Uncovering the institutional foundations of specialization patterns in the Indian pharmaceutical industry

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This article identifies the institutional foundations of the comparative advantages of the Indian pharmaceutical industry in generic bulk drugs, active pharmaceutical ingredients (APIs) and final dosages, and formulations manufacturing. Through studying six institutional areas in connection with the internationalization strategies of nine Indian pharmaceutical firms, this study illustrates how these comparative advantages have been evolving since liberalization of the Indian economy. It demonstrates how, in the post-liberalization era, both up-market outward foreign direct investment (OFDI) and the rise of contract-based partnerships are altering the way in which Indian pharmaceutical firms coordinate their action in the local sector. The shift towards more contact-based forms of coordination could support an industry-wide transition towards specialization in novel drug discovery and development. Although firms, especially larger ones, have been the main orchestrators of this shift, this study concludes that mainstreaming the necessary institutional mechanisms across the industry and employing the appropriate policy tools will be critical to supporting this transition.

1. Introduction

This study analyses the organization of business relations in the Indian pharmaceutical industry to uncover the origins of the industry's comparative advantages in generic drug manufacturing and to understand how these comparative advantages have evolved since the liberalization of the Indian economy in 1991. By framing nine case studies on the internationalization strategies of Indian pharmaceutical transnational companies (IPTNCs) through the lens of an institutional analysis, this article demonstrates that up-market OFDI and the rise in strategic partnerships and alliances in the Indian pharmaceutical industry in the post-liberalization era have been altering the organization of business relations. These relations are increasingly being organized through competitive markets and arms-length, formal contracts both at home and abroad, as opposed to through interpersonal reciprocity and networks, which were prevalent prior to liberalization in 1991. This shift in the organization of

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business relations could have important implications for the specialization patterns of firms in particular production activities over others. For instance, if properly reinforced through appropriate policy actions across the sector, these shifts could result in the Indian pharmaceutical industry developing comparative advantages in novel drug discovery and development.

Through taking an institutional approach, this paper offers a unique explanation of the evolutionary dynamics of industry-segment specialization patterns of Indian pharmaceutical firms. It thus sheds light on the domestic and sector-level institutional contexts that have shaped and been shaped by firms' strategies and interests. As a result, this article provides much-needed insights for developing an understanding of how the rapid integration of IPTNCs in the global economy since 1991 has shaken up both the local and global pharmaceutical industries.

The remainder of this article is structured as follows: Section 2 provides a brief overview of the institutional framework that is used in the article. Section 3 provides an empirical analysis of the institutional context in the Indian pharmaceutical industry. Section 4 provides a discussion of the main findings from the empirical analysis. Section 5 concludes by outlining the contributions of this study to international business and to development in emerging markets more broadly.

2. The Institutional Foundations of Comparative Advantages

A rich literature base has developed in international business on the growth, drivers, and motivations of the rapid increases in OFDI from emerging markets in general (see, for instance, Dunning, 1988, 1995, 1998; Dunning et al., 2008; Rugman, 2008; Sauvant et al., 2008; Sauvant et al., 2010) and on IPTNCs in particular (see, for instance, Athreye and Godley, 2009; Athreye et al., 2009; Bruche, 2011; Kale, 2009, 2010; Manil, 2006; Panda and Sriram, 2013; Pradhan, 2003; Pradhan and Alakshendra, 2006). International business approaches have also, in varying degrees, incorporated institutional features into their analyses. For instance, the eclectic paradigm outlines how institutional capabilities are built within a national economy, and the linking, leverage and learning approach (Mathews, 1997, 2002, 2006) also incorporates a role for institutions in supporting and shaping the strategies of emerging-market transnational corporations. To a large extent, however, institutions have been taken into account only as a background to or context for the general phenomena under consideration. As such, there is indeed room to expand upon the analysis of institutions in international business and identify which institutions are and have been most relevant for shaping the specialization patterns of firms in particular industry segments. Taking the role of institutions more seriously in international business studies, however, requires that the institutional context be reflected as an integral part of the competitive capabilities of the firm.

Recognizing this, this study employs a comparative capitalist perspective (see Hall and Soskice, 2001; Becker, 2013a; May, Nölke and ten Brink, 2014; Nölke et al., 2014, 2014a) to explore industry-level institutional arrangements in six institutional areas. These areas are (i) corporate finance, (ii) corporate governance, (iii) industrial relations, (iv) education and vocational training, (v) the transfer of innovation in the economy and (vi) the role of the state and public policy. These six areas together constitute the industry-level institutional configuration. The third section of this study focuses on identifying the way in which firms in the Indian pharmaceutical industry overcome coordination problems, i.e. through market or non-market means, in each area. It is assumed that complementarity exists across the institutional landscape, meaning that it is likely that firms will coordinate their actions in the same way in each area. Complementarity enables institutions to mutually reinforce one another and can in turn influence the pattern of the production strategies of firms and encourage them to specialize in particular industry segments. In other words, complementarity fosters comparative advantages in particular industry segments which influence the specialization patterns of firms.

