Working Paper Series

#2007-031

Innovation and Competitive Capacity in Bangladesh's Pharmaceutical Sector

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Innovation and Competitive Capacity in Bangladesh's Pharmaceutical Sector[1]

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September 2007

ABSTRACT

The global pharmaceutical sector is highly patent intensive, and firms rely on product, process and formulation patents to protect their innovations. Intellectual property rights on pharmaceutical products, as contained in the Agreement on Trade Related Aspects of Intellectual Property Rights (hereafter, the TRIPS Agreement) have been defended on grounds of extensive R&D investments required to discover and develop new drugs. But at the same time, grant of uniform pharmaceutical patents in all developing and least developed countries that are members of the World Trade Organization in accordance with the TRIPS Agreement, raises a range of issues for access to medicines. These issues can be framed under three broad areas: the restriction of reverse engineering possibilities for firms in developing countries and its implications for catch-up in this sector, higher prices of drugs and access to medicines as well as access to technologies due to patents on upstream technologies. The transitional arrangements under the TRIPS Agreement specifically mandated that all developing countries that are members to the WTO enact national laws that are TRIPS-compliant by 2005. As a result, from 2005 onwards, several countries like India, which played an important role as producers and exporters of generic copies of brand name products patented outside the country, can no longer produce such drugs due to the introduction of TRIPS-compliant patent regimes in their countries. Least developed countries have an extension until 2016 to implement the pharmaceutical patent provisions of the TRIPS Agreement under the Doha Declaration on TRIPS and Public Health. However, such legal flexibility is quite meaningless for least developed countries in the absence of local technological capabilities to produce generic drugs amongst least developed countries.

Bangladesh, although a least developed country, is an exception in this regard with thriving domestic processing sectors that are actively engaged in producing textiles and ready made garments (RMGs), processed food products and generic drugs. Therefore, the question that looms large in the global access to medicines debate is whether Bangladesh's pharmaceutical sector can gradually evolve to provide low-cost substitutes of important patented drugs to other developing and least developed countries? This study is an original empirical investigation into issues of innovative capacity and competitiveness of the local pharmaceutical sector in Bangladesh.

UNU-MERIT Working Papers
ISSN 1871-9872

Maastricht Economic and social Research and training centre on Innovation and Technology, UNU-MERIT

UNU-MERIT Working Papers intend to disseminate preliminary results of research carried out at the Centre to stimulate discussion on the issues raised.

[1] This study has been funded by the IDRC, Canada. I am grateful to Muhammed Taher and his team, who helped to coordinate the questionnaire survey in Bangladesh. My sincere thanks to Prof. Banji Oyeyinka, Director of Research and Operations, UN-HABITAT, Prof. Carlos Correa, University of Buenos Aires and Prof. Jorge Katz, University of Chile and Sisule Musungu, Independent Consultant for detailed comments on an earlier draft. I thank Erika Moran and Wladimir Raymond for research assistance and Eveline in de Braek for secretarial help. All errors of fact and analysis are for the author.

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1. INTRODUCTION

The global pharmaceutical sector is highly patent intensive, and firms rely on product, process and formulation patents to protect their innovations. Intellectual property rights on pharmaceutical products, as contained in the Agreement on Trade Related Aspects of Intellectual Property Rights (hereafter, the TRIPS Agreement) have been defended on grounds of extensive R&D investments required to discover and develop new drugs. But at the same time, grant of uniform pharmaceutical patents in all developing and least developed countries that are members of the World Trade Organization in accordance with the TRIPS Agreement, raises a range of issues for access to medicines. These issues can be framed under three broad areas: the restriction of reverse engineering possibilities for firms in developing countries and its implications for catch-up in this sector, higher prices of drugs and access to medicines as well as access to technologies due to patents on upstream technologies.

The transitional arrangements under the TRIPS Agreement specifically mandated that all developing countries that are members to the WTO enact national laws that are TRIPS-compliant by 2005. As a result, from 2005 onwards, several countries like India, which played an important role as producers and exporters of generic copies of brand name products patented outside the country, can no longer produce such drugs due to the introduction of TRIPS-compliant patent regimes in their countries. Least developed countries have an extension until 2016 to implement the pharmaceutical patent provisions of the TRIPS Agreement under the Doha Declaration on TRIPS and Public Health. However, such legal flexibility is quite meaningless for least developed countries in the absence of local technological capabilities to produce generic drugs amongst least developed countries. The Doha Declaration on the TRIPS Agreement and Public Health provides that developing countries like India can still continue to produce generic versions of patented drugs for consumption in least developed countries without manufacturing capabilities under compulsory licenses even after 2005. The 30th August 2003 Decision of the WTO contains a waiver on the TRIPS requirement that compulsory licensing is predominantly for the domestic market (Article 31), and provides the mechanism through which this can be actualized. In a further attempt, the 06 December 2005 Decision of the WTO transforms the waiver contained in the 2003 decision to be a permanent amendment to the TRIPS Agreement. A minimum of two-thirds of the WTO members are required to

ratify this change, for it to become a permanent amendment of the TRIPS Agreement. Until December 2007 which is the deadline for the ratification process, the waiver under the 30 August 2003 decision is in place.

Bangladesh, although a least developed country, is an exception in this regard with thriving domestic processing sectors that are actively engaged in producing textiles and ready made garments (RMGs), processed food products and generic drugs. Therefore, the question that looms large in the global access to medicines debate is whether Bangladesh's pharmaceutical sector can gradually evolve to provide low-cost substitutes of important patented drugs to other developing and least developed countries? This study is an original empirical investigation into issues of innovative capacity and competitiveness of the local pharmaceutical sector in Bangladesh.

2. LEARNING, INNOVATION AND COMPETITIVENESS IN THE PHARMACEUTICAL SECTOR: DETERMINANTS AND GLOBAL TRENDS

Innovation in the global pharmaceutical sector can easily be classified into two broad categories: the introduction of new chemical entities (NCEs) which relies extensively on R&D activities and incremental innovation activities, also called "imitative R&D", or "me-too" drugs (Botazzi et al, 2001). Discovering new chemical entities is not just a matter of R&D capabilities; it involves extensive risk-taking, since the result is erratic and outcomes highly unpredictable. Only 154 new chemical entities have been introduced between 1975-1994 world wide, and although the search for blockbuster drugs is what drives the R&D process in pharmaceuticals (Grabowski, 2002), much of pharmaceutical innovation centres around the second category due to reasons of diversification of risk portfolios for the larger firms, and the lack of risk-taking abilities for most of the other firms worldwide. This second category of imitative R&D ranges from inventing around existing molecules, to creating new combinations of existing molecules, to discovering new ways of drug delivery (NDDS) as well as more direct generic drugs production (Botazzi et al, 2001).

Generic manufacturing of pharmaceutical drugs further consists of two steps: the production of active pharmaceutical ingredients (APIs), which requires chemical synthesis skills and is commonly referred to as 'reverse-engineering' capabilities, and final formulations, which is a purely manufacturing activity and involves the mixing of active

pharmaceutical ingredients with other non-active ingredients into pill, tablets, or other forms of administration (Bumpas, 2007).

2.1. Spectrum of Technological Capabilities for Pharmaceutical Innovation

How firms fare in both NCE-based and on-NCE-based pharmaceutical innovation depends on their technological capabilities. These technological capabilities can be mapped along a spectrum, that begins with mere manufacturing skills that are required for formulation activities, and progresses to acquisition of chemical synthesis skills for reverse-engineering the APIs, to more sophisticated generic competition in terms of new drug delivery systems (NDDS), or inventing around molecules, to finally being able to conduct NCE research at the frontier. Each stage is accompanied by learning activities of various kinds, and an innovative firm proceeds through all these stages of capabilities accumulation, from manufacture to more knowledge-based activities that begin with reverse engineering. This trajectory of capabilities accumulation is not peculiar to the pharmaceutical sector alone; firms across a variety of high technology and low technology sectors demonstrate similar behaviour (Oyeyinka and Gehl Sampath, Forthcoming). Table 1 below contains a non-exhaustive list of countries that exhibit varying degrees of capabilities for pharmaceutical innovation.

