7. Entrepreneurship and the institutional context: dynamic of development of the locally owned generic pharmaceutical industry in Bangladesh

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INTRODUCTION

Conventional state-to-state international trade has lost much of its efficacy and importance in the new century to the point that states have been increasingly replaced by different types of firms. Such fundamental changes in the mode of economic relationships have been facilitated by an increasing trend of harmonization of economic protocols at the global level, which are being adopted and adapted rapidly at national levels as well. Nations, irrespective of being developed or developing, are creating interdependent trade relationships with multiple counterparts with different motives which include both resource seeking and market seeking (Dunning, 1993). Such efforts are initiated and carried by two actors – international entrepreneurs and international firms. Oviatt and McDougall (2005) describe international entrepreneurship as the discovery, enactment, evaluation and exploitation of opportunities across national borders that create future goods and services. The most visible embodiment of international entrepreneurship is the firms that are active in developing, mobilizing and exploiting resources of different types and origins in order to exploit specific opportunities across the borders. Dominant explanatory approaches relating to the internationalization of firms (for example the incremental approach and its extensions based on the work of Johanson and Vahlne, 1977; born global and international new ventures and their extensions based on the works of Cavusgil, 1994; Knight and Cavusgil 1996; Oviatt and McDougall, 1994) do not directly and completely answer the questions as to how international entrepreneurship develops in a certain region and why firms from certain regions

and industries come into the international market more prominently than others.

In international business in the last two decades, following in the footsteps of the 'Dragon' multinationals (Mathews, 2006), entrepreneurs and firms from the emerging market countries like India, China, Brazil, Turkey and Mexico have made powerful entry into both advanced and developing country markets. These new entrants are not necessarily only new start-ups. A significant number of domestic market successful firms changed their growth and strategic orientation and emerged as international firms. There are several examples of such firms from different countries in different industries. The Indian firm TATA in the automotive industry and Chinese firm Haier in the household electronics industry are two prominent examples in this regard. Neither the incremental nor the born global approach is powerful enough to explain why and how such domestically focused firms emerged as international firms. Bell et al. (2001) identified such firms as 'born again global' firms, but did not address the issues relating to their emergence. The conceptualization of international entrepreneurship (Oviatt and McDougall, 2005) provides a domain where both international start-ups and born again globals fit and which can be applied as the analytical framework for searching for the answers to the why and how questions mentioned before.

Shane and Venkataraman (2000) identify entrepreneurship as the act of discovery, evaluation and exploitation of future goods and services. International entrepreneurs identify and exploit opportunities at the cross-border level. Sahne and Venkataraman (ibid.) further explain entrepreneurial opportunities as situations in which new goods, services, raw materials, markets and organizing methods can be introduced through the formation of new means, ends or means–ends relationship. Sarason et al. (2006), being founded on the structuration theory (Giddens, 1991), describe sources of entrepreneurial opportunities as being extant features which provide the context for the creation of entrepreneurial ventures. Sarason et al. (2006) note social structures and institutions as extant features which both constrain and enable entrepreneurs in the processes of the discovery, evaluation and exploitation of opportunities. The entrepreneur acts as a reflexive agent in this process. This mechanism of entrepreneurial opportunity identification and exploitation also fits the postulation of international entrepreneurship. McDougall and Oviatt (2000) explain the domain of international entrepreneurship by including the extent of entrepreneurial behaviour and action involving multiple countries. Such domain specifications of international entrepreneurship tell us that an international entrepreneur has to deal with different institutional frameworks and conditions, for example compelling institutional frameworks

and conditions in home and destination countries as well as supranational institutional frameworks and conditions. Differences and complementarities among these institutional frameworks and conditions generate entrepreneurial opportunities and determine their means of exploitation. Nasra and Dacin (2010, p. 538) comment 'institutional variation is likely to be even more pronounced in international entrepreneurship, especially when firms from developed economies attempt to expand and venture into emerging economies or vice versa'. Analysis of the state–firm relationship has not been highlighted often in international entrepreneurship research (ibid.). National governments can influence the way the market functions by adding and removing different regulatory barriers which produce incentives and discouragements for the firms in their respective positions. The supranational institutions, with their own regulations, create compelling environments for the national institutions to adjust their own regulatory environments. This interacting regulatory institutional dynamics determines the opportunity and incentive structures for the firms in a particular region, country and industry. If such institutional dynamics change an enabling environment, new types of entrepreneurs emerge to exploit opportunity whether it is in the domestic or international market.

In this chapter, we rely on Shane and Venkataraman's (2000) central argument that entrepreneurial opportunities exist in the environment and means and ends applied to capture them are the responses of the entrepreneur. We have applied this argument for analysing the emergence of international entrepreneurship in the generic pharmaceutical industry in Bangladesh. This chapter analyses the role of the institutional framework and conditions in the development of a locally owned generic pharmaceutical industry in Bangladesh. It focuses on the analysis of the country and world system level institutional frameworks and conditions, as conceptualized in Etemad (2004) and suggested by Szyliowicz and Galvin (2010), in different phases of the development of the generic pharmaceutical industry in Bangladesh and its emergence in the international market. Bangladesh has a local entrepreneurs-dominated generic pharmaceutical industry consisting of 238 firms, which supply 97 per cent of the human drug needs of its 160 million inhabitants with their own output. Bangladeshi generic drug manufacturers have exported their products to 69 countries. The World Trade Organization's (WTO) Trade Related Agreement on Intellectual Property Rights (TRIPS) has been a crucial regulation to reconfigure the Bangladeshi generic pharmaceutical industry. This chapter keeps its scope of institutional framework and conditions limited to local and international regulations relating to the pharmaceutical industry and the local level institutions that are related to human resources, financing and the general business climate. Though this

chapter analyses one industry case in one country, it contributes to the understanding of the context of the development and boundary expansion of the entrepreneurial activities in developing countries.

In first part of the chapter the key regulatory perspectives relating to the emergence of a locally owned and managed generic pharmaceutical industry in Bangladesh are described. In the next part, a chronological picture relating to the different dimensions of the development of the Bangladeshi pharmaceutical industry is presented. From a world system level, the key international regulations influencing the current and future course of action of the Bangladeshi pharmaceutical industry in the national and internal market are described in the next part of this chapter. Entrepreneurial responses to the institutional frameworks and conditions and different phases of industry development are shown in the following section through the description of four firm-level cases. A discussion of the whole issue is followed by the conclusion and implications.

THEORETICAL FRAMEWORK

'Institutions are any form of constraint that human beings devise to shape human interaction' (North, 1990: 4). Institutions influence human actions by forming and enforcing different types of rules. Institutions can be formal institutions (laws, regulations and policies which exert an influence on individual behaviour) and informal institutions (customs, values and norms which represent a broad societal influence on individual behaviour). Both forms of institution constrain or enable the context which influences the emergence of certain types of entrepreneurial opportunities as well as influences the collective and individual perception of such opportunities (Smallbone et al., 2010). Aldrich and Wiedenmayer (1993) note that the institutional context can effectively contribute to the creation or destruction of entrepreneurship. Shane (2003) explains that the institutional context consists of the economic, political and cultural environment in which the entrepreneur practices the act of entrepreneurship.

We take Shane (ibid.) as the main analytical frame for conceptualizing the institutional context related to two types of entrepreneurship; entrepreneurship in general and international entrepreneurship in particular. Gnyawali and Fogel (1994) describe the entrepreneurial environment as the combination of the factors which play a role in the development of entrepreneurship in general. These factors include government policies and procedures, socioeconomic conditions, entrepreneurial skills and knowledge and the availability of financial and non-financial assistance. Glaeser and Kerr (2009) reveal that demography, natural cost advantage, custom-

ers and supplier conditions, the labour market condition, and conditions relating to technological spillover and entrepreneurial culture determine the rate and nature of entrepreneurship as well as local industry development. Among other institutional elements, the policy and administrative actions of governments and the societal norms toward entrepreneurship impact entrepreneurial action more directly (Bruton et al., 2010). In the case of international entrepreneurship the most critical point in analysing the institutional context is the consideration of different institutional perspectives belonging to different nations which enables or limits opportunity identification and exploitation by the international entrepreneur.

Hillman and Keim (1995) note that the nature and complexities associated with the different forms of economic activities have necessitated the emergence of different types of economic organizations and regulations to govern their transactions. Such institutional arrangements vary among the countries due to the difference in the availability, relevance and level of efficiencies of the formal and informal institutions in those places. Such differential institutional arrangements in countries constitute the institution–international entrepreneurship interfaces. In international entrepreneurship, opportunity identification, creation and exploitation happens in different interfaces which can be nation specific and/or supranational. Coviello et al. (2011) comment that the institutional context can explain opportunity recognition and the existence of different venture types in different countries. Bruton et al. (2010), in their review of 44 articles published in the period 1999–2009, have revealed that the application of institutional theory and its aspects such as the institutional setting for entrepreneurship, legitimizing the role of the institutions and the entrepreneurial role of the institutions are getting increasing attention in entrepreneurship research. Yet we have a number of frameworks that can be applied as the analytical framework for analysing the institution–international entrepreneurship interfaces.

