Chapter 2

Overview of the TRIPS Agreement

The TRIPS Agreement, which came into effect on 1st 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 including service marks; geographical indications including appellations of origin; industrial designs; patents including the protection of new varieties of plants; the layout-designs of integrated circuits; and undisclosed information including trade secrets and test data.

The three main features of the TRIPS agreement are:

1. **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.
2. **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 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.
3. **Dispute settlement**. The Agreement makes disputes between WTO Members in respect of 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 contains a number of safeguards, which may be used to protect public health and promote competition, such as compulsory licensing and exceptions, which facilitate the marketing of generic drugs ("Bolar provision"). These safeguards can be used to mitigate the potential negative impact of the TRIPS Agreement on access to drugs. However, in order to use these safeguards, countries have to incorporate them in their national legislation.

In reference to drugs and pharmaceutical industry, patents are very important. There are several reasons for the importance of patents for the pharmaceutical industry:

1. The costs of pharmaceutical R&D are high. While the actual amount is being disputed, it is in any case significant.
2. There is a disclosure requirement, at the time of registration.
3. Usually, imitation is relatively easy; therefore, the patent is important to protect the invention.
4. It allows the company to make extra profits. Because of the monopoly rights the patent confers, the company can charge a higher price and earn more than would have been possible in case of free competition. Obviously, from these profits, R&D costs have to be recovered; however, the US Office of Technology Assessment has published a study demonstrating that profits in the pharmaceutical industry are considerably higher than in other industries and that the rate of return is much higher than what is needed to cover the costs.

2.1 Problems Of Access To Drugs

With regard to inadequate access to drugs, two major gaps can be identified: 1) a "discovery/development"gap between the morbidity/mortality and available remedies; and 2) an "access imbalance" between consumption of medicines in the developing and the developed world. The exposure of poorer countries to the discovery/development gap is particularly acute because of mitigating circumstances of poverty, poor infrastructure and urbanization.

In addition, there are other pharmaceuticals-related gaps that contrast the health situation in the "North-South" context:

a) *The Quality/Counterfeit Medicines Gap*: Patients in developing countries are more frequently exposed to substandard products and counterfeits, due to the relatively large gap in regulatory capability and training between developed and developing countries as well as the differences in enforceability and penalties for counterfeiting activities;

b) *The R&D Imbalance*: While the relative incidence of infectious diseases is higher in developing countries, until now little pharmaceutical research and development has taken place in these countries;

c) *The Urban/Rural Gap*: The minority of the population living in towns receives three-quarters or more of medical services and products; this is a global phenomenon, but it bears most heavily on poorer populations in developing countries; and,

d) *The Drug Production Imbalance*: With over 3/4th of the world's population, developing countries produce less than 1/10th of the drug output; further, 2/3rd of the latter production is concentrated in a few developing countries, such as India, China, Egypt, Republic of Korea, Brazil. Thus, many developing countries have choices of products from just a few sources.

The 'Declaration on TRIPS Agreement and Public Health' reemphasizes the flexibilities that members have in implementing the TRIPS agreement, especially to achieve public-health goals. The flexibilities mentioned in the declaration include compulsory licensing, parallel imports and price controls. Of course, flexibilities related to patent standards also exist though these are not referred to in the declaration. Using these policy options, various solutions to achieve lower drug prices in developing nations can be adopted.

One probable solution suggested is differential/tiered pricing (market segmentation) by big pharmaceutical companies. This means selling drugs at lower prices in developing nations and at higher prices in developed nations where price elasticity is low (one reason for this is that most patients are covered by public or private medical insurance). This way firms can earn higher profits by selling in both markets and consumers in low-income nations have access to drugs at low prices. However, there are barriers to the adoption of this solution as discussed below:

- *Limited funds:* funding is often insufficient to provide even the most basic healthcare services and products in developing countries. Hence, low prices of selected drugs may not necessarily mean that people have the capacity to purchase them.
- *Absence of a 'social security umbrella' :* Unlike in developed countries where the expenses on medicines are covered by insurance and social security measures, in developing countries e.g. India the percentage of people having access to support for purchasing drugs is quite small and expenses for drugs are borne by the people directly.

