signed and is awaiting implementation by the US Congress. The intellectual property chapters of
these FTAs often provide for higher levels of protection in areas already covered by the TRIPS agreement. In a recent FTA with Australia, for example, the US Government sought even better protection for biopharmaceutical patents, in particular with respect to non-tariff trade barriers such as Australia's Pharmaceutical Benefits Scheme.

The US Government is seeking similar high-level intellectual property protections in the ongoing bilateral negotiations with Bahrain, Panama, and the five members of the South African Customs Union, and in additional negotiations with Andean nations and Thailand. Intellectual property protections are also key discussion points in negotiations toward a Free Trade Area of the Americas that would encompass all nations in North and South America, as well as in the Asia Pacific Economic Forum that includes 21 Pacific Rim countries. Bilateral, regional, and multilateral trade negotiations have, overall, been a key tool for the US Government in its efforts to further strengthen and harmonize intellectual property protections for the biopharmaceutical industry worldwide.

**FOCUS: BRAZIL, CHINA, AND INDIA**

In many countries around the world, certain problems are involved in implementing TRIPS-mandated standards into domestic law, and in enforcing existing domestic patent laws. Brazil, China, and India are all fast-growing economies with large markets and populations, and they have been of particular concern for research-based biopharmaceutical companies. These three countries also have substantial generic drug industries, which
are often able to exert a significant influence on commercial and industrial policy. In addition, Brazil and India have established themselves as leaders of a coalition of developing nations, often opposing US positions on stronger patent standards and enforcement.

**BRAZIL**

Some measures inconsistent with Brazil's obligations under TRIPS continue to be in effect. The 1999 amendment to Brazilian patent law gave the Country's National Sanitary Supervision Agency (ANVISA – Agencia Nacional de Vigilancia Sanitaria) authority to review all patent applications for pharmaceuticals, and the agency has denied secondary-use patents to innovative companies despite approval from the Brazilian Patent Office. ANVISA's review authority has been a major factor in delaying patent applications. The agency's authority also discriminates against biopharmaceutical products, as other patented products are not subject to such reviews by regulatory authorities.

Another area of concern is Brazil's industrial property law that requires both domestic and simultaneous manufacture of every patent claim. Failure to adhere to this law can justify the issuance of a compulsory license. This requirement is in place despite TRIPS Article 27, which obligates member states to recognize that importing a product satisfies the requirement that a patent be "worked" in a member state. On a positive note, Brazil has not yet issued any compulsory licenses, although a relevant presidential decree governing the grant of compulsory licenses gives broad
discretionary powers to government officials, and the Brazilian Government has threatened the use of this decree in negotiations with the biopharmaceutical industry.

**CHINA**

Ever since China's accession to the WTO in 2001, the country has been bound by the high intellectual property protection standards of the TRIPS agreement. While the Chinese Government has undertaken serious efforts to improve patent protection, numerous problems persist. Inadequate enforcement of intellectual property rights, as well as an inability of the Chinese Government to control widespread production and distribution of counterfeit pharmaceuticals, continues to create a difficult operating environment for biopharmaceutical companies. The innovative pharmaceutical industry loses an estimated 10 to 15 percent of its annual revenue in China to counterfeit products. Counterfeit pharmaceutical products are easily available in highly public areas, underlining the scope of the problem. Due to these problems, the US Government continues to closely monitor China's IPR practices.

**INDIA**

The beginning of 2005 and the recent passage of a new patent law have marked a significant step forward in the area of patents for biopharmaceutical products in India. While patents were not previously available for medicines, the TRIPS agreement required India to provide such protection by January 1, 2005. Pursuant to this requirement, the president of India issued a Patents Amendment Ordinance on December 26, 2004. The
ordinance requires patents to be granted on new medicines as of January 1, 2005, as well as on medicines for which companies filed a patent application after 1995. This is in accordance with the "mailbox system" envisioned by the TRIPS negotiations. While India and other developing countries have been permitted to delay implementation of the standards under the TRIPS agreement until 2005, they have been required to establish a mailbox system to receive patent applications filed since 1995.

India is required to "open the mailbox" and grant patents for approximately 9,000 applications filed. The 20-year term for patent protection will be counted from the submission date of an application, although a product is not protected until a patent is granted. Companies manufacturing generic versions of drugs that now receive patents will not, therefore, be responsible for infringement retroactively, but must cease production once the patent is granted. The ordinance was ratified by the Indian parliament on March 23, 2005. The passage of this law is expected to have a significant impact on India's pharmaceutical industry, one of the world's biggest producers of generic drugs.