Etemad's (2004) explanation of international entrepreneurship as a dynamic adaptive system offers an extensive and integrated framework which identifies different interfaces involving interactions between different agents and contexts in different layers that lead to the emergence and expansion of internationally active entrepreneurial firms. In the first layer the entrepreneur and firm interact reciprocally, which recognizes the role of the entrepreneur as a reflexive agent who is embedded in the firm. The international entrepreneur needs the firm in order to exploit the entrepreneurial opportunities that the entrepreneur has developed as a result of the interactions of the profile of the entrepreneur with a given structure (Giddens, 1991). In the second layer the firm interacts with the market. In the third layer the market interacts with the international

environment. The international environment includes both compelling and country-specific institutional aspects. These three layers together comprise the overall environment of international entrepreneurship in which the entrepreneur, firm and market are embedded. The entrepreneur and firms explore and exploit opportunities through interacting with the market where the market is embedded in the environment. Such an environment includes formal and informal institutions which enable or restrict creations and exploitations in different markets. We concentrate on the second and third layer of Etemad's (2004) analysis as the framework for our investigation of the dynamic of the institutions and development of an increasingly internationalizing generic pharmaceutical industry in Bangladesh. Szyliowicz and Galvin (2010) generally agree with Etemad's (2004) conceptualization and suggest that the analytical domain of international entrepreneurship should capture four levels, for example: the entrepreneur (cultural and cognitive process), the firm (practice and structure), the country (state, systems, regime and norms and value governing trust) and the world system (international governing mechanisms).

METHODOLOGY

A simple two-step approach has been applied in this research (Coviello and Jones, 2004). In the first step, evolving institutional contexts and the emergence and internationalization of the locally owned generic pharmaceutical industry in Bangladesh has been described. For this, data and information were collected from different published sources on web and print media. These publications are composed of both academic and non-academic documents including legislative documents, reports published by the government, professional and development agencies and organizations, newspapers, internet sites and blogs, and books and academic journals. Due to the unavailability and difficulties in accessing data and information sources relating to the development of the pharmaceutical industry in Bangladesh, diverse types of sources had to be exploited.

In the second step, for figuring out the firm-level response under the given institutional framework conditions, a qualitative case study has been conducted. For the case study four firms were interviewed personally with an interview guide. Firms were selected according to the years of their inception which represent some milestones in the path of the development of the pharmaceutical industry in Bangladesh. From each of the firms, one functional manager, who was knowledgeable about the firm's growth over the period of time, was interviewed. An interview guide was used by the interviewer. Interviewees were asked about their firm's historical

Table 7.1 Summary of the case selection and investigation method

	1st generation firms	2nd generation firms	3rd generation firms	
Phases of the industry development	Pre-independence to pre-DOC (1947–1982)	Post-independence to pre-DOC (1971–1982)	Immediate post-DOC (1982–1990)	Post-DOC and pre-TRIPS (1990–2005)
Ownership character	Local entrepreneurship	Local entrepreneurship	Local entrepreneur buys TNC's local interests	New generation local entrepreneurs in maturing market
Dominant competitor during inception	TNCs	TNCs	Reducing presence of the TNCs and established local firms	Pre-dominant and powerful local firms
Name of the firms	Square Pharmaceutical	BEXIMCO Pharmaceutical	Eskayef Limited	Incepta Pharmaceutical
Information provider	One knowledgeable mid-level manager from each firm			

accounts of their growth in the industry and how their firms responded to the institutional framework conditions in different phases of their growth. Interviewees' individual accounts were analysed and a common picture of them was developed (Eisenhardt 1989). Table 7.1 gives a summary of the selection criteria of the cases analysed in this research.

EVOLVING INSTITUTIONAL CONTEXT AND DEVELOPMENT OF THE BANGLADESHI PHARMACEUTICAL INDUSTRY

Enabling Context for the Emergence of the Locally Owned Generic Drug Industry in Bangladesh

In the early 1970s under a changed world perspective marked by the sharp rise in oil prices, US departure from Vietnam, nuclear capability

development by India and a strong political role of the non-aligned movement (NAM), third world countries attempted to exert more self-control over the determination of their course of action relating to their economy and welfare, where tackling the increasing cost of healthcare was an important element on the agenda (Chowdhury, 1996). Per capita annual expenditures for human drugs in some selected countries in 1970 reveal the typical nature of the public health challenge in the developing countries. The top three countries – Japan, Germany and Canada – spent US$400, $215 and $121 respectively, while the bottom three countries – India, Mozambique and Bangladesh – spent US$$3, $2 and $2 respectively (Chowdhury, 1996). Among the reasons for such a poor scenario in the developing countries was that pharmaceutical transnational corporations' (TNCs) practices had been alleged to be contributing to public health disasters, as reported in the literature focusing on this issue, for example marketing drugs with a misrepresented therapeutic value (Silverman et al., 1992), dumping in third world countries (Guha, 1986), little therapeutic value drug marketing in the third world (Davies, 1994) and unethical profit targeted drug promotion and marketing (WHO, 1977). It was a heightened necessity to streamline the pharmaceutical TNCs' and the importers' detrimental practices and to promote local pharmaceutical industry development, in order to improve the public health situation in the developing countries. Developing countries started initiating reforms for their pharmaceutical sectors with this purpose. Instances of reforms were seen in the following: the enactment of the Indian Patent Act (1970); the establishment of the Sri Lankan National Formulator Committee (NFC) in 1967; the introduction of the Drug Generic Name in Pakistan in 1971; the Haiti Committee for investigating the pharmaceutical sector in 1976; the introduction of the Generic Drug Law of Afghanistan in 1976; Chilean initiatives to control TNCs; NAM's call for drug regulation in 1976 and finally WHO's publication of the list of essential drugs in 1977 (Chowdhury, 1996). These initiatives impacted on the public health activists and experts, encouraging them to put pressure on their governments to come forward to lessen the burden of the cost of healthcare and to promote their local pharmaceutical industry. In response to this call, the Bangladeshi government took initiatives to draw a full-fledged drug policy suitable to support the healthcare of a developing country like Bangladesh by constituting an expert committee on 1 April, 1982. The recommendations of this expert committee, after revisions and due process, emerged and were enforced as the Drug Ordinance (Control) 1982 (DOC 1982).

A generalized drug policy in the form of the DOC 1982 supported the following major public health objectives (Ahmed 2002):

1. To ensure the supply of the essential drugs at an affordable price as well as to make sure that prevailing drugs in the market be of a standard quality including efficacy and safety.
2. To put gradual strict control on importing or manufacturing expensive drugs which are not essential for treatment and for which equivalent cheap substitutes are already available.
3. To prohibit the import, manufacture and sale, as well as to destroy the current stock of the drugs with immediate effect which are adjudged as injurious and without any significant therapeutic value by the experts.
4. To exercise government control over advertising and promotion in the mass media, in order to protect public interest related to quality and affordability of healthcare.
5. To exercise control on the import of drugs and raw materials, in order to keep control over availability and price. If necessary, the government can also regulate the import and manufacturing of packaging materials with similar purpose.
6. To encourage local companies to manufacture drugs which they can produce in adequate quantity with an assured level of quality, and to encourage foreign companies to manufacture drugs which require substantially high technological and management capabilities.
7. To make sure that all local/foreign companies produce all essential drugs in Bangladesh in their own manufacturing facilities.
8. To curb the manufacture, sale and distribution of prohibited, useless, bogus, adulterated and substandard drugs by ensuring that the people and companies engaged are punished under purview of strict law.
9. To gradually initiate steps to manufacture, distribute and sell drugs by their generic names.

The expert committee did the most significant work by delivering 16 criteria for drug production, marketing and promotion in Bangladesh (Chowdhury, 1995), which was later enforced by the DOC 1982. It marked 1742 drugs as non-essential or therapeutically non-significant and banned their production and distribution in Bangladesh. The committee suggested 150 drugs as essential drugs and 100 drugs as specialized drugs. It was suggested that these listed drugs were to be used at three levels, that is Level I: 12 drugs for village health workers, Level II: 45 drugs for primary health care and Level III: all 150 drugs for tertiary medical care. They also named 76 drugs as specialized drugs and 24 drugs as innovative drugs. They recommended that Level II drugs be manufactured and sold by generic name only and that the TNCs should be discouraged from producing simple drugs like analgesic and anti-allergic drugs. The committee also suggested the amendment of The Drugs Act 1940, development of the National

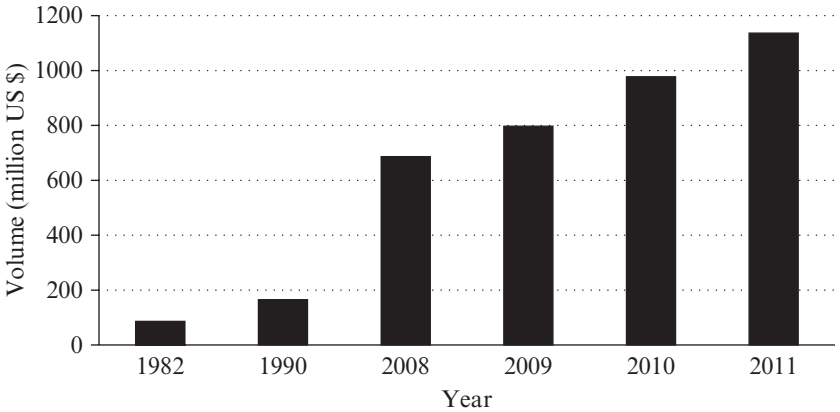
Formulary, mandatory implementation of good manufacturing practice (GMP), setting up a National Drug Testing Laboratory and building the capacity of the Bangladesh Drug Administration. Among the 1,742 drugs that the expert committee identified as harmful, inappropriately formulated or therapeutically ineffective, 176 were being produced by the TNCs, 617 were being imported and 994 were being produced by 156 local manufacturers.

