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World Development Vol. 37, No. 9, pp. 1478–1483, 2009

0305-750X/$ - see front matter

doi:10.1016/j.worlddev.2009.01.002

Product Cycles, Innovation, and Exports: A Study of Indian Pharmaceuticals

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Summary. — This paper studies the product cycle and neo-technology theories of trade in the context of generic pharmaceuticals. It analyzes the export performance of 131 Indian pharmaceutical firms for the period 1989–2004. The results indicate that technology proxied by foreign patent rights has a positive impact on exports. This suggests that developing countries with innovation skills for process innovations are capable of penetrating international markets in the later stages of the product cycle by using patents, which were the barriers to trade in the early stages of the product cycle.

Key words — product cycle, exports, generic drugs, patents, Indian pharmaceutical industry, Asia, India

1. INTRODUCTION

In pharmaceuticals, technology is one of the most important factors determining international trade flows. The value of goods and services that countries trade increasingly resides in their intellectual content, technology, R&D, and human creativity that is sought to be protected by intellectual property rights (IPRs). Under the new international order advocated by the World Trade Organization (WTO), IPRs are fast emerging as a "global currency for power" (Zimmerman & Dunlop, 1994). For the first time in international law, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) sets out the procedures that governments must provide under their domestic law so that IPRs can be effectively enforced.

Technological activities are being undertaken in a growing number of firms and countries from the South, along an increasingly differentiated technological frontier and at different stages of the product cycle. The main motivation of the paper is to test the neo-technological theories of trade for a technology-intensive sector like pharmaceuticals. While many studies have been conducted on the relationship between technology and trade, most of them have been carried out for industrialized countries. Little attention has been focused on technological assimilation by developing countries and their capability to export technology-intensive products like pharmaceuticals in competitive international markets. However, with rising health care costs and uniform laws for patent protection across all countries under TRIPs and particularly for process patents, the spotlight is on low-cost generic drug exports for off-patent drugs from developing countries like India. In addition, while earlier studies have used technology input indicators like R&D expenditures or S&T personnel for studying the relationship between technology and trade, this paper goes a step further and uses a technology output indicator given by foreign patent rights (FPRs) for individual firms. Further, earlier studies were based on cross-sectional analysis, whereas this paper examines the role of FPRs on the export competitiveness of Indian pharmaceutical firms using a dynamic panel data model, and finds that after accounting for other firm characteristics like size and profitability, FPRs positively affect exports.

The rest of the paper is organized as follows: Section 2 is an overview of the main features of the Indian patent system. Section 3 briefly describes the literature related to international trade and technology. Section 4 describes the data and variables used in the study. Section 5 outlines the model estimation, and Section 6 lists the results of the study. Section 7 ends with the conclusion and policy suggestions.

2. OVERVIEW OF THE INDIAN PATENT SYSTEM

The pharmaceutical industry in India has been a success story for the development of an indigenous and self-reliant industry. At the time of Independence, India inherited the Patents and Designs Act 1911, which provided product patents for all inventions including foreign inventions. However, to reduce its dependence on imports for bulk drugs and formulations and promote the indigenous pharmaceutical industry, the government of India introduced the Patents Act 1970, which abolished product patents for pharmaceuticals. It allowed only process patents [1] in the areas of food, pharmaceuticals, and agricultural chemicals. The lack of protection for product patents in pharmaceuticals resulted in "reverse-engineering" [2] of drugs that were under patent protection as products in industrialized countries.

The liberalization era that began in 1991 brought with it policy changes for the pharmaceutical industry with lower price and production controls. Further, India being a signatory to TRIPs was required to amend its Patent Act 1970 to meet the minimum standards regarding patents for pharmaceuticals. The Patents (Amendment) Bill 1999, which was enacted in 2002, lengthened the patent term to 20 years. It also allowed pre-market testing of generics during the patent term so that

* I would like to thank seminar participants at the 34th European Association of Researchers in Industrial Organization (EARIE) Conference and the National University of Singapore for valuable comments. I am also grateful to Åke Blomqvist, Partha Sen, and Sanja Samirana Pattnayak for helpful discussions. Most importantly, I would like to express my gratitude to three anonymous referees for their insightful comments and suggestions. Final revision accepted: January 26, 2009.

they could be marketed immediately upon expiration of the patent. This pro-patent shift culminated in India's accession to the Paris Convention and the Patent Cooperation Treaty. Finally, product patents were introduced for pharmaceuticals and agricultural chemicals with the enactment of the Patents (Amendment) Act, 2005. Thus, the option of imitating patented drugs is no longer available to Indian pharmaceutical firms, and they have to invest in basic research in order to compete in international markets (for a more detailed analysis, see Chadha, 2009).

