The TRIPS agreement has not been able to deliver the benefits promised to developing countries, which now need to plan ways to ensure that strict IP regimes do not become a tool for pharma companies in developed countries to milk the poor in the developing world.

Fifteen years after the signing of the Trade Related Intellectual Property Rights (TRIPS) agreement, experts from developing countries are trying to find ways to guard against rising cost of technology and healthcare due to it.

TRIPS agreement signed in 1994 required developing countries to bring about significant changes in their Intellectual Property (IP) laws to raise their standards of intellectual rights protection. As a result, costs of technologies like climate change related and healthcare related ones increased significantly.

Southern experts suggest stronger technological co-operation between southern countries and wise use of the flexibilities offered under the agreement to prevent rising costs and of technology and increase their access under the TRIPS regime.

TRIPS—What for Developing Countries?
The TRIPS agreement that was conceived to expand and strengthen intellectual property rights has not been able to deliver the benefits promised to developing countries at the time of its signing—namely transfer of technology, stimulation of local innovation and increase of foreign direct investment.

Developed countries prompted the negotiation of the TRIPS agreement on the argument that an expanded and strengthened protection of Intellectual Property Rights (IPRs) would bring about increased flows of foreign direct investment (FDI) and technology transfer to developing countries and those changes in IPRs would also stimulate local innovation.

"The experience of implementation of TRIPS suggests that serious doubts can be raised about the extent to which such positive effects of TRIPS have been realised," Abhijit Das, head of the centre for WTO studies at the Indian Institute of Foreign Trade (IIFT) said at a conference that reviewed the impact of TRIPS on developing countries.

He added that studies at the IIFT show that the agreement favoured the developed countries whose multinational companies held patents over many high technology products that they could manufacture or sell at very high prices.

According to Martin Khor, executive director of the Centre for Interdisciplinary Studies on Industrial Property and Economic Law at the University of Buenos Aires, the provisions include extension of patent term beyond 20 years, grant of exclusive rights over data on pharmaceutical products, obligation to refuse marketing approval to a generic version of the product.

Under TRIPS agreement, patents must last for 20 years from the date of...
With specific reference to pharmaceutical products, the Doha Declaration, exempts least developed countries from having to grant patents and from providing for the protection of undisclosed information until 1 January 2016.

application. TRIPS-plus provisions extend the period beyond 20 years (usually indefinitely) with the excuse that need to obtain marketing approvals for new chemicals takes time and reduces the effective term of patent protection and possibility of recovering research and development funds.

FTAs promoted by USA led to obligations by some countries to extend the patent term to compensate for delays in the examination of patent application and in the process of marketing approval and this prevented access to several drugs at an affordable cost.

Sanya Reid Smith, legal adviser at Third World Network, an NGO working on developmental issues, in a paper presented at the conference showed that in Jordan extension of patent term, grant of exclusive rights over data, increased the price of medicines by 20% since 2001 when the Jordan-USFTA began while extension of patent term by 3 years in Korea would cost $ 529 million.

The TRIPS agreement requires WTO members to protect undisclosed test data on pharmaceutical products against unfair competition. Under this rule, members are not obliged to grant exclusive rights over data.

However, FTAs negotiated by USA oblige the parties to grant exclusive rights for at least five years counted from the date of approval of the product, irrespective of whether it is patented or not and in most cases, whether the data are undisclosed or not. It covers chemical entities that are not new as they may have been previously approved in other territories.

This may be of particular significance in countries that have recently introduced patent protection for pharmaceutical products. In these countries, medicines that are off-patent may become subject to exclusive rights. This creates an effective barrier to competition from generics because marketing approval cannot be granted to generic manufacturers even for medicines that are off-patent unless they replicate the full set of data necessary to obtain approval—a process that is costly and time consuming.

FTAs insist that the national drug authority must refuse marketing approval to generic version of a product if a patent is in force, unless the patent owner consents to it. The authority is also required to inform the patent owner about applications for the approval of the generic drug. This shifts the onus of responsibility to prevent possible infringement to the state authorities in developing countries who lack the knowledge and experience to assess the claims of a patent or its possible infringement.

Besides, under a linkage system, pharmaceutical patents that cover a wide range of chemical entities like salts, esters, ethers apart from the main active ingredient may become a serious obstruction to generic competition.