To identify the coordination mechanisms within the institutional configuration in the Indian pharmaceutical industry, this study makes use of primary and secondary data collected on the internationalization strategies of the following nine Indian firms: Biocon, Cadila, Dr. Reddy's Laboratories (DRL), Glenmark, Jubilant, Nicholas Piramal, Ranbaxy, Sun Pharmaceuticals and Wockhardt. In the context of a larger research project by the author on the evolution of the Indian pharmaceutical sectoral system,[1] extensive interviews were conducted with these firms as well as with developed-economy pharmaceutical TNCs and Indian regulatory officials. The information collected from these interviews was used to construct case studies on the internationalization strategies and production patterns of these firms in the author's broader research project (see Taylor, 2015). These case studies serve as the basis for the material presented in the remainder of this article. Where noted, secondary sources were used to supplement the primary sources, including archived documents, corporate reports (including corporate web sites), published books, newspaper and magazine reports, as well as other case studies done on the above-mentioned firms. Roughly 4,000 pages of archival documents were collected for each firm from their establishment until 2014. In order to ensure validity, only data that could be corroborated from multiple sources have been included in the case studies.

[1] In this context, "Indian pharmaceutical sectoral system" refers to the sector-level institutional arrangements supporting the growth and competitive strengths of firms in particular sector segments. At the sector level, the six institutions outlined in the text represent an autonomous subsystem of institutional arrangements that have developed and evolved over time to support the specialization patterns of firms in specific industry segments. Thus, the features of and interdependencies among the six institutional areas generate competitive advantages of organizations in specific sector-level institutional contexts. For further explanation of sectoral systems, please see Taylor (2015).

3. The Institutional Configuration of the Indian Pharmaceutical Sector

This section identifies the coordination mechanisms and the extent of complementarity among the six previously discussed areas in the institutional configuration of the Indian pharmaceutical industry. The discussion concludes that the industry has comparative advantages in the manufacture of generic bulk drugs, APIs and final dosages, and formulations. In doing so, it also demonstrates that the up-market internationalization of IPTNCs that followed liberalization and the growth of contractual partnerships have altered the coordination mechanism within each area. This could eventually support a shift in the specialization patterns of IPTNCs in favour of novel drug discovery and development. As this section highlights, through up-market internationalization and in response to global economic and policy developments, firms – especially larger ones – have been the main orchestrators of this shift. However, fully supporting an industry-wide transition to leverage comparative advantages in novel drug discovery and development will require developing and mainstreaming the necessary institutional mechanisms and employing the appropriate policy tools.

Corporate Financing: Prior to the liberalization of the industry, corporate financing tended to be significantly correlated with the stage of development of a firm, combined with its size and ability to make use of informal business and kinship networks. A common tendency among Indian firms during the pre-liberalization period was to generate funds primarily through family, friends and business connections (Bhandari, 2005). A small portion of firms, such as Ranbaxy and DRL, were able to utilize banks or financial intermediaries, to obtain credit to invest in building capacity in APIs and formulations. However, the amount they were able to obtain was and continues to be rather limited, as a result of under-lending by banks to the corporate sector (Bhandari, 2005). Internal financing in the form of retained earnings remains the most significant source of long-term financing, whereas with short-term financing, IPTNCs have preferred to utilize trade credits and current liabilities, something which has been supported by the significance of informal business networks at work within the economy. This type of corporate financing, based on internal funds and bank credit, has strongly complemented the development of specialization in the manufacture of generic bulk drugs, APIs and formulations as both internal funds and bank credit have relatively low capital intensity.

Since the liberalization of the industry, IPTNCs have increasingly turned towards capital markets to finance both internationalization and technological upgrading. Compared with firms in other manufacturing and services industries, this development is indeed peculiar to the pharmaceutical industry, as firms in the manufacturing and services sectors in India "primarily use internal funds and bank credit for their operations" (Nölke et al., 2014a: 9). Although IPTNCs have funded their generic bulk drug and

formulations operations in this way, since commencing research and development (R&D) activities *and* up-market OFDI, firms have also begun to make use of bond-based debt and selling equity. Thus, a number of firms have issued global depository receipts and/or American depository receipts in order to have their stocks traded internationally and have also sold debt through issuing foreign currency convertible bonds (KPMG, 2006). Moreover, the firms studied for this analysis are all listed in India, and most are also listed on at least one foreign stock exchange. The funds that IPTNCs have raised through selling debt and issuing equity have been used to finance joint ventures, to acquire tangible and intangible assets at home and abroad, and to finance drug discovery and development operations.

Some firms, such as Sun Pharmaceuticals and DRL, have separated their R&D operations and listed them on Indian stock exchanges in order to finance R&D in novel drug and technology discovery. Although in these cases the promoters, i.e. controlling families, of these R&D spin-offs continue to own a large portion of the separated entities, the high cost and high-risk nature of innovation in discovery pushed them to separate their R&D operations. By doing so, firms have been able to pursue a combination of vehicles to raise capital to finance. Most commonly, these firms have raised capital to finance these R&D efforts by selling equity (Sun Pharmaceuticals).

State financing has been limited in the Indian pharmaceutical industry. Only a marginal amount of IPTNCs have been able to make use of direct or indirect state financing through financial guarantees and credits from state-owned banks (Nölke et al., 2014a: 9-10; Goldstein, 2007: 98). Although the state controls up to 75 per cent of the national banking assets in India (Nölke et al., 2014a: 9), securing credits and guarantees from these banks has proven particularly difficult for small and medium enterprises (SMEs) in the industry. Despite the fact that the state and the Reserve Bank of India have put in place a set of provisions to encourage lending to SMEs, "banks are most often observed to have denied credit…due to failure in providing security" (Pradhan and Sahu, 2008: 112). Generally speaking, under-lending by banks to the corporate sector seems to be a symptomatic problem in securing credit from financial institutions in India. Although it has tended to have a larger impact on SMEs, it is nevertheless a feature of the institutional configuration that has affected all firms regardless of their size (Bhandari, 2005; Das, 2006).

