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Phase of Internationalization from Emerging Economies:
A study in the Indian Pharmaceutical Industry**

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W.P. No.2008-02-05
February 2008

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**Motivations, Capability Handicaps and Firm Responses in the Early
Phase of Internationalization from Emerging Economies:
A study in the Indian Pharmaceutical Industry**

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Abstract

This paper identifies and analyses the motivations, capability handicaps and responses of a sample of Indian pharmaceutical firms in the early phase of internationalization. It distinguishes between the experiences of two types of internationalisers –initial internationalisers and later internationalisers - in the industry. It argues that the initial internationalisers face several discontinuities vis-a-vis the experience of meeting the needs of domestic market. They need to cultivate new capabilities by leveraging on whatever is available within the firms and the external environment. Their capability to cultivate depends on their internal processes to absorb the new experiences. The later internationalisers do not experience these handicaps. They can benefit from the industry experience and congregate capabilities to move faster. Their capability to congregate depends on the initial endowments of the founders. Based on its findings, the paper outlines scope for further research in capability building for internationalization in the context of emerging economies.

Motivations, Capability Handicaps and Firm Responses in the Early Phase of Internationalization from Emerging Economies: A study in the Indian Pharmaceutical Industry

1. Introduction

1.1 From Dependence to Independence and Internationalization

From being an import dependent industry in the 1950s, the Indian pharmaceutical industry has achieved self-sufficiency and gained global recognition as a producer of low cost and high quality bulk drugs and formulations¹. It has emerged as the fourth largest, in volume terms and thirteenth largest, in value terms (\$8.5 Billion), pharmaceuticals industry in the world. It is ranked among the top 20 pharmaceutical exporters in the world. Exports during 1990-94, 1995-99 and 2000-04 grew at 13%, 23% and 45% respectively². Leading Indian pharmaceutical companies have their presence in more than 70 nations, including United States of America. India has the largest number (60) of United States Food and Drugs Administration (USFDA) approved plants outside USA and a large number (126) of Drug master File (DMF) and product registrations³. Indian companies have licensing deals with MNC's for New Chemical Entity (NCE) and New Drug Delivery System (NDDS), contract manufacturing, Research and Development (R & D) alliances and alliances for clinical trials. Leading companies like Cadila Healthcare Limited, Cipla Limited, Dr. Reddy's Laboratory Limited, Lupin Limited, Matrix Laboratories Limited, Ranbaxy Laboratories Limited, Torrent Pharmaceuticals Limited and Wockhardt Limited have been recognized at international levels.

1.2 The Foundation

The foundation for this achievement was laid by the establishment of Indian Drugs and Pharmaceutical Ltd. (IDPL) in 1954 and Hindustan Antibiotics Ltd. (HAL) in 1961 by the Government of India to manufacture bulk drugs. These public sector units helped to grow the industry through spillover of knowledge and talent (Pradhan, 2006). The introduction of the Indian Patent Act (IPA) that recognized only process patents and not product patents in 1970 facilitated the setting up of formulation units on the strength of process innovations and reverse engineering. The next milestone in Indian pharmaceutical

¹ www.pharmainfo.net/magazine

² Ciionline.org/industrial sector-Drugs & Pharmaceuticals/

³ Deccan Herald: "Drugs Patent: A Viagra for Indian Pharmaceutical Industry", April 4, 2005

industry was the introduction of New Drug Policy (NDP) of 1978, which allowed Foreign Direct Investment (FDI) up to 74% in high technology drugs. It forced the Multinational Corporations (MNCs) in the sector to start manufacturing bulk drugs in India, if they wished to sell formulations in the local market. The talent flow from MNCs enabled the Indian companies to develop capabilities in bulk drugs also. The next milestone was harnessing opportunities abroad. Indian companies developed off patent drugs and entered international markets. Later they even acquired pharmaceutical companies abroad. By 2009 many blockbuster drugs would go off patent that would accord opportunities to supply bulk drugs and formulations to advanced markets.

1.3 The Questions

We need to understand and analyse the above experience and draw lessons in the internationalization of knowledge intensive industries in the emerging economies, focusing specially on the early phase. The emerging economy firms typically hail from economies with underdeveloped institutions and market intermediaries that add to the transaction costs of accessing resources and doing business in general (Khanna and Palepu, 1997). The challenges in internationalisation in terms of overcoming capability handicaps as late movers and competing with firms from developed economies that have better access to financial capital, advanced technologies and managerial capabilities have been well documented. (Lall, 1983; Wells, 1993; Guillen, 2000; and Khanna and Palepu, 2006). Chittor and Ray (2007) noted that the Indian pharmaceutical firms followed different internationalization strategies though they were in the same geographical, economic and industry context. They raised the following questions:

- (i) Why do different firms follow different internationalization strategies / path / trajectories even though they are subject to identical environments?
- (ii) Is it the firm level factors that affect the internationalization strategies or is it environmental factors?
- (iii) What are the paths of internationalization?

In the context of these questions the paper focuses on the early phase of internationalization of the Indian pharmaceutical industry. It argues that the early phase marks several discontinuities for the firms engaged in meeting the needs of domestic market. It has its expectations and anxieties arising from the motivations to

internationalize and capability handicaps that delay the realization of motivations. How firms respond to them decides the trajectory of subsequent developments in internationalization. The paper draws insights from in depth studies of six pharmaceutical companies and a quick study of the seventh one. It identifies the motives of the firms, barriers for entry and entry facilitators during early phase internationalization. It also identifies the sequence in which the international markets were approached and products offered. It analyses the key capabilities required and developed during this phase. Based on the insights it outlines the scope for further research in capability building for internationalization of emerging economy firms.