FTAs with their perceived benefits are being used as a carrot to make developing countries comply with TRIPS-plus provisions. For example, Europe is pushing for restriction of affordable generic medicines as part of the ‘investment chapter’ in its trade deal with India.

Other methods adopted to ensure that developing countries comply to such provisions include adopting new rules and programmes that give mandate to custom authorities and postal services of the respective countries to become IP enforcement agencies with the responsibility of seizure of consignments of generic medicines in transit from one country to another even though their use is perfectly legal in both countries.

Solution in South-South
Technological Co-operation

Government representatives and civil society groups from developing countries believe that in the face of such attempts developing countries could share the technological resource base that exists with them and establish their own intellectual property regime to keep the cost of technologies like climate and health care related ones low.

“We need to strengthen the technological pool in the south and benefit from each other’s innovations instead of being dependent on developed countries and wasting our energies opposing the regime they are imposing on us,” said Rajeev Kher, Additional Secretary to Government of India, at the workshop on ‘15 Years of TRIPS: Rethinking Intellectual Property and Development’.

“Closer ties and stronger co-operation among developing countries could help developing countries establish their own IP provisions and stop being dictated by the IP regime established by the developed world,” Khor said supporting Kher’s suggestion.

TRIPS Flexibilities

The TRIPS agreement also provides for some flexibility that developing countries can use to address the economic and social concern of these countries. While the bilateral agreements or free trade agreements try to nullify many of these flexibilities, the challenge before
Before the WTO Hong Kong Ministerial Conference, the WTO TRIPS Council extended the transition period for least developed countries from mandatory compliance with the TRIPS agreement until July 2013. Developing countries is to make most efficient use of these flexibilities.

The World Health Organization (WHO) Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property urges governments to "consider, whenever necessary, adapting national legislation in order to use to the full flexibilities contained in the agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by Doha.

Despite the opportunities provided by TRIPS flexibilities, many countries have yet to amend their laws to incorporate optimally the flexibilities, which is a precondition for their use. A UNDP study conducted in 2007 found that only six countries had a provision on the international exhaustion of rights in their legislation. However, countries like Brazil, Thailand, Rwanda and India have shown how the flexibilities can be used to ensure access to medicines within the TRIPS regime.

The Government of Brazil demonstrated that public health related flexibilities could be effectively used to negotiate lower prices for antiretroviral drugs. Using the threat of compulsory licensing, it brought about significant price reductions of efavirenz and nevirapine in 2001, lopinavir in 2003, the combination of lopinavir and ritonavir in 2005, and tenofovir in 2006. In 2007, after protracted negotiations, a compulsory licence was issued for efavirenz, an important antiretroviral drug used by a third of Brazilians on treatment through the national programme bringing down the price of the drug from $1.60 per dose to $0.45 per dose for the imported generic version.

In 2006, Rwanda passed a law requiring generic medicines to be used for all treatment programmes when available and in July 2007 it became the first country to announce its intention to use the WTO 30 August 2003 decision to import a generic fixed-dose combination of zidovudine, lamivudine and nevirapine from a Canadian generic manufacturing company. The compulsory licence issued under the Canadian Access to Medicines Regime authorized the delivery of enough of this fixed-dose combination for one year's treatment of approximately 21,000 people living with HIV at the most affordable price globally of $0.19 per tablet.

In late 2006 and early 2007, Thailand issued compulsory licences for medicines like efavirenz, lopinavir/ritonavir and clopidogrel (a drug used for heart disease). This decision prompted widespread protests from multinational drug companies, but by early 2008 the number of patients using lopinavir/ritonavir had tripled. In early 2008, the Thai Government issued additional compulsory licences for letrozole (a breast cancer drug), docetaxel (a breast and lung cancer drug) and erlotinib (a drug used for treating lung, pancreatic and ovarian cancer).

When revising its patent law to comply with TRIPS requirements of pharmaceutical products to make them patentable, India adopted stringent patentability criteria to prevent rampant patenting that could affect the generic medicine industry in the country and hamper access to cheaper medicines. It introduced Section 3d into its Patent Act, according to which "the mere discovery of a new form of a known substance that does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant" is not considered an invention and is thus not patentable under the Indian Patents Act.

Other countries can learn from these examples and plan ways to ensure that strict IP regimes do not become a tool for pharma companies in developed countries to milk the poor in the developing world and deny them their rights to better health by making medicines more and more difficult for them to procure.

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