Table 1: Mapping technological capabilities in the pharmaceutical sector

NCE research	*Imitative innovation*	*Manufacture*
Requires extensive R&D capabilities at the frontier	Requires extensive incremental innovation capabilities, including R&D	Requires formulation skills
Examples: USA, Germany, Switzerland, UK	Examples: France, Italy, Japan, India, China	Examples: Bangladesh, Kenya, Brazil

Source: Author; Botazzi et al (2001).

Innovation from the viewpoint of the firm essentially comprises the practice and production of all product and process technologies that are new to them and their context and not necessarily to the universe (Nelson and Rosenberg, 1993). All activities at the firm level that enhance learning skills, expand the knowledge base and increase competitiveness both locally and globally, are innovative activities. R&D is one form of knowledge production, but such a definition of innovation includes also all other forms of activities through which firms access knowledge and technologies in order to progress

along the learning curve. The information and knowledge that form the primary inputs to technological learning and innovative capacity in firms, originate from within the firm and from outside (the knowledge system).

2.2. Institutional Frameworks for Innovative Capacity and Competitiveness

Firm-level capacity to absorb knowledge and apply it to innovation (Cohen and Levinthal, 1990) is determined primarily by the extensive and complementary relationship between firms and the knowledge system in which they are embedded. How much and how fast firms' in any sector transition to build technological capabilities to compete at the frontier depends on how well the institutional framework is geared towards promoting coordination within the various parts of the domestic knowledge system. Organizations such as universities (for human capital provision), financial institutions (for venture capital and financing of research), industrial infrastructure (for manufacturing products or acquiring information related to production), entrepreneurial associations (for marketing and assessment of market-based conditions), all provide incentives (or disincentives) for firms to tap knowledge sources, both internal and external.[2] Institutional efficiency in such a context can thus be defined as how effectively access to knowledge for local firms can be achieved at minimal transaction costs, and is critical in explaining the process of knowledge sharing that underlines interactive learning and innovative success.

In the pharmaceutical sector, the institutions for human skills formation (universities and centres of excellence for biomedical research), industrial infrastructure, regulatory policy for drugs, innovation incentives including appropriate intellectual property protection, and support policies for the enterprise sector are critical to enable learning and innovation activities. In developing country contexts, several limitations in the macro, meso and micro institutional environment limit the building of innovative capacity in the sector, and these are set out in Table 2 below. Therefore, achieving optimal coordination and performance amongst these institutions (and organizations that are created under them) is normally a predominant aim of industrial policy for the sector in countries that seek to promote technological capacity in the pharmaceutical sector (see Towse, 1995, among others). Additionally, recent evidence seems to point out unequivocally to the fact that the

[2] Users (both domestic and foreign) as well as competing firms, especially those from outside the economy can also play important roles as providers of knowledge.

absence of intellectual property protection enables early stages of pharmaceutical innovation capacity, which comprises mainly of reverse engineering and imitative activities (Correa, 2004; 2007; Gehl Sampath; 2007).

Table 2: Macro, meso and micro-level limitations in institutional frameworks

Macro level limitations	*Meso level limitations*	*Micro level limitations*
Disjuncture between demand for health research and on-going activities in the sector.	Lack of access to information and technological inputs.	Intellectual isolation of researchers
Lack of scientific culture among scientists and researchers (including emphasis on collaboration).	Weak scientific support infrastructure for universities, public research institutes and firms.	Lack of incentives for collaborative research (e.g., low salaries, restriction of career opportunities, lack of on-job training, etc)
Bureaucratic rigidity and corruption.	Inadequate human capital formation	
Weak public support.	Institutional instability	

Source: Author; adapted from CHDR (1990).

Competitiveness is thus the outcome of these various institutions that impact upon performance and access to technologies for local firms. Cheap labour can be an aspect of competitiveness in sectors that thrive upon low cost technologies, like the textiles, agro-processing but in the case of more sophisticated sectors like pharmaceuticals, labour can hardly be a determinant of competitiveness (Gehl Sampath, 2007). Climbing up the productivity or technological ladder requires rents/ subsidies in sectors attempting to catch-up (Noman and Stiglitz, 2007, p. 10). These rents, in order to be sustained over the mid-term or the long-term, need to accrue from value-added activities and not just labour. In the case of the pharmaceutical sector, this will involve the acquisition of new technologies and moving up the value chain.

2.3. Methodology

This study is based on extensive primary research on the pharmaceutical sector in Bangladesh between May 2006 and May 2007, using both quantitative and qualitative techniques. The research process was detailed and consisted of three main stages; in the first stage, a background report and a pilot survey on the state of innovation and the main incentives that play a role in driving innovation in the pharmaceutical sector in Bangladesh was conducted jointly with a local research team. The second stage consisted of 130 firm-level surveys; guided by data generated through the background report and the pilot survey. A total of 130 questionnaires were administered to firms, universities and public research institutes active in biomedical research and hospitals. The third stage consisted of face-to-face interviews conducted with a cross-section of firms, as well as a variety of other actors, such as professional associations and agencies and the concerned government departments. These detailed interviews have been used as case studies to interpret the results of the survey. A total of 68 persons (including CEOs, and top level management, and government officials) were interviewed for the study.

In keeping with the framework for analysis, the study defined innovation as the application of new practices and production of all products and process technologies that are new to the firms in question (Nelson and Rosenberg, 1993). Innovation was measured by the number of new product and process development applied by the firms in the past five years. The study attempted to capture a realistic picture of innovation in the pharmaceutical sector, in order to understand the various factors that promote/hinder innovation, competitiveness and access to medicines issues, both for the local and global markets. In order to do so, the survey covered the enterprise sector, as well as public sector research institutions – namely, universities and public research institutes as well as hospitals. Amongst firms, the survey covered both indigenous pharmaceutical firms and subsidiaries of MNCs operating within the country, in addition to both public and private universities. Hospitals and medical practitioners often play a key role in generating demand for pharmaceutical innovations, as well as participate in research activities through training hospitals, in many countries. In order to assess these inter-linkages, the survey covered hospitals as well. A total of 45 firms, 43 university and public research institute respondents and 50 hospitals were surveyed all over the country for the survey.

Competitiveness of the firms is measured through indicators such as exports (manufacturing exports as a percentage of overall production of the firm), evolution of the sector over time (policies and institutions as well as response of the main sector actors), comparison among competences of different size classes (small, medium, large sized firms), observed rates of innovation, costs of production, including sources of machinery and production inputs (local and foreign) and other productivity figures.

3. BANGLADESH: COUNTRY FACTS

The domestic economy of Bangladesh is characterized largely by low technology endowments, dominance of trading and services in the absence of significant natural resource assets. In the 1970s and 1980s most of the economy relied on the agricultural sector for job creation due to lack of human resources and scientific and technological infrastructure and resulting low levels of industrial development. During the 1990s, liberal economic policies that emphasized labour-intensive manufacturing and agro-based industrial production have gradually focused attention on non-farm activities in the country (World Bank, 2005a). Policy reform was initiated through Structural Adjustment Programs and Enhanced Structural Adjustment Programs that were initiated in 1982, 1985-1986 and then again in 1991-1992 (see Hossain and Karunarathne, 2002), which resulted in a unilateral trade liberalization of Bangaldesh's economy (Dowlah, 2003).