DOC 1982 initially caused a huge stir among medical practitioners, pharmaceutical companies' representatives, pharmaceutical TNCs worldwide, different national governments and the legislative bodies including the US Congress and the German Bundestag. They protested and pressured the Bangladeshi government to back off from DOC 1982, citing it as an alleged effort by the government to jeopardize the freedom of choice in general and a deliberate move detrimental to the business interests of the pharmaceutical companies. At the same time, DOC 1982 was hailed by the different rights groups, philanthropic bodies and the professional organizations at home and abroad. In particular the rights groups in the USA fought against the US Congressional Committee in favour of it (Chowdhury, 1996). The Bangladeshi government finally did not back off from DOC 1982. Later this initiative was hailed as an example for the other developing nations to follow, to make the pharmaceutical industry fit in with public health benefits. This legislation was further dubbed as the turning point of the local pharmaceutical industry development in Bangladesh (Reich, 1994).

Development in the Pharmaceutical Industry in Bangladesh Post 1982

Drug Ordinance 1982 has been successful in realizing the radical objectives it proposed by laying down the foundation for a modern pharmaceutical industry, which is now an issue of discussion in the international arena and also in Bangladesh (Reich, 1994).

The demographic and the economic context have substantially changed over the periods in Bangladesh. If the period 1970–2005 is considered, the population count stands at 153.3 million in 2005 up from 79 million in 1970, though the fertility per woman has dropped down to 3.2 from 6.2 children, infant mortality rate has been reduced to 54/1000 births from 145/1000 births and the birth time life expectancy has improved to 62 years from 43.5 years. In 2006, for this population there were 1,683 hospitals and 51,044 hospital beds with 44,632 registered physicians, that is one physician for 3125 people (Bangladesh Bureau of Statistics, 2007). In the same period, health expenditure on the part of the government was 0.09 per cent of GDP and the private contribution was 2 per cent, whereas the



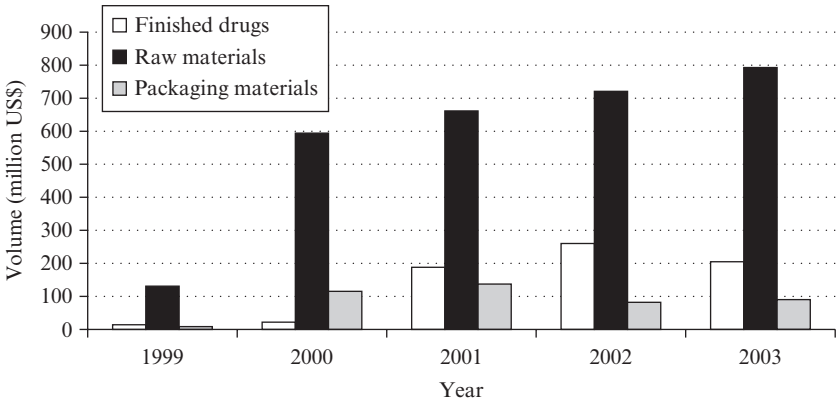
Source: Constructed from Lincoln and Bhattacharjee (2007) and *Financial Express* (2012).

Figure 7.1 Development of the national drug market in Bangladesh (1982–2011)

per capita health expenditure rose to US$64 from the US$2 per capita drug expenditure in 1990. These developments along with the regulatory reforms served as the driver of the pharmaceutical industry development in Bangladesh, which is illustrated in Figure 7.1.

Over the period of time the Bangladeshi pharmaceutical industry has been successful in meeting the demand for modern medicine by its huge home population. Local companies are the producers of generic drugs in their own brand name. There are 237 licensed drug manufacturers in Bangladesh and among them 150 are in operation,[1] while 138 are registered members of the Bangladesh Association of Pharmaceutical Industries (BAPI),[2] the apex body of the pharmaceutical drug manufacturers of Bangladesh. This industry employs 65,000 skilled people directly and 15,000 unskilled people in an indirect manner (Lincoln and Bhattacharjee, 2007). Local producers supply 97 per cent of the yearly domestic demand for the human pharmaceutical drugs of the country, while the remaining 3 per cent import finished drugs which include only high-tech therapeutic drugs[3] (Faroque, 2006). Figure 7.2 shows that imports of the finished pharmaceutical drugs have not increased significantly over the time. Imported finished drugs were exclusively state-of-the art drugs. As the population and quality of life has increased, the demand for such drugs has also increased; the local industry does not produce these kinds of drugs.

Figure 7.2 shows that the import of the pharmaceutical raw materials



Source: Constructed from Ahmed (2004) and Begum (2007).

Figure 7.2 Import scenario in the Bangladeshi pharmaceutical industry (1999–2003)

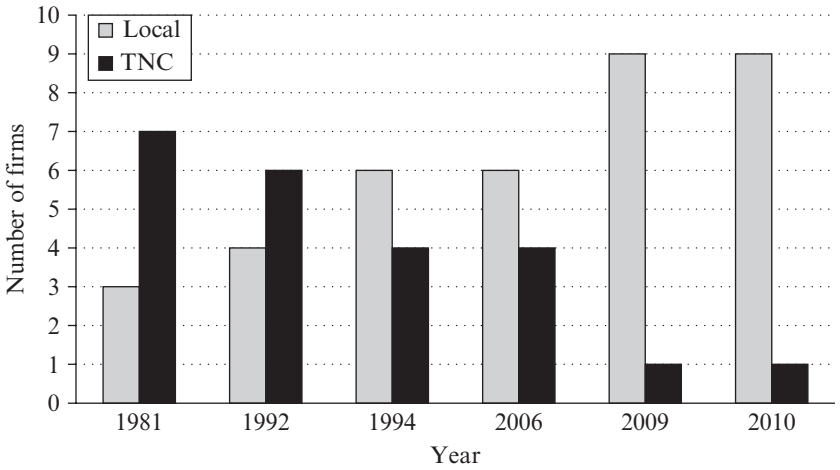
and the packaging materials for the pharmaceutical product delivery have increased to meet the growing demand of the local manufacturers.

Local producers utilized the opportunities sprouting from DOC 1982 in a proactive and market-oriented way. Pre-DOC 1982, 75 per cent of Bangladesh's pharmaceutical drug market was served by the TNCs, while in the post-DOC period their share has been reduced to a meagre 7 per cent (Faroque, 2006).

Figure 7.3 shows that the local drug manufacturers have not only increased their dominance in the market as a group, but also at the individual level they have successfully toppled the TNCs in terms of their market shares in the local market. Not only have they replaced the TNCs, they also developed competition among themselves to increase their individual share, which is evident by the advancement of the newer firms in the leading positions.

There are about 450 generic formulations in Bangladesh with registration from the Directorate of Drug Administration (DDA). Among them, 117 are in the controlled category, that is in the essential drug list. The remaining 333 generics are in the decontrolled category. The total number of the brands/items that are registered in Bangladesh is currently estimated to be 5,300, while the total number of dosage forms and strengths is 8,300 (Sarker, 2006).

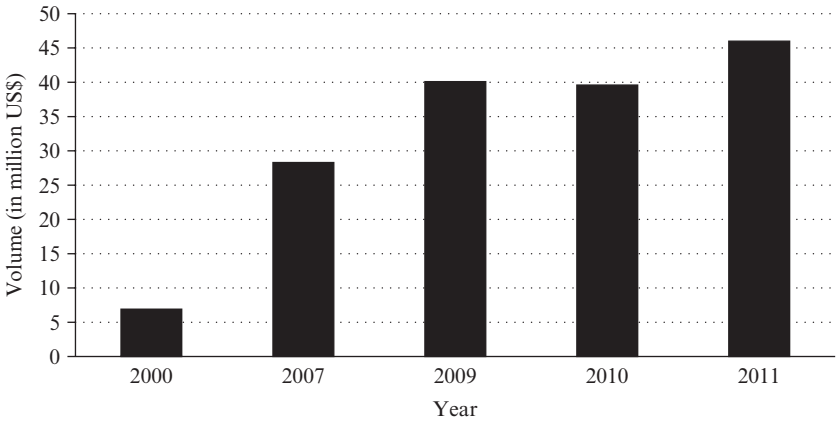
After consolidating the positions in the domestic market, leading Bangladeshi pharmaceutical firms tried to explore markets outside Bangladesh. They initially went out to the neighbouring non-regulated



Source: Constructed from Lincoln and Bhattacharjee (2007) and information from key industry personnel.

Figure 7.3 Top ten firms in the national pharmaceutical drug market of Bangladesh

markets, for example Nepal, Myanmar and Sri Lanka, mainly with bulk formulations and few finished formulations (Begum, 2007). Local firms have begun to get into export ventures systematically as a serious business option since 1992 (Lincoln and Bhattacharjee, 2007). Beximco, a leading Bangladeshi manufacturer, exported active pharmaceutical ingredients (APIs) to Hong Kong and later it exported finished formulations there in 1993. In the post-1992 period, local drug manufacturers were encouraged by their initial experiences of success in the neighbouring market as well as by the unfolding of the events in the Soviet Union and other communist countries. The collapse of the Soviet Union changed the world's political geography and gave birth to the new economies in Central Asia and in Eastern Europe, which were exposed to serious challenges in the initial periods of their adjustment with the new system. The newly emerged nations found that their demands for the necessary supplies including medical drugs are much higher than their existing supply capabilities, and the free falling of the purchasing power made this situation even worse. These newly emerged nations looked for low cost but quality sources to fill the gaps, while such suppliers looked forward to get into these markets as an opportunity for their expansion. Several Bangladeshi pharmaceutical manufacturers made efforts to get into the CIS (Commonwealth of Independent



Source: Constructed from Board of Investment Bangladesh Handbook (2007) and BRAC EPL Stock Brokerage Ltd (2012).