Although firms in the industry have not been able to take advantage of direct or indirect state financing, they have benefited from fiscal incentives. The state offers a number of grants and tax breaks and a limited amount of incentives to help finance technological development as well as R&D activities related to the development of novel drugs and drug delivery systems.

To sum up, post-liberalization IPTNCs have primarily financed their operations through a combination of internal accruals, equity *and* debt. This is a distinguishing feature of

the Indian pharmaceutical industry, especially in comparison with other manufacturing and services sectors in India, and it corresponds to the manner in which firms finance their operations in the pharmaceutical industry in developed economies. These financing patterns have meant that IPTNCs only partially act independently from the pressures of global capital markets. On the one hand, internal savings have helped cushion short-term volatilities in global capital markets and enabled IPTNCs to excel at generic bulk drug, API, and formulations manufacturing, as these are not capital-intensive activities. On the other hand, as internationalization and investments in R&D have primarily been financed through equity and debt, IPTNCs are no longer fully independent from global capital markets and investor profit expectations.

Wockhardt serves as a good example to illustrate this latter point. Wockhardt's up-market internationalization was financed through a combination of debt from global capital markets and domestic banks. Wockhardt raised finance through a mixture of secured and unsecured loans and bonds that were issued both domestically and on global capital markets (Unnikrishnan, 2012). Furthermore, it issued a number of complex currency contracts with domestic and foreign banks to hedge currency exposure and decrease interest on its foreign loans. Huge debt and losses accrued through the complex currency derivatives, and when these surfaced in 2008, "Wockhardt defaulted on certain tranches of its derivative transactions" (Ghosh and Mehta, 2009). This led domestic and foreign banks to discontinue funding the firm, and forced the company to default on its US$110 million foreign currency convertible bond, a move that saw its stock price plummet 80 per cent between 2008 and 2009 (Ghosh, 2012). Wockhardt was then forced to enter into a corporate debt restructuring agreement (CDR) led by the ICICI Bank. The CDR renegotiated the interest rate and repayment schedules for Wockhardt's domestic and foreign debt and forced Wockhardt to divest from a number of its non-core businesses just as the global financial crisis went into full swing.

Corporate Governance: Corporate governance in the Indian pharmaceutical industry is based on a combination of insider control and dispersed minority owners. Indeed, families or individuals hold the majority of shares in IPTNCs. However, as IPTNCs have become more involved in capital markets, dispersed shareholders have begun to play an increasingly important role. While the largest blocks of equity in most listed firms typically remain in the hands of the founding family or controlling shareholders (Allen et al., 2012: 411), minority shareholders, consisting of both foreign and domestic capital sources, have significantly altered the corporate governance systems in the industry. In particular, the use of global depository receipts, American depository receipts and foreign currency convertible bonds has effectively forced a change in the reporting systems and management structures of IPTNCs, to make their operations more transparent to investors. For example, IPTNCs have had to use generally accepted accounting principles (GAAP) and meet segmental reporting

requirements.[2] They have also had to overhaul their management structures by introducing independent boards and management councils consisting of chief executive, operating and financial officers as well as others. These changes have enabled IPTNCs to meet the disclosure duties associated with raising capital through debt and equity on international capital markets.

The growing role of minority shareholders in IPTNCs has pushed IPTNCs to develop corporate governance systems that are in line with those in the global pharmaceutical industry. Strong institutional complementarities between the systems of corporate governance and corporate finance are highly prevalent. These complementarities have allowed IPTNCs a degree of flexibility in their strategies and investments, despite the majority stakes in these firms still being held by original trustee families or individuals. However, the use of global capital markets to finance internationalization has put certain restrictions on IPTNCs and forced them to be more responsive to short-term profit margins than previously. Moreover, it has pushed them to streamline their corporate governance and reporting systems to be in line with global transparency standards in the industry.

The growth in contractual partnerships in the industry has opened up a new role for external actors in the strategic decision-making processes of firms. To this end, external agents may be considered as insiders, to the degree that their experience and creativity is included in the processes of collective learning and may be involved in the processes of organizational integration. The extent to which partnerships allow for decision making to be shared between firms depends on the nature and context of the agreements that are signed between firms. As such, depending on the agreement, external partner firms may have a participatory role in the organization of the central activities of the counterpart firm. This would enable external partner firms to share in and affect the counterpart firm's strategy and performance.

One final interesting development in IPTNC corporate governance systems to note is the growing integration of scientists specialized in molecular biology and chemical engineering into upper management and onto the boards of firms. This move corresponds with the corporate governance structures in the industry in developed economies and is symbolic of the significance that the scientific process of R&D holds in deciding the type of investments that firms make and how the returns from those investments are distributed. Thus, scientists are becoming integral to the strategic processes and decision making of IPTNCs.

[2] GAAP refers to the guidelines, principles, standards, detailed rules and industry-specific practices that exist for financial reporting. Segment reporting refers to the requirement to separately report the results of individual business units, something which is required for all publicly listed firms in the United States.

