Emerging Strategies for Implementing TRIPS Obligations: A Case Study of India's Pharmaceutical Policy

Amy Kapczynski
UC Berkeley School of Law, Boalt Hall

The recent history of international IP law was a history of harmonization. Significant new multilateral treaties were negotiated, most importantly the WTO's TRIPS Agreement. Today, the age of harmonization appears to be on the wane. New multilateral treaty-making efforts have foundered, and conversations instead are moving towards topics of implementation and enforcement. In this new age of international IP, questions about the internalization of international IP law will become key.

Based on six weeks of field research, this paper offers a case study of the implementation of international IP law in the pharmaceutical sector of India. In order to comply with its TRIPS obligations, India amended its patent law in 2005 to permit product patents on pharmaceuticals. This has potentially major implications for the affordability and availability of medicines in India and elsewhere in the world. The setting is important in another respect: It provides a limit case for an inquiry into the mechanics of international IP law. India has significant motivation and capacity to minimize the local impact of TRIPS-compliance and has implemented several innovative mechanisms that substantially facilitate this goal. The case study thus permits us to identify a range of levers that countries may deploy to adapt TRIPS to their local needs. It also allows us to address critical questions in the domain of international IP: How much flexibility does TRIPS actually permit, in a practical as well as a formal sense? Should we expect the harmonization of law at the transnational level in fact to lead to substantial harmonization of national laws and practice? If so, how?

Part I of the paper provides an overview of the mechanisms incorporated into Indian law to comply with TRIPS while protecting local priorities in the health and industrial sectors. It demonstrates that the patent levers available under TRIPS are substantially more diverse and have substantially more potential to undermine exclusivity in the area of medicines than is commonly assumed. If applied strictly, India's patent law would render a significant number of the pharmaceutical patents available in the United States invalid in India. Those pharmaceutical patents that do exist would provide very limited assurance of exclusivity.

Numerous contextual conditions, however, limit the use of these policy levers, as a close consideration of the Indian example shows. These influences range from the dense network of training and exchange between Indian patent offices and developed country patent offices to the resource constraints that undermine the government's ability to exert administrative control over its patent offices and articulate its alternative vision of patent law. But as Part II of the paper will show, the Indian example suggests a series of strategies that countries may seek to deploy to make effective use of TRIPS flexibilities despite these constraints. The effectiveness of these strategies cannot be fully determined in advance. Ultimately, as the paper seeks to demonstrate, we must view

TRIPS implementation not as a process of command and control, but rather as a process of interpretation and contestation. This process is shaped not only by formal texts and negotiations, but as importantly, by the context, institutions, and resource disparities that surround the Agreement and that ultimately give it its meaning.