TRIPS, WTO and IPR: Counterfeit Drugs

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The World Trade Organization (WTO) was set up in 1995 and has been the custodian of all matters related to the implementation of the TRIPS Agreement endorsed by the 153 member countries. WTO is therefore the most important body which monitors and influences working of global intellectual property rights protection in all its member countries. This opinion discusses counterfeit drugs.

Are Provisions Under TRIPS Compromised?

The TRIPS Agreement, the seminal document which dictates the setting up and implementation of a global system for protection of intellectual property rights by the 153 members of the World Trade Organization is under severe stress and strain in recent times largely due to perceptions on its role in developing a uniform trade order equitable to both the poor and rich countries of the world. At the end of five years after the famed Doha Declaration which pronounced that whenever public health was threatened, public’s rights over innovations will supersede private interests, the international agency OXFAM concluded that rich countries are taking little or no action towards their committed obligations and are in some cases actually undermining the declaration. A further five years down the line, in 2010 the situation is not considered to be any different. The essential approach mandated by the TRIPS Council to make drugs of the right quality available to the poor countries at affordable prices has not been implemented in any meaningful manner in any country.

An Indian View

In a recent lead story in one of the Indian dailies, it was reported that the Department of Industrial Policy and Promotion has prepared a discussion paper of examining the option of introducing compulsory licences under the Indian Patents Act. Also being considered is a review of the Foreign Direct Investment (FDI) Policy which at present allows 100 per cent FDI in the pharmaceutical sector. One of the reasons quoted is the recent spurt in acquisitions of Indian companies by the MNCs. Concerns are being increasingly expressed rightly or wrongly that the new trend will lead to the dominance of MNCs in the Indian pharmaceutical sector (as was the case pre-1970) and higher prices of drugs in the Indian market. This will be particularly so in the case of patent protected drugs which enjoy a monopoly even if for a limited period of time. During the period 1972 to 2005, India became a global lead player in the manufacture and marketing of pharmaceuticals, including patented drugs in view of the fact that in the absence of product patent protection, Indian companies were free to produce drugs as long as they did not infringe valid process patents. India thus became the world’s major supplier of generic drugs, Active Pharmaceutical Ingredients (APIs) and drug intermediates. With the advent of the new TRIPS compliant patent system, Indian companies have no such opportunity. Fortunately for India, due to a variety of reasons including depleting pipeline of patented new drugs and patent expiry of a large number of block buster drugs, the potential for generic markets to grow continues to be great. Indian dominance in generic drugs for the global markets thus will reap rich benefits for the Indian companies.

Generic Market

India’s drug industry is among the top 5 in bulk drug production and within the top 20 in export of drugs. The export market grew over 17 per cent in 2009 over the year 2008, while the domestic market had a growth rate of only 9.5 per cent in value terms. The exports are primarily generic products with the target markets being both developing and developed...
countries. Estimates of the global markets available for new generics during the coming years are placed at around US $100 billion at current prices which as generics would come down to half to one third that value. The world’s largest selling single branded drug, Lipitor with current sales of over US $14 billion loses patent protection in 2011 and so too will many others. At that level, if the Indian industry can command 25 per cent of the new generic market, that would constitute around an additional US $10 billion which is more than the current domestic market for pharmaceuticals. Since generic drugs attract low prices and margins, the high cost economies of the developed countries of North America, Europe and Japan are more than likely to turn to the low cost economies of India, China and Brazil to outsource their drug needs.

Non-Tariff Barriers

Even though the advent of TRIPS as part of GATT was meant to encourage free trade, reduce tariffs and ensure a more equitable as well as level playing field for all WTO members, in reality many non-tariff barriers and restricted market access continue to affect some of the countries, more so the developing countries. These barriers come in different forms. Recourse to sanitary and phytosanitary considerations based on quality provided for under TRIPS is one such. Perceived or actual poor standards of Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), Good Clinical Practices (GCP) etc., are often quoted as barriers to trade among the members dealing with pharmaceuticals. A new development in recent times has been the charges of patent infringement by Indian companies whose drugs transited through Netherlands’ ports on way to African countries. Neither the manufacturing country (India) nor the importing country had valid patents on the drugs involved. Even though according to the patent system any form of unlicensed dealing is violation of the patent holder’s rights, in this case the dealing was between parties in whose territories there was no patent protection.

These charges are frivolous, particularly in the pharmaceutical area where even the TRIPS Council has emphasized through the Doha Declaration the need to make even patent protected drug available at affordable costs to those who badly need them.

Counterfeit Drugs

The global pharmaceutical markets have always suffered from a spate of counterfeit products including fake, spurious, substandard and fraudulent preparations which apart from resulting in huge economic losses to the nation, states and corporations also severely affect the health and well being of populations. The distinction between the above preparations are vague; however counterfeit drugs are those produced and sold with the intent of deception, misrepresenting the origin, and sacrificing the efficacy and safety of the product. They belong to all categories and are put into the markets of all geographical territories through clandestine means. In a report published by WHO for the period 1999 to 2002, it was concluded that the largest numbers (28 per cent) belonged to the antibiotics class followed by hormones and steroids. Due to lack of control and monitoring, the menace has now spread to anti-retrovirals and other anti-HIV drugs. Some products from China were found to be counterfeit when in 2009–2010 several consignments of fake anti-malarial drugs found their way to Nigeria labeled as ‘Made in India’. Counterfeiting of drugs is recognized as a criminal offence and realizing the seriousness of such nefarious activities leading to such products, the WHO in February 2006 created a global initiative known as the International Medical Products Anti-counterfeiting Task Force (IMPACT). The Declaration of Rome in 2006 further emphasized the need for every one of the 193 members (of WHO) to take immediate steps to create awareness and take punitive steps to stem this menace.

Relating Counterfeit Drugs to Generics

The most unfortunate development during the last few years has been attempts to relate generics with counterfeit products. Under the Indo-EU trade negotiations, issues connected with the signing of Anti-Counterfeit Trade Agreement (ACTA), WHO’s IMPACT and a host of other agreements are being discussed. Currently, the right to determine what is counterfeit is left to the customs regulators of the respective country as well as to the Interpol, which unilaterally determine what is counterfeit and seize the concerned goods even while in transit to another country. It is wrong to conclude that generic versions of patent expired drugs are more likely to be counterfeit, an assumption which smacks of total ignorance of the dynamics of this business. India has rightly insisted on the formation of an Inter Governmental Committee under WHO to sort out the norms rather than leave it to these agencies or to
IMPACT. Legitimate generic versions of patent expired drugs of the right quality as established through regulatory approvals fall strictly outside the purview of counterfeiting. In fact a large number of patent protected drugs are also subject to counterfeiting and are floating in the international markets.

On the other hand, if the goods in transit are seized on the basis that they have infringed valid patents, that issue can be settled through reference to the provisions under TRIPS and their fair and correct interpretation. Such charges of infringement have been challenged by India at the Dispute Settlement Board of WTO with Brazil being a co-plaintiff. Subsequently, Canada, Japan, Ecuador, China and Turkey have joined India and Brazil in this dispute. The verdict of the Dispute Settlement Board on this matter is eagerly awaited. Genuine & quality generics are not only legitimate from the regulatory point of view, but are also very much needed to ensure patient welfare through affordable medicines.