Industrial Relations:[3] Regarding labour relations, wages in the industry are typically negotiated at the firm level. IPTNCs have based their competitive advantages on cost leadership, which is related to their low-cost advantage in generic bulk drugs, API, and formulations manufacturing. Institutional wage-setting processes, which take place within firms and regulate the wages of employees, have underpinned this low-cost advantage, especially as the labour market is relatively inflexible, given that retrenchment is not permitted by Indian labour law (Kuruvilla et al., 2003: 189). However, as IPTNCs have begun to concentrate on upgrading their technological base and innovative competencies, corresponding changes in compensation have also occurred (Venkata Ratnam, 1998; 2006) and a number of firms have started to implement performance-based payment systems (Venkata Ratnam, 2006).

Despite these changes, IPTNCs have been slow to adopt best practices in human resource management and labour relations. Unsurprisingly, as most IPTNCs are family controlled, management hierarchies tend to be paternalistic. There is limited union participation, and labour management relations are a mix of paternalist cooperation and conflict. This accords with the fact that in the industry the "work organization is quite Tayloristic, with relatively little multi-skilling" (Kuruvilla et al., 2003: 177). Thus, not only are jobs clearly defined but there is also a "clear separation between managerial [staff] and employee[s] result[ing] in a semi-skilled workforce engaged in repetitive tasks"[4] (Venkata Ratnam, 1998: 6).

IPTNCs do invest in training their relevant staff in regulatory requirements. Such investments are geared towards ensuring that the products developed within the firm meet the regulatory requirements and standards of the markets in which the products are marketed and/or distributed (Kuruvilla et al., 2003: 177). Despite this, there remains a substantial need to train the broader workforce across the industry to adhere to quality assurance and compliance standards.

Labour relations in the industry strongly complement family-owned systems of corporate governance and corporate finance. This has posed challenges for the integration of many of the up-market international assets of IPTNCs, as labour relations in developed economies are coordinated much differently. Despite strict labour laws, the growing presence of contractual relations in the industry may

[3] Labour regulation in India is a complex issue. To provide a brief overview: The law makes a distinction between workers employed in organized sectors and those employed in unorganized sectors. Workers in the organized sectors are fully covered by labour laws, while those in the unorganized sectors are not, largely as a result of the informal nature of their employment. The pharmaceutical industry is considered an organized sector and, as such, workers in the industry are covered by Indian labour law. For more information on Indian labour regulations and their complexity, please see Agarwala et al. (2004), Reddy (2008), Papola et al. (2008), Thakur (2008), Pais (2008) and Sundar (2008).

[4] This pattern is not unique to the pharmaceutical industry in India.

potentially alter labour relations by encouraging the development of new forms of contractual employment with external actors for limited time periods.

Educational and Vocational Training: IPTNCs are becoming actively involved in contributing to skill development through educational and vocational training systems. Although the State has contributed substantial funds to the promotion of skilled manpower for the industries deemed to be the backbone of Indian economic development, there has been dissatisfaction within the industry regarding the lack of a coherent and comprehensive education system that provides skills in the discovery of novel drugs and technology. The lack of talent at home has forced IPTNCs to increasingly look abroad for talent to fill knowledge gaps in molecular biology, complex molecules and rational drug design (Dr. Reddy's Laboratories, 2009).

Although the educational and vocational training system has managed to contribute to developing industry-specific skills in organic chemistry that have been vital to IPTNCs' competitive strength in generics, the inability of the system to stimulate an upgrade in R&D skills in firms is related to the focus of the system. Moreover, it has also pushed firms to pursue non-equity modes of up-market internationalization in order to overcome the relevant skill gaps between organic chemistry and molecular biology. A symptomatic problem in the system is that since independence an "Indian characteristic [has been] to give higher education priority over primary education. This remains true today: India spent 86 per cent of per capita GDP on each student in tertiary education in 2000 yet only 14 per cent in primary education" (Milelli, 2007: 6). This has produced an incredibly lopsided labour force, which has in turn fuelled an ever-increasing gap between the middle- and lower-income classes.

Government-funded education efforts, especially those in higher education, have remained somewhat stifled given that the university-structured hierarchies and low salaries of professors have prevented innovative R&D at many Indian universities. Although the Indian higher education system is constantly churning out thousands of new graduates per year, it lacks the necessary and up-to-date skills needed to upgrade the technological base and innovative competency of the Indian pharmaceutical industry. This has not only thwarted the capacity of the industry to develop a specialization in novel drug discovery and development but also hindered its capacity to develop skills beyond the first two phases of clinical trial development, i.e. phases III and IV. Although the industry, in particular the contract research and manufacturing services (CRAMS) segment, has started to gain a competitive edge in phases I and II of clinical trials, especially because of its low-cost advantage and large population, it has not been easy given the general lack of trained professionals who have the skills needed to run the trials according to international standards.