3.1. Knowledge Infrastructure

Bangladesh has very weak knowledge infrastructure gauged by conventional indicators such as R&D investments as percentage of GDP, centres of excellence for basic and applied research in both the public and private sectors of the economy, and scientists and researchers per million of the population. Table 3 shows available education information for Bangladesh for the years 2000-2005, and Table 4 contains information on R&D investments as percentage of GDP and researchers per million, among others. As Table 3 shows, Bangladesh' success in terms of near-universal primary school enrolment (World Bank, 2005b), does not extend to secondary and tertiary education. There is a drastic drop in enrolment rates from primary to secondary and tertiary education, which draws a bleak picture of the human skills available in the country with severe repercussions for innovative capacity, a result that was corroborated by data collected in the survey.

Table 3: Education Indicators Bangladesh 2000-2005

	2000	2001	2002	2003	2004	2005
Education						
School enrollment, primary (% gross)	109	108	107	106	109	NA
School enrollment, primary (% net)	89	90	91	93	94	NA
School enrollment, secondary (% gross)	50	51	52	51	NA	NA
School enrollment, secondary (% net)	47	48	49	48	NA	NA
School enrollment, tertiary (% gross)	6	7	6	7	NA	NA
Pupil-teacher ratio, primary	57	55	56	54	NA	NA

Source: World Development Indicators database, World Bank, 2007.

There is no data available on researchers involved in R&D and data on R&D expenditure for the country is also not available since 2003. However, findings of several earlier investigations on LDCs help to gauge the situation. As UNCTAD (2006) notes, the gross expenditure on R&D in 2003 was 0.2 per cent of GDP in LDCs (about ten times less than in developed countries) and the number of researchers and scientists engaged in R&D activities per million population in 2003 were 2 per cent of the level observed in developed countries.

Table 4: Investment and R&D in Bangladesh 2000-2005

	2000	2001	2002	2003	2004	2005
Investment and R&D						
Foreign direct investment, net inflows (% of GDP)	1	0	0	1	1	-
Merchandise imports (current US$)*	8,883	9,018	8,592	10,434	12,023	13,868
Research and development expenditure (% of GDP)	1	1	1	-	-	-
Researchers in R&D (per million people)	-	-	-	-	-	-
Financial Support						
Domestic credit to private sector (% of GDP)	26	27	29	29	30	32
Interest rate spread (lending rate minus deposit rate)	7	7	8	8	8	6
Market capitalization of listed companies (% of GDP)	3	2	3	3	6	5

* Amounts in 100,000

Source: World Development Indicators database, World Bank 2007.

3.2. Present Patenting Regime in Bangladesh

As a least developed country, Bangladesh is exempt from implementing the general provisions of the TRIPS agreement until 2013, and has an extension until 2016 to implement its provisions on pharmaceutical patents (in accordance with the Doha Declaration).[3] However, the country is presently working towards gradual compliance with the TRIPS Agreement pursuant to a bilateral treaty with the EU that requires

[3] If Bangladesh manages to transition to the "developing countries" group before 2016, this transition deadline will no longer hold.

Bangladesh to amend its national IP regime to conform to the TRIPS Agreement. The EU-Bangladesh Commission is currently negotiating the U.S-Bangladesh Bilateral Investment Treaty and Article 1(c) of the agreement defines investment to include intellectual property protection.[4] Bangladesh's Parliament is expected to amend the country's trademark, patent, and copyright legislations, following a lengthy inter-agency approval and clearance process, in order to make the country's IP regime TRIPS-compliant.

As part of these obligations, the Law Commission of Bangladesh has formulated a new Trade Marks Law that makes Bangladesh TRIPS-compliant, in consultation with the WIPO, expected to be placed before the Advisory Committee of the Cabinet for approval in May 2007.[5] Similarly, new legislations for Patents and Designs (provisionally called the Patent Law 2007, and the Designs Law, 2007) have been formulated by the Ministry of Industries, which are presently with the Ministry of Law and Parliamentary Affairs for legal vetting and are expected to be enacted next year.[6] The Draft Patent Law of 2007 grants an exemption to the pharmaceutical sector, and provides that "It shall come into force at once except the provisions relating to examination, sealing, grant and post-grant matters of the patents relating to pharmaceutical and agricultural chemical products, but excluding the grant of exclusive marketing rights therefore and mailbox filings which shall come into force on and from the first day of January, 2016" (Section 1). Until these laws come into force in Bangladesh, its present policy framework for intellectual property protection consists of the Patents and Designs Act of 1911, the Trade Marks Act of 1940, the Copy Right Act of 2000 and the Merchandise Marks Act of 1889.

3.2.1. Present patent regime

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 sixteen years (Section 14), calculated from the date of application (Section 7), and allows a further extension of ten years (Section 15(a)(1)).[7] Section 8

[4] Article 1 (c) of the treaty specifies that intellectual property rights includes rights with respect to copyrights, and related patents, trade marks, trade names, industrial designs, trade secrets and know-how, and good will.
[5] Pers. Comm., Mesbah Uddin, Registrar, Department of Patents, Designs and Trademarks, 17 April 2007.
[6] Pers. Comm., Mesbah Uddin, Registrar, Department of Patents, Designs and Trademarks, 17 April 2007.
[7] Section 7 reads: "After the acceptance of an application and until the date of sealing a patent in respect thereof, or the expiration of the time for sealing, the applicant shall have the like privileges and rights as if a patent for the invention has been sealed on the date of the acceptance of the application." Section 15(a)(1) on

contains provisions for opposition to grant of patent (within four months from the date of advertisement of acceptance of application). The law grants both process and product patents on pharmaceuticals.[8] Patent statistics between 2000 and 2005 are contained in Table 5 below. According to the local patent office, of the 182 patents granted in 2005, over 50 per cent are pharmaceutical patents.[9]

Table 5: Patents Granted in Bangladesh between 2001 and 2006

Year	*Applications Filed*			*Applications Accepted*		
	Local	**Foreign**	**Total**	**Local**	**Foreign**	**Total**
2001	56	239	295	21	185	206
2002	43	246	289	24	233	257
2003	58	260	318	16	206	222
2004	48	268	316	28	202	230
2005	50	294	344	21	161	182
2006	23	287	310	16	146	162

Source: Department of Patents, Design and Trademarks, Bangladesh

3.2.2. Export of ARVs and other patented drugs using TRIPS flexibilities

The present patent regime in Bangladesh does not contain a provision that enables firms to export to other LDCs as per the TRIPS flexibilities. Section 22 of the Patents and Designs Act of 1911 deals with the grant of compulsory licenses and revocation of patents. According to this section, any person can present a petition to the government of Bangladesh that the demand for a patented article is not being met, but this is presumably for the local market only. Under such circumstances, the government or the high court division may order the patentee to grant licenses on terms they see fit. A revocation can also be made within grant of four years of the patent, in case the patentee fails to give adequate reasons for his default (Section 22 (4)). Thus, contrary to the view projected in some recent reviews on this topic (see GTZ, 2007; Bumpas, 2007), in the absence of a law that either contains TRIPS flexibilities for export of generic versions of patented drugs to other least developed countries that have TRIPS-compliant regimes or denies the enforcement of patents on pharmaceutical exports, there does not seem to be a legitimate

'Patents of Addition' provides that "Where a patent for an invention has been applied for or granted, and the applicant or the patentee, as the case may be, applies for a further patent in respect of any improvement in or modification of the invention, he may in his application for the further patent request that the term limited in the original patent or so much of that as is unexpired, and if he does so, a patent (herein after, referred to as a patent of addition) may be granted for such term as aforesaid."

