Developing Countries and TRIPS: What Next?

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ABSTRACT

This chapter provides an overview of the current and potential impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) on low- and middle-income countries. The chapter also summarizes the findings of a meeting in New Delhi, India and explores the legitimacy of concerns about TRIPS. Access to health products relies on many factors, including the successful innovation of new technologies. Innovation, in turn, is a complex process, involving many factors (intellectual property [IP] is just one) that influences product availability and price.

Pointing to the growth of global and national public–private product-development partnerships (PDPs), the chapter highlights one way these countries are seizing opportunities—and reveals how important effective IP management has become for them. Focused on high-priority diseases such as AIDS, malaria, and TB, PDPs require the development and implementation of sophisticated IP management policies and practices in both developed and developing countries in which PDPs operate. Finally, the chapter discusses the possible role of compulsory licensing and parallel trade. The value of these flexible options, provided by TRIPS, is yet undocumented and successfully implementing them represents a significant challenge. Crucially, countries have considerable freedom to control the effects of TRIPS on the availability of new health technologies. The countries can do this most effectively by building capacity for IP management and by formulating policies and practices, for courts, patent offices, and other institutions, that favor the poor.

1. BACKGROUND

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), under WTO (World Trade Organization), mandates a minimum set of IP (intellectual property) protection for patented pharmaceutical products. TRIPS raises questions about how new global standards for patent protection will affect innovation, R&D investment, and product availability, especially for developing economies with significant innovative capacities in health R&D (such as Brazil, China, India, and South Africa). To explore these issues, the Indian Council of Medical Research (ICMR), in India, and the Centre for Management of Intellectual Property in Health Research and Development (MIHR), based in the United Kingdom, convened an international meeting in New Delhi in December 2005, titled "Living with TRIPS: Innovation of New Health Technologies for the Poor." This chapter summarizes the findings of that meeting. A full report has been published elsewhere.[1]

Attention has focused on India because of its established strengths in generic-drug production, large prospective market for low-cost medicines, and potential cost advantages as an R&D base for multinational firms. These factors make India a bellwether for gauging the impact of TRIPS on health-product innovation and access. Vigorous debates in India and elsewhere

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preceded the implementation of TRIPS, and it is timely to follow up on some of the questions raised in that debate. Will TRIPS lead to monopolies on new drugs where, previously, imitation was possible? Will TRIPS encourage foreign investment for the health industry or create external constraints? Will TRIPS lessen interest, by developing country firms, in diseases of the poor where markets are uncertain, or will it motivate the development of innovative drugs against priority diseases in these countries? And will international product-development partnerships (PDPs) that are now generating a pipeline of drugs for poverty-related diseases find it easier to form partnerships with institutions and emerging suppliers in developing countries?

2. PUTTING TRIPS IN CONTEXT

Conclusively documenting the benefits or costs of TRIPS for developing countries may be impossible. Innovation is a dynamic process influenced by many external variables. These include the level of government support for science and technology, government programs to promote trade, the capabilities of national drug-regulatory agencies, and government efforts to enhance competencies in these and other areas. Despite the difficulties of measuring the effects of TRIPS, we can at least point to historical precedent, which suggests that strengthening intellectual property will increase foreign direct investment and flows of technology transfer, as long as essential preconditions exist (namely, supportive R&D environments, effective judicial systems to enforce patent law, and viable domestic and export markets). And while definitive measurements cannot be obtained at this time, it is possible to determine the most important trends to measure.

Perhaps the most controversial issue surrounding TRIPS is its impact on the price and availability of new medicines. If patents are obtained and enforced in developing countries, TRIPS could reduce the availability of copies of patented medicines, thus adversely affecting a de facto price control on medicines in these countries. The manufacture of products that were unprotected by patents led to competition that played a key role in determining prices for HIV antiretrovirals in Brazil, India, South Africa, and other countries.

Accordingly, the price effects of implementing TRIPS should be monitored closely, both in countries with strong generic industries and in countries relying on imports of generic substitutes. But there are other underlying structural impediments to *access* besides price. These include the equity and efficiency of health-care financing and drug/vaccine distribution systems, the availability of evidence-based analysis to improve current practice, and local community involvement. An instructive and often-cited example of delivery failure is the uneven access to medicines on the World Health Organization's (WHO's) list of essential drugs, of which less than 5% are on-patent. To accurately measure access requires carefully considering the historical and social contexts of drug delivery.

