TRIPS and Parallel Imports — Impact on Drug Prices

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In the ‘parallel imports’ products are made and marketed by the patent owner (or trademark- or copyright-owner, etc.) in one country and imported into another country without the approval of the patent owner. The legal principle here is ‘exhaustion’, the idea that once a company has sold its product, its patent is exhausted and it no longer has any rights over what happens to that product. It is a method of ensuring affordable access to essential goods. The paper discusses in detail the various provisions of TRIPS related to parallel imports and how it is being dealt with in USA, European Union, UK, Japan and Australia, and outlines the impact of parallel imports on prices. Some suggestions for enforcing ‘exhaustion regime’ in India are given.

Even the most ardent detractors of the new WTO regime with regard to its impact on developing countries, would admit that there has been an earnest attempt to provide equitable access to justice while framing and implementing its provisions to all Members, regardless of their developmental status. Apart from the provision for different transition periods for implementation, based on the economic status of countries, WTO provides assistance to developing countries to understand the various finer aspects of their rights and for negotiating for more rights. In the areas of disputes between Members, when some of them are not equipped to handle their cases, they are provided assistance through an Advisory Centre on WTO Law and two full time and two part time lawyers. In a dispute between a Member of a developing and a developed country, the former can request an accelerated processing of the case, in case the delay will have economic implications. Specific issues on various agreements may be raised by any Member and clarification sought from the Committee on Trade and Development. What is unique about WTO is that all decisions are generally taken by consensus, which means that there is a right to veto any ruling. Further negotiations and discussions are held until consensus is reached. Under Articles 8.10 and 12.10, the Dispute Settlement System, when a developing country is in

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dispute with a developed country, the former has the right to have at least one panelist from a developing country. The developing country Member will also be accorded enough time, if desired, to prepare and present its arguments to the panel. Disputes have so far been settled between Members in areas of agreements in agriculture, textiles, subsidies, countervailing measures, anti-dumping, environmental issues, etc. While many developing countries including India have been involved as plaintiffs or defendants, so far no least developed country has been a party to disputes in WTO.

**Parallel Imports**

One of the areas where there has been considerable debate in recent times has been the impact of TRIPS on public health. The concern has been that the product patents regime mandated by TRIPS will make, even life-saving drugs, particularly for diseases of the developing world unaffordable to its vast populations. Even though the Doha Declaration has once again reconfirmed that public health concerns will supersede commercial interests, the mechanisms for remedying the problem of availability and accessibility of patented drugs have not been addressed. The conduit for achieving these is supposedly through the compulsory licence route. However, very few developing countries have the technical capability to produce modern drugs even if they have no patent hurdles. The way out would be to make compulsory licences valid for imports of the patented goods in addition to manufacture. Alternatively, permitting imports from the cheapest source in the world will ensure availability of the needed drugs at the lowest possible cost. That is where parallel imports come in.

Parallel imports are imports of goods produced under protection of a trademark, patent or copyright in one market, imported into a second market without the authorization of the local owner of the intellectual property.

Article 6 of TRIPS recognizes the possibility of legally allowing parallel imports from the territory where it has been licensed, based on the principle of ‘exhaustion of rights’, which means, that, once the patent holder has exercised his patent rights, they are considered to be exhausted. Once the goods are put in the market, he has no further rights to control the use or resale of these products. While this practice is legally allowed within the European Union, the US feels that Article 6 is restricted to the dispute settlement process only, since under this Agreement, “subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights”. It would thus appear that, as long as the principles of national interest (Article 3) and most favoured nation (Article 4) are respected, parallel imports could be permitted with appropriate national, regional or international exhaustion of rights. The R&D-based MNCs feel that parallel imports should be banned in the interests of upholding the principles of enforcement of IPR to encourage innovation. Others feel that a liberal parallel imports regime will answer the many problems resulting from
the nexus between patents and drug prices. The issues reached high visibility with the South African position on imports of anti-AIDS drugs from the cheapest sources even when they were under product patents. There are also criticisms that developed countries practise double standards on this issue. For example, the European Union allows parallel imports and exports among Members, but not with non-Members of the Union. In a ruling by the European Court of Justice, under Article 30 of the Treaty of Rome, free circulation of goods takes precedence over IPR. In the US, the rights of the owner are exhausted under the First-Sale Doctrine and he cannot prevent re-sale of goods anywhere within the country. The fact that high drug costs are of concern even in the US was reflected, when in July 2000, the US Congress and the Senate approved a bill (subsequently vetoed by the President), whereby the pharmaceutical trading houses could have imported cheaper patent-protected drugs from other countries, in special cases. UK, Japan and Australia allow parallel imports under stipulated conditions.

Impact on Prices

It is very well known that prices of the same drug sold under the same brand and therefore, of the same quality vary considerably between countries. Fixing differential prices in different markets (tiered pricing) is a strategy based on *per capita* GNP, prevailing purchasing power parity, nature of competition, prescription practices and price control mechanisms. Even among the developed countries of North America, Europe and Japan, patented products are sold at prices varying some times up to 100% or more. However one of the concerns in this area is that if a drug price is discounted in a poor country, if parallel imports are allowed, the lower priced versions would find their way back to the markets in US and Europe. The western pharmaceutical companies also argue that parallel imports are prohibited under Article 28. Thus the final verdict on this important issue is far from pronounced.

The Case for India

The World Health Assembly in Geneva adopted a resolution in May 1999 seeking to explore and review options available under various international agreements including on trade and related issues, to ensure affordable access to essential drugs, regardless of their IPR status. Compulsory licences and parallel imports are two approaches within the ambit of the provisions under WTO mandates, which can bring some degree of relief to poor patients by bringing drug prices down. In view of the capabilities of the Indian pharmaceutical industry, India can also be a partner for parallel exports from India by the patent holder in addition to the country, in the interests of the consumers, exercising its option of resorting to parallel imports. For that, we need to develop strategies which will lead to enforcement of an ‘exhaustion regime’, which may be national or regional exhaustion, depending on our ability to extend the rights to free trade within defined territories falling under identified
regional trade blocks. Unfortunately India is not a member of any economically strong trade block. Article 6 like many other provisions under TRIPS can be interpreted and enforced in a manner which will be beneficial to the country, particularly since, together with the provision for more favourable terms in the issue of compulsory licensing after Doha, parallel imports can contribute to maintaining drug prices at more affordable levels even after a globally harmonized patent regime becomes operative in India.