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Knowledge Sources and International Business Activity in a Changing Innovation Ecosystem: A Study of the Indian Pharmaceutical Industry

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ABSTRACT The Indian pharmaceutical industry has experienced rapid growth, becoming the world's largest provider of generic drugs, based on product and process innovation. The industry has undergone dynamic changes in recent decades, operating in a rapidly evolving environment affected by domestic and global policies; a key example of the latter is the TRIPS agreement. Taking an intellectual property perspective, we describe how changes in the innovation ecosystem have affected companies' strategies related to international activity and accessing knowledge from both internal and external knowledge sources, during the transitional- and post-TRIPS periods (1995–2004 and 2005–2014, respectively). Combining intellectual property arguments with contextual aspects of the innovation ecosystem, we conjecture that, in the post-TRIPS period, externally-sourced knowledge will be more important than internally-sourced knowledge, for Indian pharmaceutical firms' international business activity.

KEYWORDS India, innovation, intellectual property regime, international business, knowledge sources, pharmaceutical industry

INTRODUCTION

Recent research has placed considerable emphasis on emerging-market firms and the impact of institutional context on their strategic choices (Chari & David, 2012; Chittoor, Kale, & Puranam, 2015; Cuervo-Cazurra & Dau, 2009). Many such firms have transformed themselves to be globally competitive, responding to institutional transitions and the resulting ecosystem changes in their home markets over recent decades (Cuervo-Cazurra & Genc, 2008; Ramamurti, 2012a). Because innovations are embedded in institutional contexts, the country-specific triggers and drivers of innovation processes are important (Chittoor, Aulakh, & Ray, 2015; Peng, Ahlstrom, Carraher, & Shi, 2017; Thakur-Wernz & Samant, 2017).

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The strength of the intellectual property (IP) regime is one such trigger, playing a key role in driving innovation in knowledge-intensive industries such as pharmaceuticals (Brandl, Darendeli, & Mudambi, 2019; Kale & Wield, 2008; Papageorgiadis & McDonald, 2019). The high costs of developing drugs, combined with the presence of stringent regulations, makes IP rights particularly important in this sector, in terms of the appropriation of monopoly rents by inventors (Kale, 2010; Pisano, 2006; Teece, 1986).

In recent decades, greater levels of liberalization and globalization have encouraged rapid internationalization by emerging-market firms (Ramamurti, 2012b). With home markets characterized by institutional voids (Khanna & Palepu, 2000), resource constraints, and tendencies toward risk-aversion (Courtney, Kirkland, & Viguerie, 1997), many emerging-market firms have used catching up with advanced-economy competitors as a key motivation for their internationalization (e.g., Awate, Larsen, & Mudambi, 2015). In this regard, the knowledge-seeking motive is critically important; the literature generally suggests that this is more consistent with high-commitment internationalization, such as foreign direct investment (FDI), than lower-commitment and lower-risk approaches (e.g., exporting). However, the home context plays a role in entry mode choices. There is evidence that typologies describing a progression from lower- to higher-commitment entry modes (e.g., Buckley & Casson, 1998; Johanson & Vahlne, 1977) apply to emerging-market firms' internationalization into other emerging or developing economies, which is driven more by market- or resource-seeking than a search for knowledge to transfer back home. However, the situation is different when emerging-market firms target advanced economies. In this situation, exporting may be a key strategy for market-seeking, while knowledge-seeking is the primary motivation behind FDI.[1]

The Indian pharmaceutical industry offers a prime example of this dichotomy, with exports, to both emerging and developed markets (Chittoor, Ray, Aulakh, & Sarkar, 2008), contributing over 50% of its total revenues. Though knowledge resources are recognized as key export drivers for innovation-driven pharmaceutical firms (Chittoor, Sarkar, Ray, & Aulakh, 2009), less is understood about the nature of the knowledge-performance relationship in the face of a changing IP regime (Chatterjee & Sahasranamam, 2018; Nair, Guldiken, Fainshmidt, & Pezeshkan, 2015). India offers a useful environment for considering how a drastically-altered innovation system affects companies' knowledge sourcing strategies and, in turn, their international business activities.