[8] Pers. Comm, Mesbah Uddin, Registrar; Farhad Hossain Khan, Assistant Registrar (Patents) and Azim Uddin, Assistant Registrar (Copyrights), Department of Patents, Designs and Trademarks, 17 April 2007.

[9] Pers. Comm, Mesbah Uddin, Registrar; Farhad Hossain Khan, Assistant Registrar (Patents), 17 April 2007.

legal basis for firms to indulge in exports, even if they can produce the drugs locally. The local patent regime especially needs to focus not just on the express permission to export *but on simplifying the procedures for application of compulsory licenses* (which are presently extremely cumbersome) and also *on including export as a ground for issuing a compulsory license.* The enactment of a law that states 'exports' as a ground for issuing a compulsory license is very important, in the absence of which if a drug for the cure of HIV/AIDS is patented in Bangladesh under the present patent regime, local companies will not be able to argue for the issue of a compulsory license purely on the basis of the local market since there is no local HIV/AIDS crisis in the country.

Table 6: Exports of patented drugs by Bangladesh's pharmaceutical firms

Exports of patented drugs by Bangladesh's firms: Key legal pre-requisites
Local firms in Bangladesh could export to other least developed countries generic versions of drugs patented elsewhere, if both Bangladesh and the importing countries do not provide pharmaceutical patents. Bangladesh's own patent regime presently recognizes product and patent protection for pharmaceuticals. It is not clear if many of the important drugs that are essential to ensure access to medicines are already patented within Bangladesh.
Furthermore, most African and non-African least developed countries have granted product patent protection to pharmaceuticals as required by the TRIPS Agreement, despite the 2016 extension (UNCTAD, 2007). Therefore exporting patented drugs to these LDCs requires: (a) a national legislation in the importing country that incorporates the TRIPS flexibilities, including the 30 August 2003 decision; and, (b) a legislation in Bangladesh that allows the local firms to export to other TRIPS-compliant countries through a compulsory license (ibid.).
Under the Doha Declaration on TRIPS and Public Health and 30 August 2003 Decision on the implementation of paragraph 6 of the Doha Declaration, least developed countries without adequate manufacturing capabilities can obtain supplies from another country with manufacturing capabilities, such as Bangladesh, under a compulsory license. This compulsory license would be issued to the local firm in Bangladesh solely for purposes of supplying the patented product to the least developed country in need of the product, but lacking the local manufacturing capabilities to produce it.
Under the present patent regime in Bangladesh, if international firms choose to patent their drugs in the country, it would be illegal for the local firms to engage in their production. Section 84 (10) of the Draft Patent Act of 2007 incorporates the TRIPS flexibilities in this regard, which is a legal prerequisite for the local firms to produce and sell generic versions of patented drugs to other least developed countries which do not have pharmaceutical manufacturing capabilities. Thus, enactment of the draft Patent Act is a key legal pre-requisite.

Source: Author.

The draft Patent Act of 2007 contains all the exceptions for pharmaceutical products in accordance with the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health, but may not be enacted soon due to the political situation in the country. Section 84, clause 10, of the Draft Patent Act of 2007 contains provision for grant of compulsory licenses for the "…manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity

in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country." This compulsory license is solely meant to be for the manufacture of that particular pharmaceutical product for which the license is obtained, and to the country that grants the license, under terms and conditions specified by the importing country and the registrar of the Patents Office of Bangladesh (Sec. 84, clause 11). For purposes of this section, "Pharmaceutical products" are defined as any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use." Thus, the enactment of the Draft Patent Act is an imperative for the export of patented drugs by Bangladeshi firms.

4. THE PHARMACEUTICAL SECTOR IN BANGLADESH

Bangladesh exports a wide range of pharmaceutical products (therapeutic class and dosage forms) to 67 countries.[10] The Drug Control Ordinance of 1982 placed a ceiling on selling imported drugs in the local market promoted self-reliance in its pharmaceutical sector, prior to which the local manufacturing catered to only 20 per cent of the total needs. Local exports have risen from USD 0.04 million in 1985 to USD 27.54 million in 2006 (Export Promotion Bureau). As opposed to relying on foreign companies for 75 per cent of their drug supply prior to the Ordinance, local firms now cater to 82 per cent of the markets, whereas subsidiaries of MNCs supply 13 per cent of the market and 5 per cent of the drugs are imported (Ibid.). Square Pharmaceuticals is the largest firm in the market for many years now, and is followed closely by Beximco, Incepta, ACME and Eskayef (IMS, 2006). Other firms in the top ten bracket include Aristopharma, General, Healthcare Pharma, Novartis and Drug International (Ibid.).

[10] Pers. Comm., Dr. Habibur Rahman, Director, Drugs Administration, 11 April 2007.

4.1. Nature of Innovation in the Local Pharmaceutical Sector

Pharmaceutical firms in Bangladesh are mainly engaged in formulation of APIs requiring manufacturing skills only, and are presently struggling to build capacity in the more knowledge-intensive processes of reverse engineering active pharmaceutical ingredients (APIs). Formulation activities are carried out in most indigenous firms and a small percentage of subsidiaries of international firms that operate in the market, and both groups were captured by the survey.

Apart from Beximco, Square Pharmaceuticals is currently engaged in the manufacture of several drugs that are part of ARV combinations and are expected to the available in the market later this year. These include: Adiva (Efavirenz), Hivarif (Lamivudine), Avudin (Lamivudine and Zidovudine), Tivizid (Abacavir, Lamivudine and Zidovudine) and Nelvir (Nelfinavir). Indian firms like Aurobindo (which has four drugs approved for PEPFAR supply – Nevirapine, Lamivudine, Efavirenz and Stavudine), Cipla, Hetero and Dr. Reddy's, all supply APIs to Square Pharmaceuticals.*

*Pers. Comm. Parvez Hashim, Executive Director Operations, Muhammadul Haque, Director Marketing and Md. Nawabur Rahman, Assistant General Manager, Square Pharmaceuticals, 9 April 2007.

Approximately 450 generic drugs, in 5,300 registered brands having 8,300 different presentations of dosage forms and strengths are manufactured by 237 registered companies (including 5 multinationals) in the sector. The local companies produce a wide range of products that include antiulcerants, flouroquinolones, antirheumatic non-steroid drugs, non-narcotic analgesics, antihistamines, and oral antidiabetic drugs. The survey shows that many of the bigger firms are now venturing into the production of anti-cancer drugs, anti retroviral drugs for the treatment of HIV/AIDS[11] and anti Bird Flu drugs.

4.2. Firm Size and Market Concentration

The companies include specialized multinational companies, local large companies with international links and smaller local companies. Out of the 237 registered companies, only around 150 are estimated to be in a functional state.[12] The Bangladesh Association of Pharmaceutical industries (BAPI) is the main professional association for the sector, and has 150 member companies that lobby the government for policy changes, among other activities. The local market is extremely concentrated with the top ten firms cater to about 70 per cent of the market and only two companies, Beximco and Square hold 25 per cent

[11] Square Pharmaceuticals is currently engaged in manufacturing eight drugs that are part of several ARV combinations that are expected to be available in the market later this year. Pers. Comm. Parvez Hashim, Executive Director Operations, Muhammadul Haque, Director Marketing and Md. Nawabur Rahman, Assistant General Manager, Square Pharmaceuticals, 9 April 2007.
[12] Pers. Comm.., Dr. Habibur Rahman, Director, Drugs Administration, 11 April 2007.

of the entire market (Chowdhury et al, 2006). This also points out to the extreme disparities in firm sizes and capabilities, as far as innovation as well as marketing capabilities is concerned.