Figure 7.4 Pharmaceutical drugs export from Bangladesh during 2000–2011

States – the organization of new countries emerging from the break-up of the Soviet Union including Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan and Uzbekistan) countries' markets (Begum, 2007). Beximco was the first to export pharmaceutical drugs to Russia in 1994. Currently, the local producers are increasingly looking to enter international markets as a part of their regular growth and expansion strategies. Though the monetary value of Bangladesh's pharmaceutical exports is quite insignificant in terms of its contribution to the national export earnings (see Figure 7.4), it is an important indicator of export diversification. Export diversification with a knowledge-based and technology-based product is highly encouraging for a country like Bangladesh with a death of knowledge and technology, as it suggests that the country has achieved some success in technology and knowledge capability building which can be extended further. Such exports can be extremely important, as exposure to competition and networks in the export market can be an important source of learning, capability building and improvement for the sector (World Bank, 2008).

Bangladeshi pharmaceutical producers mainly export generic finished formulations in dosage and bulk form as well as a small amount of API (ibid.). They mainly export to moderately regulated markets, that is, where certification and registration rules are not as stringent as in the highly regulated market, for example USA, Canada, UK, Japan, Germany,

France, Italy and other EU countries, and to the non-regulated markets, that is where the regulatory requirements are minimum (Chowdhury, 2006). Bangladeshi pharmaceutical products are exported to as many as 69 countries of Asia, Africa, North America, South America and Europe, including Russia, Ukraine, Malaysia, Tanzania, Vietnam, Philippines, Germany, Sweden, USA, Netherlands and Brazil, to name a few.

CHANGES IN THE INSTITUTIONAL FRAMEWORKS AND CONDITIONS IN BANGLADESH DURING THE POST-1982 PERIOD

Regulations of the Local Pharmaceutical Market

Recently, the Bangladesh government has proposed 'National Drug Policy (NDP) 2005', accommodating and encouraging investments from the pharmaceutical TNCs' in the local pharmaceutical industry in high-technology and innovation-focused areas as well as the import of the sophisticated drugs and raw materials (MHFW, 2005).[4] NDP 2005 has been encouraging for production and technology transfer focused FDI and joint ventures in the pharmaceutical sector. NDP 2005 reserves the provision for the foreign companies to have their own production plant or joint venture with the local firms under the condition that the aspirant foreign firm must have at least three original drug discoveries which are registered in at least two of the countries, for example USA, UK, Switzerland, Japan, Germany, France and Australia. It also allows the import of state-of-the-art life-saving drugs, if those drugs are registered with a similar brand name in any of those countries. NDP 2005 also allows contract manufacturing and toll manufacturing for other local and foreign firms and imports of specific high-tech drug production are being encouraged. NDP 2005 has made these friendly provisions with foreign firms mainly with the objective to facilitate technology transfer in the country at a faster pace and guide the industry from brand-based competition toward a more technology-based competition. Besides the manufacturing level surveillance on the quality and safety of the drugs, NDP 2005 puts emphasis on the post-marketing surveillance on the quality and safety of the drugs. It entrusts DDA to implement these surveillances. The local pharmaceutical producers are not comfortable with the NDP 2005 provisions of allowing the import of foreign drugs. NDP 2005 has been designed for taking the local pharmaceutical industry to the next level, where attainment of the production of the API, that is pharmaceutical raw materials, and shaping up the structure of the industry make it suitable as

a really export-focused industry. Progress in the implementation of this policy is not yet evident, as the enforcing and monitoring institutions are far from getting them to fit in with it. Local producers and rights groups are airing their reservations against the new policy (Faroque, 2007).

The present patent protection regime comprises the Patents and Designs Act of 1911 (last amended in 2003) and the Patent and Design Rules of 1933. The Act deems patents to be valid for a total of 16 years (Section 14), calculated from the date of application (Section 7), and allows a further extension of ten years (Section 15(a)(1)). Sections 7 and 8 of the law grants both process and product patent rights for pharmaceutical products. The Patent Office has issued approximately 40 drug formula patents. It issues approximately 300 patents in total per year, 90 per cent of which are held by TNCs (Khan, 2006). Bangladesh has been awarded a waiver period for TRIPS (Agreement on Trade Related aspects of Intellectual Properties) until 2016. Among the TRIPS waiver recipients of 49 least developed countries (LDCs), only Bangladesh has a modern pharmaceutical industry. The patent law in Bangladesh is inconsistent with TRIPS in many ways, the most basic of which is that Bangladesh is not required to enact patent legislation of any kind until 2016. The Department of Patent, Designs and Trademarks within the Ministry of Industries has been preparing a Draft Patent Act since 2006. This draft law, written with the assistance of the World Intellectual Property Organization (WIPO), excludes pharmaceutical patents and includes the Bolar Provision and parallel importation. The current 1911 law already provides a process for compulsory licenses but the option has never been used (VanDuzer 2003). The current compulsory license legislation is extremely cumbersome; a verdict must be obtained from the appellate court.

The Bangladesh Foreign Exchange Regulation (FER) Act 1947 (amended in 2003) is quite unsupportive of the international level capability building of the industry through its restrictive clauses toward foreign currency remittance. A number of Bangladeshi firms are ready to make acquisitions and buy licenses from small European firms and set up their own export management and communication establishments in foreign countries, however national foreign currency regulations are not supportive to these possibilities, which hinders the capability development of the industry (Islam, 2009).

Enforcement and Monitoring Institutions Relating to the Pharmaceutical Industry

In 1976, the Directorate of Drug Administration (DDA) was established under the Ministry of Health Family Welfare (MOHFW). DDA is the

principal mentoring agency in the pharmaceutical drug manufacturing sector of Bangladesh. It is the drug licensing and registration authority for the pharmaceutical drugs produced in or imported into Bangladesh, and is the certification authority in regard to compliance of the GMP guidelines at the production level. In this regard DDA is the local enforcement and monitoring authority of WHO's GMP guidelines. DDA's mission statement says that it is 'to ensure the quality, safety, efficacy and usefulness of all kinds of drugs and medicines including Homeopathic, Unani, Ayurvedic and Herbal drugs which are produced, imported and marketed in the country'. In respect to such a broad mission, the DDA is significantly under-resourced. It has 44 drug inspectors, among them 16 located in Dhaka, the capital city of the country as well as where most of the production plants are located around this region. The other inspectors are assigned to the rest of the 63 administrative districts of the country. The inspectors on average inspect manufacturing facilities for license renewal once every two years. In most of the cases, the inspectors are not professionally qualified experts in the field of pharmaceutical production. Inspectors are also in charge of monitoring the implementation of the maximum retail price (MRP) of the drugs in the market. Drug inspectors are not all trained professionals from the pharmaceutical science and technology field. The fairly limited quantitative and qualitative capacity of the main monitoring agency is the most significant impediment to the industry's development. In a growing market like Bangladesh for generic drugs, the DDA needs to be more dynamic and have a more competent role in the inspection, certification and drug registration process.

For drug testing and registration, the DDA has only two testing laboratories, one in Dhaka and another in Chittagong. Dhaka laboratory is managed by the National Institute of Health, while the Chittagong one is under DDA's own management. There are 250 generic producers with their own brand names. As the market is growing and the TRIPS waiver period approaching its deadline, producers are adding newer drugs in their production line extensively. The extent of diversification of the product portfolio is the major competitive strength in Bangladesh's domestic pharmaceutical market. The DDA has exceeded its capacity to deal with the number of drug registration applications. Dhaka laboratory is the more technologically and functionally capable one, and is simply overburdened with jobs. Chittagong laboratory is operating with a fairly limited capacity both in terms of manpower and equipment. This limited capacity of the testing laboratories impedes the healthy development of the industry, as the large and politically powerful firms often manipulate the DDA to shorten the registration and testing time in their favour, and thereby retain their monopolistic competitive advantage at the expense of the new and small producers.

There is no testing facility available in the country for determining the bioavailability and bioequivalence of the pharmaceutical products. Local entrepreneurs get it done with support from Singapore, Malaysia and the European countries. The bioavailability and bioequivalence measure is particularly important for the producers who want to export their products to the medium and highly regulated pharmaceutical markets. Getting these tests done in foreign countries involves time and cost (for example it could be US$30,000–$60,000 per drug), which later proves to be the source of non-competiveness for the Bangladeshi producers in the international market.

INSTITUTIONS IN THE WORLD SYSTEM AND THE PHARMACEUTICAL INDUSTRY

TRIPS Agreement and the Pharmaceutical Industry

In April 1994, the Uruguay Round of the GATT (General Agreement on Tariffs and Trade) concluded ten years of negotiations. As one of the outcomes of this negotiation, 123 countries signed the agreement on Trade Related Aspects of Intellectual Rights Including Trade in Counterfeit Goods (TRIPS) in Marrakech, Morocco, to make it effective from January 1995 under the supervision of the TRIPS Board of WTO. TRIPS includes a set of regulations for the WTO member states regarding the establishment of a harmonized patent regime for the intellectual outputs in trade. The member states are required to adjust or develop their own patent regulations and practices in accordance with TRIPS within specific deadlines. The deadline of 1 January, 2000 was set for the developing and the transition countries which already extended patent protection to their intellectual outputs, while 1 January, 2005 was set for the developing and the transition countries which did not provide patent protection to any specific area of the tradable intellectual outputs at the closing of the Uruguay Round. For the LDCs, the deadline was until 1 January, 2006 with a provision of extension on request, which has ultimately been set to be until 1 July, 2016. The TRIPS Agreement implied the generalization of a minimum level of patent protection for the pharmaceutical products including the product patent, which has been an issue of concern for the LDCs from a public health expenses and necessity point of view.