The adoption of TRIPS[2] in developing countries has varied over time, often depending on the roles played by global actors (Brandl et al., 2019). In the Indian context, it is useful to consider two distinct periods of TRIPS adoption – transitional-TRIPS (1995–2004) and post-TRIPS (2005–2014) – to understand the impact of IP changes on knowledge sourcing strategies. With non-equity-based modes[3], firms can source knowledge either internally, through investment in research and development (Kumar & Aggarwal, 2005), or from external resources

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through licenses, trade agreements, or blueprints against a royalty fee (Bhat & Narayanan, 2009; Lane & Probert, 2007). In high-technology industries such as pharmaceuticals, firms tend to focus on developing technology internally in areas in which they have key strengths, and source other technology externally (Dunlap, McDonough, Mudambi, & Swift, 2016). While the distinction between internal and external knowledge has been addressed in the innovation literature (e.g., Casillas, Moreno, Acedo, Gallego, & Ramos, 2009), less is understood about the roles of internal and external knowledge sources in driving international business activity (Denicolai, Zucchella, & Strange, 2014; Wang, Cao, Zhou, & Ning, 2013). Research has suggested that internal R&D and external knowledge acquisition represent complementary innovation strategies, but that the complementarity is sensitive to the institutional environment (Cassiman & Veugelers, 2006). The TRIPS-induced IP reforms created fundamental changes in the institutional environment for India's pharmaceutical industry, forcing domestic firms to reconfigure their knowledge resources and capabilities, and to acquire new capabilities (Brandl et al., 2019; Chittoor & Ray, 2007; Chittoor et al., 2009). Against this background, using the perspective of IP (Pisano, 2006; Teece, 1986), we discuss how changes in the IP regime influenced firms' strategies related to internal and external knowledge sources, and speculate about the subsequent impact on their international business activities.

Many Indian industries, including pharmaceuticals, experienced an exogenous shock when India became a signatory to the World Trade Organization (WTO) on 1st January 1995. Given a transition period of 10 years to amend its patent laws, India moved from an era of process patents to honoring product patents starting from 1st January 2005.[4] Now that over a decade has passed since the new patent regulations have taken effect, we are able to consider how IP reforms influence knowledge sourcing, by comparing the transitional- and post-TRIPS periods.

In this article, we contribute to the literatures on innovation and intellectual property in several ways. First, we use IP frameworks to illuminate the role of knowledge sources in firms' international business activity during a period of regulatory transition. Specifically, we extend the understanding of the impact of institutional context, by focusing on the effect of IP reforms on emerging-market firms (Chittoor & Ray, 2007; Chittoor et al., 2008; Kale & Little, 2007; Kale & Wield, 2008), addressing how knowledge sourcing strategies differ under different institutional environments. Considering the historical institutional context of the innovation ecosystem, we conjecture that internal knowledge sourcing strategies are less important for the international business activities of Indian pharmaceutical firms in the post-TRIPS period. However, the strong patent systems in the post-TRIPS period mean that external knowledge sourcing is likely to be influential. Second, we provide insights into the complementary aspects of internal and external knowledge sourcing, and the associated role of the innovation ecosystem (Bilgili, Kedia, & Bilgili, 2016; Cassiman & Veugelers, 2006); in the face of a changing innovation

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ecosystem, we conjecture that Indian pharmaceutical firms draw more from external knowledge sourcing opportunities, to complement historical weaknesses in their internal knowledge sourcing. Finally, we add to the understanding of innovation management in the Indian context, which has received limited attention in prior literature (Chatterjee & Sahasranamam, 2018; Nair et al., 2015). Specifically, we highlight the evolution of the Indian pharmaceutical industry in the face of multiple changes in the innovation ecosystem since 1947, especially the exogenous shock created by TRIPS, and how this history shapes firms' knowledge sourcing strategies associated with their international business activity.

EVOLUTION OF THE INDIAN PHARMACEUTICAL INDUSTRY AND KEY INSTITUTIONAL CHANGES

The evolution of the Indian pharmaceutical industry in the post-independence period, and the ensuing institutional changes, can be divided into three phases (Chaturvedi, Chataway, & Wield, 2007). The first phase (1947–1970) corresponds to the regulations according to the Patents and Designs Act of 1911, which was a holdover from the pre-independence period of British rule. This patent regime provided protection for all inventions, apart from those related to atomic energy, offering exclusive rights for a period of 16 years from the date of application (Pradhan, 2007). The regime is viewed as having had a negative effect on the growth of the domestic pharmaceutical industry, resulting in high drug prices (Mohammad & Kamaiah, 2014), leading to domestic pressure to move to a less restrictive patent regime (Desai, 1980).