5. INNOVATIVE CAPABILITIES OF FIRMS IN BANGLADESH'S PHARMACEUTICAL SECTOR

Local pharmaceutical firms in Bangladesh are struggling to master the process of manufacturing APIs from scratch. The few firms in Bangladesh that are presently producing APIs locally are only able to perform the last few steps in the process with help from technologies bought from Indian firms.[13] Square Pharmaceuticals, which is the largest local firm, lists the following thirteen APIs as its mainstay: Amoxycillin Trihydrate (both Compacted and Micronised) BP/USP, Amoxycillin Trihydrate (Micronised) BP/USP, Cloxacillin Sodium (Compacted and Micronised), Cloxacillin Sodium (Micronised) BP/USP, Paracetamol BP/USP, Diclofenac Sodium BP/USP, Diclofenac Di Ethyl Amine BP, Diclofenac Potassium BP, Diclofenac INN (Free Acid), Flucloxacillin Sodium (Compacted and Micronised) BP, Cephalexin Monohydrate (Compacted and Micronised) BP/USP.[14] Beximco, another major local pharmaceutical company, has two top-selling brands - Neoceptin R (Ranitidine) and Napa (Paracetamol) in the local market.[15]

The lack of reverse engineering capabilities amongst the pharmaceutical firms was confirmed through observed R&D investments over 2000-2005 as captured by the survey. The survey shows that there was not much difference in the amounts invested in R&D between the pharmaceutical firms, and those in agro-processing and textiles and garments (about 1 per cent). At a first glance, this seems to be a surprising result, since it implies that R&D and innovations are not (statistically and significantly) correlated with one another in the pharmaceutical sector in Bangladesh, although generally speaking the pharmaceutical sector is very technological intensive and far more innovative in terms of new product/process innovations when compared to low technology sectors such as

[13] Pers. Comm., Parvez Hashim, Executive Director Operations, Muhammadul Haque, Director Marketing and Md. Nawabur Rahman, Assistant General Manager, Square Pharmaceuticals, 9 April 2007; Amanullah Chowdhury, Executive Vice President and Habibur Rahman, Vice-President and Director, Rangs Pharma, 16 April 2007.

[14] Square Annual Reports, 2006-2007.

[15] Beximco Pharmaceuticals could not be interviewed personally for the study due to political circumstances in the country and the firm's management at the time of the survey. However, the company participated in the survey.

textiles and agro-processing (Gehl Sampath, 2007). But in the context of LDCs, it confirms the extensive relationship between firms and the knowledge systems they are entrenched in. The difficult state of the domestic knowledge system in the country (see UNCTAD 2006, Chapter 6), forces firms operating in what is normally a high-technology sector to focus on manufacturing and excludes the more knowledge-intensive activities from their reach.

This lack of capacity to locally produce APIs reduces the competitiveness of the firms enormously, since between 30 and 50 per cent of the production price of the drugs is taken over by the expenses of securing APIs from external sources (Bumpas, 2007). The top local firms (around six in total) are trying to secure skills and scientific infrastructure in order to venture into API production and reverse engineering.[16] However, they are stifled by lack of adequate scientific and physical infrastructure. Lacking scientific infrastructure includes missing human resources as well as the incapacity of domestic research and development institutes, (RDIs) and universities in assisting the firms in developing these chemical synthesis skills due to under-funding of research, disillusion of scientists and researchers and lack of a cogent focus amongst core university faculties that do work on medical sciences. This disarticulation between various components of the domestic knowledge systems illustrates a prevailing phenomenon that prevents effective learning and absorption by the enterprise sector in most LDCs. Most exporting firms in the survey pointed out cheap labour costs as their main advantage in the international markets, but even the biggest firms like Square Pharmaceuticals were skeptical about whether they could capture markets in other African and Asian countries on the basis of just cheap labour when they did not possess the economies of scale and reverse engineering skills on par with their Indian counterparts.[17]

Apart from this, a range of factors, including lack of common industry infrastructure, lack of capabilities to conduct bioequivalence tests in the country, and the lack of biotechnological capabilities to branch out into emerging options such as biogenerics, all curb their innovative capacity. The top Bangladesh firms are keen on diversifying exports

[16] Pers. Comm., Joint meeting with the members of the Bangladeshi Association of Pharmaceutical Industries (BAPI), 11 April 2007.

[17] Pers. Comm., Parvez Hashim, Executive Director Operations, Muhammadul Haque, Director Marketing and Md. Nawabur Rahman, Assistant General Manager, Square Pharmaceuticals, 9 April 2007; Amanullah Chowdhury, Executive Vice President and Habibur Rahman, Vice-President and Director, Rangs Pharma, 16 April 2007.

between regulated and unregulated markets, since sales from regulated markets can be huge once the initial hurdles of market entry are countered. Square Pharmaceuticals, for example, has invested huge sums in setting up production facilities that meet exporting requirements to the UK (and planning to expand to the USA too) just outside of Dhaka. The absence of infrastructure support to conduct bioequivalence tests and the lack of biotechnological capabilities pose big barriers to such firms seeking to branch out into emerging options such as bio generics or focus on exporting to regulated markets. All these factors are their impact on innovative capacity are discussed in detail here.

5.1. Disarticulation within the Local Knowledge System for Pharmaceutical Research

The gradual transition from manufacture to knowledge-intensive reverse engineering skills in the pharmaceutical sector assumed the availability of human skills and scientific and physical infrastructure. For developing countries seeking to build capacity, this is a significant hurdle to surmount. As elaborated already in section 3 of the paper, Bangladesh has very weak knowledge infrastructure, in terms of secondary and tertiary enrolments, R&D investments and scientists per million of the population. Specifically in the context of pharmaceutical research, the survey reveals that the disarticulation between university and public sector research and the enterprise sector is very strong, and one of the largest impediments to building API skills.

University education: University education of relevance to the pharmaceutical and health sector in Bangladesh can mainly be divided into three fields: medical education, nutrition and biochemistry and pharmacy education. In the public sector, there are 13 governmental medical colleges, two institutes for health technology, six post-graduate institutes, three specialized institutes and five medical assistant training colleges in Bangladesh, all meant to impart training of relevance to both the pharmaceutical and health sector (Osman, 2004). Among the university faculties, Dhaka University is highly reputed with very established departments that deal with pharmaceutical sciences followed by others such as Jehangir Nagar University. Apart from these public universities, Bangladesh has recently seen the mushrooming of several private universities, like BRAC University, North-South University, Stanford University, among others.

R&D institutions in biomedical sector: There are a number of R&D institutions under the Ministry of Health and Family Welfare. These institutions conduct study and research in specific areas. Some of these are: Institute of Public Health; Bangladesh Medical Research Council; Bangladesh National Research Council; Institute of Epidemiology Disease Control and Research; International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B); National Institute of Cancer Research and Hospital; National Institute of Cardiovascular Disease; National Institute of Ophthalmology and Hospital; National Institute of Population Research; National Institute of Preventive and Social Medicine; and Rehabilitation Institute and Hospital for the Disabled.

Despite the presence of these institutions, very low levels of collaboration between firms and public sector institutions involved in R&D, teaching and delivery of health services is observed in Bangladesh. Table 7 shows the observable patterns of product and process innovations in the Bangladesh's pharmaceutical sector based on survey data. These patterns of innovation amongst firms and public sector actors are quite different from what one would expect. More specifically, almost no universities and public research institutes and no hospitals are involved in new product development (4.65% and 2% respectively) and new process development activities (6.98% and 2% respectively). Furthermore, a very small percentage of universities and public research institutes (2.33%) and none of the hospitals are involved in both product and process development. As for the pharmaceutical firms, a majority of them (95.56%) are involved in new product development. While the percentage of firms involved in new process development is much higher than universities/ public research institutes and hospitals, it is much lower (31.11%) than that of firms involved in new product development. When the sector is taken as a whole, 33.33 per cent of all actors are involved in new product development and 13.04 per cent are involved in new process development and 10.87 per cent are involved in both.