Article 31(f) of the TRIPS agreement states that a compulsory license can only be issued for domestic use primarily. This paragraph precluded generic drug production for export to countries without their own domestic capabilities, so as not to leave the poorest countries without access to

generic drugs. This waiver has also allowed a country to issue a compulsory license for either domestic use or export on the grounds of the public health need (Abbott, 2005).

Paragraph 6 of Article 31 of the Doha Declaration included a flexibility clause for the export and import of pharmaceutical drugs for the member states. This clause, which includes provision for the LDCs, informs that where no-patent status prevails and there exists no or insufficient production capacity, there could be trade among the LDC members under the rule of flexibility under the following guidelines (Baker, 2004):

1. No quantity limit for trading in pharmaceutical drugs among LDC members
2. An LDC exporter can export drugs off-patent; with no patent filed or found to be invalid; a pre-1995 drug if the national patent system did not grant it a patent; a drug previously sold by the patent holder or with its permission (this option can be restricted by contract or by limited sales in the exporting)
3. No-patent countries permitted to export, depending on their national legislation, include:

    - Non-WTO members not bound by TRIPS if they have not patented particular medicines
    - LDCs until 2016
    - Countries that did not grant patents protection for pharmaceutical 'products' until compelled by national legislation or who routinely make generic versions of unpatented drugs
    - Countries where a particular medicine is not patented because no patent was ever filed or because the patent has expired or been found invalid

4. Paragraph 6 also authorizes 'parallel import' to offer cost relief for the patented drugs, where parallel import allowed by the national law is most commonly understood to permit the importation, without the direct consent of the patent-holder, of a product voluntarily and legally marketed in another country by the patent-holder or its authorized licensee. The rationale for permitting parallel importation is to promote pricing equity by allowing the importation of a patented product marketed more cheaply in another country. This indirect self-competition is thought to increase the likelihood of fair pricing between the countries. LDCs and the developing countries are mostly expected to utilize this provision, making their national regulations conform to this policy.

5. If authorized by the local law, Article 31 of the TRIPS Agreement permits a competent government authority to license the manufacture, sale and distribution of an invention to an authorized third party or government agency without the consent of the patent holder.

TRIPS and the Pharmaceutical Industry of Bangladesh

Bangladesh, as an LDC, has been awarded a TRIPS waiver period (2005–2015), so that the national government and the industry can prepare itself for being TRIPS compliant from the beginning of 2016. On the one hand, these preparations include the restriction of the existing and development of the new national legislations and the monitoring and enforcement institutions so that the country becomes capable of honouring intellectual property rights (IPR). On the other hand, the local pharmaceutical industry develops its own capabilities through expertise accumulation so that they can remain reasonably competitive in the post-2015 period. The immediate effect of TRIPS (until the end of 2015) on the pharmaceutical industry of Bangladesh includes:

1. Among the 49 LDCs, Bangladesh has had a modern pharmaceutical industry capable of reproducing pharmaceutical finished formulations[5] on a large scale for at least the last 30 years. Bangladesh's pharmaceutical industry has a huge potential to be the most important import source of pharmaceutical drugs for the other LDC countries. Bangladesh's industry estimates that if the national government assures certain local regulatory and administrative reforms, the Bangladeshi pharmaceutical producers are capable of increasing their exports significantly.[6]
2. Bangladesh can manufacture and market patented drugs both for domestic use and export to the LDC markets consisting of 700 million consumers, which at the same time can increase the supply of more modern drugs in Bangladesh's local market at a cheaper price, as the manufacturers will get more economies of scale due to the availability of the additional markets.
3. Paragraph 7 of the Doha Declaration provides 'the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least developed country Members pursuant to Article 66.2'. Since Bangladesh has the fundamental structure of the industry as well as a satisfactory amount of production experience, Bangladesh's pharmaceutical industry can benefit from getting into technology transfer oriented ventures with the developed country firms' to upgrade the qualitative status of the industry to the next level.

4. For the production of the finished formulations, Bangladeshi producers rely approximately 80 per cent on the imported APIs. Among these APIs, 20–25 per cent is patented (World Bank, 2008). Bangladeshi pharmaceutical producers import APIs mainly from India and China, and a few from other countries including South Korea, Taiwan, Japan and the EU. As India and China have fallen under the TRIPS compliance regime since 2005, the cost of the patented API will certainly increase, which will ultimately lead to the soaring of the production cost for the Bangladeshi manufacturers in relevant categories of the drugs.

After the expiry of the TRIPS waiver period, the pharmaceutical industry in Bangladesh will be faced with a great challenge to retain its price competitiveness. From 2016 Bangladeshi firms have to abide by all the IPR clauses laid under TRIPS, which will eventually increase the cost of drug manufacturing, as the local manufacturers have to pay royalties or licensing fees for producing and marketing patented drugs.

The Bangladeshi pharmaceutical industry is riding on the high hopes of transforming itself into a significant supplier of generic formulations in the international pharmaceutical market. The immediate focus of industry is to position itself in the medium regulated and non-regulated markets. At the same time, it views the highly regulated markets as the focus of its strategic growth and expansion, and it is working towards this purpose.[7] The global generic drug market grew to US$78 billion in 2008 (IMS, 2008). The European generic market is expected to grow as an effect of the new contracting law by the German government and the promotion of the awareness and education programs across Europe focusing on the rational use of the pharmaceutical drugs[8] and permitting the marketing of biosimilar epoeitin alfa in the European market (Edery, 2008). The US generic market is expected to grow to be two-thirds of the total prescribed drugs in the US market. The world's generic drug consumption is expected to be significantly contributed to by the growth of the domestic pharmaceutical market in seven emerging nations, known as the pharmemerging, that is China, Brazil, Mexico, South Korea, India, Turkey and Russia, as the pharmemerging market is expected to grow by 12–13 per cent with a value of US$85–90 billion (ibid.).

In 2008, the Chinese pharmaceutical export was US$11.3 billion (Wang, 2009), being the top exporter of APIs. In the same period, India exported US$668 (IBEF, 2008) million as the third largest API exporter and as the most rapidly growing exporter of the finished formulations in dosage forms. India and China are increasingly focusing on R&D for the new pharmaceutical compound (NPC) and formulations, which is making

them shift their focus of the business greatly toward the markets with higher purchasing capacities. Bangladeshi pharmaceutical producers view this strategic development of the Chinese and the Indian pharmaceutical industries as the opportunity to internationalize their businesses (BAPI)[9]. Bangladeshi manufacturers can enter into some parts of the generic finished drug markets that are no longer lucrative for the Indian and Chinese firms. Increasing cost pressure in the Indian and Chinese industries may also encourage the Chinese and Indian manufacturers to offshore some part of their manufacturing activities in Bangladesh.

TRIPS is a double-edged sword for the pharmaceutical industry of Bangladesh, which the industry has to utilize with discretion. Within the TRIPS waiver period (2005–2016), Bangladeshi manufacturers can keep the practice of the reverse engineering of the patented drugs and can export them to the designated 50 LDCs. TRIPS focuses on honouring the product patent including the APIs. India and China have been TRIPS compliant since 2005, and are the major sources of import of APIs by the Bangladeshi pharmaceutical industry. It has made the import of the patented APIs more expensive than before, which is the biggest concern of the Bangladeshi pharmaceutical industry. The long-term growth of the Bangladeshi pharmaceutical industry does not depend on the opportunity to export to the 50 TRIPS-designated LDCs, as the markets of these countries are quite small, considering that the government and the private spending in healthcare in those countries are quite limited, with a limited foreseeable opportunity to increase further in the near future.

The biggest benefit the Bangladeshi pharmaceutical industry can add to the development of its long-term competitiveness during the TRIPS waiver period is to enhance its capability for API production (VanDuzer 2003). The Bangladeshi industry should concentrate on developing the capacity to produce as many APIs as it can, unless the country has to honour the patents. The industry needs more technology transfer and investment, where foreign parties should be included, in order to make this process faster.

The Bangladeshi pharmaceutical industry is not expected to develop a substantial level of R&D in the meantime (up to this point by 2016[10]), which may threaten its dominance on the TNCs in the local market post-2016. In the post-2016 period, local producers will not be in a position to reverse-engineer the patented modern drugs, and their capabilities to serve the growing domestic market will be reduced significantly. Due to the public health demands, regulations may not prove enough to keep TNCs away from the domestic market in such circumstances. This might bring back the pre-1982 situation in the country's pharmaceutical and healthcare sector.