2.2 Summary of The First Workshop

As per the terms of reference of the project, a workshop -to elicit inputs from various stakeholders in the healthcare sectors- was organized on February 14th, 2005. The deliberations at the workshop were divided into three main sessions viz:

1. TRIPS & its impact on Pharmaceutical R&D,
2. TRIPS & its impact on Pharmaceutical prices, and
3. TRIPS & its impact on drug availability

The opening session was presided over by Prof. Harkishan Singh and the keynote address was delivered by Prof. Nitya Nand. Three dedicated sessions were organized on specific themes pertaining to the project and ten resource persons representing the stakeholders were invited to put their views across. The concluding session was coordinated by Dr. Naresh Kumar, Scientist G, of Institute of Microbial Technology, Chandigarh.

The workshop was inaugurated by Prof. Harkishan Singh, Professor emeritus, University Institute of Pharmaceutical Sciences, Punjab University, Chandigarh and an eminent pharmaceutical scientist. In his inaugural address, Prof. Singh spoke of

the drug pricing controls prevalent in colonial India, especially during the first and second world-wars. These were meant to avoid shortage of medicine and to regulate the availability of drugs as most of them were imported and were also needed for war fronts. However, in the present times the availability is dictated by the production, pricing and purchase capacity.

"The issues are same but the conditions are different. In this era, no country can stay in isolation and deny to its people best of goods including drugs and healthcare products. We have either to join multilateral agreements like WTO or sign 30-40 bilateral agreements with as many countries, which is not only time consuming and cumbersome but also does not make economic sense" said Prof. Singh. He expressed hope that this workshop would adequately address the issue of impact of TRIPS on the availability of drugs as affordable prices.

The key-note address in the inaugural session was delivered by Dr. Nitya Nand on the topic, "The Indian Pharma Industry with India as a WTO member: Challenges and Opportunities". In his address, Dr. Nitya Nand spoke of three distinct phases of growth of pharmaceutical industry, the first from 1947-1970, the second from 1970-90, and the last from 1990 onwards. According to him, the Indian industry is producing quality APIs and generics at low cost. India is one among the top five producers of bulk drugs in world, 14th largest exporter, accounts for 8% of world production by volume and 1.5% by value. This indeed is a position of strength and needs to be defended with appropriate legislations. He felt that the present patent regime should be made favorable to Indian needs and for this all possible measures should be taken.

In the following sections, the views of speakers in each session are presented.

2.2.1 Session I: TRIPS & its impact on Pharmaceutical R&D

In the first session on "TRIPS and its Impact on Pharmaceutical R&D", Dr. Amarjit Singh in his talk on "TRIPS and its Impact on Drug Delivery Research in India" presented a comprehensive scenario of development of New Drug Delivery Systems. Accordingly to him, of the total world pharma market of US$ 355 billions the drug delivery system based products account for nearby 13%. Hence, they offer a very good research and market potential. He felt the industry needs to concentrate efforts in this area.

Dr. H.R. Bhojwani in his talk on “Japan Inc breached: India alerted?” spoke how globalization is going to affect the prices of medicines in India and how global players are looking at Indian markets. He felt that India must think and work like a corporate entity if it has to be a global player. Through the example of Japanese drug industry, Dr. Bhojwani charted the challenges which Indian sector of drug industry shall have to face in the post TRIPS regime.

Dr. N. K. Ganguly in his talk on “Drug Discovery and Development: Challenges and Opportunities for India” shared with the audience his thoughts on emerging disease profiles and the measures required to contain them.