Apart from the potential effects 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 over time, the rate of pharmaceutical innovation will be a key variable in measuring the health impact of strengthened patent regimes.

IP management skills will need to be developed so that TRIPS can be adapted to a nation's advantage. Developing countries that choose to invest in science and technology must, of necessity, address IP issues to participate in the international marketplace. IP competencies will enable these countries to gain access to emerging tools, technologies, and resources. Indeed, an acute need exists to establish policies and procedures and to train staff in effectively managing intellectual property. 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 and universities. To provide the most useful and most accurate information, evaluations of the costs and benefits of TRIPS should consider investments in capacity building as an important variable.

3. EMERGING STRATEGIES TO REACH THE POOR

Assessing the implications of TRIPS for the development of new products to treat diseases of poverty is difficult. Technology transfer and innovation, in general, are strongly viewed as ways to strengthen an economy; clearly, however, emerging pharmaceutical industries can do more than generate new knowledge, skilled labor, and markets. These industries can address social objectives by developing health-related products to meet local needs. But will the emerging pharmaceutical industries in Brazil, China, India, and elsewhere become sources of new medicines for diseases that disproportionately affect low- and middle-income nations? Early evidence suggests the answer is no. Pharmaceutical firms in India are focusing globally, exploiting their strengths to develop or improve therapeutic drugs for well-characterized medical conditions that exist in robust global markets. For example, based on projected sales growth, Ranbaxy Laboratories aspires to increase its percentage of revenue from sales to member countries of the Organisation for Economic Co-operation and Development (OECD) from 20% in 2000 to 70% in 2007 (presentation at investors conference in Mumbai, September 2004).

The public sector predominantly remains responsible for promoting the development of new technologies to meet local needs. For example, the government of India is addressing this task by promoting investment in drug development through several innovative schemes, such as increased R&D tax benefits and subsidies to support industry–university partnerships. The New Millennium Indian Technology Leadership Initiative, for example, supports local technology partnerships between publicly supported R&D institutes and industrial companies. Among health-related activities, the program supports the development of new targets, drug delivery systems, bioenhancers, and therapeutics for latent mycobacterium tuberculosis to better manage India's high disease-burden of tuberculosis. Researchers are also working to identify gene-based drug targets for prevalent cancers in India. The program may serve as a model for supporting local public–private partnerships in other regions, especially as firms seek academic ties to enhance their R&D base in drug discovery. Importantly, when the public sector invests in product development, it can control the intellectual property to help benefit the poor (for example, by setting conditions for how the covered technology is to be distributed or marketed).

Equally important, the new global IP standards have emerged just as public–private product-development partnerships (PDPs) are pioneering creative forms of IP management. PDPs use intellectual property as a negotiating tool for developing high-quality, affordable therapeutics and vaccines for diseases of the poor. For example, the Medicines for Malaria Venture (MMV) has formed technology partnerships to develop an artemisinin-derived lead compound for malaria. In explaining the success of the partnership, MMV points to its pragmatic approach to collaboration with the private sector, an approach made possible by the effective identification and management of intellectual property. Indeed, each PDP must adapt its IP strategies to the contributions of its public sector and industrial partners. Nonetheless, PDPs share the common goal of constructing deals that both provide incentives to the private sector and meet the social objectives of the public sector. These deals are achieved through negotiated agreements on territorial markets, pricing structures for public and private markets, or field of use, among other areas. The synergistic relationships of PDPs are represented in Figure 1.

4. TRIPS AND PUBLIC-HEALTH SAFEGUARDS

TRIPS also raises issues related to compulsory licensing and parallel trade.[2] These public-health safeguards are provided under the TRIPS agreement and were reinforced by the Doha Ministerial Conference. In December 2005, the WTO Council permanently adopted a key policy on compulsory licenses that had existed as a waiver since 2003. The waiver has significantly improved the ability of developing countries without manufacturing capabilities to import patented drugs from sources other than the originator company.

The waiver will become a formal part of the agreement after WTO members ratify it.