ANALYSIS OF THE FIRM LEVEL CASES

Four firms were chosen for in-depth interviews. Firms were selected based on their respective entry time in the industry which reflects a transition point of the industry. Another criterion for selection was that the firms should have had continued existence since their inception. The argument behind such selection criteria was that such firms have faced different institutional and industry contexts and responded to them with certain types of actions resulting in their continued existence and success, as the purpose of the case studies was to find out the pattern of firm-level responses to the given institutional and industrial context. Based on the historical analyses of the institutional and industrial framework conditions relating to the Bangladeshi pharmaceutical industry, firms in this industry have been categorized into three generations based on the time of their inception. 'First generation (pre-1971–pre-1980)' reflects the context where TNCs were the dominant players in the industry, local entrepreneurs had no mentionable position in the industry and there were no specific institutional inputs for this industry. 'Second generation (post-1980–late 1990s)' is represented by the activists' pressure on the government to act on the allegations against the TNCs and the government's response by enforcing DOC 1982 which significantly reduced the scope for the TNCs in the Bangladesh market. 'Third generation (late 1990s–2006)' is featured by the maturity of the local industry, the dominance of locally owned firms and the expansion of the local firms in the international market and enforcement of TRIPS by WTO in the pharmaceutical industry.

DESCRIPTION OF THE CASES

Square Pharmaceutical Ltd. (SPL)

SPL started its operation in 1958 as a partnership between three local entrepreneurs. SPL was among the very few locally owned pharmaceutical drug producers in the Bangladesh market at the time, while the market was dominated by the TNCs. SPL entered into technical collaboration with Janssen Pharmaceutical, Belgium (a subsidiary of Johnson & Johnson USA) in 1975 and with F. Hoffman-La Roche, Switzerland in 1984. SPL invested heavily in its technical, manufacturing and management capability, building up to position itself in the new market scenario due to the enactment of DOC 1982, which strictly redefined the operational areas for the TNCs. SPL was the first national company to attain market leadership in the local market in terms of annual sales volume in 1985.

Since 1985, SPL has maintained this position. The continuous renewal and extension of capabilities is at the core of SPL's management and strategic planning. In 1996, SPL upgraded its technical capability with the assistance of Bovis Tanvec Ltd., UK. In 2005, SPL acquired a state-of-the art antibiotic (Cephalosporin) production with assistance from Telstar SA Spain. SPL manufactures pharmaceutical finished products, formulations and basic chemicals. It is among the pioneers to bring new and high-tech drugs in different disease and therapeutic classes to the local market. Until the first quarter of 2007, SPL had 497 offers of different therapeutics in the market in molecular and dosage form. In the first quarter of 2008, this offer size increased to 532, bringing in 35 new offers to the market. The quality assurance of the drugs is the most important concern for SPL. Apart from WHO GMP, SPL obtained ISO 9000-1 certification in 1998. In 2007, SPL obtained Medicines and Healthcare Products Regulatory Agency (MHRA) UK compliance certification as the recognition of its maintaining the excellent quality of its products. SPL was engaged in exporting since 1987. The continuous capability extensions are pushing SPL to look beyond the horizon as a part of its regular growth options. In 2009, SPL was exporting its products to 32 country markets, while exporting to another 22 country markets is in the preparation phase, for example obtaining quality, safety and administrative clearances from the importing nations. SPL has been proactively and aggressively looking forward to expanding into the main European markets. SPL has registered its own distribution subsidiary in London in 2007. SPL is engaged in 'toll manufacturing' for some of the European firms and is in the process of buying licenses from European manufacturers. SPL hopes that successful execution of these initiatives will expedite its efforts of entering into international market more intensively and in a more diverse manner.

Beximco Pharmaceutical Limited (BPL)

Though BPL was registered as a pharmaceutical manufacturing and marketing unit by one local entrepreneur family in 1976, it started its production and marketing as the licensee of the products of Bayer AG Germany and Upjohn Inc. USA in 1980. BPL started production and marketing of its own brands in 1985. BPL has the second position in the national market in terms of annual sales volume as of 2008. BPL produced both generic finished pharmaceutical products and APIs. In 1990, BPL got its own API unit for the first time. BPL is among the leaders in the market that introduces new and high-tech drugs in different therapeutic classes in the local market. In 2008, BPL's total offer in the market was 240 products (excluding dosage and delivery forms). BPL was the first Bangladeshi firm to intro-

duce Anti-HIV drugs in 2003, and Roche granted BPL a license to produce its anti-retroviral drugs in 2007. It is among the leaders in technology pioneering in the local industry. It has several compliance certifications to its credit which reflect the quality assurance strength of the firm. In 2008, BPL achieved Therapeutic Goods Administration (TGA) (Australia) approval, being the first Bangladeshi firm to do so. TGA is recognized by more than 20 developed countries including Canada, Germany, the UK, France and Italy. BPL is known as the most internationally committed pharmaceutical firm of the country. It exports its products to as many as 26 country markets, and in 2007 earned 122.75 million Tk. from export. BPL has its management and associates in as many as eight foreign countries, and is engaged with major TNCs as a contract manufacturer. In 2000, it executed an inhaler manufacturing job for GlaxoSmithKline (GSK). In 2005, BPL entered into a 'toll manufacturing contract' for manufacturing the liquids, ointments, creams and suppository products for Novartis.

Eskayef Bangladesh Limited (SK+F)

SK+F is a second generation local firm that sprouted directly from the backdrop of streamlining the TNCs in the local market through the enactment of DOC 1982. Beecham, a UK pharmaceutical firm, merged with SmithKline & French (SKF) USA in 1986, which was operating in Bangladesh. The Bangladeshi conglomerate TRANSCOM acquired the assets, business and management of SKF's Bangladesh interests in 1990. This move turned the Bangladesh interests of world-renowned SKF into a Bangladeshi private limited company, Eskayef (SK+F), under full Bangladeshi ownership and management. SK+F inherited the technology and management through its lineage to SmithKline & French. In the 2004–2007 period, SK+F further expanded its production facilities and made technological upgrades in cooperation with Elomatic and Elomatic-Pharmalab, a Finnish and Finnish–Indian pharmaceutical engineering and consulting firm, in order to upgrade its facilities to the European standards. It has built its own separate R&D and QC facilities in line with its commitment toward capability building. SK+F locally manufactures and markets 157 products (excluding dosage forms) in 59 therapeutic classes. Besides finished products, it is the only manufacturer and marketer of 'timed release blended pellets' in Bangladesh since 2001. SK+F has been constantly introducing new drugs to its credit. In 2008, it received the accreditation of MHRA-UK for its world class production, quality control and management.

SK+F rose to the position of the fifth largest pharmaceutical firm in Bangladesh in 2007 and maintained its position amid intense competition in the local market in 2008.

Since 2005, SK+F turned to international expansion as one of its growth paths. SK+F has been exporting both bulk pellets and finished generics to 16 country markets of Asia and Africa and Latin America. It is systematically stepping up to enter into mainland European markets. In 2008, SK+F set up its own office in the UK and started negotiating with a number of European producers in order to buy their product and brand licenses. SK+F plans to produce those products in their own production facilities and export them back to the European markets.

Incepta Pharmaceutical Limited (Incepta)

Incepta, started only in 1999, is the most aggressive and dynamic pharmaceutical firm of Bangladesh, which represents the third generation of Bangladeshi pharmaceutical firms. Incepta was initiated by Abdul Muktadir, a former senior manager of BPL, and some of the dedicated and highly skilled professionals without any foreign collaboration or licenses. Incepta rose to the position of the second largest firm in terms of sales volume in the Bangladesh market in 2008, while its position was thirty-first in 2000. It has been relying heavily on its capability to introduce new drugs in the market since its inception, and introduced on average 12 new generics in the local industry every year during the period 2000–2008. In 2007, Incepta offered 450 products (280 generics) to the local market in 50 therapeutic classes. Incepta has been successfully producing high-tech therapeutic and biotech products, and has its own state-of-the-art production facility. Incepta received European GMP Compliance Certificate' in 2008 from the European Agency for the Evaluation of Medical Products (EAEM) and was the first Bangladeshi firm to do so. Incepta has created its own R&D department to explore and exploit opportunities for introducing more new generics and cutting-edge technologies in the firm and in the local industry. Incepta turned its eyes to the international market in 2006. It started with exporting its finished formulations in different countries. In 2007, it exported its products to as many as ten country markets. Incepta is in the process of registering its products and making arrangements for exports to ten more country markets. It is looking for aggressive expansion in international market in different forms, and has already executed a contract with Austria-based Bano Pharmaceuticals, where Bano will outsource its production to the newly built production facilities of Incepta. Also Novartis is outsourcing some of its productions to Incepta.

A summary of the analyses of the interviews is presented in Table 7.2.

