TRIPS and Public Health: The Doha Declaration

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The Doha Declaration on TRIPS and Public Health has very little new matter. It is rather a reiteration of the fundamental tenets embodied in the TRIPS Agreement. Increased flexibility for interpretation and implementation by the members is the cardinal feature of the new document. India needs to evaluate all the implications of the provisions of the new Declaration and through appropriate legislations ensure that maximum benefits accrue to the Indian industry and the public.

The 4th WTO Ministerial Conference ended and contrary to many predictions, members did manage to put together a declaration in the true WTO tradition of give and take and consensus. While some may argue that most of the statements in the various declarations are innocuous and ambiguous, which will lead to different interpretations and new problems, one of the areas where the point of view of the developing countries has been conceded is related to provisions for treating public health concerns and the impact of TRIPS on them. Paramount to the issue is the assurance that the restrictive clauses under the TRIPS Agreement on drug patents will not override such concerns. The Ministerial Declaration on TRIPS and Public Health was prompted by the recent criticisms on the high treatment costs with patented drugs for HIV/AIDS, anthrax, etc and the inability of governments and patients to access lower-priced generic versions because of the patent system. Essentially, the new declaration has very little new matter. Rather, it is a reiteration of the fundamental tenets already built in the TRIPS Agreement. In other words, the Declaration has reindorsed more emphatically the following points:

— Need for the WTO Agreements on TRIPS to address the public health problems affecting the developing (DCs) and the least developed countries (LDCs) especially for HIV/AIDS, tuberculosis, malaria and other epidemics.

— Recognition of the importance of IPR protection for innovation of new medicines, while at the same

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time recognizing the unaffordable high prices of patented drugs.

— The rights of members to interpret and implement through appropriate measures protection of public health and promotion of access to medicines subject to respecting Articles 3 & 4 referring to MFN treatment to nationals and non-nationals.

— The rights of members under para 5 of the Declaration to determine the grounds for compulsory licences, define national emergencies and implement exhaustion rights.

— Methodology to assist countries with no technological capabilities to implement compulsory licences, to be addressed by the General Council before end of 2002.

— Provisions for technology transfer to LDCs under Article 66.2 to continue and the LDCs not obliged to implement Articles 5&7 of Part II of TRIPS Agreement till January 2016.

Use of Compulsory Licence Provisions under TRIPS

An essential feature of the patent rights to the inventors is the granting of exclusive rights to prevent others from making, selling or using the products of the protected invention and thereby enjoying a monopoly on the product, even if for a limited period. The only exception available to a third party in the absence of a licence, is obtaining a compulsory licence under Art. 31 of the TRIPS Agreement. A compulsory licence allows the use of the invention by the person who has been given the permission by the competent authority. The various grounds for the grant of a compulsory licence, according to TRIPS are:

— Emergency and extreme urgency
— Anti-competitive practices
— Public non-commercial use
— Dependent patents
— Protection of the environment and
— In Public interest

It is clear that there is a very wide flexibility available to member countries even under the present TRIPS, to interpret, legislate and implement a compulsory licence system, which will benefit the country and her people. One of the restrictions imposed under Art. 31, however, is that, as and when the conditions which led to the issue of a compulsory licence are no longer applicable, the licence could be revoked. Even though under TRIPS, working of a patent includes imports, this provision has not been universally accepted by all countries. For example, the Brazilian Law (1996) has made it obligatory for the patent holder to manufacture locally or agree to the issue of a compulsory licence. Many countries, including UK under the crown use clause, U.S. under Anti-competitive Laws and Canada under public benefits provisions have, in the past, enforced compulsory licences provisions in the area of pharmaceuticals.
What Then is New in the Doha Declaration?

The Doha Declaration recognizes the fact which was implicit under Articles 7 & 8 of TRIPS, that considerations of public good which includes public health could be the overriding factor while offering IPR protection for medicines for specified diseases and ‘epidemics’, particularly for DCs and LDCs. The term ‘epidemics’ is not defined and would give room for differing interpretations. Additionally, there will be a substantial time gap between an acute need in the wake of an unexpected epidemic and implementing a compulsory licence. It is gratifying that judgments on interpretation and implementation of the rights of the members is strictly with them and not (even though not mentioned) within the purview of WTO and its Dispute Settlement Board. The details of possible and beneficial mechanisms for transfer of technology for making life-saving medicines to DCs and LDCs are yet to be considered by the General Council. In this connection, it is surprising that there is no mention of “Parallel Imports” as a possible mechanism to reduce dependency and keep drug prices low.

What are Parallel Imports?

Parallel imports are goods imported into a country without licences for their IPR rights, including patents, trademarks and copyrights. In other words, countries permitting parallel imports want to ensure access to the cheapest products from other countries. Even though there have been considerable debates on this issue, even the most patent-savvy members of WTO have seriously considered this option in the interests of the public. The US Congress and the Senate had approved a Bill to allow import of cheaper drugs under special conditions. However, the Administration under President Clinton refused to endorse the Bill, presumably under pressure from the powerful US MNC lobby. To legitimize parallel imports, countries can now take recourse to the Doha Declaration by implementing the exhaustion of patent rights provisions.

What India Needs to Do?

Under the Indian Patents Act, 1970, Indian patents for pharmaceuticals were being endorsed with automatic licences of right, in the event the patentee did not work his patent within three years of the issue of the patent. However, during the last three decades, not a single case is known where this provision has been effectively utilized by any Indian company. It is therefore somewhat fallacious to believe that the issue of compulsory licences under less stringent conditions as provided for in the Doha Declaration is going to attract investments, production and marketing of life-saving drugs at affordable prices. Since compulsory licences are going to be for life-saving drugs for the poor, they will naturally be in the government’s price control scheme, somewhat similar to the 1986 Drugs Prices Control Order (DPCO), which provided for the lowest mark-up for essential drugs. This factor, coupled with the fact that compulsory licences will be non-exclusive and
therefore available to multiple producers, will lead to pricewars and consequently low margins. If one goes by the experience of the 1986 DPCO, Category 1 products constituting essential drugs were the lowest priorities for pharma companies to invest in, leading to shortages in the market. To make such investments attractive, the possible way out will be for the provision to legally access global markets for such drugs, so that economies of scale will ensure adequate returns to the investing company. DCs and LDCs should be allowed parallel imports as South Africa did in cases where drugs for AIDS protected by Patents were excessively priced.

What India needs to do is to make a thorough and detailed analysis of the Doha Declaration on TRIPS and public health and bring in appropriate legislations, rules and guidelines which will be beneficial to the healthcare needs of the country and the domestic industry. The core strength of the DOHA Declaration is not so much the legislative aspects involved, but the spirit of understanding on the part of the Members to interpret the provisions and implement them in the most equitable manner. The ball is now in the Members’ courts.