Additional recent improvements in India have involved reforms that streamline the nation's patent-application process, in particular the area of pre-grant opposition, timings, and deadlines. In addition, patents are not strictly limited to new chemical entities; secondary uses are also patentable. Recent patent legislation has not yet provided for an effective period of data
exclusivity as required by Article 39 of the TRIPS agreement, although the
issue is under discussion.

THE PROTECTIVE UMBRELLA OF TRIPS COVERS
THE FOLLOWING IPRS

(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 three main features of the Agreement are Standards.

In respect of each of the main areas of intellectual property covered
by the TRIPS agreement, the 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 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 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 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 a Berne and Paris-plus agreement.

**Enforcement.**

The second main set of provisions deals with the 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 and 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 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.

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.

**THE REQUIREMENTS OF TRIPS**

TRIPS require member states to provide strong protection for intellectual property rights. For example, under TRIPS:

- Copyright terms must extend to 50 years after the death of the author, although films and photographs are only required to have fixed 50 and to be at least 25 year terms, respectively.(Article 7(2),(4))
- Copyright must be granted automatically, and not based upon any "formality", such as registrations or systems of renewal.
- Computer programs must be regarded as "literary works" under copyright law and receive the same terms of protection.
- National exceptions to copyright (such as "fair use" in the United States) are constrained by the Berne three-step test.
- Patents must be granted in all "fields of technology," although exceptions for certain public interests are allowed (Article 27.2 and 27.3) and must be enforceable for at least 20 years (Article 33).
- Exceptions to the exclusive rights must be limited, provided that a normal exploitation of the work (Article 13) and normal exploitation of the patent (Article 30) is not in conflict.
- No unreasonable prejudice to the legitimate interests of the right holders of computer programs and patents is allowed.
- Legitimate interests of third parties have to be taken into account by patent rights (Article 30).
- In each state, intellectual property laws may not offer any benefits to local citizens which are not available to citizens of other TRIPS signatories by the principles of national treatment (with certain limited exceptions, Article 3 and 5). TRIPS also have a most favored nation clause.

Many of the TRIPS provisions on copyright were imported from the Berne Convention for the Protection of Literary and Artistic Works and many of its trademark and patent provisions were imported from the Paris Convention for the Protection of Industrial Property.
The agreement focuses on the following issues.²

- how basic principles of the trading system and other international intellectual property agreements should be applied.
- how to give adequate protection to intellectual property rights.
- how countries should enforce those rights adequately in their own territories.
- how to settle disputes on intellectual property between members of the WTO.
- special transitional arrangements during the period when the new system is being introduced. Intellectual property: protection and enforcement.

During post independence and pre 1970, the cost of the drug in India was very high with low availability and high import dependency. Export initiative was very less and R&D activities were practically non-existant due to lack of patent protection. During this period 80% of the ownership and 90% of the market share was with MNCs’.

Enactment of Indian Patents Act 1970 serves as the basis for patent protection in India. It explicitly disallows product patents for "substances intended for use, or capable of being used, as food or as medicine or drug. Only method or process of manufacture patents are allowed for such substances under the 1970 Act. The first major transition in the patents

scenario in India took place with the Indian Patents Act 1970 which came into force on 20th April 1972 replacing the Indian patents and Designs Act of 1911.

It ought to be appreciated that the Indian Patents and Designs Act 1911 in force until 20th April 1972, was fairly liberal as patenting of products related to foods, pharmaceutical, chemicals, etc. was available with a full term of 16 years in India.

Protected patent regime provided a safe platform on which pharmaceutical and chemical industries could strike roots and grow in India and also meet the need for increased production rather than relying on imports, which was then critical for the infant Indian national economy. Expertise in institutions, R&D capabilities, infrastructure and industry during the last few decades has selectively developed to extraordinary levels as compared to that in most developing nations. However the Indian pharmaceutical industry has built its structure along traditional lines of manufacturing molecules that have been invented in other countries and not having patent protection in India as per the Indian Patent Act 1970, developing cost effective processes, formulations, and drug delivery systems.

**PROTECTION OF PATENTS**

The agreement says patent protection must be available for inventions for at least 20 years. Patent protection must be available for both products and processes, in almost all fields of technology. Governments can refuse to
issue a patent for an invention if its commercial exploitation is prohibited for reasons of public order or morality. They can also exclude diagnostic, therapeutic and surgical methods, plants and animals other than microorganisms, and biological processes for the production of plants or animals other than microbiological processes.

