

Executive Summary

1. India was a signatory to the TRIPS agreement, 1995 under which it had been proposed to harmonize rules governing Intellectual Property Rights, in all countries signing the agreement. The basic concept behind the same was to remove bottlenecks to trade caused by fears of the developed countries, that their products would be copied illegally in developing countries owing to 'porous' patent regimes in those countries.
2. Under TRIPS, *two* major changes were quite significant for India- *firstly*, a uniform increase in patent term for all products and processes to twenty years and *secondly* introduction of product patents for drugs. Under the existing Indian Patent Act, the term of process patent for food, drug or medicine was five years from date of sealing of patent or seven years from date of filing of application, whichever was shorter. Product patents were not allowed for food, drug or medicines.
3. India was granted a transition period of ten years, 1995-2004 to amend its national laws and bring them in conformity with the laws for intellectual property protection as envisaged under the TRIPS agreement. Term of all patents was uniformly extended to 20 years and provision for mailbox applications and exclusive marketing rights (EMR) was also introduced. Recently, w.e.f. January, 2005 India has also allowed product patents vide amendments to the patent act.
4. While on one hand, there was a desire on part of the country to be part of the global system and grant due protection to inventors and innovators of new medicines and drugs, at the same time there were concerns at national level that monopoly rights associated with patents would push up drug prices.
5. Accordingly, a study was undertaken by the National Institute of Pharmaceutical Education and Research (NIPER) under the sponsorship of WHO and MoHFW, to study the impact of TRIPS on pharmaceutical prices, with specific reference to generics. Ten years of data (1996-2005) on selected drugs in various therapeutic categories was compiled and analyzed, in addition to reviewing related aspects.

6. There are more than 60,000 formulations in nearly 60 categories available in the Indian market (OPPI compendium, 2004). Tabulating the price of each formulation and comparing trends over a ten year period (1995-2005), posed an immense task. Hence, a suitable model for the study had to be selected. One alternative was to select the major therapeutic categories at global level and study the changes in prices of drugs in these select categories only. However, this posed a practical difficulty for the study in the Indian context. Therapeutic categories in the world are classified according to the value of sales of drugs in that particular category e.g. in 2003, Cholesterol and Triglyceride reducers ranked number one in sales, with a figure of US\$ Billion 26.1 representing 5.6% of the total sales (OPPI compendium, 2004). The same category cannot be extrapolated to India, because the figures include US and European markets, in which drug prices are much higher as compared to those in India. Hence, though the actual consumption of a drug in volume terms may be low in India, the same may rank at the top in a therapeutic category because of high international prices.

Since the prices of Indian drugs are lowest in the world, sales turnover is NOT an accurate reflection of actual units of a drug being consumed. Also, owing to peculiar socio-economic conditions of our country, certain diseases which are virtually non-existent in developed countries e.g. water-borne infections, are quite rampant in our country. Malaria, Tuberculosis and AIDS have been identified as the three major killers in our country (OPPI presentation proceedings, 1998). Accordingly, for the present study, it was decided to survey the prices of select drugs in various therapeutic categories, post 1995. Relevant therapeutic categories and drugs were selected mainly on basis of studies carried out by Nagesh Kumar (2003) and Lanjouw (1998). Prices of drugs were studied over a ten year period (1996-2005), by compiling data from the Jan-Feb. issues of Indian Drug Review, for each year. In addition to prices, the data on the number of manufacturers for each drug was also collected.

7. It was found that all drugs being manufactured in India till January 2005 can be effectively classified as 'generic drugs' (*generic drugs are those which are off-patent or not under patent control*). This is because the country did not grant product patents prior to January, 2005. It is true that provision for Exclusive

Marketing Rights and Mailbox Applications had been introduced in India vide Indian Patents Amendment Act, 1999. Such a provision resulted in a situation wherein the Controller of Patents was placed in a difficult position as he was not able to examine applications containing claims for new products or refuse such applications. Hence, Controller devised a method to classify such applications (containing claims for the new products) as WTO applications and kept such applications separately without taking any action till the Patents act 70 was amended on 1.1.2005. Since such applications were kept separately these were known as "Mail Box" applications. Due to ambiguity in this not many EMR's were granted and it hardly made any impact on the drug prices. Moreover, in the modified patent act under TRIPS, there was nothing in the Act to prevent a manufacturer from making the drug patented elsewhere. Moreover, EMR for pharmaceutical products was granted for five years only. Thus, drugs for which patents had been filed abroad could still be legally manufactured in India.

Secondly, mailbox applications though accepted in the patent office, were to be examined only after January, 2005. During this period, even those drugs for which patent application had been filed, could be freely manufactured, since applications had not be examined, published or granted patents. Now under the amended patents act, 2005 it has been specified that manufacturers making drugs, for which patent applications had been filed in the mailbox, will not be penalized and may continue to manufacture the same, after paying reasonable royalty to the original patentee. Hence, this practically means that all drugs prior to 2005 can be classified in 'generics category'.