The second phase (1970–1995) covers the period after India introduced its own Patents Act in 1970, which was operational until the country became a signatory to the WTO on 1st January 1995. During this phase, product patents were offered for most inventions; exceptions were food, medicine, drugs, and substances produced by chemical processes, for which only process patents were available (Pradhan, 2007). This change in the innovation ecosystem led to rapid growth in the Indian pharmaceutical industry, boosting local innovation in the form of adaptation and reverse engineering. The number of Indian pharmaceutical firms grew from 2,257 in 1970 to over 23,000 by 2005 (Haley & Haley, 2012); by the 2000s, domestic pharmaceutical companies enjoyed a market share of 60–70%, compared to 10% during the 1970s (Kale, 2010). To the benefit of domestic firms, foreign pharmaceutical multinationals in India were disadvantaged on two counts. First, the weak product patent regime offered foreign firms little incentive to market their patented products. Second, they were losing market share to price-competitive Indian firms in global markets, due to the patent regime that allowed Indian firms to reverse engineer drugs' chemical molecules (Chittoor et al., 2009).

This pre-TRIPS period also witnessed a stark fragmentation of the pharmaceutical industry, between Indian firms and foreign multinationals, based on their

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divergent views on the trade regime. In particular, the Indian firms generally perceived the TRIPS agreement as a threat to their continued success. This fragmentation led to the rise of two industry associations (Sinha, 2016). The Indian Drug Manufacturers Association (IDMA) had been formed in 1961 to represent the interests of domestic firms (including Ranbaxy and Cipla) to the Indian government. Foreign and multinational companies had established the other association – the Organization of the Pharmaceutical Producers from India (OPPI) – in 1965. By the late 1990s, the interests of eight large, research-oriented Indian companies, which had developed a more positive view on the TRIPS patent regime (Sinha, 2016), diverged from the views of the IDMA, leading to the formation of a separate coalition – the Indian Pharmaceutical Alliance (IPA) – to interact with the government. Still, the clearly-divergent interests of domestic firms and foreign subsidiaries meant that there was little knowledge spillover between them during this pre-TRIPS period (Brandl, Mudambi, & Scalera, 2015).

The third phase began in 1995. In the pre-TRIPS era, the Indian pharmaceutical industry was supported by favorable government policies and soft patent regimes. When India joined the WTO and became a signatory of TRIPS, Indian pharmaceutical firms were forced to make the transition from protection under process patents to protection based on product patents (Chittoor et al., 2009). The introduction of product patents was expected to have a negative impact on the Indian pharmaceutical industry, blocking the Indian firms' main source of chemical molecules (Watal & Mathai, 1995). Under the process patent regime, Indian firms had been free to reverse-engineer new technologies or molecules without formal licenses from patent holders (Kale & Wield, 2008). As the TRIPS era came closer, during 1994–1995, multiple camps arose within the domestic pharmaceutical industry, comprising some in favor of the regime change, some who wanted to oppose it at any cost, and some in denial of its potential impact (Sinha, 2016). The broad consensus view was, however, that TRIPS was essentially a necessary evil (Sinha, 2016).

The transitional-TRIPS period of 1995–2004 saw the changeover from process to product patents, through a series of three legislative amendments. In 1999, the Indian government enacted a patent-reform amendment to the Patents Act of 1970. Retroactive to 1995, this amendment provided for a 'mailbox system' of patent applications, enabling firms to file patents for future approval. This allowed companies to file for patents that would be approved upon implementation of the product-patent regime in 2005 (Haley & Haley, 2012). A second amendment was enacted in 2002, extending the patent duration to 20 years for existing and pending applications. The third amendment came into effect from April 2005, providing for product patent protection for pharmaceuticals (Pradhan, 2007).

Despite the radical change in the IP regime and the necessary transformations in the innovation ecosystem, the Indian pharmaceutical industry's revenues – both domestic and from exports – continued to grow. By 2013, it had become the world's third-largest, in terms of value (Horner, 2014), partly attributable to the evolution of firms' dynamic capabilities as strategic responses to the regulatory

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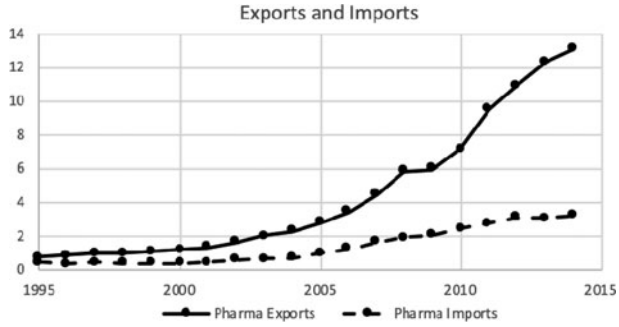