2. Insights from Literature

2.1 Stages in Internationalization

Crick (1995), Johanson and Vahlne (1977); Johanson and Wiedersheim-Paul (1975); Anderson (1993); Bilkey and Tesar (1977); Leonidou and Katsikeas (1996); Root, (1987) conceptualized the stage theory of internationalisation. According to them internationalization takes place in stages i.e. firms start with exports as an entry strategy and move to 100% subsidiary abroad. The intermediate stages are licensing and joint venture. The firms are identified as non-exporters, export intenders, sporadic exporters and regular exporters. Other researchers (Sullivan and Bauerschmidt, 1990; Welch and Loustarinen, 1988; Barney, 1991; Oviatt and Mc Dougall (1994) have argued that firms need not follow the stages to internationalize their business They could emerge as a global firm from day one. Knowledge for initiating exports and top management commitment, (Palumbo, 1996), superior products, service quality and technology (Westhead, Wright and Ucbasaran 2004)) are identified as the facilitators of internationalization. It has also been found that entrepreneurial management, flexibility and responsiveness to change and proclivities towards technological and financial innovations enable firms to overcome resource barriers in the early stage of internationalization (Karagozoglu and Lindell, 1998). The progress of internationalization is affected by factors like organization's capacity in terms of people, structure, finance, firm specific intangible assets, technological level of the firm, size of the firm, the age of CEO (Chief Executive Officer), and planning and the perceived dynamism in the firm's environment (Anderson, Gabrielsson and Wictor 2004). Researchers have studied dimensions of early phase of internationalization in isolation along dimensions like

markets entered, products offered, market entry strategy and motives of internationalization. The factors identified for selection and developments of markets in early phase have been psychic and geographical distance from home market, culture, local skills, social and political stability, host government policy and previous experience with the country (Child, Sek and Christine 2002). It is contended that firms offer products similar to the products offered in local markets and use exports as market entry strategy (Chetty, 1999). Motives have been to follow their clients who spread activities internationally, expansion of their own activities (Post, Widerom and Douma, 1998; Sluyterman, 1998) and responding to opportunities in international markets (Karagozoglu and Lindell, 1998).

2.2 Internationalization of firms from Emerging markets:

Emerging markets are countries experiencing rapid economic development, with their economic institutions also undergoing rapid adaptation to free market ideologies (Arnold and Quelch, 1998; Hoskisson et al., 2000). A decade before, these markets were, in most instances, characterized by a lack of international competition and a domination of state-owned firms in the economy. The customers had limited choices, and competition was generally low in most product segments (Aulakh et al., 2000). Within a decade these markets underwent a radical change, with increasing globalization and openness to international competition: Foreign competition and newer opportunities brought by globalization have led many firms in emerging markets to seek internationalization. The changes made some firms more ambitious than others. They sought to harness growth opportunities abroad.

Despite their motivation to seek international markets, firms from these markets face several constraints in pursuit of their international expansion strategy. First, since they were located in environments that had previously offered institutional protection from foreign competition to local firms, emerging market firms have developed products and services independently of international markets, making the transition process very difficult (Eriksson et al., 1997). Second, unlike established multinational firms (MNCs), the competitive advantages of these firms are based on price competition rather than on leading edge technology or product differentiation (Kumar and McLeod, 1981; Lall, 1983; Wells, 1983). Therefore, while these firms possess some resources, they are not of the kind that would lead to monopolistic advantages in international markets. Third, since

these firms' focus was on low-cost products, they operated as suppliers to other manufacturers or depended on third-party distributors to distribute their products. As a result, they lack requisite international experience compared with established firms in developed countries (Vernon-Wortzel and Wortzel, 1988; Brouthers et al., 2005). Finally these firms are relatively small in size compared with developed country rivals, and are usually handicapped by limited organizational resources. In addition to these handicaps, they also face the costs and perils of international operations due to liabilities of foreignness (Zaheer, 1995). Therefore there is a need for these firms to learn and develop the capabilities to operate abroad (Barkema and Vermeulen, 1998). Questions to be answered are what are the capabilities required for internationalization of firms from emerging market to overcome the barriers mentioned above and how do they develop these capabilities? The preparation to respond happens in the early phase of internationalization. The next section presents the profile of the firms being studied by us to respond to the questions relating to motivation, entry sequence, capability handicaps and strategies for overcoming the handicaps.

3. Firm Profiles

Out of the seven firms studied, two firms, SLC and CRM, were later internationalizers and the rest were early internationalizers in the pharmaceutical industry. The later internationalisers embarked on their internationalization almost immediately after they were set up in the post liberalization era. The others focused on domestic market for an extended period. The internationalizing experiences of these firms were profiled through interaction with their top and senior executives of the company. Special focus was on interacting with executives associated with the early phase of internationalization. Data was collected during February to August 2006. Additional data on the firms was gathered from websites, promotional brochures, news letters, business reports, news articles and balance sheets of the selected companies. The qualitative data was classified and tabulated for analysis. The variables studied were motives of the firms, barriers for entry, facilitators, timings of entry, sequence of markets entered, products offered and market entry strategy in early phase of internationalization. Capabilities required and developed during the early phase of internationalization were also identified. Pattern matching analysis helped in identifying aspects of similarities and differences. A grouping of the firms is given in table 1.

Table 1 Grouping of Sample Firms

Firms	Motivation	Outcome
XBR, PTR	Were well established in local market, moved aggressively, explored international markets on their own	Highly successful internationalization having presence in all market segments
SLC	Both the firms were established after 1990s. One of the firm i.e. SLC had previous experience therefore was aggressive and moved faster than the other one i.e. CRM which had cautious approach. SLC ventured on its own while CRM recruited an experienced hand	SLC moved faster as the promoters had previous internationalization experience
CRM		CRM adopted an incremental approach, as it was new to pharmaceutical business
LDC, PEL	Mainly focused on domestic market. Low level of aggressiveness and used experienced hands	Moderate level of success as partial interest in internationalization, well established in local market
LSA	Diversified firm, high level of intentionality but lacked planning. Used consultants to gain insights	Repeated failures but had high intentions, got success at the end

Firms with high level of intentionality are XBR, PTR, SLC and CRM. They are either highly successful or growing and successful firms. Firms XBR and PTR got early mover advantage but at the same time they had to overcome barrier by venturing on their own through trial and error. SLC's management had previous exposure to internationalization through their association with earlier firm. CRM could get experienced hands from the market. LSA also had high level of intentions but they lacked planning for internationalization therefore it failed repeatedly. It also had cushion in terms of major revenues from other product line. Pharmaceutical constituted negligible proportion (less than 0.5%) of their sales. Other firms LDC and PEL had domestic business as their main focus. They also had low level of intentionality which restricted them to be aggressive for internationalization. Therefore they could achieve moderate level of success.