Unlike the global pharmaceutical industry, the Indian industry has been largely fragmented, but is now witnessing some restructuring with a trend toward consolidation. There has been a significant rise in inflows of foreign direct investment (FDI) with the pharmaceutical industry being recognized as a sunrise industry by the government of India. Indian pharmaceutical exports have risen sharply over the recent years, particularly in the developed markets of the United States and European Union, which shows the ability of Indian pharmaceutical firms to adopt international standards for stringent quality control in formulation manufacturing. The main competitive advantage of Indian firms lies in their ability to do reverse-engineering and speedily bring down costs through process innovation for generic drugs by employing skilled manpower in the fields of molecular biology, biotechnology, and chemistry. It is noteworthy that Indian firms did not seek foreign assistance to reverse-engineer the patented drugs, and were able to imitate the patented drugs by using the information provided in the patent title owing to their well-developed chemical infrastructure and process skills (Fink, 2001). Thus, Indian firms were free to use a different process of production to make the same products developed by foreign MNCs, which were then sold at much lower prices.

India's leading pharmaceutical companies spend around one-tenth of their revenues on R&D (Perlitz, 2008), and these research costs are 60% the costs in Western countries (PriceWaterhouseCoopers, 2007). Some of the companies like Ranbaxy have been granted exclusive marketing rights for the generic versions of blockbuster drugs like Pfizer's Lipitor and Merck's Zocor, with annual sales worth $12.7 billion and $4.6 billion in 2007, respectively. Since the price of generic drugs falls with the entry of new players, only cost-effective firms can break into the export markets.

According to the Pharmaceutical Export Promotion Council, pharmaceutical exports grew by 16% to reach $6.68 billion in 2007–08. Indian generic drugs have been able to penetrate the highly regulated markets of North America, Western Europe, Japan, and Australia. This has been aided by the growth of the US and the EU generic markets over the past few years driven by patent expirations and concerns of rising health care costs, particularly in the light of the growing aging population.

3. THEORETICAL LITERATURE

In the neo-classical or Heckscher-Ohlin model of international trade, factor endowments are the key determinants of trade, but technology has no role to play as it is assumed to be universally and freely available to all. To account for technological change, various neo-technological models of international trade have been postulated (Grossman & Helpman, 1991; Krugman, 1979; Noland 1997; Posner, 1961; Vernon, 1966) Vernon's (1966) product cycle theory identifies four stages in the life cycle of a product including innovation and saturation in the domestic market followed by foreign investments and exports in foreign markets. This theory says that new goods are more likely to be introduced in developed countries, but will reach other countries as the product matures. In some cases, weak patent laws have resulted in the last two stages being appropriated by imitators from developing countries, rather than by foreign investments. As exports decline, the innovator firms start locating production facilities in developing countries for meeting the local demand and also for exporting back to developed countries. Thus, developed countries export new goods like brand-name drugs, and the developing countries export mature goods like generic drugs. Developing countries can play an important role in the international division of labor by specializing in the later stages of the product life cycle and eventually exporting hi-tech products in international markets. Glass (1997) develops a dynamic general equilibrium model of product cycle and shows that market penetration by developing countries initially occurs at low levels of technology and then reaches higher levels. The Southern markets penetrate the Northern markets by imitating previous quality levels, and the Northern firms counter this by inventing higher quality levels. Moreover, she finds explanations for the increased penetration of East Asian countries into markets for high-technology products on the basis of greater resources being diverted for production and imitation as well as weaker domestic patent rights but not R&D subsidies. Cooper (1994) puts forth the view that since technological competition is less severe in some sectors or parts of sectors than in others, it provides entry opportunities for firms or countries with lower endowments of technology. In this way, countries like Korea and Japan started industrialization in technologically undemanding sectors, and after accumulating a wider range of capabilities, moved up to technologically more advanced sectors. In fact, rapid industrialization in Korea stemmed from creative imitation (Kim, 1997).

The neo-technology theories of trade emphasize on the role of technology in explaining trade flows, and explain how new product innovations by developed countries and process innovations for imitating those products by developing countries may lead to trade. As international markets become more competitive, technological ability protected by patents is likely to become increasingly important for all countries. Particularly for developing countries, protection of IPRs leads to greater innovation and promotes development (Chen & Puttitanum, 2005). We study the role of FPRs in the trade performance of Indian pharmaceutical firms at the mass production stage of the product cycle when the patents on brand-name drugs expire and generic drugs are allowed to enter the market. We demonstrate that patents, which act as barriers to technological diffusion between the North and the South in the initial stages of the product cycle, can become the vehicle for greater market penetration by Southern countries in the later stages of the product cycle, to the extent that generic versions of brand-name drugs are also covered by patent protection.

It is worthwhile to study the relationship between technology and trade because it is the high-quality products that are likely to cross borders and enter foreign markets. The more technology-intensive products are expected to successfully cater to the tastes and demands of foreign consumers. A number of firm-level microeconometric studies have found a positive relationship between technology (measured by R&D spending, S&T personnel, or patents) and exports (Willmore, 1992; Bernard & Wagner, 1997; Fagerberg, 1996; Hasan & Raturi, 2003; Kumar & Siddharthan, 1994; Lal, 2004; Lefebvre, Lefebvre, & Bourgault, 1998; Smith, 2001; Sterlacchini, 1999; Wakelin, 1998; Yang, Chen, & Chuang, 2004).