The agreement describes the minimum rights that a patent owner must enjoy. But it also allows certain exceptions. A patent owner could abuse his rights, for example by failing to supply the product on the market. To deal with that possibility, the agreement says governments can issue “compulsory licenses”, allowing a competitor to produce the product or use the process under license. But this can only be done under certain conditions aimed at safeguarding the legitimate interests of the patent-holder.

IMPLEMENTATION IN DEVELOPING COUNTRIES

The obligations under TRIPS apply equally to all member states, however developing countries were allowed extra time to implement the applicable changes to their national laws, in two tiers of transition according to their level of development. The transition period for developing countries expired in 2005. The transition period for least developed countries was extended to 2016, and could be extended beyond that.

Developed countries are massive net-exporters of copyright, patent and trademark-related royalties. It has therefore been argued that the TRIPS standard of requiring all countries to create strict intellectual property systems will be detrimental to poorer countries' development. Many argue
that it is, prima facie, in the strategic interest of most if not all underdeveloped nations to use any flexibility available in TRIPS to write the weakest IP laws possible.

This has not happened in most cases. A 2005 report by the WHO found that many developing countries have not incorporated TRIPS flexibilities (compulsory licensing, parallel importation, limits on data protection, use of broad research and other exceptions to patentability, etc) into their legislation to the extent authorized under Doha.

TRIPS IMPLICATIONS ON INDIA

Signing of Trade Related Intellectual Property Subjects (TRIPS) is considered to be a landmark step towards development of intellectual property rights in the international law sphere. Compliance with TRIPS mandates all the WTO member countries to amend their national legislations and bring it in conformity with its provisions. It is the developing countries and the least developed countries, which are required to make the most extensive changes. All the WTO members were given one year, i.e. upto January 1996 to ensure that their national laws were TRIPS compliant. The developing countries were given an additional four years i.e. up to January 2000, and the least developed countries ten years i.e. up to 2006, to do so. A further period of five years up to 2005, were given to the developing

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countries to introduce product patents in fields of technology which had so far been excluded from their national patent laws.

India is a member of various international Treaties on patents and intellectual property rights. As per the TRIPS agreement under the WTO regime, India amended the 1970 Patents Act in 1999. India being a developing country was given a grace period of 5 years to change its Patent Laws under agreement on TRIPS. At the same time a grace period of 10 years was also granted for technologies previously unprotected in market. During this interim period of ten years all patent applications were put in a black box. However pharmaceutical companies could apply for an Exclusive Marketing Right (EMR) for their products for 5 years only even before the patent regime is fully transformed (product patent).

**SCENARIO PRE-TRIPS**

The Indian Pharmaceutical industry is one of the largest in the developing world. Over the past 30 years Indian drug industry has emerged from almost non-existent to a world leader in the production of generic drugs. With the changes brought about by the Patents Act of 1970, Indian drug manufactures became experts in the field of reverse engineering and increased its supply of less expensive copies of the world’s best-selling patent protected drugs. This could only be possible because there was no product patents system for drugs and medicines. While the Patent Act of 1970 in its original form does provide a distinction between product patents and process patents, the exception provided in section 5 of the Act of 1970
(which has been omitted by the amendment of 2005) offered only a process patent for food, medicine or drug substances and specifically excluded product patents for the same. Thus India was able to copy foreign patented drugs without paying a license fee and was able to make it available to the masses at one-tenth of the original price. Moreover the Drug Price control Order, 1970 put a cap on the maximum price that could be charged and ensured that the life saving drugs are available at reasonable prices.

The Act of 1970 could be considered to be one of the most progressive statutes that safeguard both the interest of the inventor and the consumer in a balanced manner. The Act has been promulgated keeping Directive Principles of State Policy contained in Article 39 of the Constitution in mind. Hence with a regulatory system focusing on process patents and being in the grip of a rigid price control framework, the Indian pharmaceutical industry has emerged from an import dependent industry in 1950s to having achieved world wide recognition as a low cost producer of high quality pharmaceutical products.

The distinction between a product patent and process patent that existed prior to the 1995 TRIPS agreement helped India to develop a huge generic drug industry, which had its basis on reverse engineering of brand name drugs through slightly modified processes.
PERIOD BETWEEN 1970 AND 1995

Important steps taken by the Government are as follows

(1) Introduced Drug Price Control Order (DPCO) to protect the Consumers against high price. In 1970, the government introduced the DPCO to guarantee its citizen access to ‘essential drugs’, at a reasonable cost with adequate rate of return to companies without compromising quality. In response to the DPCO, many firms discontinued the production of the controlled item and concentrated on production of nonessential drugs and other combinations to escape the control. As a result, essential drugs were more difficult to access than before the introduction of DPCO. Another derivative effect of the DPCO was that it exempted smaller firms from price controls, thereby encouraging them to participate in the pharmaceutical industry. This caused small companies to be represented more prominently than might otherwise be expected. To address afore mentioned problems while still adhering to its objectives, the government issued a revised DPCO in 1995. The DPCO of 1995 declassified 70 out of 146 drugs, dropped some clauses that favoured small companies, and exempted newly (locally) produced products from price controls.