8. Prices of drugs in the post-TRIPS period (1996-2005) were analysed and the following have been observed:
 - There is so far no significant increase in the prices of drugs, since the implementation of the TRIPS provisions.
 - Rather, there has been a distinct fall in prices of some of the drugs.
 - Most of the drugs being marketed by multinationals are also being simultaneously manufactured by Indian Drug Makers.
9. The results were interpreted as follows:

- The vast quantity of drugs being consumed by the population, belong to generics whose prices are determined by technological strengths and socio-economic conditions. In India, presence of a strong indigenous manufacturing base ensured that prices remained stable and low as compared to those sold by multinational companies.
 - In some categories, there was a fall in prices after TRIPS, rather than increase. This was due to increased competition as indicated by increase in number of manufacturers. Also, Indian manufacturers freely carried out innovations and improvements in processes resulting in decreased production costs. In contrast, multinationals hesitated to experiment with new and often more efficient processes because in their countries, adoption of new processes for making drugs also required approval, which was sometimes quite a long and expensive process.
10. Based on analysis of data and other related aspects, a simple model on 'drug prices' has been proposed by us. According to this model, the 'NIPER 2D Model' , prevailing prices of widely used drugs in any country are the outcome of mainly two distinct parameters -
- *A. Technological Strengths*
 - *B. Socio-economic factors*, rather than TRIPS or product patents alone.
 - Countries which are not technologically sound (strong pharma industry absent) and are dependent on imports, suffer from high prices of drugs.
 - India too was one such country, following the initial years after independence. Though it was socio-economically weak, still drug prices were not low owing to lack of technological strength. However, once self-reliance in pharma production was achieved, prices fell dramatically even in the post-TRIPS period.
 - Thus "Technological Strength" is the first dominant factor which influences drug prices.
 - Secondly, socio-economic conditions play a key role in influencing drug prices. In India, vast majority of the population cannot afford even generic drugs, let alone high priced patented medicines, since there is no system of healthcare coverage of the population as prevalent in western countries.

Hence, the Indian pharma industry is 'production oriented' –focussing on bulk production at cheaper cost, by developing new and improved processes, rather than trying to develop new molecules. A large booming population ensures a market for low-priced generic medicines, which are not affected by TRIPS or changes in patent laws.

11. It is concluded that TRIPS is unlikely to have an affect on the prices of drugs in the times to come, owing to technological strengths of the indigenous pharma industry and the peculiar socio-economic conditions of the country where generics command a significant chunk of the market.
12. It is recommended that the Indian pharma industry should focus on developing competence in advanced areas of drug manufacture e.g. biopharmaceuticals, DNA based drugs etc. in which its technological strength is low. After TRIPS, prices of traditional chemical drugs are likely to remain stable and possibly even fall rather than rise, owing to infusion of better and state-of-the-art manufacturing capabilities by the domestic pharma industry. The fact that outside the United States, the highest number of FDA compliant manufacturing units is in India supports this view. However, for biological drugs (e.g. erythropoetin, insulin, gamma IgG, Colony stimulating factor, interleukins etc.) prices are likely to remain high owing to absence/limited domestic competition. Interestingly, several of the patented biodrugs themselves are falling into the 'generics' category, their patents having expired or being on verge of expiry. But their prices are not likely to come down in the near future, owing to absence of domestic challenge. Hence, it is imperative that the pharma industry and the Indian government recognize this challenge and go into mission mode to bridge this gap.
13. The study also revealed that the India pharma industry has been wrongly criticized for not carrying out R&D. It is by no means a small achievement to bypass a highly technical manufacturing patented process (process patents were allowed in India even before TRIPS, though of limited duration) developed by technologically superior countries! The fact that the Indian Pharma Industry was successfully able to meet the challenges of developing better, more efficient processes is a tribute to its R&D capabilities. The hard fact is that the prevailing socio-economic conditions in the country did not permit the industry

with its limited resources to 'hunt' for fancy, new molecules. Rather, the population and socio-economic conditions created a demand for R&D which would result in faster production of existing drugs at lower costs. The industry met that challenge by developing new, non-infringing processes for manufacturing drugs.

14. Given the vast storehouse of traditional knowledge, some of it exclusive to India, the excellent research infrastructure facilities and large pool of trained human resources available to the pharma Industry now, there stands nothing in the way of the industry to go in for new drug discovery, development of new systems of drug delivery and also new generation of drugs. TRIPS rather than being a barrier, offers new opportunities to our Industry in tapping not only domestic but also global markets, by seeking intellectual property protection for their own innovations and discoveries.