Development of the local firms illustrates the opportunistic entrepreneurial mindset of the local entrepreneurs. After the enforcement of DOC

Table 7.2 Summary of the firm-level cases

Inception	1st generation		2nd generation	3rd generation
	Square Pharma 1958	Beximco Pharma 1980	Eskayef (SK+F) 1986	Incepta 1999
Entrepreneurs and ownership	Local entrepreneurs and partnership	Local entrepreneurs and private limited company	Local entrepreneurs and private limited company	Local entrepreneurs and private limited company
Start-up background	First generation local entrepreneurs	Second generation of family entrepreneurship from other sectors	Successor of the local businesses of the TNC 'SmithKline and French'	Entrepreneurship by the former managers of the leading firms e.g. Beximco
Major initial-level technology and know-how sourcing	Collaboration with Janssen (Belgium) in 1975 and Roche (Switzerland) in 1982	Collaboration with Bayer (Germany) and Upjohn (USA) in 1980	Inheritance from 'SmithKline and French'	Suppliers in the open market
Initial products	Own branded generic products	Licensed product of Bayer and Upjohn	'SmithKline and French' products	Own branded products
Current products	532 offer in different dosage and molecule including antibiotics and formulations in all major life saving and therapeutic groups	240 offer in molecule forms including antibiotics and formulations in all major life saving and therapeutic groups	157 offer in different molecule including antibiotics and formulations in all major life saving and therapeutic groups	450 offer in different dosage and molecule including antibiotics and formulations in all major life saving and therapeutic groups

Table 7.2 (continued)

Inception	1st generation		2nd generation	3rd generation
	Square Pharma 1958	Beximco Pharma 1980	Eskayef (SK+F) 1986	Incepta 1999
Recent featured additions	AIDS Flu (Bird and Swine) Cancer Ophthalmologic Psychosomatic	AIDS Flu (Bird and Swine) Cancer Respiratory tract Psychosomatic	Flu (Bird and Swine) Cancer Cardiovascular Diabetic	Cancer Cardiovascular Diabetic Psychosomatic Hormone
Domestic market development	Top selling firm since 1985	Runner up until 2007 and 3rd in 2008	5th largest since 2007	31st in 2000 and 2nd in 2008
Export initiation	Neighbouring countries in 1987	Nepal and Myanmar in 1985	Nepal and Sri Lanka in 2000	Myanmar and Afghanistan 2005
Initiation of systematic and regular export	1990: Vietnam and others	1994: Russia and other former Soviet nations, Pakistan	2002: Vietnam and Sri Lanka	2006: Vietnam, Myanmar
Major recent upgrading	1996: BovisTanvec UK 2005: Telstar SA Spain	1996: MDI and MDS 2001: SVP 2006: OSD 2007: HFA	2006: Elomatic	2004: HVAC
Recent new product introduction	2007: 6 generics 2008: 7 generics	2007: 4 generics 2008: 2 generics	2007: 5 generics 2008: 12 generics	2007: 7 generics 2008: 9 generics

Other than default and country-specific certification	2007: MHRA UK	2008: TGA Australia 2008: GCC	2008: MHRA UK	2008: EU cGMP
Export market expansion	32 countries	26 countries	16 countries	12 countries
Other forms of international engagements	Contract manufacturing for all major TNCs in Bangladesh	Contract manufacturing for all major TNCs in Bangladesh	Contract manufacturing for all major TNCs in Bangladesh	2008: Austrian firm Bano to relocate its production site at Incepta
	2004: Production site under license of RIVOPHARM Vietnam	2005: Listed in AIM of London Stock Exchange	Negotiation for buying European licenses is on	Completion of own API plant in 2009 intensive focus on European market
	2007: Distribution subsidiary in UK	2009: 50 million US$ investment contract with AYF focusing on developed market entry		

1982, in the vacuum created by the reduction of the TNC's operations, local entrepreneurs successfully capitalized on the technological and management know-how by the TNCs. Local entrepreneurs hired the managers with TNC experience and put them in charge. First-generation firms primarily targeted the market left by the TNCs. Due to the strong demand in those markets, first- and second-generation firms received an instant cash return on their investments from the market.

In the later stage, first-generation firms put emphasis on market expansion by adding more products to their portfolios. Such a move from the first-generation firms set new ground for competition in the market, which is mainly product variety based competition. In this phase a group of TNC managers took up the entrepreneurial role and included local capital owners in this process. The second-generation firms which emerged were richer in their instant technological and management assets and strong network ties with the TNCs and other partners in developed countries. First-generation firms quickly matched up with them by employing their financial strengths and accumulated experiences in operational process management. This development led to investment-based competition in the local market. Though the local market is big in size in headcount, the purchasing capacity of the market is limited. On the other hand, in spite of strong demand due to the MRP regime, the payback period of investment was much higher than standard. As new firms entered the market, the older firms went for further product diversification and tried for market diversification. By diversifying the product, they looked for their own niche markets. In order to keep their cash position healthy and to shorten the payback period, firms in this phase looked to the international market in a similar way to their home markets. In this phase, leading firms quickly jumped on to the markets which emerged with the fall of communism worldwide.

Third-generation firms are the most aggressive entrepreneurial firms, who challenged both the first- and second-generation firms. These firms invested heavily on the installation of the latest production and quality control technology and cut-throat competition on product diversification. They redefined the rule of competition as well as markets for them. In this phase, firms of all generations looked for international markets where they defined their competitive arena both at the domestic and international levels.

DISCUSSION

As Table 7.3 suggests, development of the Bangladeshi pharmaceutical industry was really kicked off by the DOC 1982, which reduced the

Table 7.3 Firms' perception of the institutions in different phases of their growth

	Firms' focuses	Firms' perception of the institutional framework and conditions
Pre-export phase I	• Basic production technology acquisition • Production capability expansion • Development of marketing capability to maximize the outreach in the domestic market	• Adequate supply of required skilled managers • Lower wages • Fully protected domestic market through reduced scope of the TNCs • Capabilities of the local monitoring and regulatory agencies were sufficient • No consensus and compelling international patent regulations to affect reverse engineering of patented drugs in local market
Pre-export phase II	• Sophisticated technology acquisition • Adding newer products in the production line • Aggressive marketing capability expansion • Developing competitive organization	• Monitoring and support institutions started to be overloaded and not capable of servicing the growth of the industry both in volume and technological sophistication • Wage differential and production capability advantage in terms of neighbouring small markets
International entry phase	• Competitive management with aggressive and ambitious mind set-up	• Emergence of new states in Eastern Europe and former Soviet region with supply voids of essential drugs

Table 7.3 (continued)

	Firms' focuses	Firms' perception of the institutional framework and conditions
International expansion phase	• State-of-the art technology acquisition for production of more new products • Investment for achieving compliance with regional quality standard parameters • Investments in developing and hiring right minded managers • Developing right organizational culture	• TRIPS-led export opportunity to 49 LDCs under patent waived regime until 2016 • Growing demand for price-competitive generic drugs in developed markets, where entry depends on compliance with importing country and regional regulations and standards • Foreign exchange regulations incompatible • Patent regulation incompatible • No specific policy to develop the sector further including promotion of the support industry • Capability and the quality of the services of the monitoring institutions are simply less than standard and required level • Post-TRIPS waiver period challenges relating to honouring patents, which will restrict the local industry's practice of reverse engineering the patented drugs • National research base development still neglected

operational scope of the TNCs in Bangladesh. This regulation awarded a protected market for the local entrepreneurs. Apart from this regulation, neither government nor private sector initiatives were seen to improve or build up the necessary institutions to support the development and growth of the pharmaceutical industry. Rather, the data and facts relating to the institutions presented in the previous relevant sections show that Bangladesh has been in a downward trend in the quality of its institutions. The firm level analysis also suggests that, as the firms advanced from one to another phase of their development, the availability and capacity of the institutions did not match with the requirements of the respective phases.

Firm level analysis suggests that it was the entrepreneurial spirit of the Local Bangladeshi entrepreneurs that inspired them to take advantage of the Drug Control Ordinance 1982. They devised their own mechanisms to exploit the best available in a certain institutional set-up. The Indian pharmaceutical industry also started under protection, then it gradually moved from a generic manufacturing industry to an innovation and service-focused industry. This development has been rightly supported by the strengthening capacities of the institutions in the country, for example the quantitative and qualitative improvements of the institutes of higher education and research both in the private and government sectors; fitting regulations and policies on the part of the government encouraging technology acquisition; collaborations between different actors and agents in technology development and sharing; encouraging joint ventures with foreign firms; and fiscal and financial incentives for the promotion of the pharmaceutical industry and its support industry. Historical analysis of the institutional and industrial framework conditions of the industry has shown that the institutions of the Bangladeshi pharmaceutical industry developed in more of a co-evolutionary way rather than with a clear cut 'preceded–followed' pattern. The development of local industry was kicked off in DOC 1982, in which the government awarded a potential playing field for the local entrepreneurs. This was in line with the government's objective of cutting the cost of healthcare for its population and reducing dependency on the TNCs in this respect. Instances suggest that industries under protection generally suffer from inertia and efficiency, where the protection lasts for a longer time period and the entrepreneurs are not dynamic. In these situations, local entrepreneurs utilized this playing field and made the best uses of the available inputs by applying their entrepreneurial spirits and looking for developing mastery in manufacturing efficiency. Here, entrepreneurs were fundamentally concerned with production and marketing inside the country.

Entrepreneurs were not much concerned about the development of the country's higher-order institutions like the science education and research

facilities, monitoring and regulatory institutions. As the industry accumulated its knowledge of the production technologies, entrepreneurs were faced with more competition inside the industry from the growing number of producers with homogenous products. Entrepreneurs felt that only a protected market could not ensure their growth in such situation. They looked for diversification of their product portfolio by diversifying technology and management resources. This need for diversification brought the necessity for different forms of institutional inputs including more graduates from science and management disciplines and capable monitoring and regulatory agencies.