(2) Indian Patent Act 1970 to ‘Process Patent’- patenting the process use to make the particular drug formulation but not the product patent (patenting the process itself).

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EFFECTS

(1) India did not provide product patents in pharmaceutical and agricultural chemicals allowing local pharmaceutical companies to replicate drugs by adopting a different manufacturing process (reverse engineer products). These reforms made new drug available cheaply and promoted import substitution by encouraging the local firms to make copies of the drugs by developing their own process followed by bulk drug production.

(2) The share of pharmaceuticals in national exports has increased from 0.55 per cent in 1970-1971 to over 4 per cent by the 1999-2000.

(3) India’s share in world exports of pharmaceuticals has risen by 2.5 times over the 1970 to 1998 period making India, the second largest exporter of pharmaceuticals after China among developing countries by exporting products to countries like Russia, Africa, China and South America.

(4) Further more Indian companies were free to ship reverse engineered drugs to patent recognizing countries on or after the day of expiry. Such a liberal patent environment benefited Indian firms at the expense of MNC’s; causing some MNC’s to opt for minimal presence in India. As a result, foreign ownership in Indian drug industry decreases to 39% in 1993 as compared to 80% in 1970 before the introduction of this Act.

(5) The characteristics of patenting between 1978 and 1996 are reviewed, based primarily on applications published by European patent office. Number of pharmaceutical applications has increased steadily, and there are now approximately 6000 published each year, or 10% of total.
INDIAN PATENT SYSTEM - PRE-TRIPS

India was the first country outside of the West to have a patent law as early as 1857. It was obviously enacted by the erstwhile colonial rulers with a view to protect imported technologies from ‘copying and reverse engineering’. India also has the distinction of being perhaps the first to review and revise it within a couple of years after achieving political independence. The 216-pages-long report of the Patent Enquiry Committee (1948-50) and the 397-pages-long report on the revision of the patents law by Justice N Rajagopala Ayyangar Committee speak eloquently of the ‘patent literacy’ of experts available for guidance and advice to the newly independent nation.

The Indian Patents Act 1970 was the product of such eminent minds working behind the scenes and getting it passed through Parliament by a determined ruling leadership even in the face of protests from predictable quarters. If over the next few decades India rose to the status of an ‘advanced developing country’, due credit should go to those technopolitical visionaries and stalwarts working in tandem for evolving a relevant national law facilitating large scale application through indigenous ‘R&D of possible industrial use’.

The major achievement that accrued from application of the 1970 Act was that based on the process-only patent framework, products developed by advanced nations with their legacy of outstanding caliber and financial resources could be indigenized and produced locally to meet India’s needs
both on the strategic (e.g. specialty chemicals including polymers and propellants, advanced materials and metal alloys) as well on the civilian (drugs and pharmaceuticals, agrochemicals, catalysts and so on) side. These enabled the nation over the years to develop credible capacities in space, nuclear and defense technologies, on the one hand, and also on health care and food security front at reasonable cost at the other hand.

But at the same time, in the absence of a truly forward-looking and self-reliant industrial policy approach, the ‘permissive’ IPR policy did not promote innovation through original patentable inventions of consequence: no new material, alloy, polymer, drug, catalyst, and so on; not even any new competitive technology. With the number of patents filed annually remaining stagnant at around 3500, it steadily lost even adequate professional recognition in the research community.

Promotion of indigenous in-house industrial R&D was, unlike in strategic sectors, never a serious policy factor in the framework of the Government of India / Reserve Bank of India’s approved guidelines for import of technology. Without giving specific examples, one may note that the GOI / RBI have invariably been approving technology transfer (T/T) agreements, though with very crucial and far-reaching conditionality clauses. Typically, in these approvals

(a) All patents in support of the transferred technology will be licensed to the licensee for use only during the licensing period.
(b) Any improvements during the licensing period will normally be the property of the technology provider.

(c) Technology and also use of the labels produced under collaboration will be subject to the condition that products are manufactured and supplied exactly as per T/T specifications and also to specified territorial limits.