Figure 1. Indian pharmaceutical exports and imports during transitional-TRIPS (1995–2004) and post-TRIPS (2005–2014) periods
Source: Authors' calculations based on WTO Data: http://stat.wto.org/StatisticalProgram/WSDBViewData.aspx?Language=E, accessed on 22.03.2014

changes (Athreye, Kale, & Ramani, 2009). Manufacturers of generic drugs remained the dominant players in the industry, with patented drugs accounting for only 1% of India's pharmaceutical market (Kochhar, 2014).

Exports played – and continue to play – a key role in the Indian pharmaceutical industry, contributing over 50% of its total revenues in 2013, and the industry's balance of trade changed dramatically during 2005–2014, as shown in Figure 1.

The post-TRIPS period has seen greater investment in R&D (Chittoor et al., 2009; Jagadeesh & Sasidharan, 2014), which has led to product patents related to new dosage forms and an increased focus on new drug discovery (Agarwal, Gupta, & Dayal, 2007; Basant & Srinivasan, 2015). The government-run Council of Scientific and Industrial Research (CSIR) has played a crucial role in this regard; CSIR was responsible for gaining 540 new US patents during 1995–2015, compared with 27 between 1950 and 1993 (Brandl et al., 2015). Many domestic firms followed the government's lead by investing more resources into R&D. With the largest number of USFDA-approved manufacturing plants outside of the US (Balakrishnan, 2014), the Indian pharmaceutical industry experienced improvements that enabled it to target lucrative western markets via exporting.

The change in the nature of the patents, from process to product, makes it important to study the transitional-TRIPS (1995–2004) and post-TRIPS (2005–2014) periods separately (Brandl et al., 2019). Thus, we consider the two timeframes, and explore the effect of IP reform on the relationship between knowledge sources and international business activities in the context of the Indian pharmaceutical industry.

THEORY AND LITERATURE REVIEW

Innovation Ecosystems, Intellectual Property Rights, and Emerging Markets

A focus on institutions and ecosystems has been a dominant feature of innovation and entrepreneurship research in India (Chatterjee & Sahasranamam, 2014;

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Sahasranamam & Ball, 2018; Schøtt, Madhavan, Jensen, & Li, 2019). The innovation ecosystems view incorporates private firms and public organizations, and investigates their mutual interactions as well as their relationships with the social and institutional framework in which they are embedded (Lundvall, 1999).

A key issue in research involving innovation ecosystems pertains to how the selection of a particular appropriation mechanism influences the distribution of value across innovating firms, rivals, consumers, and suppliers (Papageorgiadis & McDonald, 2019). Teece (1986: 287) acknowledges the need for strong appropriability for capturing value from innovations, noting that the 'regime of appropriability refers to the environmental factors, excluding firm and market structure, that govern an innovator's ability to capture the profits generated by an innovation'. In the absence of such protection, imitation is relatively easy, and the profits from innovation tend to accrue to the owners of key complementary assets, rather than the innovator.

The efficacy of IP protection varies across contexts (Papageorgiadis, Cross, & Alexiou, 2014; Papageorgiadis & McDonald, 2019), and the value capture literature discusses legal protection as a critical context-dependent institutional factor (Lanjouw & Schankerman, 2001; Sahasranamam & Nandakumar, 2018). The strength of the legal protection regime affects the cost of imitation; weak regimes, with lower penalties, are characterized by greater likelihood of patent infringement (Papageorgiadis, Cross, & Alexiou, 2013; Papageorgiadis et al., 2014). Strong appropriability regimes allow firms to identify, and defend against, infringement (Lanjouw & Schankerman, 2004). In countries with weaker appropriability regimes, including many emerging markets, firms face greater difficulty in defending against infringement (Krug & Hendrischke, 2003; Sahasranamam & Raman, 2018).

KNOWLEDGE SOURCING AND INTERNATIONAL BUSINESS ACTIVITY

For firms from emerging markets, including India, internationalization is a particularly risky strategy, considering the extent of resource investment needed and the firms' often-limited prior experience with competing in global markets (Contractor, Kumar, & Kundu, 2007; Luo & Tung, 2007). Until economic liberalization in 1991, the heavily-regulated home market did not encourage Indian firms to explore foreign options, and the large domestic population meant that international expansion was not an imperative (Kumaraswamy, Mudambi, Saranga, & Tripathy, 2012). However, post–1991, Indian firms have internationalized and become globally competitive. Consistent with the literature (e.g., Agnihotri & Bhattacharya, 2015; Buckley & Casson, 1998; Johanson & Vahlne, 1977), exporting is often the initial internationalization strategy for Indian firms, and remains key today.