Table 7: Observable patterns of product and process innovations

New product development	*New process development*											
	Universities/ PRIs			**Firms**			**Hospitals**			**All**		
	No	**Yes**	**Total**	**No**	**Yes**	**Total**	**No**	**Yes**	**Total**	**No**	**Yes**	**Total**
No	39	2	41	2	0	2	48	1	49	89	3	92
%	90.70	4.65	95.35	4.44	0	4.44	96	2	98	64.49	2.17	66.67
Yes	1	1	2	29	14	43	1	0	1	31	15	46
%	2.33	2.33	4.65	64.44	31.11	95.56	2	0	2	22.46	10.87	33.33
Total	40	9	43	31	14	45	49	1	50	120	18	138
%	93.02	6.98	100	68.89	31.11	100	98	2	100	86.96	13.04	100

Source: Author's survey, 2006-2007

Table 8: Collaboration matrix between various actors in the domestic knowledge system

Collaboration intensity with	*Universities/ PRIs*	*Firms*	*Hospitals*
Public research institutes	2.348	1.067	1.44
Industrial Associations	-	2.535	1.10
Universities	3.027	1.758	1.700
Private Laboratories	2.304	3.796	1.600
Hospitals and med. practitioners	2.790	4.066	2.640
Other firms	1.835	1.935	-
NGOs	1.837	1.510	-
Government Agencies	2.736	2.555	-

Source: Author's survey, 2006-2007

Table 8 shows collaboration intensities of universities and PRIs, firms and hospitals with all other counterparts in the pharmaceutical innovation system, namely, industrial associations, medical practitioners, NGOs, governmental agencies, among others. The figures in the table present the mean of rankings between 1 (least important) and 5 (most important). Thus, any ranking above 2.5 would represent moderate collaborative efforts between any two sets of actors. The rankings in the table reveal again that there is very little collaboration between different actors in the system as far as innovation is concerned. Firms tend to collaborate strongly with private laboratories and medical practitioners (for sale of their products, see discussion in section 5.3), and moderately with industrial associations and governmental agencies (for lobbying). Similarly, universities tend to collaborate strongly with other universities and moderately with medical practitioners and governmental agencies.

This result is quite the inverse of what is observed in most countries with thriving pharmaceutical sectors, where public sector institutions play an important role in the

acquisition, use and application of knowledge to newer products. Thus normally, one would expect to see strong collaborations between public sector institutions (who conduct primary and applied research of relevance) and firms (for product development), as well as interactions with other actors such as hospitals (for supply) and governmental agencies (for infrastructure support).

In Bangladesh, there are several reasons for the disarticulation between public sector research and pharmaceutical product development as well as the skewed patterns of collaboration. To begin with, university and research in PRIs is grossly under-funded. The government allots only 12 crore takas (equivalent to USD 1.75 million) for public sector research for the entire country which are to be shared amongst universities, PRIs, NGOs and all other public sector institutions.[18] The status of research even under the premier university departments and PRIs is not sufficiently supportive towards developing local API skills.[19] There is a lack of university courses that are tailor-made to produce chemistry-based skills of the kind required to reverse engineer in the pharmaceutical sector. Additionally, lack of funding and focus are major handicaps for all the universities. The laboratory facilities in disciplines such as pharmaceutical sciences and biotechnology research, which are being taught in several public and private universities, are also not enough to create human skills that can be directly deployed by the industry.[20] Whereas several universities are only now creating courses for both these disciplines (which implies that it will take several years for competent streams of manpower to develop), the curriculum and quality of the courses also need to be assessed. There are no official rankings available of the quality of academic courses in the universities within the country, and the procedures for accreditation of courses for newer universities need monitoring.[21] Most firms surveyed complained that they had to train graduates in aspects

[18] Joint meeting, Department of Clinical Pharmacology, Department of Pharmaceutical Chemistry and Department of Pharmaceutical technology, Dhaka University, 10 April 2007.

[19] Pers. Comm., Parvez Hashim, Executive Director Operations, Muhammadul Haque, Director Marketing and Md. Nawabur Rahman, Assistant General Manager, Square Pharmaceuticals, 9 April 2007; Amanullah Chowdhury, Executive Vice President and Habibur Rahman, Vice-President and Director, Rangs Pharma, 16 April 2007.

[20] Joint meeting, Department of Clinical Pharmacology, Department of Pharmaceutical Chemistry and Department of Pharmaceutical technology, Dhaka University, 10 April 2007; Joint Meeting, Department of Pharmacy and Department of Microbiology, Jehangir Nagar University, 12 April 2007. The Biotechnology Policy of 2005 has created five national executive committees on biotechnology, and development of pharmaceutical biotechnology falls under the National technical committee on medical biotechnology.

[21] As mentioned earlier, on an unofficial basis, Dhaka University is rated to be the best on grounds of its historical importance as well as the fact that it receives maximum support from governmental initiatives

of clinical pharmacy for a year after they are employed (field interviews) since university graduates are not geared for clinical work in firms. [22]

5.2. Lack of GMP Standards and Bioequivalence Facilities

Presently, there is no law prescribing GMP standards for the pharmaceutical drugs that are sold in the local market. Around six of the big firms are in the process of receiving GMP certification, and Square Pharmaceuticals has received regulatory approval from the British authorities earlier this year.[23] The New Drug Policy of 2005 states in its objectives that the sector requires the enactment of good manufacturing standards in order to promote safety and efficacy of drugs for the local market. There is a need to enact rules that promote this objective in order to boost the export of pharmaceutical products, as well as to ensure safe and efficacious access to medicines in the local market.[24]

Lack of facilities within the country to conduct bioequivalence tests means that even the biggest firms like Square Pharmaceuticals have to outsource their products to bioequivalence laboratories in countries like Malaysia (field interviews). In addition, the country does not have any good laboratory facilities for biotechnology-based work, which is another big hindrance to the bigger firms seeking to diversify their exports to the regulated and semi-regulated markets worldwide.

(field interviews) but how Dhaka university as well as other universities fare in relative and absolute terms as far as the quality of education in pharmaceutical sciences is concerned is unclear.

[22] Refer to Annex 5 for a 'Policy Support Vision' Statement drafted by the professors of the various faculties at the Dhaka University for policy action in this regard.

[23] According to the office of the Drug Directorate, around 8 drug firms have WHO-pre-qualified products, and another 6 are presently in the process of acquiring WHO prequalification but this could not be corroborated by the survey. Pers. Comm., Dr. Habibur Rahman, Director, Drugs Administration, 11 April 2007. This may be due to confusion between WHO prequalification for products and certificates for pharmaceutical products, which is also a WHO certification scheme but national authorities issue the certificates for firms who comply with the form and content prescribed by the WHO.

[24] Several factors prevent cheap access to medicines in the local market within Bangladesh, especially in the public sector health institutions. For a detailed analysis see Gehl Sampath (2007).

