Emerging patterns of engagement with science and innovation for improved access to essential medicines in India: Lessons from the experience of policy design

Dinesh Abrol, NISTADS, India

Abstract

The challenge of fulfillment of the goal of improved access to essential medicines means solving a number of problems connected with deficient medical infrastructure, imbalances between prices and ability to pay, and the absence of a system of innovation capable of developing medicines specific to the diseases endemic to local population in India. With the inclusion of Trade Related Intellectual Property Rights (TRIPS) Agreement in the WTO and its defensive acceptance by a large section of the political bureucratic leadership and the domestic pharmaceutical industry the latter issue of how the policies in respect of science and innovation must be designed for the development of new medicines has come to fore in a big way before the policymaking community in India.

First of all, the relevant constitutencies continue to engage on the issue of how India should design the post-TRIPS patent legislation. There is still the unfinished agenda of TRIPS implementation concerning the legislative changes to be finalized in respect of scope of patentability of pharmaceutical products and data exclusivity. There is the pending issue of the formulation of patent examination manual. The issue of how to separate the process of drug regulation from the influence of the processes of patent law enforcement is also haunting the policymaking community. Engagement is characterized by a debate continuing over the design of policy of intellectual property rights (IPRs). Tussle is between the two broad positions around which the various kinds of interest groups are now set.

Argument of the large sections of domestic industry is that how the country's stage of development of S&T capabilities is still not of the level of the capabilities of developed countries and would be harmed in the building of its health-related innovation system by the adoption of the institution of stronger IPRs[1]. Representing the interests of big pharma and emergent service providers of both domestic and foreign origins in the form of CROs the other side arues that how the adverse nature of impact of TRIPS on access to essential medicines is likely to be better compensated through the gains being made for innovation[2]. They argue that since the markets for knowledge for product innovation are

[1] This view has dominated the submissions of Indian Drug Manufacturers Association (IDMA) an interest group reprsenting the view point of a large section of domestic pharmaceutical industry.

2 See the latest work of Granville and Leonard (2003). The claim of these scholars is that "neither trade liberalisation nor TRIPs requirements are likely to suppress the spread of research and innovation and of generics production, which are a result of knowledge distribution and spillovers as well as property rights protection. Learning by doing is a self-sustaining process that leads naturally not only in imitative and generic production in pharmaceuticals but to innovation, for which incentives build up. Even limited R&D and pharmaceutical production, as taking place now through the expansion of pharmaceutical production

receiving much encouragement in respect of the formation of incentive and institutions, it is better to strengthen liberalisation and implementation of the stronger IPR regime. The claims made regarding how with the introduction of strong patent regime the country would benefit quite hugely in respect of foreign direct investment (FDI), technology licensing, overseas R&D and domestic innovation played a key role in the design of the post-TRIPS patent provisions relating to patentability of pharmaceuticals and microorganisms, pre-grant opposition, compulsory licensing, patent examination and renewal, patent disputes and many other related issues.

Second, the engagement is now building up on the issue of how the institution of public science has to be steered to create a national system of health-related innovation. Debate is over the role to be assigned to the development of public-private partnerships for the creation of health-related innovation system to achieve the goal of improved access to essential medicines. The challenge is growing in respect of the policy concerning the development of public sector industry, be it for the supply of vaccines or for the production of essential medicines. There is a debate on the introduction of Bayh-Dole like legislation in India. In the case of Bayh-Dole like legislation again the place to be accorded to the institution of intellectual property rights (IPRs) is at stake in the overall schema of science, technology and innovation policy. Policies to be adopted for the maximization of spill overs from the pharmaceutical knowledge markets under development are now under the scanner of citizen groups constituted by public health movments.

In this paper we examine the experience of close to fourteen years in respect of the design of policies for science and innovation and their implementation in the post-TRIPs Agreement period in India. We review the available evidence from the sphere of impact of the policymaking on the promotion of R&D and building of innovation capacity through the development of public science institutions and the capabilities of domestic pharmaceutical industry in India. We analyse the prospects of the routes preferred by pharmaceutical industry related domestic firms for its growth via export of generics to regulated markets, contract manufacturing and hosting for outsourcing of drug discovery research, drug development and clinical research. We assess the evidence emerging out of the steps being taken by the foreign and domestic pharmaceutical firms in respect of the promotion of technology licensing, R&D and innovation after the enforcement of TRIPs Agreement.

Contrary to the above discussed predictions of studies on strong IPRs, we show that as of today the policy design has failed to stimulate the large domestic pharmaceutical companies to invest in R&D and innovation in respect of the development of medicines related to local needs of India and other developing countries health conditions. Their insertion in to the emerging international division of labour within pharmaceutical

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and sales in transition and emerging economies, is knowledge intensive and has some impact. The multi-layered impact of cooperation will make it possible for these economies to access learning. Both, generics as well as patented products tap into learning, and they are both increasingly responsible for expanding markets in the pharmaceutical sector" (Granville and Leonard, 2003, p 27).

industry is tending to lead the existing clusters of pharmaceutical production and the linked innovation systems to move even further away from the goal of development of medicines for developing countries health conditions. At the moment the national system of innovation is working far more efficiently to utilize the emerging market opportunities for contract manufacture & R&D in a selective way. We take a view on the subject of challenges facing the government and pharmaceutical industry in the light of the available evidence on the changing character of pharmaceutical knowledge markets. Finally, based on the analysis of existing gaps and mismatches we propose a new policy framework to improve the coordination of technology and markets with a view to foster a better strategic response with regard to R&D, innovation and local production for improved access to essential medicines among the institutions of public science and pharmaceutical industry in India.