The firms studied reflect diversity in terms of age, gap between the year of incorporation and initiation of export, first market for entry and infrastructure facilities to cater to international markets. The oldest firm was established in 1946. It was also the last to start exporting. The youngest firm set up in 1998, ventured out in the first year itself. The markets entered and sequence of entry has been different for different firms. The product facilitating entry in the initial phase has varied. The firms set up before 1990 had to build new facilities/up grade facilities to meet the regulatory requirements. The firms set up after 1990 built facilities as per international regulatory requirements to serve

international markets. Geographically, there is a concentration in the western part of the country. We have one company in the Northern part and one in the South, Rest of them is in the western part of the country. Table 2 (a) shows the initial status. The size of firms in terms of turnover in 2006 ranged from Indian Rs. 70 crores to Rs. 3714 crores and their exports turnover ranged from Rs 20 crores to Rs 2755 crores. Present status of the firms with respect to physical infrastructure, products offered and number of market entered also varies. Table 2 (b) gives the details of their status as of 2006. By 2006 they are capable and well established pharmaceutical exporters. They have international standard manufacturing facilities with presence in multiple countries and therapeutics.

In the next section we will present an analysis of the motives of internationalization, entry into various international markets and entry strategies, products offered timings of entry, sequence of market entered, handicaps faced by the firms and response of sample firms in various markets. We will also discuss the capabilities identified in the early phase and the process of building these capabilities.

Table 2 (a) Firm Profiles: Initial Status

Firms & Location	Year of establishment	Year of internationalizing	Products offered for exports in the initial years	Sequence of markets entered	Facilities / Infrastructure
LSA, South India	1946	1997	Aspirin	Targeted US market but first order executed for South East Asia (Bangladesh)	Upgraded plant matching international standards
XBR, North India	1961	1977	Anti-infective Segment	Africa	Manufacturing units complying local regulations for API and formulations
PTR, Western India	1972	1983	Veterinary products	Russia	Plant complying local requirements to manufacture API and formulations for domestic market
PEL, Western India	1982	1991	DENOL (Colloidal Bismuth Subcitrate)	Russia	API and formulation plant for local market
LDC, Western India	1991	1991	Broad product base (multiple therapeutic segments)	Africa	Plant (API and formulations) matching Indian standards
SLC, Western India	1994	2001	Multiple Products (Large volume and small volume parenterals)	Africa	Plant matching requirements of international regulatory authorities
CRM, western India	1998	1998	Large volume parenterals	Africa	WHO-cGMP Plant

Table 2 (b) Firm Profiles: Status as of 2006

Firms	Exports of 2006 (Rupees)	Turnover in 2006 (Indian Rupees)	Facilities / Physical infrastructure	Presence in international markets	Products offered
LSA	2.58 crores	559 crores	International standard plant	Presence in few countries	Diversified company, products offered are sugar and aspirin
XBR	2755.86 Crores	3714 crores	Manufacturing facilities matching international standards at multiple locations and state of the art R & D centers	Ground presence in 49 countries and products sold in 125 countries	Formulations and API, presence in multiple therapeutic segments
PTR	138 crores	744 crores	Plant meeting WHO-cGMP requirements / State of the art R and D centre	Products registered in about 50 countries	Formulations and API, presence in multiple therapeutic segments
PEL	7.73 crores	383 crores	Production unit complying with international standards	Products sold in African and Asian countries	Formulations and API, multiple products
LDC	About 200 crores	About 500 crores	World class manufacturing for formulations and API, CRO (Clinical Research Organization) for clinical trials	Ground presence in 4 countries and sales in 46 countries	Formulations and API, wide product base
SLC	About 120 crores	284 crores	Manufacturing facilities approved by various international regulatory authorities	Selling products in about 76 countries	Intravenous fluids and injectables
CRM	About 20 crores	About 70 crores	WHO-cGMP certified plant matching USFDA requirements	Selling mainly into third world countries i.e. Africa and South East Asia	Intravenous fluids and injectables (Large volume and small volume parenterals, respiratory, ophthalmic and antibiotic therapeutic segments)

4. Motives and Opportunities for Internationalization

The motives for internationalization have varied from firm to firm. However, the most mentioned motive for internationalization has been to harness the opportunity to grow and realize higher margins in exports. The other motives have been survival in the new era of globalization, following the success of other Indian pharmaceutical firms in international markets and taking advantage of benefits given to exporters by the Government of India. The opportunities were created by bilateral agreement with Russia, enquiries for contract manufacturing by overseas buyer, opening of markets for generics in developed economies. The firms which were established before 1990's i.e. XBR, PTR, PEL, LSA looked at international markets to expand their operations as opportunities were available to export at competitive prices and obtain higher earnings from exports. These firms were operating in domestic market and when they saw opportunities for growth and higher margins they ventured out. While the firms set up after 1990's i.e. LDC, SLC and CRM were established for international operations since beginning. Out of these three firms, two of the firm's i.e. SLC and LDC top management had previous exposure of internationalization in the form of their association with the earlier firm. Consultant associated with LSA revealed that "the firm got tempted to enter international market seeing success of some of the Indian companies in international markets". XBR looked at international markets as opportunities to expand up to the year 1990s and grow with higher margins in international market. The CEO of XBR in early 1990s opined that "in the new era of globalization and product patent to be a significant player in the Indian market, firm must aspire to be a global player". PTR's executive was of the view that "the opportunities for internationalization of the industry arose in the early 1980s were from bilateral agreement with Russia". The CMD of CRM shared that he was motivated to set up the pharmaceutical unit for exports because he observed that full plane loads for pharmaceutical products were exported to Russia. Incentives offered by government of India during those days and margins in pharmaceutical exports also motivated him to set up export oriented unit. A detailing of motivations and opportunities is in Table 3.