5.3. Nexus between the Pharmaceutical and Health Sector and Misallocation of Human Skills

There is a relatively large mismatch amongst the qualifications of personnel as well as facilities available to enable them to perform in the various organizations and several of these accrue from the (dis)incentives to various actors in the local pharmaceutical sector. Aspects of the health sector in the country, especially those related to drug procurement and sales, interact perversely with pharmaceutical production incentives and contribute to low competitiveness of the Bangladeshi firms. Since local firms mainly engage in formulation activities, quality control and quality assurance personnel are in large demand. The country produces a large number of qualified pharmacists most of whom are absorbed by the pharmaceutical firms, and employed for quality assurance and quality control activities for the manufacture of drugs. As a result, most pharmacies in the country are run by pharmacy owners, or personnel who have very little professional training (field interviews).

Furthermore, the internal market is characterized by branded competition: each product essentially a generic, competing on the basis of brand names. In the absence of control mechanisms that check for GMP standards and bioequivalence of drugs marketed locally, the drug distribution system is organized solely around pharmacies (run by unqualified or inadequately qualified personnel) and doctors. This offers ample scope for the sale of low quality drugs at high prices, with firms relying solely on extensive distribution systems that promote their brand name products through medical practitioners, often in unethical ways. This is the reason for the skewed patterns of collaboration observed in table 8: firms tend to collaborate very highly with medical practitioners for distribution of their products. Also, drug supplies through both institutional and private pharmacies proceed through suppliers and retailers in a market that is not well regulated, and offers ample scope for price-fixing and other anti-competitive practices (World Bank, 2007a).

Table 9 below shows, for each group (firms, universities and PRIs and hospitals) and for the whole sector, descriptive statistics of the key actors that are expected to carry out innovation empirically. It lends strength to the analysis on incentives of actors and the performance of the local innovation system. The table shows that employment in 2005 is much larger on average in pharmaceutical firms than in universities/ PRIs and hospitals,

which confirms again the dismal state of research infrastructure as well as supply-side institutions to provide medical services in the country. Similarly, pharmaceutical firms are much older on average than university departments/ PRIs and hospitals, the last two groups being equally old on average. The division of skilled labour amongst these various organizations (universities, PRIs, firms and hospitals) as captured by the survey and presented in table 9 is very important in explaining several of the innovative patterns in the sector presently and call for a closer look. The largest percentage of R&D performers in any year of the period 2001-2005 is found in pharmaceutical firms (82%) and the smallest one is found in hospitals (10%). The pharmaceutical firms, who are the largest R&D performers in the system, have the largest share of personnel with bachelors' degrees. This again is an indicator of the kinds of innovation the firms are engaged in. The R&D personnel in 2005 are the largest in universities/ PRIs (with the largest share of staff with PhD degrees) which have hardly any funds to support their activities.

Table 9: Descriptive statistics: Key actors of innovation

Variable	*Mean*	*(Std. Dev.)*	*Mean*	*(Std. Dev.)*	*Mean*	*(Std. Dev.)*	*Mean*	*(Std. Dev.)*
	Universities/ PRIs		**Firms**		**Hospitals**		**All**	
Employment in 2005 (FTEs)	116.837	(324.278)	922.867	(694.716)	181.320	(206.148)	403.036	(578.664)
Age (in years)	10.884	(11.280)	21.444	(15.56)	10.060	(10.296)	14.029	(13.476)
% of staff with PhD	0.146	(0.200)	0.001	(0.001)	0.032	(0.042)	0.057	(0.129)
% of staff with MSc	0.243	(0.240)	0.348	(0.180)	0.107	(0.078)	0.228	(0.201)
% of staff with BSc	0.100	(0.175)	0.298	(0.115)	0.108	(0.090)	0.168	(0.158)
Non-R&D performers 2001-05	0.535	-	0.178	-	0.900	-	0.551	-
R&D personnel in 2001-2005	0.091	(0.184)	0.008	(0.008)	0.001	(0.006)	0.031	(0.110)
# of observations	43		45		50		138	

Source: Author's survey, 2006-2007

The survey also found that there is an overlap of competencies between medical practice, teaching and research in the sector, due to the lack of relevant manpower to conduct these activities, as well as regulations that prevent professionals from getting employed in conflicting activities. Practicing doctors also teach at university departments (with very little time or effort on improving course curricula) and also are involved with several large/ medium scale firms in their formulations activities as research consultants. This is once again confirmed by the collaboration patterns reported in Table 8: university

researchers, for example, collaborate intensely only with other universities and medical practitioners. This creates inherent conflicts of interest, and is one of the biggest problems in the nexus of the health and pharmaceutical sector in the country.

5.4. Lack of a coherent policy framework to promote pharmaceutical innovation

The problems of disarticulation between public sector research and product development, as well as misallocation of skills owing to perverse overlaps between the pharmaceutical and health sectors can all be credited to the lack of a coherent policy regime for the pharmaceutical sector. The Drug Control Ordinance of 1982 was in several ways, very similar to India's policy initiative of a similar kind that triggered self-reliance in its pharmaceutical sector, but this policy has not been supported by complementary industrial policy measures to support the sector. Thus, although it promoted the growth of the sector, its present deficiencies can be traced back to the absence of a consistent, strategic policy framework that could steer it into a profitable and competitive trajectory. Table 10 below contains a comparison of the similarities and differences between India's and Bangladesh's policy support regime for the growth of the pharmaceutical sector. A period of twenty years from the date of the introduction of the drug control regulations in both countries has been taken into account for this comparison.

Table 10: Comparing Bangladesh and India's Policy Regimes for Pharmaceutical Self-Sufficiency

Bangladesh's Policy Support Regime, 1980s to 2000s	***India's Policy Support Regime, 1960s to 1980s***
Similarities	
▪ Drug Control Ordinance of 1982. ▪ Setting up of public research institutes but lack of funding and vision. ▪ Setting up of government-held companies for production.	▪ Drug Price Control Order, 1970. ▪ Setting up of government-held companies to boost the local production of drugs. ▪ Setting up of extensive public research infrastructure for pharmaceutical research.
Differences	
▪ No restrictions on pharmaceutical patents under the 1911 Act. ▪ No comparable role of the government or public sector institutions to help firms to acquire reverse engineering skills. ▪ No funding to public sector institutions; the BCSIR is almost defunct.[25] ▪ Lack of vision and funding to reform	▪ Restrictions on patenting of foreign pharmaceutical products under the Patents Act of 1971. ▪ Proactive role in technology transfer related to reverse engineering to local firms, through public research institutes. ▪ Extensive funding to public sector organizations to boost the capacity for

[25] BCSIR stands for Bangladesh Centre for Scientific and Industrial Research.

the university education system.	pharmaceutical research, especially CSIR, CDRI and IDMR.[26] ▪ Introduction of university education to suit industry requirements (in chemistry and pharmaceutical sciences). ▪ Other industrial policy measures, such as investment and ownership restrictions on multinational companies.

Source: Author's surveys in India (2005) and Bangladesh (2006-2007).

Apart from the few similarities, which helped to boost pharmaceutical manufacturing by local firms, the many differences are helpful to unravel the tale of missing competencies amongst Bangladesh's pharmaceutical firms. The missing investments in public sector research, common industry infrastructure services, university education of relevance to building up reverse engineering skills as well as other industrial policy measures for technology transfer and investment all account for the difficulties faced by even the best firms in the country today.

The pharmaceutical sector falls under the Ministry of Health and Family Welfare (MHFW) in Bangladesh, rather than the Ministry of Industry and Commerce (or Ministry of Science and Technology), which is generally the case in other countries. The sector has not been a leading sector in the most recent economic policies that seek to provide a variety of incentives for exports, although the government has enacted a New Drug Policy (2005) and a National Biotechnology Policy (2005), and is in the process of establishing an API park. The New Drug Policy (2005) contains provisions for technology transfer and some other incentives to MNCs to set up production facilities in the country both on a joint venture or independent basis, although it is not clear how this alone will help in the absence of other institutional incentives that promote knowledge intensive activities, such as human skills. The Directorate of Drug Administration is the key department in charge of the sector, and is supported by the Institute of Public Health, which has the mandate of supporting public health activities, quality control, and production of biomedicals, training and research. Both organizations are severely under-equipped and under-funded.[27] One of the few services offered by the Directorate is the Bangladesh National Formulary,

[26] The full forms are: Centre for Science and Industrial Research (CSIR), the Central Drug Research Institute (CDRI).