In the next phase, when some firms accumulated advanced technological and management knowledge and the rules of competition in the domestic market turned to diversity based, entrepreneurs' investment increased significantly. Some entrepreneurs were not in a position to invest that much, and others found that relying on the local market could only slow down the recovery of their investment and growth. In response to this context, entrepreneurs started looking for foreign markets, which they did successfully. In this phase, the character of demands for the institutions changed significantly. At this point, the necessity for more friendly outward international remittance rules and sophisticated government drug testing laboratories emerged. In the TRIPS regime, the post-2005 period, industry has found enhanced foreign market opportunities and is faced with a tougher time in the future post-2016 period, when the industry has to come under the patent regime. In this context, more intensive long-term focused institutional interventions are in demand. These include: allowing successful local firms to buy small firms in developed countries so that they can have quick access to technological and management knowledge and an instantly validated identity in the foreign market; a highly capable monitoring and regulating authority capable of giving quick and quality service; the government's participation in reducing the industry's dependency on imported raw materials; modifying and harmonizing the country's patent law so that the industry can take advantage of the TRIPS waiver period; and investment of more public funds in building education and research capabilities relevant to this sector, in order that the industry can build and develop capabilities beyond manufacturing generic drugs as well as entering newer segments of international business in the pharmaceutical sector, for example research service outsourcing, contract manufacturing and so on. In spite of the pressures from the industry, the government, due to its resources, management and cultural limitations, could not address the needs in the ways the industry expected. Though it is slow and inadequate, the government is responding.

Entrepreneurs on different occasions have devised private arrangements

to compensate for the institutional capability of the country, especially in the case of research and development. For example, Beximco developed its CFC-free inhaler with a research collaboration with CIBA Specialty Chemicals Switzerland. In order to take the industry to the next level, private entrepreneurs initiated exploration of the international markets. Bangladeshi pharmaceutical manufacturers have already made substantial investments in modern production technologies and quality control systems and equipment which has helped the industry get recognition as a quality producer of pharmaceutical drugs. In the period 2007–2009, the industry received local investment worth about US$250 million (Bobhate, 2010) and the majority of this investment was put into upgrading the technological capacity of the industry. In this phase, the industry is investing with the target of not only achieving higher technological and quality standards from its own point of view, but also with the purpose of getting the technological and quality standard of the industry recognized by the renowned pharmaceutical certification agencies around the world, for example the US Federal Drug Administration (FDA), Medicines and Healthcare Product Regulatory Authority (MHRA) UK, Therapeutic Goods Administration (TGA) Australia and the EU Good Manufacturing Practice (GMP). Local manufacturers are investing in order to attain these quality standards in addition to the local regulatory quality requirement – WHO GMP.

CONCLUSION

If the whole context is taken into account, it could be postulated that the entrepreneurs are the drivers of the emergence of the new industry and the role of the institutional frameworks and conditions of technical development is context specific. The Bangladeshi generic pharmaceutical industry case has shown that DOC 1982, by reducing the operational scope of the TNCs in Bangladesh, created the first enabling condition, which ensured a protected domestic market for the local entrepreneurs. Already exiting local firms jumped on this opportunity to cash in with their technological and market knowledge. This lucrative domestic market attracted new entrepreneurs to enter this industry. An increasing number of entries on the one hand filled the supply voids left by the TNCs and on the other hand produced competition among the firms in this industry. However, the efficient production capabilities of the firms started to become insufficient for acquiring and sustaining their competitive advantage in the domestic market, as all the firms started investing aggressively to acquire such capabilities by buying imported package technology. Groups of

entrepreneurs started to top-up their existing advantages by adding the capabilities to introduce new products, which gradually changed the rule of competition in the domestic market from production efficiency focused to innovation focused. Innovation in this context is producing new generics, reverse engineering new drugs and bringing them to the local market. Focusing on expanding the varieties of drugs called for more investments from the entrepreneurs. As a way of quicker recovery of the investments and in the quest for finding some leverage against domestic competition, leading entrepreneurs started looking for neighbouring international markets where regulatory and other institutional requirements were not very much different from their home markets. Here, the first group of international entrepreneurs emerged in this industry. These entrepreneurs further extended their international entrepreneurial venturing in the wake of the emergence of the markets in the former Soviet countries. The whole progress up to this point was made in the context of DOC 1982.

The second enabling context was supplied by TRIPS 2005, which opened 49 LDC markets to Bangladeshi manufacturers. Here, a large number of Bangladeshi entrepreneurs extended their operations in the international market primarily starting with countries from the list of 49 LDCs. The TRIPS waiver period lasting until 2016 has forced the local manufacturers to go for more aggressive reverse engineering for the bustling domestic market which offers them instant cash and technological learning for the future. The investment pattern in the local industry in a TRIPS context has been changing. Groups of firms are investing in technological upgrading and attaining compliance with technical and quality parameters required for entering the highly regulated developed country markets. Such investment motives are focused to take the industry to the next level in the post-2016 period, where there will be no drug reverse engineering options. Increasing generic drug markets in developed countries welcome price-competitive quality suppliers. TRIPS has set a context which the local entrepreneurs can exploit to reconfigure their international venturing by shifting from low-value LDC markets to the high-value developed country markets. These industrial and entrepreneurial dynamics in the generic pharmaceutical industry of Bangladesh confirm the role of the institutions as the previous works did (see Baumol, 1990; Chang, 2002; Bowen and De Clercq, 2008; Minniti, 2008).

IMPLICATIONS

This chapter was devoted to analysing how a certain type of entrepreneurship develops in a certain region and how such entrepreneurships

evolve further in response to the different types of environments in which they are embedded. It reveals that in Bangladesh a locally owned generic pharmaceutical industry emerged primarily in response to changes in regulations and policies relating to the operations of the pharmaceutical drug producers in Bangladesh in 1982. Since the 1990s a number of domestically focused firms stretched out to venture into the international market, responding to the supply vacuum in the newly emerged low-priced market in the former communist regions. Taking advantage of the enforcement of TRIPS regulation, since 2005 firms in the Bangladesh pharmaceutical industry are increasingly and proactively entering into the international market. They are pursuing the international market as their strategic growth centres. These development episodes are clearly linked with the changes in the institutional contexts relating to the pharmaceutical industry in Bangladesh, in some regions of the world and finally the global pharmaceutical industry. Such development of entrepreneurship and industry in the pharmaceutical industry of Bangladesh offers an important message for similar types of developing and emerging countries who are trying to develop new industries or reorient their existing industry to international expansion. Appropriate intervention in the macro- and meso-level institutions is capable of creating enabling conditions where some individual entrepreneurs may reconfigure their entrepreneurial responses which can be targeted to both the domestic and international market. We have seen such a response in the case of Bangladesh. When it comes to the question of international entrepreneurship, Bangladeshi entrepreneurs produced outbound responses. There could be inbound entrepreneurial responses from the non-local entrepreneurs to certain enabling conditions. Location factors are important in attracting more intensive forms of engagements of the TNCs including FDI (Dunning, 1977). We have seen in the Bangladesh case that TNCs, although entering contract manufacturing arrangements with local Bangladeshi firms, have started rediscovering Bangladesh not principally as a market, but rather as the production outsourcing destination. It indicates that the emergence of an inward version of international entrepreneurship in the Bangladeshi pharmaceutical industry has been facilitated by the enabling environment. Being encouraged by the opportunities arising from TRIPS until 2016, and feeling challenged by the post-2016 scenarios, firms in the Bangladeshi pharmaceutical industry are focusing not only on enhancing their capabilities in finished product manufacturing but also on developing pharmaceutical raw material manufacturing capabilities. In the post-2016 period, the competitive advantages of the Bangladeshi manufacturers in finished products manufacturing may decrease. They can offset it by decreasing dependency on imported raw materials as well

as by entering into the growing international market for pharmaceutical raw materials. This shows that the creation of an enabling environment not only creates new entrepreneurship and firms but also facilitates the emergence of related entrepreneurships, firms and industry. Porter (2000) explained such a mechanism in a generic way in explaining how local clusters go global. Our work showed that such a development is not only limited to clusters, but also it facilitates development and diversification of international entrepreneurship.

From an academic point of view, this chapter contributes to the understanding of the role of the institutions in different levels in the emergence and growth of international entrepreneurship. Bruton et al. (2008) note that there are a lack of studies of the government and firm relationships in emerging country contexts, while in a developing country context they are hardly traceable. This chapter has contributed to this call satisfactorily. From a policy point of view, this chapter gives the message that ensuring the appropriate institutional context should be an integral part of entrepreneurship promotion packages, as different actors are embedded in the institutional context. Change in the institutional context triggers different types of responses from such actors. The case of the pharmaceutical industry in Bangladesh has shown that such responses may start in the domestic level, but can expand well beyond it.

NOTES

1. Professor Habibur Rahman, The Directorate of Drug Administration (DDA) Bangladesh revealed in a press conference in Dhaka on 11 April, 2007.
2. Information collected in October 2007 from 'Bangladesh Association of Pharmaceutical Industries (BAPI) – the apex association constituted by the members of the Pharmaceutical Industry in Bangladesh.
3. Principally vaccines, hormonal drugs and anti-cancer drugs.
4. Ministry of Health and Family Welfare, People's Republic of Bangladesh.
5. Pharmaceutical export: Poised to take off' by Adnan Khandker in *The New Age* for the supplement 'New Age Xtra' 6–12 June, 2008.
6. Nazmul Hassan, CEO, Beximco Pharmaceutical Limited and General Secretary, BAPI in 'Future of pharmaceutical export: major surge expected in second half of FY 2007–2008' reported by Mashiur Rahman in *The New Nation*, 23 March 2008.
7. Interview with Nazmul Hassan, General Secretary, BAPI in an article 'Immense possibility in medicine exporting' (originally in Bengali) by Maruf Mullick, published in a supplement, 'Business and Career', of *Daily Jaijaidin* on 6 August 2006.
8. http://www.euro.who.int/pharmaceuticals/Topics/Overview/20020414_10 (accessed on 05.10.2009).
9. See note 6.
10. Under the current version of TRIPS 49 LDCs have been granted a waiver period till the end of the 2015, which may be extended upon the request of the LDCs.

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