Table 3 Motivations and Opportunities of the Sample Firms

Firm	Year of establishment	Year of start of exports / internationalizing	Motives of Internationalization
LSA	1946	1996	Inspiration from success of Indian firms in international market
XBR	1961	1977	Conviction of top management that to survive in new era of globalization firms will have to expand globally
PTR	1972	1983	Opportunities because of bilateral agreement with Russia for growth by expanding business in new territory, higher margins in international markets
PEL	1982	1991	First phase i.e. in the year 1991 and reason for internationalization was opportunity because of contact with buyer and better margins, second phase i.e. early 2000 saw success of other Indian firms in international market motivated firm to prepare themselves for exports
LDC	1991	1991	Growth and margins / had internationalization experience in the form of association with earlier firm
SLC	1994	2001	Opportunities for growth and margins / had previous exposure of internationalization / started afresh by setting new firm i.e. SLC
CRM	1998	1998	Growth and margins / motivation from quantity of export orders executed for Russian market by other Indian pharmaceutical firms / benefits to exporters

5. The Forays

5.1 Into Markets

5.1.1 The Russian Market:

The then USSR provided the first opportunity to internationalize the Indian pharmaceutical companies. The bilateral agreement helped in the initial internationalization efforts. Under the Rupee-Rouble trade, pharmaceutical products, among other items, were exchanged between India and Russia. It softened the regulatory requirements that were critical to enter any international pharmaceutical markets. Both

PTR and XBR were the beneficiaries of this. The executives of PTR that entered Russia in 1983 explained the mode of entry as follows.

In the Russian market purchasing of pharmaceutical was through centralized government purchases. The orders were awarded through tenders and it was more like public relations activity with the Ministry of Health (MOH) officials of Russia.

This view was supported by the executive of XBR. PEL entered the Russian market because of contact of CMD of the firm in 1991. It received an order that took about two years to execute. It also was the supply to MOH. The firm got repeat orders but firm did not accept it as in 1993 the market was facing turmoil.

5.1.2 The African and Asian Markets

All the firms studied have internationalizing initiatives in African and or South East Asian markets. They entered these markets during the late 1980s and early 1990s. According to the respondents the entry was facilitated “since regulatory requirements of these were matching with the requirements of Indian regulatory authorities it was not very difficult to enter these markets”. They also concurred that the diseases were more or less like Indian diseases and therefore products offered in domestic market had the potential in Africa and Asia. Six of them entered the markets through the exports route while one preferred the joint ventures and partnership route. XBR executives revealed that it had partnership arrangement in most of the market and were selling through prescription route that helped them to get higher margins. They pointed out, however, that the marketing and administrative expenses involved in the ventures were also high. Table 4 provides the details of the foray into Africa.

Table 4 Entry into African / Asian Market

Firms	Year of Entry	Markets Entered	Market entry strategy
XBR	1977, late 1980s and early 1990s	Nigeria in 1977, multiple markets of Africa and Asia	Joint Venture in Nigeria / partnership arrangement in African and Asian markets
SLC	2001	Multiple Markets of Africa	Exports
CRM	1998	Started with Uganda and later targeted multiple markets	Exports
PTR	Late 1980s and Early 1990s	Multiple markets of Africa and Asia	Exports
LDC	Early 1990s	Multiple markets of Africa and Asia	Exports
PEL	Late 1990s	Multiple markets of Africa and Asia	Exports
LSA	Early 2005	South Asia	Exports

5.1.3 The Latin American, Australian, New-Zealand and South African Markets

Firms clubbed Latin American market with Australia, New -Zealand and South Africa as in all these markets regulatory requirements were similar. They termed these markets as semi-regulated, as the regulatory requirements in these markets were not as liberal as in Africa or Asia and not as stringent as in North America. Among the seven firms studied only three firms i.e. XBR, PTR and SLC entered semi-regulated markets. They entered the market through a marketing subsidiary or acquisition. All of them entered in 2000 or later. Table 4 provides the details. The reason cited by executives of the firms for such market entry strategy was that “these markets had very high potential and offered good margin for ethical generic company. To effectively sell in these markets firm should have a ground presence”. The discussion with executives also revealed that they targeted Brazil as it offered good potential for generics. We may thus note that the companies under study were motivated to earn more and exploited the opportunity provided by regulation facilitated markets through the export route. The next move to semi-regulated market was by a select few who saw further opportunities in semi-regulated markets. These markets offered volume and higher margins. Table 5 provides the entry details.

Table 5 Entry into Latin American / Australia / New-Zealand / South African Markets

Firms	Year of Entry	Markets Entered	Entry Strategy
XBR	2000	Brazil	Marketing subsidiary
	2006	Italy and Spain	Acquisition
PTR	2003	Brazil	Marketing subsidiary
SLC	2003	Brazil	Marketing subsidiary

5.1.4 Entry into USA and European Markets

Only two companies out of the seven studied forayed into USA and Europe. They saw them as highly regulated markets as regulatory requirements were stringent and very difficult. It required longer lead time for planning and preparation. Market entry strategy adopted by the firms was acquisition, marketing subsidiary or joint venture partnership. The firms needed a long term internationalization strategy to be in these markets. The executive of the XBR viewed that “Indian firms first entered into partnership agreement and later preferred to have wholly owned marketing subsidiary after getting exposure to the market”. XBR started targeting USA since 1988 as their plant got USFDA approval in 1988. It acquired a company in USA in 1995. It could start ethical marketing only in 1998. It also fought and won several law suits. PTR set up a subsidiary in USA in 2006 and got approval from USFAD for one of their plants.

The foray into Europe was through the acquisition route for XBR. The executives mentioned that the German and French markets were in mature stage for generics and therefore it opted for acquisition route to enter the market faster. PTR also used the acquisition route to have faster entry into the German market. 2003 to 2006 was an active phase of internationalisation for PTR. XBR has been following a consistent well chalked out strategy of internationalisation. The entry of sample firms into regulated markets indicates a stronger resolve to internationalise and possession of a broader base of resources. Table 6 provides the details.

Table 6 Entry into USA / Europe

Firms	Year of entry	Entry strategy
XBR	1995 (USA)	Acquisition
	2000 (Germany)	Acquisition
	2004 (France)	Acquisition
	2004 (North and central Europe)	Joint Venture / partnership
PTR	2004 (Germany)	Acquisition
	2006 (USA)	Marketing Subsidiary

5.1.5 The Japanese Market

The Japanese market began opening in 2005. The route choice of each firm differed, though it was subject to similar environmental opportunities and threats. Three companies from our sample were successful in foraying into this market. Two companies were from the Western part of the country and one was from North. On the difficulty in entering this market, the executive from LDC remarked, “Guidelines to enter Japanese market were not available till 2005. It was a closed and non-transparent market. It has started opening up since 2005”. LDC chose exports; XBR chose joint venture while PTR opted for setting up a marketing subsidiary. Table 7 provides the details.