Import of technology became a strategy for only an ‘assisted take off’, but got steadily reduced to one of ‘diminishing returns’ unless the same unit repeatedly upgraded its technology by continued import and that too again under similar conditionality clauses. In other words, our industrial policy continued to be a total failure in this aspect, with even the so-called ‘screw driver technology’ losing steadily its shine. With T/T continuing by and large, the major accepted strategy of public and private sectors for industrial development, patents never got to be a true instrument of techno-industrial modernization.

Nevertheless, this aspect got reflected through relevant international trade forums like UNCTAD; according to statistics compiled by them, the developing nations such as India were, in practice, shelling out huge amounts to the technology providers of developed countries as part of the T/T fees. These were reinforced by other restrictive clauses that ended up enforcing intellectual property (IP) protection through the backdoor. These problems, as summarized in the study called UNCTAD Resolution 39(III), became a point of serious contention in international trade negotiations.
Whereas the developing countries wanted that the international patents and trademarks regime be reviewed and revised to meet their special needs and thereby aid T/T, technology providers were in the opposing camps. Things, however, changed in the late 1970s to the disadvantage of the developing nations. Surendra J Patel, the acclaimed UNCTAD expert, has summarized these in his presentation ‘Indian Patent Act 1970 and the Revision of the World Patent System and the Paris Convention’ in a conference organized by the National Research and Development Corporation (NRDC) on Patents and Trade Marks, New Delhi, February 1987.

To quote him, ‘the negotiations on UNCTAD Code were stalled; those on the Revision of Paris Convention were blocked. Global Round was abandoned. Confrontation replaced cooperation. Despite this deadlock, the developed countries went ahead and presented their proposals on Trade-Related Aspects of Intellectual Property (TRIPS). Instead of extending the scope of exclusions, they ask for reduction. Instead of reducing the duration, they want extension. Instead of opening wide the window of opportunities for new technologies, they want it to be closed. Instead of putting more teeth into compulsory licensing, they want to weaken, even abolish it. Instead of prohibiting abusive practices, they want to provide grounds for perpetuating them.

Instead of expanding flexibility of national laws in the Third World, they want these laws to be carbon copy of their laws. It is a reversal of past
commitments by the developed countries to assist in promoting the development of the Third World. The clock is to be made to move only backwards, its acceptance would severely inhibit technical change and act as a major barrier to the development of the Third World’.

SCENARIO POST-TRIPS 5

The most important amendment of 2005 extends full TRIPS coverage to food, drugs and medicines. It requires patents to be provided to products as well, while the patent regime provided by the Act of 1970 required patents only to be granted for chemical processes, which resulted in the production of a particular drug. The other implications for the pharmaceutical sector under the new Act are as follows.

(i) The term of a patent protection has been extended to twenty years compared to the seven years, which was provided by the Act of 1970. This was made applicable to all the member countries and hence rules out all the differences with respect to patent protection, which prevailed in different countries.

(ii) If the law of the country provides so, then the use of the subject matter of the patent shall be permitted without the authorization of the patent holder, including use by the government or any other third party authorized by the government. However such use shall be permitted only if prior to

5 Garima Budhiraja, Campus Law Centre, Delhi “Product patent in pharmaceutical industry”, (2008) www.indlawnews.com
such use, the user has made efforts to obtain the authorization of the patent holder and such efforts have not been successful within a reasonable period of time. This requirement can be waived in case of a national emergency after notifying the patent holder and 

(iii) The burden of proof with respect to infringement matters has been reversed under the new Act. The onus of proving on a legal complaint that the process used by one enterprise is totally different from that, which has been used by another, would lie on the defendant. Prior to the amendment the responsibility was on the patent holder to establish patent infringement.

The new amendment was not to affect the drugs, which were in the market prior to 1995. Drugs, which were produced between 1995 and 2005, will have the right to continue to produce them in return for the payment of a fixed royalty to the patent holder. The main problem arises for those drugs, which are now being manufactured and patented. The only way by which such drugs can be manufactured in India is by way of compulsory licenses. The government grants such compulsory licenses on grounds such as non-availability, high prices, public interest etc. The process ought to be simple and easy but the problem lies in the fact that the procedure has been left very ambiguous by the new Act.

The immediate and the most drastic effect that TRIPS compliance and introduction of the new Act of 2005 is with respect to the health sector in India. The patients are the ultimate beneficiaries of the pharmaceutical research and development. By denying product patents India will be able to
encourage bulk generic drug production at cheap prices. However generics are not the only solution to counter the problem of access to medicines. Generic production of drugs will not necessarily result in the innovation of new and more effective drugs and by not acknowledging innovation.