Access to knowledge is essential for enhancing product quality, identifying new opportunities, and increasing competitiveness (Grant, 1996; Zhou & Li, 2012).

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In the absence of equity-based relationships, knowledge acquisition is most likely to occur through internal mechanisms, such as R&D, or externally through royalties and licenses. The TRIPS regime gave greater protection to inventors, leading to a two-pronged reaction by Indian firms: (1) augmenting their own research capabilities in order to transition from core process research to new drug development, and (2) sourcing external knowledge by forging commercial alliances with global companies (Khan & Nasim, 2016).

Table 1 presents a summary of key quantitative studies of the relationship between exporting and both internal and external knowledge sourcing in the Indian context. While the results are mixed, and reflect little research pertaining to the post-TRIPS period, there is some evidence of the impact of TRIPS, especially on the relationship between R&D and exporting.[5] This suggests that a more nuanced consideration of different periods in the TRIPS adoption process – e.g., transitional-TRIPS and post-TRIPS – is necessary to explore how changes in the IP regime may affect the relationship between knowledge sourcing and international activity.

Internal Knowledge Sourcing

R&D investment levels provide a broad indication of the priority that firms give to developing new products using internal sources of knowledge (Kumar & Siddharthan, 1994; Lall & Kumar, 1981). High R&D investment suggests a focus on internal exploration for developing new products and/or markets (Chittoor & Ray, 2007), and has been identified as influential for gaining market share and helping firms to be more globally competitive (Boso, Story, Cadogan, Micevski, & Kadic-Maglajlic, 2013).

It is reasonable to assume that the relationship between R&D and international business activity – export intensity in particular, for the Indian pharmaceutical industry – evolves under a changing IP regime. Pharmaceutical firms face a protracted process of moving from drug discovery to commercialization, and very expensive R&D makes IP protection crucial for knowledge ownership (Kale & Wield, 2008). However, the impact of IP protection on the relationship between R&D investment and export intensity in high-technology Indian industries is complex. On one hand, considering the expropriation protection argument (Teece, 1986), the stronger IP protection post-TRIPS might incentivize R&D investment, leading to improved international performance. In addition, greater competition from foreign MNEs in a stronger IP regime (Hu, 2010) may make domestic firms upgrade their internal knowledge capabilities through R&D, to survive and then compete globally (Chatterjee & Sahasranamam, 2018; Kumaraswamy et al., 2012). Such increased R&D investment helps to translate resources into innovative products, which may give firms temporary monopoly positions (Roberts, 2001) or reduce entry barriers (Harris & Li, 2009), enabling

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Table 1. Summary of quantitative studies on the relationship between exporting and knowledge sourcing in Indian firms

						Estimated coefficient (b) *[Observed significance level* (p), *Effect size* (r)*]*	
Article	*Industry context*	*Time period*	*Modelling approach*	*Sample size* (n)	*Number of explanatory variables* (k)	*Internal knowledge sourcing (R&D)* b[p,r]	*External knowledge sourcing* b[p,r]
Pre-TRIPS							
Lall & Kumar (1981)	Multiple industries	1966–1968	OLS	100	2	−0.03[0.04,0.27]	
		1976–1978		58	2	−0.04[0.04,0.17]	
Lall (1986)	Engineering	1978	OLS	100	10	−0.25[0.02,0.24]	0.10[0.47,0.08][a] 0.28[0.01,0.26][b]
	Chemicals			45	8	0.42[0.00,0.52]	0.08[0.63,0.08][a]
Kumar & Siddharthan (1994)	Pharma-ceuticals	1987–1990	Tobit	102	10	0.46[0.86,0.02]	1.58[0.73,0.04][c]
	Electrical machinery			75	10	−1.58[0.50,0.08]	1.36[0.01,0.27][c]
Pre-TRIPS to transitional-TRIPS							
Bhaduri & Ray (2004)	Pharma-ceuticals	1994–1995	Tobit	71	5	1.69[0.00,0.47]	13.08[0.00,0.34][d]
	Electronics			52	6	2.31[0.00,0.51]	−6.50[0.32,0.15][d]
Siddharthan & Nollen (2004)	IT	1994–1998	Tobit	117	6		0.58[0.01,0.26][d] −0.07[0.78,0.03][e]
Transitional-TRIPS							
Chittoor et al. (2009)	Pharma-ceuticals	1995–2004	Panel	1104	14	0.24[0.11,0.05]	0.23[0.00,0.10][f]
Jauhari (2007)	Electronics	2000–2005	Tobit	116	9	0.00[0.99,0.00]	0.00[0.97,0.00][a] 0.01[0.07,0.18][e] 0.00[0.22,0.12][g]

