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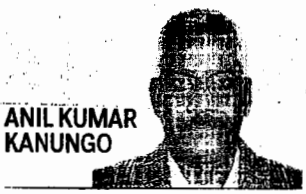
Don't trip-up public health

TRIPS-compliance in developing countries should follow proper IP management



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Public health is once again in the spotlight with the chief of the US Food and Drugs Administration (FDA), Margaret Hamburg, vociferously outlining the quality of the medicines that can be exported to America. However, affordability of medicines and public health has become an issue of concern the world over, especially in the wake of major epidemics like HIV/AIDS, tuberculosis, etc. With public health coming under the trade-related intellectual property rights (TRIPS) agreement of the WTO, it is timely to analyse its implications for the developing nations.

One of the most significant matter being dealt with in the Doha Round of the WTO is the interface between TRIPS and the objective of universal and equitable access to public health. The overarching importance of this subject can be gauged from the fact that there was a separate Ministerial Declaration on TRIPS and public health of the WTO.

TRIPS sets the minimum standards on intellectual property (IP) applicable to all WTO-member countries. While certain relaxation in implementation was given to the developing countries and the least-developed ones, within years of the agreement being signed, it was felt that universally equitable and affordable access to health could be severely compromised unless concessions were made by amending the agreement.

On December 6, 2005, the agreement was amended to incorporate safeguards ensuring that public health concerns were not compromised for the developing and least-developed countries. These amendments have been left hanging as two-thirds of the WTO-members are yet to ratify the same. The deadline to ratify the amendments was postponed to December 31, 2013, by the General Council. However, the General Council decision of November 26, 2013, extends the deadline to December 31, 2015.

The most controversial issue surrounding TRIPS is its impact on the price and availability of new medicines. If patents for new drugs are obtained and enforced in developing countries, TRIPS could reduce the availability of cheaper generics, undermining affordability. The manufacture of products unprotected by patents led to competition that played a key role in determining prices for anti-retroviral drugs used for controlling HIV in Brazil, India, South Africa and other countries.

The price effects of TRIPS should be monitored closely, both in countries with a strong generics industry and in those relying on imports of generics. But there are other structural impediments to access besides price. These include the equity and efficiency of healthcare financing and drug/vaccine distribution systems, the availability of evidence-based analysis to improve the current practice, and local community involvement. One example of delivery failure is the uneven access to medicines on the WHO list of essential drugs, of which less than 5% are on-patent.

Apart from the effect of patents on post-TRIPS pricing and availability, the comparative therapeutic benefits of new chemical entities over available generics will have health implications. So, in assessing TRIPS, the rate of pharmaceutical innovation will be a key variable in measuring the health impact of strengthened patent regimes.

IP management skills to adapt TRIPS to a nation's advantage need to be developed. Developing countries investing in science and technology must address IP issues to participate in the international marketplace. IP competencies will enable access to emerging tools, technologies and resources. An acute need exists to establish policies and procedures and to train staff in effectively managing IP. Priorities include training in contract negotiation, statutory protection, patent searching and filing, technology valuation and business strategy development, as well as the development and implementation of IP policies and strategies at the institutional level, especially within public research institutions. Evaluations of the costs and benefits of TRIPS should consider investments in capacity-building.

The significant part of the debate on TRIPS-compliance by developing countries in general, and by India in particular, focuses on a product-patent regime. It has been contended on the one hand that a product-patent regime would encourage innovation and FDI in a developing country, while on the other hand, it would severely undermine the capability and growth of the domestic generics industries. Such a regime would not only make public health more expensive but also push it out of the reach of the poor living in developing countries.

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