Table 7 Entry into Japan

Firms	Year of entry	Entry strategy
XBR	2005	Joint Venture
LDC	2005	Exports
PTR	2006	Subsidiary

It may be observed from the experience presented above that the internationalization phase of Indian Pharmaceutical companies started with less regulated markets like Africa, South East Asia in late 80’s and early 90’s because of increasing opportunities and the necessary competitive advantage and matching guidelines that of India. During late 90’s the firms started looking at Latin America, Australia and New Zealand and South African markets owing to experiential learning from Africa and Asia Pacific markets, competitiveness and globalization. The next target markets for Indian firms were USA and Europe. Indian pharmaceutical companies started targeting Japanese market from the year 2005 as the regulatory authorities of Japan become open to foreign companies and relaxed the regulatory requirement. Table 8 provides the summarized sequence of markets entered for internationalisation.

Table 8 Sequence of International Markets Entered

Firms	Sequence of markets entered
LSA	Targeted US market but first order executed for South East Asia (Bangladesh)
XBR	Africa-Asia-USA –Europe and Latin America-Japan
PTR	Russia- Africa-Asia-Brazil-Germany-USA-Japan
PEL	Russia-Africa and Asia
LDC	Africa-Asia-Japan
SLC	Africa-Asia-Brazil-South Africa
CRM	Africa-Asia

The Indian companies entered international markets in the sequence i.e. Russia- Africa- Asia-Pacific- Latin-America, Australia, New-Zealand and South Africa –USA and Europe –Japan. The regulatory requirements also increase in the same order sequentially. The requirements in African markets and some of the South East Asian markets were matching the requirements of Indian authorities therefore it was not much difficult to enter these markets. The early phase internationalization started with Russian, African and some of the Asia-pacific markets. Later during late 90's the firms started looking at Latin America, Australia and New Zealand and South African markets. In early 2000 most of the firms started preparing to enter USA and European markets. XBR targeted USA market as they found that to grow faster it is important to target one of the biggest markets of the world, while firm PTR targeted Latin American market i.e. Brazil as they found that it easier in terms of regulatory requirements to enter Brazil compare to USA. Firm XBR instead of moving from less regulated to highly regulated market, moved straight to highly regulated market USA and then entered Brazil i.e. semi-regulated market. XBR had a clearer internationalizing strategy. It had articulated its motivation as being a part of the global industry and the top management of the company was committed to it. Others reacted to an opportunity provided by the market or followed the success of players in the industry. Once in, they moved on to act with a strategy. The firms established before 1990 started targeting international markets in early 1990s. The firms which were established after 1990's i.e. SLC and CRM looked at various markets simultaneously as they were set up to cater to international markets with all required resources in terms of physical infrastructure to cater to various international markets. They leveraged on the experience of the industry and set up their practices as per the international regulatory requirements.

5.2 Products for the markets

While the sample firms attacked similar markets, did they offer the same product? Did they focus on the same therapeutic area? Did they offer whatever they were making in the domestic market? The discussion with executives of the firms reveals that most of them started with their existing product portfolio to enter international markets. Since the local market was very big for Indian pharmaceutical firms for almost all types of products,

firms were not required to develop specialized products to enter international markets. Once the firm got a foothold in the specific foreign market, it started developing products specifically for foreign markets. Most of the firms developed products going off patent in foreign markets. PEL and PTR developed products specifically to sell in Russia. Veterinary products were not the main line of business for PTR; however, it developed the product to serve international markets. In Africa and South East Asia, it extended its range of cardiovascular, neurological and respiratory therapeutic segment related products. Later it also started developing off patent products. Similarly, PEL also developed the product DENOL especially for Russian market. It was not very difficult to get product quality approval as the Government of India had bilateral agreement with Russian government. PEL's next strategy was to enter into a licensing agreement to manufacture and sell the products of licensee in domestic and some of the foreign markets. They have entered into number of licensing agreements to manufacture and sell products with innovators. The CMD of the firm is of the view that "it is not possible to match the quality of innovator's product. They followed a philosophy to never violate the product patent; therefore they entered into licensing agreement".

LDC and CRM developed products for contract manufacturing with foreign buyers and buyers in India for export markets respectively. LDC's experience can be captured as follows:

It entered into an agreement which included product development and sales in foreign market with the contract manufacturer. The development expenses were to be borne by the foreign party which wanted LDC to develop the product. The foreign player also agreed to purchase the product from LDC up to certain time period and of certain quantity.

The executive of LDC viewed that this was a risk free model to enter international markets. Since Indian firms had competitive advantage in terms of product development and manufacturing cost such opportunities were available in international markets. To identify such buyers, the firm looked at large distributors of generic products in the foreign markets. The firm identified such distributor by attending conferences and by

referring directories. CRM started with Large Volume Parenterals (LVP), a simple and common product with potential in domestic as well as international markets. CRM learnt the requirements of international market from other Indian firms that entered into contract manufacturing agreements. Once in the market, the Indian pharmaceutical firms that were into exports of formulations got enquiries for injectables. Such firms passed on the enquiry to CRM. Later on it ventured into specialized products i.e. ophthalmic and respiratory range of Small Volume Parenterals (SVP). The executives of XBR and SLC viewed that “since new product development is costly and time consuming most of the Indian firms identify products going off patent in near future and start developing it so that on day one of product becoming generic the company can launch it in the international markets”. SLC started with a range of products which could be offered in both the markets as its promoters and employees had previous experience in internationalization. To LSA, a diversified company, it was a question of selling its products manufactured from raw material of a by product profitably. They were selling this product in the domestic market. They needed to develop a specific grade of this product to sell in international markets. After trial and error they succeeded in developing the desired product and export. Table 9 provides the details of the products offered by the sample firms in different markets. We may note the wide range of therapeutic segments targeted by the companies. The target therapeutic segment differs from country to country and firm to firm. The range is the widest for Brazil. Thus we may see that as an industry, the Indian pharmaceutical industry has a much diversified market, product and therapeutic scope. What were the capability handicaps and the responses of the firms that enabled them to reach the current state of progress? The next section provides the answers.