Table 1. Continued

Article	*Industry context*	*Time period*	*Modelling approach*	*Sample size* (n)	*Number of explanatory variables* (k)	*Estimated coefficient* (b) *[Observed significance level* (p), *Effect size* (r)*]* *Internal knowledge sourcing (R&D)* b[p,r]	*External knowledge sourcing* b[p,r]
Transitional-TRIPS to post-TRIPS							
Bhat & Narayan (2009)	Chemicals	2001–2007	Tobit	847	14	4.35[0.02,0.08]	−4.73[0.02,0.08][a] 0.10[0.65,0.02][e]
Majumdar (2010)	IT	2001–2006	Panel	138	11	0.70[0.05,0.17]	
Mishra & Jaiswal (2012)	Multiple industries	2000–2008	Panel	264	9	0.28[0.79,0.02]	1.16[0.00,0.26][c]
Tyagi et al. (2014)	Pharma-ceuticals	2000–2012	OLS	13	2	0.79[0.00,0.93]	
Post-TRIPS							
Rentala, Anand, & Shaban (2014)	Pharma-ceuticals	2005–2013	Panel	251	11	−0.00[0.08,0.12] (result driven by large exporters)	1.69[0.00,0.38][a]
Pre-TRIPS to post-TRIPS							
Singh (2009)	Multiple industries	1990–2005	2SLS	41434	7	1.17[0.00,0.05]	
Franco & Sasidharan (2010)	Multiple industries	1994–2006	Panel	22525	10	0.09[0.03,0.02]	

Notes: Effect size (r) is calculated as the square root of $t^2/(t^2 + (n - k - 1)$, where t is the test statistic for assessing the significance of the estimated coefficient (Durlak, 2009). The interpretation of r, per Cohen (1988) and Rosenthal (1996), is: 0.1: small, 0.3: medium, 0.5: large, 0.7: very large.

Types of external knowledge sourcing: [a]Royalties paid, [b]Licenses, [c]Technology imports, [d]Raw materials imports, [e]Capital goods imports, [f]International technical resources (including capital goods, royalties, know-how, and raw materials), [g]Spares and stores imports

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them to capture new opportunities in international markets (Hasan & Raturi, 2003).

On the other hand, the Indian pharmaceutical industry's focus on generic drugs may mean that firms struggle to benefit from increased investment in R&D, at least in the short term; the capabilities associated with generic drugs are not necessarily useful for developing higher-value, breakthrough drugs (Dunlap-Hinkler, Kotabe, & Mudambi, 2010). Translating R&D investment into innovation requires both substantial expertise in therapeutic areas and strong communication across disciplines. However, the traditional specialization of Indian pharmaceutical firms – generic drugs based on reverse engineering (Haley & Haley, 2012) – is based on different types of expertise, lower cost, and less extensive need for cross-disciplinary interaction (Henderson, Orsenigo, & Pisano, 1999). The Indian firms' more limited prior experience with developing new molecules may delay the translation of R&D investments into new drug formulations, competitive advantage, and export intensity (Tyagi, Mahajan, & Nauriyal, 2014). Given these short-term disadvantages related to developing capabilities associated with the new focus on product-related patent protection, we propose:

Proposition 1: Among Indian pharmaceutical firms, the relationship between internal knowledge sources and international business activity will be weaker post-TRIPS than in the transitional-TRIPS period.

