Impact of TRIPS on Healthcare Costs

Costs of healthcare have in recent years become a highly debated and sensitive issue not only in developing countries, but also in developed economies. Even economically most advanced countries are reeling under the pressure of escalating healthcare costs and lack of ideas to contain them at affordable levels. Total costs of meeting healthcare needs of the population through public and private programmes and insurance schemes have reached double digit percentage of GDP in most of the developed world including US, and Western Europe. And yet in most countries there is inadequate and suboptimal provision of healthcare to large segments of population. The recent healthcare legislations in the US brought in by the Obama administration while meaning to provide healthcare for all is likely to pose huge economic burden on the country. It is in this context that efforts are being taken to contain healthcare costs. One of the components though not the major one in healthcare costs is the cost of drugs which has become a cardinal issue for governments, policy makers, consumer groups and the patients. It is obvious that high costs of drugs are related to limited monopoly and exclusivity in the market place for patent protected drugs.

High Costs of Drug Discovery & Development

The high and unaffordable costs of drug research with estimates of over 1 billion dollars for every new drug discovered and developed, very low success rates, high degree of obsolescence due to undesirable adverse drug reactions, decline in the pipeline of new drugs and patent expiries leading to generic competition have all significantly contributed to the problems of this lifeline industry. The strategy adopted by the large R&D based corporations to get bigger and bigger through mergers and acquisitions to improve cost-effectiveness and productivity of R&D has so far not worked effectively.

TRIPS & Innovation

TRIPS Agreement is deemed to be an important instrument for promotion of innovation since the protection system embodied therein provides for and constitutes a reward system for the innovator. Any dilution of the terms of this agreement is therefore likely to be a disincentive for investments in research and consequently of discovery of much needed new drugs. Due to the compulsion for recovery of investments in R&D and inordinately high costs involved in R&D, innovating corporations are forced to charge very high prices for patented products. At the same time, it is important to ensure that the drugs so discovered are made available to the needy patients at prices they can afford. Striking a balance between these two somewhat contradictory objectives has been the greatest challenge for the R&D based pharmaceutical companies.

Safeguards & Flexibilities in the TRIPS Agreement

Purely from a technical and legalistic point of view, TRIPS makes it very clear through its Articles 1, 7 and 8 that nothing in the agreement should stand in the way of ensuring public good and social benefits arising out of creation of intellectual property. The provision for the grant of compulsory licenses under Article 30 and 31 also emphasize the need for ensuring availability of patented products when the patent holder is unable to meet the consumer’s demands. In addition, the DOHA Declaration of 2001 mandates that wherever and whenever there is a
conflict between public health issues and IP rights, the former will prevail as the major consideration. These safeguards and flexibilities in TRIPS which have wide latitude for legislation, interpretation and implementation by the member states need to be properly understood and effectively used by the members to derive maximum benefits.

How to Reduce the Costs of Drug Discovery Research?

The high cost of research responsible for the high prices, force companies to engage themselves mostly in research projects which have high market potential. Diseases affecting largely the poor are often at times not ready targets for investments. For example diseases such as Malaria, Tuberculosis, Leishmaniasis, Parasitic infections, Trypanosomiasis, Schistosomiasis, etc. are often not in the R&D portfolios of leading companies. Among the approaches being increasingly mooted for encouraging investments for R&D in these areas are two recent developments initiated by some of the world bodies and leading pharmaceutical companies. They are the use of Open Source Drug Discovery (OSDD) approaches and the development and use of patent pools.

Open Source Drug Discovery

The TRIPS Agreement does not in any way hinder either of these two approaches; however since both these involve the use of IP as an important component of the drug discovery and development process, matters related to IP rights in the context of TRIPS become relevant. OSDD is basically a system of pooling global information sources, expertise, facilities and management systems for drug discovery where individuals, groups and organizations pitch in to develop new drugs by offering their resources and services in an open format. Free access to all required information and their use in an integrated manner by designated groups will accelerate the process of drug discovery. Such an approach has been successfully deployed in the case of the Linux operating system in the IT area and the Human Genome project in the biological space. The Indian Government through the aegis of CSIR has allocated Rs 150 crores for the OSDD project. The primary objective is to discover drugs for tropical diseases through the OSDD programme with the first efforts in the area of anti-TB drugs. Hopefully bringing together of genomics, computational biology technical and scientific skills and infrastructure of several groups from all over the world would lead to meaningful outcomes in terms of reduced costs and time frames than those expended for current models.

Patent Pools

While patents are indeed the lifeline of the pharmaceutical companies, it is a fact that over 90% of the patents granted by various patent offices are never exploited through commercialization. The reasons are many. Lack of adequate markets, protecting technology territories from third party entries, defending and building fortresses around successful products, large investment needs, capacity problems etc are just a few of the reasons. Thus a large number of innovations protected through patents but not exploited remain on the shelves which eventually lapse without any attention being paid to them. The consequence is that very valuable and potentially very useful innovations which could have benefited patients are never put to use. The concept of patent pools involves collective management of IP to expand access to needed medical technologies and products. Patent pools are based on an agreement between two or more patent owners to pool those of their patents which are of no direct commercial interest to them and license them to one of them or to a third party under pre-determined licensing terms for exploitation by a sponsor. It is also understood that patent owners are agreeable to have a collective management of the patent pool for more expeditious discovery and development of drugs. The concept had its origin in the need for expediting discovery and development of new drugs and drug combinations for HIV/AIDS.

Unlike compulsory licenses provided for under TRIPS, patent pools are voluntary offered by the patent holder and as such TRIPS rules and regulations are not relevant to patent pools. The merits of this approach include generation of good will for the patent holders; regular assured returns on successful outcomes and advantages of public-private partnerships and speedy exploitation of the innovation through participation of the best drug development agencies. It is essential that there is a central sponsor for the implementation of this system and at present, the potential sponsors are WHO, UNAIDS,UNCTAD, WIPO, UNITAID etc. It is to be noted that one of the flip sides to this approach is that drug discovery and development is a multidisciplinary professional process which has been in the realm of
the R&D based pharmaceutical industry who are best equipped to carry out the whole exercise. In addition, while patent pools permit open use of patents, they do not provide the much needed technology and know-how. To what extent they will impact on total cost is also not known since the costliest component in new drug research is for development and not for discovery.

These are issues which need to be tackled in the coming years. After all, the concept is hardly two years old and already within this limited time, a number of leading companies have pledged their support for the project and hopefully when fully implemented, drug discovery particularly for neglected diseases will get much needed support.