Dr. H. P. S. Chawla’s presentation on “Impact of TRIPS on Pharma Industry” covered the impact of TRIPS on pharma market and charted a road map for Indian pharma research. He felt that India should concentrate in those niche areas where there are more visible technology barriers e.g. racemate switches to chiral drug, New Drug Delivery Systems, well researched herbal products and Generic Biotechnology products.

2.2.2 Session II: TRIPS & its Impact on Pharmaceutical Prices

In the second session on “TRIPS and its Impact on Pharmaceutical Prices, “ Dr. Dinesh Abrol in his talk on “Impact of TRIPS on Prices of Medicines” mentioned that even developed countries are concerned about rising prices of drugs. In India now dependence on imports is growing. Easing of production and price controls is resulting in higher prices, domestic industrial orientation is weakening those players who can ensure the supply of innovative drugs to market. According to him, our needs and consumption patterns are different from the developed countries and our patient and drug laws must take notice of them. Even a World Bank study on fluoroquinolones has indicated 100 to 400% price rise when control measures were absent. He felt that public sector must be encouraged and also a thorough study on impact of TRIPS is required.

Sh. Amitava Guha in his presentation on “TRIPS Agreement and its Impact on Medicine prices” spoke of strange pricing paradigm where the govt. reduces price control for the market forces to take control of pricing. He mentioned that only 3-5% drugs in market are under patent is not correct as a study from UK has reported that during 1994-2004; 30 NCEs were introduced in the market. He mentioned that in 2003 alone more than 150 new drugs came into Indian market, most of them highly

priced. He felt that under the new patent regime we have lost the opportunity to bring in a patent regime which is not only TRIPS compliant but also very well takes care of our country's unique concerns. According to him, we should have taken care on the definition of the patentability, provisions of EMR, compulsory licensing, parallel imports and limited data protection. He felt that the Doha declaration's intent on parallel import is impossible to meet.

Dr. A. D. Damodaran in his presentation on "The Patents (Amendment) ordinance, 2004 - a SWOT analysis through a Contemporary Case Study" spoke on the hurried implementation of patent ordinance and felt that unless it is critically examined it is going to affect all areas of technology and manufacturing. He illustrated his point of view with the example of anticancer drug Glivec. He felt that India had state of art R&D, technology transfer and commercialization capabilities, the patent ordinance 2004 should have aimed at providing the required intellectual property thrust. According to him, India has weak capacity for innovative R&D which needs to be looked at.

2.2.3 Session III: TRIPS & its Impact on Drug Availability

The third session on "TRIPS and its Impact on Drug Availability" had Mr. Gajanan Wakankar speaking on "Impact of TRIPS on Pharmaceutical Prices/availability" wherein he felt that this ordinance should be put to a joint parliamentary committee when it comes for confirmation. He opined that India needs a new law under drugs act to negotiate and control prices of patented drugs as a condition of drug approval.

Dr. A.K. Gupta in his talk on "TRIPS and its Impact on drug availability" spoke on the impact of TRIPS on hospital services. According to him, TRIPS will adversely affect the hospital budgets. It would also change the prescribing patterns of doctors. He wanted the doctors to prescribe off – patent drugs from hospital formulary as much as possible. He felt that TRIPS is loaded in favour of the developed countries and MNCs and the only way to improve is through distribution efficiency and decreasing marketing cost.

The last speaker, Dr. Amit Sengupta, in his talk "Manufacture of generic drugs in India: Post 2005 scenario" felt that with the new patent regime the small scale drug sector is getting squeezed up, medium sector is at cross-roads and it is only the large sector which is going up. According to him trade and patents are two ends of a spectrum and both should live in balance.

In the concluding remarks, Dr. Naresh Kumar summarized that with TRIPS being a reality, the question is how to make best use of its provisions. As of now, it is a mixed bag of goodies and duds; only time, may be another 2 years or so, will tell what we have on our plate and what should we take and what not. At this point of time, the pointers on how the indigenous industry in Japan and Italy has gone the multinational way are indeed ominous.