External Knowledge Sourcing

With the TRIPS agreement changing the nature of the IP regime, Indian pharmaceutical firms began to forge commercial alliances with foreign inventors, aimed at sourcing knowledge (Khan & Nasim, 2016). India's emerging-market status and the technological nature of the industry made external knowledge sourcing particularly important for international competitiveness for several reasons. First, technology accessed solely from within an emerging-market firm, or from domestic sources, may be insufficient to support international success in a rapidly-changing technological environment (Chatterjee & Sahasranamam, 2018; Li, Chen, & Shapiro, 2010). Hence, firms seek external knowledge for developing new innovations (Awate et al., 2015; Thakur-Wernz & Samant, 2017). Second, because new inventions emerge from a recombinative process using different streams of knowledge (Fleming, 2001), external sources are especially valuable for helping emerging-market firms to develop internationally-exploitable innovations (Wang et al., 2013). Third, external knowledge sourcing offers opportunities for close interaction with foreign partners, enabling emerging-market firms to develop deeper insights into the nature of international markets and build a valuable network of foreign contacts. As emerging-market firms tend to be later internationalizers, these benefits are crucial for increasing export intensity (Gaur & Kumar, 2010; Singh & Gaur, 2013). Finally, external knowledge acquisition can accelerate

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firms' innovation processes, facilitating catch-up in both domestic and international markets (Awate, Larsen, & Mudambi, 2012; Kumaraswamy et al., 2012).

In the absence of effective patent protection (e.g., during the pre- and transitional-TRIPS periods), fear of imitation impedes external knowledge sourcing (Kale, 2010). Foreign firms with the potential to offer external knowledge support may be reluctant to share their proprietary know-how, due to concern about reverse engineering of their licensed technologies (Horner, 2014). However, stronger patent protection (e.g., in the post-TRIPS period) should promote technological development by encouraging the acquisition of knowledge through market mechanisms such as technology licensing and royalty agreements (Arora, Fosfuri, & Rønde, 2013; Smith, 2001). Advanced-economy universities and research institutions may also be valuable sources of external knowledge for emerging-market firms (Perri, Scalera, & Mudambi, 2017), with knowledge transfer facilitated by stronger IP regimes (Papageorgiadis et al., 2013). Considering the increased importance of external knowledge sources, and the more conducive conditions for sourcing knowledge in an enhanced IP regime, we propose:

Proposition 2: Among Indian pharmaceutical firms, the relationship between external knowledge sources and international business activity will be stronger post-TRIPS than in the transitional-TRIPS period.

DISCUSSION

The IP reforms initiated in 1995 changed the Indian pharmaceutical industry's innovation ecosystem substantially (Bouet, 2015; Chittoor & Ray, 2007; Chittoor et al., 2009). We argue that understanding the impact of this change requires distinguishing between internal and external sources of knowledge (Cassiman & Veugelers, 2006), and their relative importance for firms' international activities, in the distinct IP regimes of the transitional-TRIPS and post-TRIPS periods. Kale and Wield (2008) concluded that Indian pharmaceutical firms adopted an ambidextrous capability development approach (O'Reilly III & Tushman, 2011), involving both exploitation and exploration, to adapt to the post-1995 IP environment. This entailed entering advanced markets (US and Europe), exploiting existing process-related R&D skills, and investing in explorative capability development for R&D aimed at innovation. Bouet (2015) found that, while necessary for innovation, TRIPS compliance is not sufficient for increasing the value of exports. We suggest that Indian pharmaceutical firms' explorative capabilities may be more dependent on the market for external knowledge that was created by TRIPS compliance, rather than on internal knowledge generated through R&D. In addition, during the transitional-TRIPS period, Indian firms would likely have had limited access to high-quality external knowledge.[6]

However, the historical development of the Indian pharmaceutical industry complicates the story. The strong pre-TRIPS focus on generics, reverse

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engineering, and government dependence meant less focus on developing breakthrough drugs, relative to many foreign competitors. The Indian pharmaceutical firms' relatively low investments in R&D may have been insufficient for transforming internally-developed knowledge into the types of innovations needed to increase exports, especially for higher-value drugs. Indian pharmaceutical firms did increase their R&D investments substantially after 1995. Ranbaxy's R&D spending rose from INR 36 crores (~USD 11 million) in 1994–1995 to INR 486 crores (~USD 112 million) in 2005. Similarly, Dr. Reddy's Labs' increased its R&D spending from INR 13 crores (~USD 3 million) in 1999 to 437 crores (~USD 101 million) in 2008. However, this spending is still quite low, relative to established global pharmaceutical firms (Bedi, Bedi, & Sooch, 2013), and suggests that the Indian pharmaceutical industry may have stalled in a consolidation phase, moving slowly towards a mature phase in which R&D investments are likely to deliver substantial returns (Kumaraswamy et al., 2012).