Table 9 Products Offered in the Early Phase of Internationalization:

Firms	Markets	Products offered
LSA	Targeted US market but first order executed for South East Asia (Bangladesh)	Analgesic therapeutic segment(Aspirin)
	USA	Analgesic therapeutic segment (Aspirin)
XBR	Africa	Anti-infective, Anti-viral segment
	Asia	Anti-infective, Anti-inflammatory and Anti-viral segment
	USA and Europe	Anti-infective, Anti-viral, Anti-inflammatory, Cardiovascular, Anti-diabetic segment
	Latin America	As Above
	Japan	As Above
PTR	Russia	Veterinary products
	Africa	Ant-infective and Anti-inflammatory segment
	Asia	Central Nervous System (CNS), cardiovascular, anti-infective, anti-diabetic, Rejuvenator etc.
	Brazil	As above
	Germany and USA	As above
	Japan	-
PEL	Russia	DENOL (Anti-Ulcer / Anti-bacterial)
	Africa	Anti- infective, Multi Vitamin, Dietary supplement, consumer and cosmetics
	Asia	As above
LDC	Africa	Anti-infective, Anti-diabetic, Anti-inflammatory, Cardiovascular
	Asia	As above
	Japan	Bulk Drugs (Anti-infective)
SLC	Africa	Large volume common solutions, electrolytes, Antibacterial,
	Asia	Large volume common solutions, electrolytes, Antibacterial, Anesthesia, blood products, plasma volume expanders and Diuretics
	Brazil	Large volume common solutions, electrolytes, Antibacterial, Anesthesia, blood products, plasma volume expanders, Enteral and Parenteral Nutrition, Renal & Transplant, Oncology, Infusion Therapy and Diuretics etc.
	South Africa	As above
CRM	Africa	Large volume parenterals, Electrolytes and common solutions / Anti bacterial)
	Asia	Large volume parenterals (Electrolytes) as well as Small volume parenterals (ophthalmic and respiratory range)

6. The Capability Handicaps and Responses

6.1 The capability Gaps

In realizing their motivation and entering multiple markets with multiple target therapeutic segments and products, the sample firms faced multiple handicaps relating to regulation, quality, logistics and talents. Responding to handicaps in one did not resolve the handicaps in another automatically. The firms had to pay deliberate attention to each market requirement and respond accordingly. As a consequence, each market entry built its own portfolio of capabilities.

The handicaps were capabilities to understand and respond to the requirements of World Health Organization-current Good Manufacturing Practices (WHO-cGMP), USFDA, international manufacturing practices, quality assurance and quality control, product registration, market seeding and development, logistics for international market, sourcing, legal knowledge of intellectual property (IP) rights, and the country conditions. Entry to the Russian market was facilitated by the bilateral agreement, but the firms had to develop capabilities in tendering and winning the tenders on competitive pricing.

6. 2 Firm Responses

6.2.1 Responding to Regulatory Requirements

The early internationalisers in the pharmaceutical industry had to first build the knowledge of the regulatory requirements of various markets and then devise ways of responding to them. They had the option of in-house initiation through trial and error or of hiring an experienced executive and empowering him to develop the capabilities either through new hire or through internal training. The later internationalisers could leverage on the experience of the industry and develop their capabilities. The regulatory requirements of various countries were in the public domain and could be obtained from regulatory authorities of respective countries. The firms needed the help of technical and legal experts to comprehend the nuances of the regulations. XBR and PTR which ventured into international markets early could not get experienced professionals. Therefore, they developed this capability in-house with the help of agent / distributor in

foreign markets and developing rapport with officials of regulatory authorities. Based on dossiers submitted to regulatory authorities, authorities gave their comments / raised queries. These queries were replied by taking the help from officials of authorities and local partner. In case of plant approval, authorities visited the plant and guided the firm executives to take appropriate actions for meeting the requirements. Other firms (LDC, PEL, CRM, LSA) recruited experienced hands as they could get them from Indian companies which started early and developed in-house capability. Later PTR hired an international consultant to enter the Latin American market. XBR continued to learn through trial and error by giving freedom to its employees to learn and implement decisions. It hired international legal experts and developed a full fledged IP cell in the company with employees having legal and domain knowledge. Firms organized in-house training programmes to develop regulatory competency among other employees. The employees were deputed to attend seminars / workshops / conferences so that they could update themselves about changes in regulatory requirements.

XBR and PTR were helped by the bilateral agreement in entering Russia. The already developed manufacturing capabilities in the domestic sector were leveraged to respond to the requirements of the first order. They used this exposure to make further entry into other international market. PEL also benefited from the Russian regime, but they incurred heavy losses from exports to Russia as USSR got disintegrated at the time of their entry. The company then became conservative and focused on domestic markets. It then became aggressive only during early 2000. The later internationalisers CRM and SLC were able to leverage on the Indian exporting experience, hired experienced professionals from India to meet the regulatory requirements. CRM recruited second –in-command experienced person from already internationalized firms and made him in-charge of the internationalization initiatives. Therefore they could start as day one internationalizers. The promoters of SLC had earlier promoted another pharmaceutical company that had exported significantly. They were familiar with the regulations and characteristics of various markets. Table 10 provides the details of the handicaps faced by the sample firms in various markets and their responses. Table 11 provides the details of firm wise responses.

Table 10 Handicaps and Responses in Various Markets

Market	Handicaps	Responses
Russia	Internationalization exposure	Environmental support in the form of Bi-lateral agreement with Russian government helped firms to internationalize
Africa and South East Asia	WHO-cGMP plant	Firms up graded / set up WHO-cGMP plant
Latin America /	Knowledge of internationalization	Firm PTR hired international consultant / firm XBR and SLC learned on their own through trial and error
USA and Europe	USFDA / IP knowledge / Internationalization knowledge	Up graded plant to USFDA requirements / hired international consultants for IP and developed IP cell in the firm
Japan	Non availability of guidelines	Japanese government opened up the market