IPTNCs have actively engaged in changing the institutional domain to better support the continued training of current and future employees in the industry in three distinct ways. First, they have begun lobbying the Government for higher salaries for professors

in Indian universities in the hopes of attracting young and innovative scholars to join academia (Mittal, 2006: 19). Second, in addition, many Indian firms have also begun their own in-house training programs, investing in developing industry-specific skill sets in their employees (Dr. Reddy's Laboratories, 2009; Sun Pharmaceuticals, 2009; Wockhardt, 2008, 2009). Similar types of investments are also made by firms in the pharmaceutical industry in developed economies; however, fluid labour markets in most developed economies enable these skill sets to be transferred across firms. In comparison, the inflexible labour market in India means that firms can potentially retain more from these investments as they are investing in developing skill sets in employees who are likely to remain employed in the firm over the long term. Third, IPTNCs have actively engaged in the educational and vocational training system through the roles played by upper and senior management on executive boards and management committees in selected academic institutes and universities.[5] IPTNCs have the potential to use these connections to influence the curricula and educational requirements of university programs that are relevant to the industry.

Transfer of Innovation: The way in which institutions foster the transfer of innovation throughout the economy is a crucial element for enabling technological growth at the firm level. In the late 1960s and early 1970s, the Indian Government overtly chose to specialize in high-priority industries, such as the pharmaceutical industry, and thereafter set up an institutional and regulatory environment that would cater to growth in these industries. At that point, barriers to entry were constructed in these industries and regulations were set as to how large firms were allowed to become (Balcet and Bruschieri, 2010). A crucial element of this system was the establishment of public sector units and public research institutes. Many of the individuals and family heads who currently control IPTNCs started their careers in these public sector units and institutes (Mazumdar, 2013), then went on to start their firms in the early 1980s. Many of these firms continued to benefit from the network of contacts and financial leverage provided by these individuals.

After the initial start-up phase of the industry, barriers preventing the entry of both foreign and domestic firms began to be removed and policies were created in the 1980s and 1990s to encourage more private firms to enter the industry. The liberalization of capital controls and the FDI regime have been particularly crucial to enabling firms to expand abroad. The former has enabled firms to access global capital markets to finance OFDI, while the latter has made it legally possible for IPTNCs to pursue up-market OFDI projects and has also encouraged them to do so.

Two interrelated developments since liberalization have also affected the transfer of innovation within the system. They are (i) the sharper focus of firms on drug discovery

[5] Aside from this, they have also taken on roles in business associations and policy committees in order to influence regulatory frameworks and macroeconomic policy.

R&D and (ii) the rise of various forms of contractual partnerships among firms, both at home and abroad. The first has directly influenced the geographic distribution of IPTNC internationalization since 1991. As IPTNCs have sought to upgrade their innovative capabilities, they have invested in developed economies in order to gain and leverage skills in their R&D operations at home. Regarding the second development, relations in the industry are highly competitive and based on formal contracts as well as networks. The rise of contractual agreements has corresponded with a general phenomenon in the global pharmaceutical industry in which firms have been pursuing avenues to share the costs as well as the risks of developing and bringing a new drug candidate to market.[6] This has in turn led to an increase in the extent of cooperative contract-based relations with firms at home and abroad. However, although firms are creating contract-based partnerships with foreign firms, they remain competitors in domestic and foreign product markets.[7]

A common contract-based strategy has included both in-licensing and out-licensing agreements. In focusing specifically on licensing arrangements related to molecular entity development, Indian firms have successfully managed to be on both ends of the spectrum. A select number of Indian firms, such as Biocon, DRL, Ranbaxy and Wockhardt, have identified and developed new chemical entities as attractive candidates to move forward into clinical trials. Due to the extensive costs incurred during clinical trials, many of these firms have out-licensed these molecules for further development through clinical trials and regulatory approvals to TNCs based in developed economies. Most typically, these out-licensing agreements have also included clauses in which Indian firms maintain marketing rights to the product domestically, and in some cases other emerging markets, while ceding marketing rights abroad to their partners. In addition, these agreements can include both up-front payments for the license and milestone payments for the licensor firm. Milestone payments can be structured according to various payment schemes, including for achieving clinical trial development, submitting a drug application for approval, launching of drug in a particular country and commercial sales.[8]

[6] On average, it costs over US$1 billion and takes up to 15.3 years to discover, develop and bring a new drug to market.

[7] This partnership surge and its impact on industry competition would likely have been significantly less intense without the signing of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS and its role in the Indian pharmaceutical industry are discussed later under the heading, “Role of the State and Public Policies”.

[8] For example, Forest Labs (United States) entered into an agreement with Glenmark in 2004 for Glenmark’s molecule GRC 3886. In addition to the upfront payment made for the molecule, in February 2016 Forest also made a US$15 million milestone payment to Glenmark for initiation of phase II trials. If development and commercialization of the molecule are successful, Glenmark could receive upwards of US$190 million in milestone payments from Forest. In addition to this agreement, Glenmark also has an agreement with Sanofi (France) for £500. In 2011 Glenmark received a US$50 million upfront payment for the molecule, and in 2014 it received a US$4 million milestone payment.

The growth in contract-based partnerships has also supported the development of the CRAMS segment and a growing number of Indian firms have been contracted to optimize, validate and screen target molecules developed by other firms. Indian firms have also rapidly become involved in clinical trial contracting. Indeed this is in spite of the regulatory constraints related to animal testing, which have precluded India from becoming an attractive location for Phase I of clinical trials. In taking advantage of their competitive advantages in medical and clinical skills, low costs and large population bases, Indian firms have successfully ensured that India, over China, has become the preferred destination and choice for contracting Phase II of clinical trials. However, owing to certain quality assurance issues and the growth of the counterfeit industry, the extent to which India will remain the leading destination for these investments has been called into question recently.

