

## Section I

# Background to the TRIPS Agreement

### 1.1 GATT and Its Transition to the WTO

WTO's predecessor, the General Agreement on Tariffs and Trade (GATT), was established on a provisional basis after the Second World War in the wake of other new multilateral institutions dedicated to international economic cooperation - notably the "Breton Woods" institutions now known as the World Bank (WB) and the International Monetary Fund (IMF).

The GATT remained the only multilateral instrument governing international trade from 1948 until the establishment of the WTO in 1995. In all, eight GATT Rounds were held. The last GATT round was the Uruguay Round (1986 -1994). The Uruguay Round, for the first time introduced discussions on trade related to agriculture, services and Intellectual Property Rights. The Round ended with the establishment of the World Trade Organisation (WTO) on 1st January, 2005.

The rule-based regime in the WTO is premised on the principle of non-discrimination. The two main elements under this principle are a) Most favoured nation, commonly referred to as MFN -- members extend the same treatment to imports from all the other members; b) National treatment -- means that imported goods, once they have met all the requirements of whatever border regime is in place and have entered into the internal (domestic) market in a member's economy, will be treated no less favourably than domestic goods are treated in the domestic market.

Recognising the very large disparities in economic and technological development among member countries, the WTO provides for exceptions to the application of WTO rules based on the above principle, including: Special and Differential Treatment for Developing Countries and Least Developed Countries, Less than full reciprocity; and protracted implementation period.

The decision-making process in the WTO uses the principle of "Single Undertaking" i.e. "Nothing is Agreed unless Everything is Agreed". So members do not have the flexibility to apply only a part of a decision. The WTO continues the GATT practice of taking decisions by consensus but if a decision cannot be reached by consensus, it is to be arrived at through majority vote. In the Ministerial Conference and the General Council, each member has one vote.

**Table : Special and Differential Treatment: Time-Lines Included in Various WTO Agreements Relative to Full Implementation of Commitments**

WTO Agreements	Developed Countries	Developing Countries	Least Developed Countries
Agriculture	6 years	10 years	Exempt
SPS	-	2 years	5 years
TRIPs	1 year	5 years	10 years
TRIMs	2 years	5 years	7 years
Import Licensing	-	2 years	-
Safeguards	Up to 8 years	Up to 10 years	-
Domestic Input Subsidies	-	5 years	8 years
Export Subsidies	-	2 to 8 years	8 years

### 1.2 TRIPS Agreement

The Trade Related Intellectual Property Rights (TRIPS) agreement, was signed as a part of the WTO agreement. It was one of the most contested agreements during the GATT negotiations. Till 1989, several developing countries had opposed even the inclusion of issues related to TRIPS in the negotiating agenda. Developing countries had argued that rights provided in domestic laws regarding

intellectual property should not be linked with trade. They had further argued that the history of IPRs shows that all countries have evolved their domestic laws in consonance with the stage of economic development and development of S&T capabilities. Laws that provide strong Patent protection can limit the ability of developing countries to enhance their S&T capabilities. It was thus natural that many developing countries had domestic laws that did not favour strong protection to Patents before the WTO agreement was signed. It was argued that it would be illogical to thrust a single patent structure on all countries of the globe, irrespective of their stage of development. These arguments were however not addressed during the GATT negotiations, leading to the signing of the TRIPS agreement. The TRIPS agreement required all countries to change over to a strong patent protection regime.

The TRIPS Agreement covers two categories of intellectual property; industrial (trademarks, patents, geographical indications, industrial designs and trade secrets) and literary and artistic (copyright and neighbouring rights). It establishes minimum universal standards in all areas of intellectual property with the aim of implementing these standards globally through an enforcement mechanism established in WTO. The Agreement requires universal patent protection for any invention in any field of technology. All WTO member countries are required to adopt in their laws minimum standards of protection for patents, trademarks, copyrights and other intellectual property rights. These relate to the protection of products and processes.

A majority of members of the WTO already had some form of intellectual property protection in existence prior to the TRIPS Agreement. For example, as of January 1995, fewer than 20 of the current WTO developing country and least developed country members excluded pharmaceutical products per se from the grant of patents. The key difference that came about after the adoption of TRIPS agreement in 1995, was that countries were bound to certain minimum universal standards of Patent protection. The TRIPS

accord, thus, prevents countries from changing their laws to suit national interests if such interests are at variance with the agreement. Further, as TRIPS is part of the WTO system, there is now also the possibility of cross-sector retaliation in the event of non-compliance by any country of its provisions. This implies that any member country failing to bring its patent law into conformity with TRIPS, if challenged by another member country, is subject to the WTO dispute settlement system. If the dispute settlement system were to rule against it and the country still insists on not changing its law, other WTO countries can retaliate by bringing in sanctions in other trade sectors.

Many developing countries had been encouraged by developed nations to amend their Patent laws to provide for patent protection in the area of pharmaceuticals. Others did not use the 10 year transition period available to them after 1995, and amended their laws well before the deadline. India - the last significant "holdout" amended its law in 2005, in order to be TRIPS compliant.

There are several ways in which the TRIPS agreement impinges on the pharmaceutical sector and on the manufacture and sale of medicines. Article 27.1 entails that patent owners enjoy the same exclusive rights with respect to imported products as for products manufactured locally. This is contrary to what countries like India and Brazil allowed for - by having provisions in domestic laws that encouraged local manufacturing. The TRIPS agreement also bars countries from discriminating between sectors, i.e. it requires that countries provide protection in all manufacturing sectors without discrimination - both for products and processes. Many countries, like India, had kept medicines and food out of the purview of Patents, but the TRIPS agreement does not allow this any more. The agreement (Article 33) allows a minimum 20 year Patent period, in contrast to many countries, prior to the agreement, providing for much shorter Patent protection.

A patent provides proprietary title over an invention, which allows the patent holder the right to prevent others from using,

making, selling, marketing the product for a specified period. There are no international patents, and patent rights are limited to the country in which it has been granted. A patent gives the patent holder a temporary monopoly on using, making and selling the invention as a "reward" for publishing the full details of the invention. In return the public pays a higher price during the patent term, but after expiry of patent, has free access to the invention.

Given the large benefit that accrues to a patent holder through the temporary monopoly that it enjoys, it is legitimate to question what amounts to a good invention to deserve this reward. Patents are a public policy tool - to be balanced against other public policy needs and governments have the power to keep this balance. Ideally health considerations should play a decisive role in defining which inventions deserve protection.

Patents on Pharmaceutical are for inventions, and not medicines per se. Thus patents may be granted for: a chemical compound or molecule; a medical indication or therapeutic effect of the molecule; the combination of products (e.g., a fixed dose combination of 2 or more molecules); or the manufacturing process (known as a process patent). There could be more than one patent for a single medicine, viz. the chemical compound as well as the process to make it can both be patented. It needs to be kept in mind that while above are the possible kinds of patents that can apply to medicines, national laws may restrict the kind of patents to be granted for medicines, viz. some laws can explicitly bar the grant of patents for drug combinations.

The fact that patents on medicines lead to higher prices has been widely documented, and this is to be expected given that patents confer a monopoly (albeit temporary) to the patent holder. Reduction in prices of patented drugs result when this monopoly enjoyed by multinational drug corporations (who hold the overwhelming majority of drug patents) is curbed and market competition is introduced. Thus, for example, the cost of triple drug therapy to treat HIV-AIDS

was in excess of US\$10,000 per patient per year, before the Indian generic manufacturer, Cipla, offered the same therapy in February 2001 at US\$350 per patient per year. As a result of generic competition, current prices for first line triple ARV therapy is approx. US\$168 in January 2005.