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A study of intellectual property protection policies and innovation in the Indian pharmaceutical industry and beyond



Dominique Bouet*

Groupe ESC-Pau, 3, rue Saint John Perse, BP7512, 64075 Pau Cedex, France
 University of Maryland University College, Adelphi, Maryland, USA

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ABSTRACT

We study the relationship between Trade Related Intellectual Property rights (TRIPS) and innovation. Using export data, this paper aims at assessing the relative impact of TRIPs on innovation, namely the ability of the Indian pharmaceutical industry to enter new markets with existing or new drugs. It examines whether India's decision to comply with TRIPS influenced its innovation, and develops a theoretical model, where innovation, being measured by the likelihood of exports of one product from one identified country to partner countries, is influenced by factor, demand and trade conditions. The paper draws on quantitative data, using Probit and Logit techniques. The model is illustrated using empirical evidence from the Indian pharmaceutical industry. We find statistically significant evidence that India's compliance with TRIPS is associated with new trade flows from India to partners. However we do not find statistically significant evidence of a relation between TRIPS compliance and value of exports. The interpretation is that TRIPS compliance has different effects: it is a necessary condition to favor innovation but it is not sufficient to increase exports value (competitiveness). Finally, we study to what extent this model can be generalized to other developing countries and/or industries.

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1. Introduction

Over the last decades Intellectual Property (IP) protection has come under scrutiny as countries with different levels of economic development started to modify their domestic IP regimes. Indeed, the rationale for IP protection policies focuses on rewarding innovation and as such, stimulating incentives to innovate. In particular scholars hotly debate whether the adoption of increased IP protection and the Trade Related Intellectual Property rights (TRIPS) stimulate innovation. This question is of particular importance for the pharmaceutical industry in developing countries (Braga et al., 2001; Chaisse and Guennif, 2007; Watal, 1998). Using export data, this paper assesses the relative impact of TRIPs on innovation, namely the ability of the Indian pharmaceutical industry to enter new markets (regulated or not) with existing or new drugs.

Some researchers have shown that stronger IPRs increase economic growth and improve development processes (Maskus et al., 2005). Others believe that Intellectual Property Right (IPR) has a weak and indirect relationship with economic growth and innovation (Bessen and Meurer, 2008; Ginarte and Park, 1997; Knack and Keefer, 2003). Other researchers have pointed out that

the TRIPS agreements would favor Research and Development (R&D) and innovation in the pharmaceutical industry, which would be profitable for all countries throughout the world in the long term (Combe and Pfister, 2001; Taylor, 1994). However, based on a review of empirical studies, Combe and Pfister (2001) also show that no robust empirical study has confirmed that increased protection of IP rights has a positive impact on R&D expenditures. These authors also conclude that the rent situation (monopoly) brought by patents may slow innovation, leading to routine behavior. Furthermore, TRIPS can be positive for developed countries if a relatively high increase in pharmaceutical firms' profits outweighs the loss of consumers' surplus (Combe and Pfister, 2001; Helpman, 1993). Maskus and Konan (1994) concludes that protection of IP rights could imply an increase in the prices of medicines by 25% to 67% which would decrease affordable access to health in developing countries. Based on a series of case studies from Mexico and Brazil, Sherwood (1990) emphasizes the positive influence of strong IP protection on the accumulation and diffusion of corporate business practices including the productivity of research, interactions between universities and the business community, and by fostering an inventive habit of mind in the population and, more specifically, in the workforce.

Taken together, most of this literature highlights the delicate balance for consumers, from poor and rich countries, between short-term negative consequences (higher protection implies

* Tel.: +33 5 59 92 64 95/+33 6 48 73 39 30; fax: +33 5 59 92 64 55.
 E-mail address: Dominique.bouet@esc-pau.fr

higher prices) and long-term positive consequences (higher protection leads to more innovation and increased availability of new medicines). Nevertheless, it can be argued that if protection of IP rights is too strong it can result in less innovation as some competition is also needed.

This paper focuses on changes in the Indian pharmaceutical industry in terms of product and market innovation following India's decision to comply with TRIPS until full adoption, and the impact of TRIPS on those changes. Its aim is to answer the following empirical question: what is the impact of increased IP protection and TRIPS compliance on innovation? We focus on the Indian pharmaceutical industry. The objective of this paper is not to reach a categorical finding on whether TRIPS compliance is a good policy instrument or not. Instead, it seeks to develop a quantitative model, based on the gravity model of trade, to assess the impact of TRIPS on innovation. The application of the model focuses on the case of the Indian pharmaceutical industry. In this study, innovation represents the ability of the Indian pharmaceutical industry and its firms to successfully launch drugs in new or existing geographic markets. Innovation is measured by the likelihood of the Indian industry and its firms to export new or existing products to existing or new geographic destinations. The statistical models used are the Probit and Logit models which allow the explanation of one binary variable using a set of independent variables. In addition to TRIPS factors, the gravity model includes factors that could also affect innovation, namely factors conditions, demand conditions and trade factors.