Despite the growth in formal contracts in the Indian pharmaceutical industry, IPTNCs do still rely on their networks. Networks include government officials and former State enterprise employees who have created their own spin-off firms. These ties have been extremely useful in terms of providing firms with additional financial leverage as well as the ability to steer domestic public policies in a manner conducive to the needs of each firm, as well as the industry as a whole. IPTNCs have actively engaged in a number of regulatory policy committees to steer the direction of the industry's development. In the post-FDI liberalization phase, these networks have become more active and have created forums and partnerships to support one another, such as the Confederation of Indian Industry, India Brand Equity Foundation, India Partnership Forum, Indian Pharmaceutical Alliance, Overseas Indian Facilitation Centre and Tamil Nadu Technology Development & Promotion Centre.

To sum up, the transfer of innovation before liberalization particularly relied on the ease of transfer of knowledge between the public sector units and public research institutes with the private sector. This was facilitated by the number of public sector unit employees who moved into the private sector. The transfer of innovations since liberalization has, however, largely taken place through internationalization and the rise of strategic partnerships, alliances and the CRAMS segment (i.e. contractual agreements). The fact that the industry has developed more arms-length means of transferring innovation corresponds not only with the way innovation is transferred in the global pharmaceutical industry, but also with the highly competitive nature of the industry. Moreover, the rise of contractual agreements and partnerships also corresponds to the fact that the industry relies on intellectual property right protection for innovation; thus, arms-length contracts have been crucial to support this type of innovation. The growth in arms-length contracts strongly complements developments in the institutional areas of corporate finance and corporate governance that have come about directly as a result of internationalization and technological upgrading, namely the increased reliance on capital markets and the growth in dispersed minority shareholders.

Role of the State and Public Policy: Indian public policy has been crucial in helping to establish an institutional environment at the sectoral level to support the creation and evolution of the Indian pharmaceutical industry. Despite attempts to build up competitive and innovative industries, such as in pharmaceuticals, the regulatory environment between 1978 and 1991 hindered the ability of inward and outward FDI to encourage innovation through technology transfer. However, it did encourage the creation of an indigenous industry with a strong set of skills that have come to be essential to the competitive advantages these firms possess today and have exploited through internationalization.

State policies both before and after liberalization significantly influenced the developmental process of the industry (Brandl et al., 2015). In creating an indigenous industry, the state put in place a set of administrative and policy barriers that not only limited the amount of foreign competition in the Indian market, but also forced the initial transfer of knowledge and skill sets in chemical processes, drug manufacturing and production. Among the most notable policies nudging the direction of the industry's development were the Industrial Licensing Resolution of 1956 (ILR), the New Drug Policy of 1978 (NDP) and the Indian Patent Act of 1970.[9] Through the ILR, a licensing system for foreign and domestic indigenous firms was put in place. The ILR also required all foreign firms to establish bulk drug production units and thereby produce drugs from the very basic stages all the way up to the final product in India. Although the ILR led to an increase in the production units and the capital investments of foreign firms, there were still little to no spillover effects in terms of increasing the technological capacity and knowledge of domestic firms in the production, manufacturing and packaging of pharmaceutical products.

In an effort to further nurture the development of the indigenous industry, the Patent Act of 1970 was implemented and thereafter only processes, not products, could be patented. This effectively stimulated an increase in reverse engineering of foreign-patented drug products. Furthermore, the Patent Act and the NDP together led to a significant decrease in the number of foreign TNCs. Through the NDP,[10] the Foreign Exchange and Regulations Act of 1973 (FERA) was applied to the pharmaceutical industry. The FERA not only required that foreign firms reduce their equity stake holdings in India to 40 per cent or less, but also put in place specific ratio regulations on the value of indigenous bulk drugs that had to be used in total formulation

[9] Two additional policies also influenced the development of the industry pre-liberalization: The Drug Price Control Order of 1970 regulating the price of drugs (an augmented version is still in place today); and the Monopolies and Restrictive Trade Practices Act of 1969, limiting the size of firms.

[10] The NDP also amended the Patent Act of 1970 and stipulated that foreign firms could patent only one process (Mazumdar, 2013).

production.[11] As a result of these policies, by 1980 foreign TNCs' share in the Indian market dropped to 50 per cent, from 68 per cent in 1970. In contrast, indigenous Indian firms' share in the Indian market increased from 32 per cent in 1970 to 50 per cent in 1980 (Mazumdar, 2013).

As foreign firms exited the Indian market, Indian firms were able to obtain "state-of-the-art factories, laboratories, products and trained staff, which supported their quest for world class quality levels" (Bruche, 2011: 4). Taken together, these policies gave Indian pharmaceutical firms access to process knowledge and technology held by foreign multinationals that had been working in India, which they in turn leveraged to create cheaper generic brands that were affordable in the Indian market. The skills and product portfolios that Indian firms started to build in the 1970s and 1980s would subsequently be a crucial element of their success after liberalization.