India will run the risk of not having access to future medicines, which will in turn affect public health. Denying patents and allowing the generic companies to freely copy the new drugs cannot be the solution to deliver medication to the patients too poor to buy them, be it rural or urban India. The actual problem lies in the fact that the product patents not only increase the cost of the drugs and medicines, but that most of them fail to introduce research and development in the neglected diseases. Lack of access to affordable medicines was a reason for the vast majority of deaths that took place due to HIV/AIDS in the developing countries. Hence while on one side the introduction of product patents will help in development of new and more effective drugs, the problem still remains that the research and development undertaken by the drug manufactures evade the neglected diseases and the diseases which are region specific such as medicines for malaria and tuberculosis which are found prevailing in developing countries like India.

Unlike in the developed countries, the lack of the penetration of medical insurance makes the people directly affected by the increase in the prices and hence decreases the affordability. The patent system makes the
lives of the people outside the sphere of social security, which forms majority in the developing countries, impossible.

A product patent system will make India dependent on the multinational companies for technology and for permission to produce the patented drug. Exorbitant prices will be charged and the Indian pharmaceutical industry will become subservient to the MNCs. They will lose the position that they had gained in the wake of the Act of 1970.

**PERIOD BETWEEN 1995 AND 2005**

(1) Exclusive Marketing Rights- This new provision has been incorporated in the Patents Act, 1970 as amended by The Patents (Amendment) Act, 1999 with effect from 1st January, 1995. EMR will be valid for a period of five years or till the date of grant of the patent or date of rejection of the application for the grant of patent whichever is earlier.

(2) It is now possible to make an application for patent claiming for a substance itself intended for use or capable of being used as Medicine or Drug, excepting the intermediate for the preparation of drug.


(4) India has a ten years transition to provide product patents viz. till the end of 2004. It is by now widely recognized that the abolition of process patents

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6 Ashwini R Madgulkar, AISSMS College of pharmacy, Pune, (2006)

www.pharmainfo.net
in chemicals and pharmaceuticals has facilitated the development of local technological capability in chemicals and pharmaceutical industry by enabling the domestic firms in their process innovative activity.

(5) Patent Amendment Act 2005

- Provision related to black box application- if filled before 1st January 2005 under the transition provision of TRIPS, any manufacturer who has made significant investment for the manufacture of product and has produced and marketed the product before 1st January 2005 will be able to continue the production after 1st January 2005 without infringing the patent.

- Parallel import, grey imports, “Exhaustion” of rights- parallel or grey market imports are not imports of counterfeit products or illegal copies these are the products sold by a patent holder in one country is exported by a buyer to another country where the price for the same patented drug is higher. This effectively reduces the profits of the patent holder as the phenomenon of parallel import usually reduces the price of the product in the country to which it is exported.

- Compulsory licenses- such licenses can be granted for manufacture and export to "any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided that compulsory license has been granted by such country." Only it limits the amount they
can export when the drug is made under compulsory licenses. All WTO member countries are eligible to import under this decision, but 23 developed countries are listed in the decision as announcing voluntarily that they will not use the system to import to various countries.

- Herbal preparations - those having medicinal values can be patented under the new amended law.

(6) In the period between 1995-2005 and there after, status quo has been seen with respect to cost of the drug and it continued that way till 2007. But after 2007 particularly after 2010 as MNC’s and research based companies start launching their patented molecules, the cost of drug is going to increase.

(7) The availability of drugs in the antibiotic segment and other agents for topical infection may not be affected but the availability of life style drugs will be affected as most of the MNC’s are engaged in new drug development in this area only but imports will remain constant.

TRIPS AND INDIAN PHARMA SECTOR:

THE EXISTING EVIDENCE

The impact of introduction of product patents in India shows that, the profits of Indian firms from producing generic drugs will decrease, as they will probably have to pay some royalty to original innovators. Secondly, stronger IPR would not augment R&D activity of MNCs in India, since R&D is a highly centralized process, where cost is not the paramount
concern. Thirdly, the incentives for investment in R&D in diseases prevalent in developing countries, as well as in creation of innovations in general, are likely to increase because the strategy of imitation will no longer be available. The behaviour of pharmaceutical multinationals and the market structure in India also changes due to product patent protection. In case, new on-patent drugs and newer varieties of off-patented products are in the same therapeutic class, it will not have a major impact on prices of drugs. But if they are altogether new products, of which off-patent generic versions are not available, rise in price associated with such products may be high.