Table 11 Firm wise Handicaps and Responses

Firm	Handicaps	Response
LSA	-Knowledge of internationalization	-Hired person having experience of international markets
XBR	-Knowledge related to internationalization -knowledge of Intellectual Property Rights (IPR)	-Gave freedom to their employees to learn through trial and error -Hired international lawyers / set up IP cell in the company with employees having legal and domain knowledge
PTR	-Knowledge of internationalization -infrastructure Facilities	-Hired international consultants / developed employees to learn through trial and error -Up graded existing plant / allocated separate plant for exports
PEL	-Knowledge of internationalization	-Hired persons having experience of international markets
LDC	-Knowledge of internationalization -WHO-cGMP / USFDA plant facilities	-Hired experienced persons -Up graded plant facilities to meet WHO-cGMP requirements / Set up new plants meeting USFDA requirements
SLC	-Image of an Indian company in terms of quality supplier -knowledge of internationalization	-Invited officials of regulatory authorities to visit the plant and entered into technical dialogues with them -Top management of the firm had experience of internationalization through their association with earlier firm
CRM	-Knowledge of internationalization -WHO-cGMP plant facilities	-Hired person with experience of internationalization in various functional areas -Set up WHO-cGMP plant

6.2.2 Plant Up gradations

The firms up graded or set up new plant facilities to respond to the requirements of WHO-cGMP / USFDA. They invited officials and consultants to visit the plants prior to the final inspection. They learnt from the inspection reports that provided guidelines for improvement and removing the credibility gaps. An SLC executive opined, “If officials of regulatory authorities are invited to visit the plant before plant approval application is submitted, it would help in removing the bugs earlier. He also opined that entering into technical discussion with the officials of regulatory authority helped firms to build credibility”. Executive of CRM is of the view that “relationship with the regulatory authorities helps in getting faster responses for queries and right guidance to comply with the queries”. The relationship was developed by inviting them to visit manufacturing plant and by responding to queries faster.

6.2.3 Developing Complementing Functional Capabilities

Firms which started early i.e. XBR and PTR offered entrepreneurial culture to employees for developing specialized capabilities for various functional areas. Others offered higher remuneration to attract and retain experienced manpower for internationalization. LDC organized training programs throughout the year for employees involved in international market operations. To manage quality assurance and control, the firms developed standard operating procedures for each and every activity starting from purchase of inputs to delivery of products to customer. Training programs were organized to help the employees to understand the procedures and responding to the instructions consistently. The executive of LDC mentioned, “For international markets quality is critical, therefore we organize training programs related to quality for all the employees across organization”. The Executive of CRM informed, “To update its knowledge we subscribe to various journals wherein some of the articles give hint about future changes. Based on the hints we start preparing for such changes and appraise all the concerned employees through in-house training programs”.

Production capability of the firms is related to setting up WHO-cGMP / USFDA compliant plants, capability to manufacture multiple products for multiple markets with

varying specifications. Since Indian firms were producing products for the local market, the capability was well developed to manufacture multiple products. Production planning was managed by clubbing small orders from different buyers based in various foreign markets. Firms like LDC, XBR, PTR, and PEL have set up supply chain management departments to manage this function. XBR and LDC used enterprise resource planning software i.e. SAP for production planning. Over a period of time all the firms had internal audit teams for QA and QC auditing. Non compliances reported by the audit teams are addressed suitably. In responding to the functional capability requirements the firms benefited from the overall manufacturing culture in the country, the network of publicly funded research and development laboratories and an extensive network of educational institutions imparting higher education in engineering and sciences.

Procurement was another area needing attention. The Firms were able to develop this over a period of time through experience. The sources of suppliers were identified with the help of databases (directories) of suppliers, internet, references / leads from existing suppliers, participating in trade fairs / seminars / conferences etc.

Table 12 shows types of capabilities required and the processes adopted by the firms to develop the capabilities.

Table 12 Types of Capabilities Required / Developed and Outcome of Capability

Type of Capability	Elaboration of the capability	Processes followed by firms to build capability
International Market Development Capability	<ul style="list-style-type: none"> -Identifying and selecting markets, products, distributors/agents, entry strategy for international market development -Product launch and promotion in international markets -Getting orders and delivering the products in time 	<ul style="list-style-type: none"> -Recruited experience employees -Developed own employees capabilities by trial and error -Hired consultants

Regulatory Capability	<ul style="list-style-type: none"> -Understanding regulatory requirements related to plant approval and product registration -Getting plant approval from various regulatory authorities i.e. MOH of respective country's Government -Getting product registration from MOH of various countries which are targeted by the company 	<ul style="list-style-type: none"> -Through experienced hands and consultants -Employees learnt through trial and error -Sought guidance from regulatory authorities and foreign partner i.e. agent -Training to employees by sending them to attend seminars, conferences, training programmes -In-house training programmes
QA / QC Capability	<ul style="list-style-type: none"> -Knowing pharmacopeia requirements, customer requirements and setting company's own standards -Complying with QA / QC requirements of regulatory authorities -Help in R and D and preparation of dossiers for plant approvals and product registration -Quality control and offering consistent quality 	<ul style="list-style-type: none"> -Experienced persons, fresher can also understand pharmacopeias and other related requirements -develop Standard Operating Procedures (SOP's) -Training to all across organization for quality requirements of international markets -Internal auditing -Subscribing related journals to update the changing requirements
Purchase and Procurement Capability	<ul style="list-style-type: none"> -Sourcing machinery, equipment , raw material and packaging material at most competitive prices and complying the requirements of international markets -Timely delivery and consistent quality of input materials 	<ul style="list-style-type: none"> -Database of suppliers / internet / lead from existing suppliers -Sending executives to attend trade fairs / seminars / conferences -On the job training to employees for negotiation
HRM Capability	<ul style="list-style-type: none"> -Ability of firm to recruit, motivate, train and retain qualified and experienced manpower -Ability to update the manpower for changing requirements -As all functional area (regulatory, QA and QC, market development, production and production planning, purchasing and procurement, R and D, finance) needs manpower who can understand requirements of international markets 	<ul style="list-style-type: none"> -Opportunities to make career in international business function to freshers -Freedom for decision making / entrepreneurial culture -Deputing employees for training / seminars / conferences -Attracting potential employees by offering higher pay

Production and Production Planning Capability	<ul style="list-style-type: none"> -Capability to manufacture multiple products for multiple markets with varying specifications -Production planning for small order quantity and complying with the GMP requirements of minimum batch size -Timely delivery of products to customers with lower inventory cost 	<ul style="list-style-type: none"> -WHO-cGMP / USFDA plant -Supply chain management department -Implementing ERP software
R and D Capability	<ul style="list-style-type: none"> -R and D capability for processes and QC -Capability for Generic product development, NDDS and NCEs -R and D for generating clinical trials and other data for dossier preparation 	<ul style="list-style-type: none"> -Recruiting talented scientist -Collaboration with university departments and other scientific laboratories -Setting up of CRO for clinical trials
Finance Capability	<ul style="list-style-type: none"> -Higher financial requirements for USFDA / WHO-cGMP plant -Finance capability for market development and product registration expenses 	<ul style="list-style-type: none"> -Internal funds -Term loans from banks -Firms uses capital budgeting and revenue budgeting