Liberalization, which began in the 1980s but went into full swing (especially for the pharmaceutical industry) after 1990, considerably changed the type of role that the State played in the industry. Since then, the direct role of the State in supporting the continued growth and development of the industry into a globally competitive force has been rather limited. Rather, the decline of policies that regulated the outward expansion of firms and the growth of foreign firms competing domestically has most recently been the driving force for significant changes in the competitive advantages and strategies of IPTNCs. However, the State continues to play a direct role in regulating competition in the industry domestically, especially in relation to drug pricing and the implementation of new patent laws with regard to life-threatening diseases that affect the majority of the population, who cannot afford access to treatment.

Changes to FDI regulations, particularly to OFDI regulations, have explicitly pushed IPTNCs to internationalize by encouraging them to attain strategic competitive positions in developed economies and by allowing them to undertake acquisition strategies that are more financially and legally risky in developed markets.[12] Between 1991 and 2008, a number of OFDI policy reforms were introduced that changed FDI approval processes, the type of investments firms could make, how much firms could invest and how firms could finance their investments.[13] In 1992 firms were

[11] Foreign firms were subject to a 1:5 ratio and indigenous firms to 1:10. Thus, foreign firms had to purchase 20 per cent of their bulk drugs for formulation in India and indigenous firms had to purchase 10 per cent.

[12] These strategies are financially and legally riskier because they require parent firms to comply with antitrust laws, perform due diligence, apply various accounting principles and take on any ongoing liabilities of the target firm. Compared with the pre-liberalization period, when formulations exports were directed to unregulated markets in neighbouring countries and in countries at a similar or lower level of development, undertaking an acquisition is much more risky in this sense.

[13] Only policy changes relevant for the rapid internationalization of firms in developed economies are discussed here. For further elaboration on other FDI changes that are unrelated to this study, please see Pradhan (2008).

granted automatic approval by the Reserve Bank of India for an OFDI investment under US$2 million. Shortly thereafter, firms were allowed to raise foreign currency abroad for investment by issuing global depository receipts, American depository receipts and foreign currency convertible bonds. In 2000, the automatic approval limit was raised to US$100 million, and by 2002 firms were allowed to invest up to 100 per cent of their net worth in OFDI projects. This increased to 200 per cent in 2006 and 300 per cent in 2008. Furthermore, in 2002, "[t]he condition of 'same core activity' for OFDI [was] removed and an Indian company [could] invest in 'any bonafide business activity'" (Kohli, 2005: 184). Not only did OFDI began to increase from 1992 onwards, but after 2002 there was a significant upsurge in up-market non-equity modes of internationalization

Although eased regulatory restrictions after 2002 enabled Indian firms to pursue up-market OFDI, the target-rich environment in the global industry also contributed to the ability of IPTNCs to acquire firms. The rising cost of R&D in the global industry combined with shorter product life cycles and increasing regulatory pressure led many developed-economy TNCs to realign their operations to focus solely on their core businesses after 2000. Many of these firms placed research, discovery and development of new chemical entities at the centre of their business, and considered pharmaceutical production a non-core area. As such, in the 2000s, these firms divested their manufacturing components and began to source manufacturing externally. This in turn led to a target-rich environment for IPTNCs looking to acquire production facilities in developed economies. These developments, combined with the changes to FDI regulations in India, worked together to influence the temporal sequencing and geographic distribution of OFDI by IPTNCs after 2000.

The implementation of the product patent regime (TRIPS) between 1995 and 2004 also had a significant effect on IPTNCs. It not only encouraged IPTNCs to expand outwards, but also pushed them to upgrade their innovative competencies. Indeed, the move towards Indian firms becoming involved in drug discovery and development began directly after the implementation of TRIPS. This has led to an increase in the rate of patents filed by Indian firms in the United States (Brandl et al., 2015). Increased patent protection has also supported an increase in foreign TNC activities in India. This has not only led to a fiercer competitive environment in the domestic industry, but also helped reinforce efforts by Indian firms to step up their involvement in drug discovery and development. However, notable impediments in the patent system remain. These impediments have cost both time and capital for many Indian firms and have been damaging to their reputation. In particular, overcoming challenges related to patent linkages, efficacy issues related to evergreening and compulsory licensing are important for encouraging foreign TNCs to remain and invest further in the Indian pharmaceutical industry. This is of crucial importance in terms of supporting potential knowledge spillovers and for enabling the CRAMS segment to continue to thrive off of contracts from these firms (Taylor, 2015: 238-244).

In conclusion, it is important to point out that there are strong institutional complementarities between the role of the state and the transfer of innovation in the industry. This is clearly evident in the role of public policy in creating the industry, but it has also been supported by the aforementioned networks, which have helped to foster innovative capacity in the industry. Although public policy and the state have had less success in directly influencing the technological upgrading of the industry since liberalization, the state still remains a key influential actor. Aside from its policy efforts such as tax breaks and tax deductions, it has also attempted to create programs and incubation projects to support the transfer of technological upgrading in the industry. One example is Pharma Vision 2020, a public-private partnership initiative to foster innovation in the industry and turn India into one of the top pharmaceutical innovation hubs by 2020. Other examples include the Drug Development Programme and the Pharmaceuticals Research and Development Support Fund, both of which were specifically developed to encourage new drug discovery and development in the pharmaceutical and biotechnology industries. Thus, it is not an overstatement to claim that IPTNCs' current transformative move to the transnational stage has been supported by their embeddedness in a policy environment that promotes the incubation and development of a select set of industries and firms, and in particular by the initial policy of a weak patent system in which reverse engineering was encouraged from 1970 to 1990 (Goldstein, 2007: 95).