India has reached such a stage in pharmaceutical production where stronger IPRs would induce greater innovation by local firms (the benefits of which would have to be set-off against the closure of other firms). TRIPS are also likely to induce greater innovation, more R&D expenditure, and more patents by both Indian and MNCs in the biopharmaceutical sector. The potential adverse welfare effects of the TRIPS Agreement on the Indian industry show that in the absence of any price regulation or compulsory licensing; total welfare losses to the Indian economy would be enormous.

INTERNATIONAL PATENTS AND INTERNATIONAL HARMONIZATION

The existence of IPRs is very old. The basic aim of conferring an IPR upon the person owning the same is to give a social recognition to its holder. This social recognition can further bring economic benefits to its holders. It is just and reasonable to award a person an IPR in the form of 'limited
monopolistic rights' for his/her labour and efforts. At the same time, exceptions in the form of various licenses are also made so that public interest cannot be compromised. The public interest and personal interests are thus reconciled in the form of limited period duration of these rights and their abuses can be tackled stringently, especially when public interest demands so. The problem of IPRs violations was not as much in ancient times as it is in the contemporary society. This has happened due to the advent of information technology (IT) and 'Conflicts of laws' in various countries. The need of harmonisation of law concerning IPRs was felt at the international level. Thus, the TRIPS agreement was formulated to bring basic level harmonisation in IPRs laws all over the world. The provisions of TRIPS agreement are the most extensive and rigorous in nature. They protect all the forms of IPRs collectively.

Increasingly global markets have rewarded biopharmaceutical companies with operations outside the United States and Europe with ample opportunities to expand successfully into new market places around the world. At the same time, innovative companies in the biotechnology and pharmaceutical industries depend heavily on the protection of their intellectual property. In today's international markets, biopharmaceutical companies’ still face rampant piracy and counterfeiting of patented products. Since the establishment of the World Trade Organization (WTO) in 1995, important progress has been made in achieving better international harmonization of patent laws; however, many challenges for innovative
biopharmaceutical companies remain, and new obstacles continue to emerge.

Through the United States Trade Representative (USTR) and in close consultation with the biopharmaceutical industry, the US Government has worked consistently for stronger and more harmonized international patent protections for innovative industries, both at the global level as well as in regional and bilateral negotiations with US trading partners. Various domestic trade laws are tools at the disposal of the US Government to protect US patents from infringement.

THE MAIN PROVISIONS OF TRIPS AS THEY RELATE TO PHARMACEUTICAL PATENTS IS AS FOLLOWS.

Among the general obligations, Articles 3 and 4 of TRIPS require member Governments to apply the principles of national treatment, i.e. equal treatment of nationals and non-nationals, and most-favored-nation (MFN) treatment, i.e. equal treatment of foreigners regardless of their country of origin. With respect to patents, Article 27.1 of TRIPS states that patents shall be available for any invention, whether products or processes, in all fields of technology which clearly encompasses pharmaceutical products. Moreover, patents shall be available whether products are imported or locally produced, which means that importation counts as working the patent. Article 31 addresses the use of patented subject matter without the authorization of the rights holder, e.g., through compulsory licenses. Although it ties such unauthorized use to specific conditions, legal
interpretations of Article 31 vary and it has been argued that national
governments have some leeway in designing rules regulating the grant of
compulsory licenses.

Article 33 sets a uniform minimum term of patent protection of 20
years counted from the filing date. Article 34.1 specifies that the burden of
proof in case of process patent infringement rests with the defendant, i.e. the
party accused of patent infringement. Finally, Article 41.1 requires member
governments to ensure that enforcement procedures are available under their
national laws so as to permit effective action against any act of infringement
of intellectual property rights and Article 62.2 obligates members to ensure
that the procedures for grant or registration, permitting the granting or
registration of the right within a reasonable period of time so as to avoid
unwarranted curtailment of the period of protection.

SPECIAL TRIPS PROVISIONS FOR PHARMACEUTICAL
AND AGRICULTURAL CHEMICAL PRODUCTS

For developing countries, providing protection for pharmaceutical
and agricultural chemical products has been a particularly controversial
issue, and in recognizing the sensitivity surrounding this issue, TRIPS
provides for special treatment of patent applications for pharmaceutical and
agricultural chemical products. Article 27 of TRIPS obligates signatories to
make patents "available for any inventions whether products or processes, in
all fields of technology." This general requirement is subject to certain
exceptions and transitional provisions.
In particular, Article 70.8 allows developing countries that do not have patent protection for pharmaceutical and agricultural chemical products upon entry into force of TRIPS to establish what is called a mailbox system for receiving and filing patent applications for these products. The purpose behind a mailbox system is twofold:

(1) It allows inventors to file for patents and thereby establish priority dates that serve as evidence of the novelty of their inventions.