Production under compulsory licenses, however, presents some operational challenges. First, companies need to secure adequate know-how from the original manufacturer, or from elsewhere, to recreate products. Second, the products must reach markets that are large enough to enable compulsory licensees to recoup development and production costs. While compulsory licenses are potentially beneficial tools, developing countries can use other ways to help ensure that intellectual property does not create barriers to access. These include both conventional licensing arrangements and, notably, the enactment of laws to permit and regulate the government's use of patented inventions. Other options include the actions of patent courts to protect the public interest, the thoughtful management of genetic resources and traditional knowledge, and the judicious framing of competition law and policy.

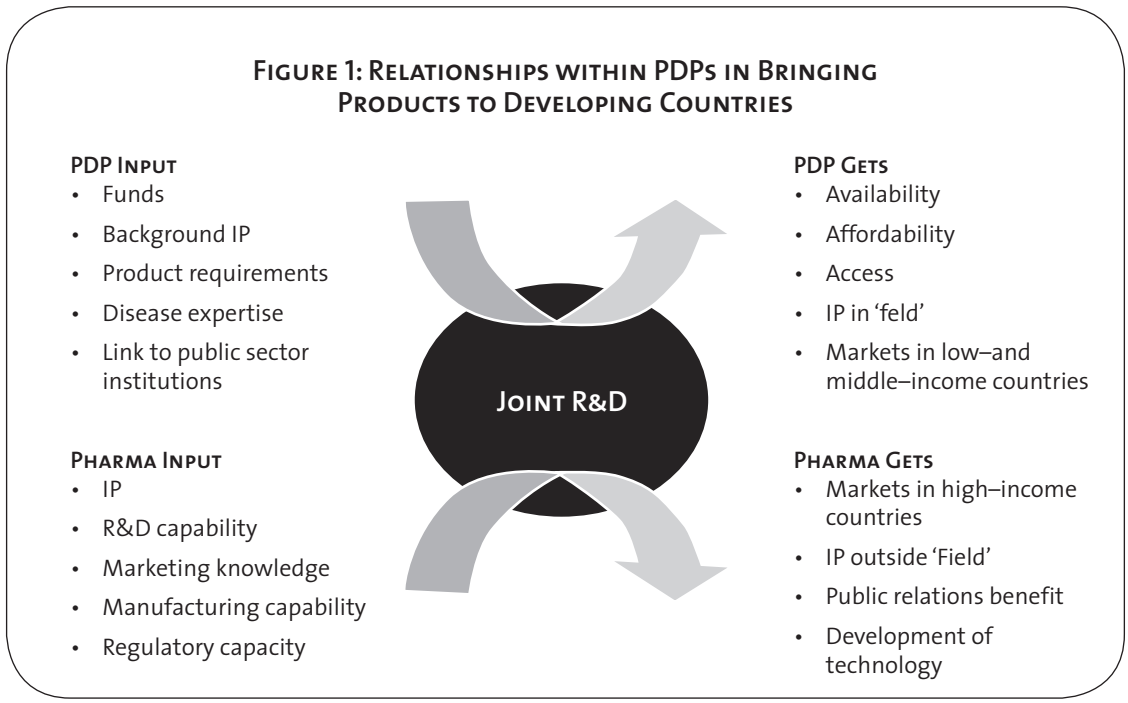
In sum, the international IP standards mandated by TRIPS allow member nations considerable discretion to enact laws and provisions that both meet treaty obligations and support national innovation policies and development priorities.

5. CONCLUSIONS

Issues discussed at the New Delhi conference and the analysis of those issues, presented in this chapter, have raised important considerations for countries adapting to the TRIPS Agreement:

- Intellectual property is one of several innovation determinants in health R&D; when assessing impact, intellectual property must be considered in the context of other competencies.
- Creatively managed, a global IP regime can be used in the public interest to improve the access of poor populations to new medicines and public health interventions.
- Countries aspiring to use TRIPS to national advantage must build institutional IP capabilities and policies in order to participate in the global marketplace and benefit from emerging technologies.
- TRIPS enables countries to establish national patent policies and practices that both meet treaty obligations and address national economic needs and social values. ■

Figure 1: Relationships within PDPs in Bringing Products to Developing Countries



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1 Eiss R, K Satyanarayana and RT Mahoney. 2006. Living with TRIPS: Innovation of New Health Technologies for the Poor. *Innovation Strategy Today* 2 (1):13–16. www.biodevelopments.org/innovation/index.htm.

2 See also, in this *Handbook*, chapter 15.4 by D Matthews and V Munoz-Tellez.