The case of India is interesting because the IP regimes changed overtime, impacting the pharmaceutical industry locally and globally, as well as India's technological capabilities. Before 1970, IP was strong in India and the market was mainly dominated by foreign Multi-national Companies (MNCs). From 1970 to 1994, modification of the Indian Patent Act in 1970 weakened the protection of IP, as only process patents were required and for a short period of time (7 years). The aim behind this decision was to build a strong and independent pharmaceutical sector to support India's health strategy of moving toward universal access to health care. The decision to comply with TRIPS in 1994, with full compliance achieved in January 2005, changed the landscape for the Indian pharmaceutical industry, as the main source of their competitive advantage – cheap access to technology through copy – disappeared. This raises an interesting question: to what extent, if at all, has the Indian decision to comply with TRIPS in 1994 and its full compliance in January 2005 impacted innovation in the Indian pharmaceutical industry?

To answer this question we designed a longitudinal framework that includes two dimensions of innovation, namely product and market innovation.

First, the newness of this empirical study is the use of export data as a proxy of innovation. Product innovation activities may have been analyzed using patents or R&D expenditures. The main advantage of patents is that they are publicly available and provide the information to make a statistical analysis over a period of time. But the value of patents differs greatly, as many patents are requested as a protection tool and many patents are never used—sleeping patents (Kemp et al., 2003). The second issue is that patents do not address the entire value chain, as they focus on R&D and do not integrate the market side of innovation (Burgelman, 2009).

Second, the study focuses on the impact of TRIPS on the ability of the Indian pharmaceutical industry to enhance innovation along with TRIPS compliance. Indeed, as already mentioned above, innovation represents the ability of the Indian pharmaceutical industry and its firms to successfully launch drugs in new or existing geographic markets. However, even though the primary purpose of the paper was to study the impact of TRIPS on innovation, the paper also examines the impact of TRIPS on the value of exports which allows taking into account different effects

of TRIPS. This also sheds light on India's firms' competitiveness on the global scene.

This study rejects the hypothesis that compliance with TRIPS is not associated with innovation. It confirms previous studies in this regard. However, it would be of interest to find out whether those results can be extrapolated to other countries or industries. Indeed, even though the context of this study relies on India and the pharmaceutical industry, it is important to mention that its applicability is broader. Indeed, this empirical study is replicable in two different directions. First, this model could be applied in the pharmaceutical industry of other developing countries, which have themselves adopted IP protection policies and find out whether the results to the research question lead to similar conclusions. This would allow making policy recommendations at a country level but could also derive new findings by comparing the results of other developing countries, namely answering the following questions: does TRIPS adoption provides uniform results among countries? And does the adoption path in terms of manner and schedule impact innovation? Second, this model could also be applied to other knowledge-based industries for which IP protection policies are critical in terms of innovation.

The rest of the paper is structured as follows. Section 2 provides a review of the literature and states the research gap. Section 3 describes the study design and the construction of the data set. It also presents the methodology, where a model is tentatively suggested. Section 4 presents the main empirical results. Section 5 discusses econometric results and provides suggestions for future studies. Section 6 concludes.

2. Literature review

The argument underlying public policy intervention to protect IP rights is that, without such protection, competitive market systems fail to provide innovators with sufficient incentives to undertake investment in new ideas and information that are of public interest. Indeed, as imitation has lower costs than innovation, then imitating firms will gain an advantage over innovating firms, unless the latter are fairly rewarded by giving them the rights to restrict the use of their innovation. As a consequence, without IP rights, innovation would be limited while it is useful as a public good. Patents offer the inventor a protection from competitors and provide a monopoly – IP rights – that the owner can exploit for its own profit, or sell, partially or totally (Scherer and Ross, 1990). Teece (1998) considers IP laws as one of the key dimensions to capture value, and patents as the strongest form of IP protection. The author points out that the level of protection may block or limit the scope of the innovation's use. In the pharmaceutical industry, where drugs are the result of expensive R&D processes, patents are an important incentive for innovation. However, economic theory has raised more questions about the implications of IP than it has answered, in particular for developing countries: "The theory of intellectual property protection is fragmented and provides no robust answer to the question of the appropriate or optimal level of protection under various sets of real-world circumstances. In particular, its relevance to a developing country concerns must be considered marginal" (Siebeck et al., 1990), p. 44.

Technological progress and innovation are critical sources of economic growth theories. IP protection is one instrument of promoting innovation and growth. Chaturvedi et al. (2007) argue that regarding the pharmaceutical industry and IP enforcement policies in India: "the concepts of knowledge-based economy, trade-liberalization, and patent harmonization have introduced a major shift in the strategies and direction for research, development, and commercialization at firm level. In part, this is driven by new policy developments in IP protection and TRIPS" (Chaturvedi et al., 2007, p. 567). IP changes and management strategies do not

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