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Abstract. This study examines the role of patent protection on the behavior of transnational corporations and market structure in the Indian pharmaceutical industry. The method of analysis is the calibration of a theoretical model to firm-level data from two therapeutic groups of the Indian pharmacy market, and a simulation analysis asking the hypothetical question of what the market structure would be if India granted patent protection to pharmaceutical products. The model developed for the simulation analysis explicitly accounts for the complex demand structure for pharmaceutical goods that results from the presence of therapeutic substitute drugs, and product differentiation among chemically equivalent drugs.

Keywords: patent laws, pharmaceutical industry, transnational corporations, imperfect competition, trade policy

The protection of patent rights is considered to be a critical precondition for private investment in pharmaceutical research and in the development of new drugs. The importance of patent protection in this industry can be attributed to the ease with which new chemical entities can be imitated in comparison with the large R&D outlays and long product cycles associated with research-based drugs. To put it in economic terms, new chemical entities—unless legally protected by patents—are weakly appropriable from the viewpoint of the innovating firm.

This paper examines the impact of patent protection on the behavior of pharmaceutical transitional corporations (TNCs) and market structure in India, which has traditionally been a fierce opponent of stronger patent rights in this sector. The Indian Patents Act of 1970 specifically excludes patent coverage for pharmaceutical products. To meet its obligations under the Agreement on Trade Related Intellectual Property Rights (TRIPS)—one of the outcomes of the Uruguay trade round (1986–94)—India will have to amend its patent laws to allow for pharmaceutical product patents by 2005. The signing of the TRIPS Agreement by the Indian Government has been accompanied by forceful publicity predicting that stronger patent rights will lead to soaring prices for pharmaceuticals and to a dominance of TNCs by “wiping-out” Indian firms. The present study is intended to shed some light on these issues and may also serve as a reference.

* This study is based on a chapter of my doctoral dissertation at the University of Heidelberg, Germany. Helpful comments by Clive Bell, Tony Venables, Jayashree Watal, the referee and seminar participants at the World Trade Organization and World Bank are gratefully acknowledged. Any remaining errors are my own responsibility. The views expressed here are my own and they should not be attributed to the World Bank.
point for other developing countries introducing pharmaceutical product patents in a ‘‘post-TRIPS’’ world.

The method of analysis is the calibration of a theoretical model to actual data from the Indian pharmacy market, and a simulation exercise to answer the hypothetical question of what the market structure would be if India allowed patents for pharmaceutical products. This technique is in the same spirit as the studies by Baldwin and Krugman (1988) on the U.S. and Japanese semiconductor industries and by Dixit (1988) on the U.S. and Japanese automobile industries, which focus on the simulation of alternative trade policy regimes.

The model developed for the simulation analysis explicitly accounts for the complex demand structure for pharmaceutical goods that results from the presence of therapeutic substitute drugs, and the practice of drug manufacturers to differentiate their products through the use of trademarks and advertising. In the absence of patent protection, firms are assumed to maximize profits, taking as constant the sales of other market participants. If patents are protected, the patent holder has a monopoly for the chemical entity, but still competes with producers of therapeutic substitutes.

This model is calibrated for two therapeutic groups—quinolones and synthetic hypotensives—using 1992 brand-level data for each chemical entity sold in the two therapeutic groups which would have received patent protection in Europe (referred to as ‘‘on-patent’’ chemical entities throughout this study), as well as brand-level data for all ‘‘off-patent’’ chemical entities in these two groups. The simulations reveal to what extent price increases, profits, and static consumer welfare losses depend on the values of the model’s parameters and provide valuable insights with regard to the role of competition among therapeutic substances.

The paper is organized as follows. Section 1 describes the development of India’s pharmaceutical industry and outlines the industry’s main features. Accounting for these features, Section 2 develops a partial equilibrium model of the Indian pharmacy market by specifying demand and supply behavior of consumers and producers of drugs. Section 3 describes the brand-level data used for the empirical investigation. Section 4 explains how the partial-equilibrium model is calibrated to these data. Section 5 illustrates the simulation procedure and discusses the simulation results. Section 6 concludes by summarizing the main findings and outlining their policy relevance.

1. Industry structure

One of the stated objectives of the Indian Patents Act of 1970 was the development of an independent Indian pharmaceutical industry. The abolition of pharmaceutical product patent protection from the inherited British colonial law was seen as the key element in advancing this objective. Looking at the pure numbers, the Indian Patents Act was a ‘‘success’’. The number of supplying firms increased from 2237 licensed drug manufacturers in 1969–1970 to an estimated 16,000 producers in 1992–1993 (OPPI, 1994a). The production of drug formulations grew at an average annual rate of 14.4% between 1980–1981 and 1992–1993; the negative balance of trade in bulk drugs and drug