7. Implications for Further Research

In the above sections we presented the experiences of sample firms in committing themselves to internationalization of their pharmaceutical businesses and developing the needed capabilities through experts' help and own trials and errors. The firms moved from a less regulated setting to a more regulated setting. The capabilities built in one were not necessarily resolving the issues of the other. The firms needed to apply themselves afresh. What facilitated the march forward was the strengthening of the motive commitment to internationalize and the learning capability of the old and new employees. The firms also learnt from inspections by and interaction with regulatory authorities. We have built further to look at various capability gaps and processes by which the firms respond to these gaps. We have also looked at facilitators in terms of overall industry, country and international experience. The later internationalizers were able to leverage on all these while the early internationalisers had to depend on international expertise and non pharma country experience. They benefited from the country's infrastructure of labs and educational institutions. This aspect of the

environment in aiding capability building is an under explored area. There is scope for research in this direction.

Our study has examined the experiences of two types of internationalisers – early internationalisers and later internationalisers in the Indian pharmaceutical industry. The early internationalisers have followed stage theory while the others did not follow stage theory. The early internationalisers support Chang (1995), and Ahuja and Katila (2004) who have argued that internationalization capabilities could be built through sequential entry. The later internationalisers could attack multiple markets on the strength of their abilities to congregate capabilities from the industry and outside. Congregation demands negotiating and co-ordinating capabilities. This aspect of congregating capabilities for formulating and implementing strategies has not been discussed adequately in the literature. There is literature on organizational learning that focuses on firms attempt to cultivate capabilities within. There is scope for further work. An efficient and effective congregation increases the speed, scope and spread of a firm's activities.

Researches on internationalization have shown that the reasons for increase in international activities are global competition, reduction in trade barriers and improved communication and information network. This research identifies that since Indian pharmaceutical industry had competitive advantage in terms of cost and there were opportunities to sell in international markets, industry could internationalize its operations. The motives of Indian pharmaceutical firms in early phase for internationalization of business were growth, expansion of activities and higher earnings through export sales which confirms to the findings of earlier researchers. The early internationalizing firms which were set up before 1990s, had motive to expand their business through exports. Firms which were set up after 1990s were specifically set up to cater to international market as they had knowledge that Indian companies are successful in international markets, therefore they wanted to exploit the opportunities.

Researchers have identified lack of resources, skills and knowledge for initiating exports as barriers in early phase internationalization. Our research reconfirms this and shows

how firms can overcome these barriers. The responses depend on the motivations of the firm and its initial commitments.

The facilitators to overcome barriers identified by researchers are superior products and service quality, technical knowledge for initiating exports and top management commitment, bundling and leveraging resources of firms. Other ways, researches have shown are entrepreneurial management, flexibility, responsiveness to change and innovations. This research identifies the contribution of top management commitment, consultants and agents in foreign markets, experienced staff, and bilateral agreement with Russia as facilitators in early phase. The barriers were also overcome by encouraging own people to learn about market requirements. There is scope for integrating this further.

The criteria to select market in early phase of internationalization as identified by the researchers are psychic and geographical distance from home market, culture, local skills, social and political status of country, host government policies and previous experience with the country. This research identifies another dimension within host country government policies i.e. regulatory requirements of Ministry of Health (MOH) of host country. Acceptance of generics and Indian products in foreign market is also one of the criteria to select the market. Firms start with the markets in which regulatory requirements are more or less similar to Indian regulatory requirements, which firms can match easily. This is a unique dimension of internationalization in the emerging economies. We should also recognize that the early regulatory regime of the emerging countries build certain capabilities in the country and the companies participating in the economic activities of the country. The firms were able to leverage on them as they faced capability handicaps. This link between capabilities then, capabilities for internationalization now and those in future needs to be studied.

This research also confirms the findings of earlier researches related to selection of products in the early phase of internationalization wherein most of the firms select similar products as offered in domestic markets, basic and common products in terms of therapeutic segments and generic products for international markets. There is another

aspect of the research which is understudied. As an entry strategy itself some firms developed products that were not a part of the current portfolio in the domestic market. The attraction here was the margins that would be gained and the new experience that could be leveraged to sell the current products. As the firms gained experience, they dreamt of developing products for international markets in anticipation. This is another unique aspect of some firms in the emerging sector. They would like to associate themselves with products in demand in the developed economies to earn higher margins and develop cutting edge capabilities. This is another area worth researching.

We also highlighted the specialized nature of the capabilities of the sector. The nature is specialized because of knowledge intensive characteristics of industry. Most of the functional area capabilities require distinct knowledge bases. It is also found that few of the capabilities are interrelated and they are required to be developed simultaneously. Research required here is the attention to simultaneity. We need to confirm and consolidate our findings by conducting research for other sectors in the emerging markets.

8. Conclusion

In this paper we identified and analyzed the motivation, capability handicaps and responses of a sample of Indian Pharmaceutical firms in the early phase of internationalization. We argued that this phase marked several discontinuities for the firms engaged in meeting the needs of domestic market. The managerial anxieties in this context arise from the motivations to internationalize and capability handicaps that delay their realization. The challenges identified were meeting the regulatory requirements, gaining customer acceptance, enlisting support from domestic operations. The decisions to be made related to goals of internationalization, market to enter, mode of entry, acquisition and development of capabilities to respond to entry requirements. The stimuli for internationalization were identified as opportunities for higher margins, market diversification, and survival in view of global competition. The capability handicaps of the firms were regulatory compliance, international plant management practices, quality assurance and control, market development, and logistics management. The firms

responded to the handicaps by congregating capabilities from outside and cultivating some through trial and error. Top management commitment to the motivation to internationalise and employee empowerment played a key role in building the needed capabilities. It integrated the insights from in depth studies of internationalization experience of six pharmaceutical companies and one quick study. It identified the scope for further research in the area of capability building, especially for internationalization.

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