A macroeconomic consideration also complicates the interplay between R&D and international activities, as the post-TRIPS period is characterized by increased regulatory barriers. A global study of 450 new chemical entities approved by the US Food and Drug Administration (USFDA) found that substantially fewer drugs were approved during 2005–2010, relative to 1996–2004, despite the doubling of R&D expenditure (Grogan, 2011). Given the stringent USFDA approval process, Indian firms, with their short-term focus and reverse engineering skills, may have made the strategic choice to continue producing generic and incrementally-modified drugs, rather than chasing innovations aimed at developing new chemical entities.

Considering the innovation ecosystem, the presence of more foreign multinationals in India, post-TRIPS, will have created greater competition for R&D talent (Chatterjee & Sahasranamam, 2018), with the lower concentration of such talent in domestic firms potentially decreasing their innovative capabilities and subsequent international competitiveness. Stronger IP protection also incentivizes individuals to capitalize on their intellectual capital through new ventures, rather than within established firms (Autio & Acs, 2010); this is consistent with India's substantial increase in general entrepreneurship rates during the post-TRIPS period (Sahasranamam & Sud, 2016).

Given opportunities for short-term gains, Indian pharmaceutical firms appear to have avoided competing with major global rivals on the basis of R&D-led innovations (Abrol, 2004). While the industry's R&D investment increased substantially during 1995–2014, the largest growth occurred during 2000–2005, just before, and at the start of, the product-patent regime's coming into effect. Indian firms may have raced to accumulate reverse-engineering-based patents before the restrictions of the TRIPS agreement (Haley & Haley, 2012). Post-TRIPS, growth in R&D investments has been much lower (even negative in some years). During the same period, however, the number of innovation-driven joint ventures between Indian and western pharmaceutical firms increased (Haley & Haley,

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2012), suggesting that Indian firms have relied more on technology transfer and external knowledge sourced from foreign firms, rather than internal R&D. This is consistent with Abrol's (2004) argument that most Indian pharmaceutical firms would likely be junior partners to global firms during the product-patent regime.

All of this offers directions for future research. First, our propositions can be developed into testable hypotheses, using fine-grained measures of international business activity that consider both breadth (e.g., accounting for countries from which the export earnings are received) and depth (e.g., accounting for the relative importance of each market). It would also be interesting to explore the role of knowledge sourcing strategies on higher-commitment, equity-based entry modes.

Second, R&D investments require time to translate into measurable outcomes. A mix of qualitative and quantitative methods may be useful for developing an in-depth understanding of the effects that process-level improvements from internal R&D have had in Indian pharmaceutical firms following the transition to a product-patent regime. Past research suggests that high-technology firms tend to rely on internal knowledge for areas in which they already have strengths and on external sources to supplement areas of weakness (Dunlap et al., 2016), emphasizing the importance of exploring, simultaneously, the process-level changes related to internal and external knowledge sourcing.

Finally, further research is needed to understand the various mechanisms that Indian pharmaceutical firms employed to overcome weak institutional support during the transitional-TRIPS period. Zhao (2006) found that Chinese firms used internal organizations to substitute for inadequate external institutions when conducting R&D. Exploring similar research questions in other emerging markets will offer a comparative basis. It would also be interesting to investigate how changes in the innovation ecosystem have influenced knowledge sourcing strategies in two other industries in which Indian firms have earned global recognition: automotive and information technology services (Chatterjee & Sahasranamam, 2018).

CONCLUSION

To conclude, we develop theoretical arguments regarding the differential effects of the IP regime changes of the transitional- and post-TRIPS periods with respect to firm-level knowledge sourcing strategies in Indian pharmaceutical firms. Integrating intellectual property arguments with contextually-embedded aspects of the innovation ecosystem, we conjecture that TRIPS compliance seems to have led these firms to rely more on the market for external knowledge, rather than on internal knowledge, in the quest to increase their international activities, especially exporting. This implies that the change in the innovation ecosystem created by the IP regime shift has had very different effects with respect to internal and external knowledge sourcing strategies in this key Indian industry.

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NOTES

[1] We are grateful to Ram Mudambi for raising this line of reasoning.
[2] Trade Related Intellectual Property Rights
[3] Other sources that firms use for obtaining knowledge include cluster spillovers and equity-based modes such as acquisitions and joint ventures.
[4] An example of a similar pharmaceutical process patent regime can be found in 19th century Germany (Murmann, 2003).
[5] Note that considering effect sizes tempers the interpretations.
[6] We are grateful to an anonymous reviewer for making this point.

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