4. Discussion of the Findings: Shifting Coordination Mechanisms in the Indian Pharmaceutical Sector

The mutually interdependent institutions analysed here have conditioned institutional comparative advantages in the manufacture of generic bulk drugs, APIs and final dosages, and formulations. The development of comparative advantages in generic manufacturing was initiated by the set of industrial polices put in place by the Indian State and aimed at facilitating a self-sufficient industry with strengths in generics and in reverse process engineering. These competitive strengths were supported by a system of corporate finance heavily reliant on family ownership and internal accruals, which complemented the development of corporate governance structures aimed at retaining insider control. The internal financial cushions supporting many IPTNCs offered them security during turbulent times and in uncertain regulatory environments. Similarly, lax enforcement of competition and intellectual property regulations enhanced the competitiveness of Indian firms and drove IPTNCs to expand strategically in the 1980s and early 1990s.

In the post-liberalization era, the coordination mechanism within the local Indian pharmaceutical industry has begun to alter. Before, it was largely based on interpersonal reciprocity and public-private alliances (Nölke et al., 2014a); however,

since liberalization it has shifted to also include competitive markets and formal, arms-length contracts. These shifts have been shaped by the following three developments: (1) up-market internationalization of IPTNCs; (2) IPTNCs' efforts to upgrade their research and discovery capabilities; and (3) the integration of IPTNCs and the Indian pharmaceutical sector into the global industry.

Specifically, the first and second developments directly altered corporate financing and the corporate governance structures of IPTNCs. In order to finance both internationalization and the upgrading of innovative competency, IPTNCs opened themselves up to global capital markets. As such, while the controlling families still own majority stakes in the firms, IPTNCs have also had to answer to dispersed minority shareholders in global markets. Moreover, in issuing debt and equity, IPTNCs have had to overhaul their corporate governance systems in order to be more transparent and meet disclosure duties. The third development has resulted in the growing presence of IPTNCs in the CRAMS segment, and their growing reliance on strategic partnerships and alliances has ushered in a new era of competitive relations in the local industry, namely one that is based on arms-length, formal contractual agreements. Indeed, although shifts in the regulatory regime enabled this change to occur, it was actually the internationalization of IPTNCs and their incorporation of operational strategies based on contractual agreements that were responsible for the alterations to the coordination mechanism.

These changes to the coordination mechanisms and certain aspects of the institutional configuration are still ongoing; as such, it remains to be seen whether and how they may affect other institutional domains of the industry. Moreover, it is still unclear if they will lead to the Indian pharmaceutical industry as a whole developing institutional comparative advantages in novel drug discovery and development. For this to happen, the Government must implement the appropriate policy tools to support this transition. This should, for instance, include facilitating greater financial inclusion among SMEs, implementing appropriate measures to improve skill development within the workforce and reinforcing intellectual property rights evenly across the industry.

For the time being, however, it can be concluded that although IPTNCs are still partly bound to their domestic institutional configuration, they have also begun to act, in part, to alter it. To this end, up-market internationalization combined with the ever-growing importance of contract-based partnerships for risk and cost sharing in the global industry have provided Indian pharmaceutical firms a way to dock onto international structures and thereby obtain and build a set of firm-specific competitive advantages outside the context of their domestic, industry-level institutional configuration. Accessing non-national institutional resources through market coordination in an international institutional context and incorporating them into domestic operations has in turn helped IPTNCs thrive at home and abroad.

5. Conclusion

The main goal of this paper was to identify the institutional foundations of the comparative advantages of the Indian pharmaceutical industry. Through studying six areas of the institutional configuration in connection with the up-market internationalization strategies of nine Indian pharmaceutical firms, this study also described how these comparative advantages have been evolving since liberalization. In addition, through focusing on the institutional configuration, this study reveals how the growth of non-equity modes of contractual international production in the industry is altering the way firms coordinate their actions in the industry. If properly reinforced by the implementation of the appropriate policy tools, more contract-based forms of coordination in the industry could further support an industry-wide transition towards specialization in novel drug discovery and development.

This research contributes to the international business literature through its exploration of the importance of the evolution of different contexts in which firms develop. It has shown the value in augmenting the established literature on firm internationalization to incorporate the role of the industry context and that of the institutional environment in shaping firm strategy. In doing so, it has illustrated that the path, location, speed and type of internationalization is correlated with the industry in which firms operate. Future research should focus on studying additional industries and their institutional configurations in order to corroborate the role of the industry context in the internationalization of firms.

Important lessons can be learned from studying the institutional configurations within industry contexts of emerging market TNCs more broadly. In particular, through highlighting the changing nature of corporate finance and corporate governance patterns in the industry, this paper provides important insight into how firms can inform and affect policy by changing the way in which they coordinate their actions in these institutional settings in relation to segments of the industry in which they operate. This could have important policy implications for stimulating financing options to develop institutional support for upgrading the innovative capabilities of firms in India, as well as in other emerging markets. Furthermore, the discussion of the regulatory public policies that are relevant for building indigenous industry capacity and critical for enabling up-market OFDI in the Indian pharmaceutical industry could be highly relevant to policy makers in other emerging economies who are seeking to nurture and influence the developmental path of certain industries. Here, support from international organizations to help identify and follow through with particular policy strategies in the context of the current global economic environment will be critical.

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