(2) While allowing countries to defer the actual granting of patents for pharmaceutical and agricultural chemical products.

After the passage of a specified period, a country must retrieve applications from its "mailbox" and review them for patentability. Article 70.8(a) requires countries availing themselves of this provision to provide means by which patent applications may be filed upon entry into force of TRIPS in January 1995. Articles 70.8(b) and (c) further require that by 2005 these countries review the mailbox applications they have received, apply the criteria for patentability, and provide patent protection for the submissions that meet those criteria. Taken as a whole, Article 70.8 requires developing countries to establish a workable system for receiving patent applications for pharmaceutical and agricultural chemical products while allowing these nations to defer amending their patent laws to provide for the granting of such patents until the year 2005.

Article 70.9 obligates countries that avail themselves of Article 70.8 to grant exclusive marketing rights to parties who file mailbox applications.
In essence, this provides a degree of protection to inventions that is short of the level provided by patent protection. According to Article 70.9, a grant of exclusive marketing rights is contingent on two preconditions: (1) The issuance of a patent in another WTO member state for the product that is the subject of a mailbox application and (2) The securing of marketing approval for the product in the country where the mailbox application is filed.

The result of the tandem functioning of Articles 70.8 and 70.9 is that developing countries are given what amounts to a limited temporal exemption from the TRIPS requirement in Article 27 calling for patent protection that would otherwise encompass pharmaceutical and agricultural chemical products. But even during this deferral period, the countries still must have systems in place for receiving and filing patent applications for later review (Article 70.8) and must also grant some degree of protection short of full patent protection by providing exclusive marketing rights for those products that are the subject of mailbox applications (Article 70.9).

The new set of challenges stem from the deeper implications of the imminent product patent regime. With the exception of a few, most Indian pharma companies are unfamiliar with the nuances of complex patent prosecution strategies. The research-based pharmaceutical companies, on the other hand, have first hand knowledge of successfully designing and implementing, sophisticated patent prosecution strategies. Therefore, the first hurdle for the Indian pharma industry is unevenness in the domain
knowledge on patents. One of the ways to overcome this is to learn the use of patents as a business tool.

**PATENT TERM EXTENSION STRATEGIES (REFERRED TO AS ‘EVERGREENING OF PATENTS’)\(^\text{1}\)**

“Ever greening” or what the pharmaceutical companies often refer to as ‘life cycle –management plans’ refers to patent term extension strategies. Using the intricacies of patent prosecution procedures, pharmaceutical companies develop “bullet proof” patent portfolios around million dollar drug molecules. Typically, multiple patents are secured covering a variety of inventive aspects in respect of a basic invention without attracting double patenting rejections. This plurality of patents directed at divergent inventive aspects can at times lead to the extension of patent terms, provided the national patent law allows such flexibilities.

According to the TRIPS Agreement, the term of protection for patent is 20 years counted from the filing date. As a patent prosecution and management strategy, ‘Ever greening’ enables patent term extension by developing a portfolio of patents around a basic invention.

Adding new claims to a basic patent disclosure is permissible in certain jurisdictions. This is achieved by the effective use of patent prosecution routes including continuation patent application, divisional patent application, continuation-in-part patent application, and application for patent of addition. It is also possible to build on chains of priority from a basic patent disclosure to preserve novelty. The limitations or restrictions in the criteria of patentability and the exclusions of certain subject matters from
the scope of patentability can impose serious limitations on patent prosecution strategies aimed at ‘Ever greening’.

**ENFORCEMENT**

TRIPS also specify enforcement procedures, remedies, and dispute resolution procedures. Protection and enforcement of all intellectual property rights shall meet the objectives to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

The TRIPS agreement introduced intellectual property law into the international trading system for the first time and remains the most comprehensive international agreement on intellectual property. In 2001, developing countries, concerned that developed countries were insisting on an overly narrow reading of TRIPS, initiated a round of talks that resulted in the Doha Declaration. The Doha declaration is a WTO statement that clarifies the scope of TRIPS, stating for example that TRIPS can and should be interpreted in light of the goal "to promote access to medicines for all”.

Furthermore, unlike other agreements on intellectual property, TRIPS has a powerful enforcement mechanism. States can be disciplined through the WTO's dispute settlement mechanism.