[27] The Directorate of Drug Administration has only two laboratory facilities (in Dhaka and Chittagong) that can test about 3,500 samples of medicines a year. About 12,000 samples of different brands of medicines remain without test every year, although the regulations require that medicines are tested for quality and efficacy twice every year (Bumpas, 2007).

produced by the Directorate of Drugs Administration which contains a list of all drugs available in the country, with manufacturing details and price.

Another peculiar problem with the Ministry of Health is that most government officials (except those that specifically occupy technical positions) that work for the ministry are medical doctors, who are forced to undertake tasks without necessary specialized skills. Doctors are assigned the task of planning and strategy, overseeing functions of the various departments, and even handle financial management responsibilities (field interviews). This seriously affects performance of the various organizations under the ministry. The survey found that within specialized institutions like the Institute of Public Health, production specialist occupations (for production of vaccines) are occupied by medical doctors. The civil service system is also based on regular two-year transfers for many of these positions. Those who invest the time to learn to perform the tasks that they are assigned to are transferred soon thereafter. Hence, most officials interviewed for the study thus expressed their frustration to invest in on-the-job learning (field interviews).

Table 7 shows the patterns of the contribution of government policies and institutions to new product and new process development in universities and PRIs (model 1), firms (model 2) and both of them (in the pooled model 3).[28] As the estimation results in the table reveal, the only factor that contributes to present innovation efforts in the pharmaceutical sector is skilled manpower and quality of local infrastructure services.[29] All other governmental policies and institutions, such as innovation incentives by the government and local research in the PRIs and universities are very weak in promoting innovation activities in the sector.

It also points out to the fact that even if the new Patent Act of 2007 that incorporates the Doha flexibilities for pharmaceutical patents in Bangladesh is enacted, strategic policy support is required to promote API and reverse engineering skills among the local firms, in order for them to effectively supply low cost generic versions of patented drugs to other LDCs.

[28] The government policy and institution variables are not present in the hospital questionnaire.

[29] A similar analysis of firms in the Indian pharmaceutical sector shows, in comparison, that skilled manpower, intellectual property protection, being a small entrepreneur and quality of local infrastructure were factors that played a role in new product/ process innovations. See Gehl Sampath (2006).

Table 11: Bivariate probit ML estimation results: Government policies and institutions

Variable	*Coefficient*	*(Std. Err.)*	*Coefficient*	*(Std. Err.)*	*Coefficient*	*(Std. Err.)*
	Model 1		**Model 2**		**Model 3**	
New product development						
Govt. innovation incentives	-1.209	(1.161)	-	-	-	-
Scientific/skilled manpower	0.319	(0.464)	0.836**	(0.307)	0.438	(0.562)
Local univ. for R&D collaboration	-0.131	(0.811)	-	-	-	-
Local research inst. for R&D collaborations	0.615	(1.220)	-	-	-	-
Intellectual property protection	0.673	(0.911)	-0.199	(0.617)	0.458	(1.109)
Quality of local infrastru. services	0.788†	(0.473)	-	-	-	-
Availability of venture capital	0.673	(0.537)	-	-	-	-
Govt.-firm technology transfer	-2.020	(1.285)	-0.725	(0.847)	-0.239	(2.171)
Staff transfer to local firms	0.610	(0.876)	0.680	(0.702)	1.313	(2.020)
Pharmaceutical firms	-	-	-	-	3.687**	(0.585)
Intercept	-0.384*	(0.189)	-0.323†	(0.185)	-2.256**	(0.567)
New process development						
Govt. innovation incentives	-0.374	(1.265)	-	-	-	-
Scientific/skilled manpower	0.303	(0.510)	1.061**	(0.378)	0.870*	(0.40)
Local univ. for R&D collaboration	0.496	(0.940)	-	-	-	-
Local research inst. for R&D collaborations	-0.050	(1.361)	-	-	-	-
Intellectual property protection	0.246	(0.981)	-0.185	(0.710)	-0.084	(0.74)
Quality of local infrastru. services	1.110*	(0.472)	-	-	-	-
Availability of venture capital	0.504	(0.490)	-	-	-	-
Govt-firm technology transfer	-1.788	(1.375)	-0.591	(0.899)	-0.279	(0.95)
Staff transfer to local firms	1.125	(0.750)	1.240†	(0.652)	1.207†	(0.67)
Pharmaceutical firms	-	-	-	-	0.921*	(0.41)
Intercept	-1.732**	(0.317)	1.570**	(0.288)	-2.089**	(0.43)
Extra parameter						
ρ	0.524*	(0.211)	0.583**	(0.181)	0.618†	(0.33)
# of observations	88					
Log-likelihood	-80.615		-86.479		-44.606	
LR test	$\chi^2_{(10)} = 11.73; p-value = 0.304$			$\chi^2_{(2)} = 83.75; p-value = 0.000$		
Significance levels: † : 10% * : 5% ** : 1%						

Source: Author's survey, 2007

5.5. Intellectual property rights and potential limitations of technology transfer

Closer scrutiny of the patents that have already been granted within the country shows that many of the patents are presently disregarded in the local market. A major explanation for this lies in the technological intensity of the local firms; their inability to reverse engineer offers the best form of protection for the foreign firms who sell their products in the local market. Given this, one is forced to question the motives of foreign firms to patent in the local market. One explanation is that the patent holder firms may wish to prevent competition from companies in other countries, such as India, who may still be keen on

generic versions of patented drugs that they can no longer sell in the Indian market for exports to Bangladesh. Another explanation is that foreign firms are resorting to patent within Bangladesh if only to avert the potential threat of competition from the local firms.

It is highly unlikely that intellectual property protection will provide a direct incentive to innovate for local firms, since they are not into innovative activities at the frontier (see UNCTAD, 2007). An empirical analysis of the impact of intellectual property rights, both as a direct incentive for innovation as well as an indirect contributor to firm level technological upgrading through avenues such as technology licensing found very little support in the pharmaceutical sector in Bangladesh (Gehl Sampath, 2007). Technology licensing to local firms is marginal and not a contributor to innovative efforts presently in the local pharmaceutical sector in Bangladesh (Ibid.). Although the new Drug Policy has provisions for joint research and technology transfer between foreign firms and local firms, efficient technology transfer for the future, especially in the case of a knowledge-intensive sector like pharmaceuticals, will hinge upon transfer of know-how (Arora, 1995, p. 41). Successful transfer of know-how, which is uncodified and costly to transfer will in turn depend on the technology absorption capacities of the recipient, and not just the willingness of the licensor (see box above).

Firms in Bangladesh require substantial help in developing local API skills, which could be promoted through south-south cooperation with the pharmaceutical sector in India. Amongst the firms that were surveyed, several large firms are in negotiation (or had failed to negotiate) transfer of skills and know-how from successful Indian firms. The government has allotted land and finances to building an API park that will also contain common effluent and waste management as well as water treatment facilities, and this may really help to speed up the process. Previous experience shows that technology transfer and collaboration helped to develop formulations capacity in the sector. Good examples are Square Pharmaceuticals which collaborated with Jansen and Vicsenco that received help from Pfizer. Even in these cases, the transfer of technology was accompanied by training of skilled manpower. But in the case of API skills, this may not be so easy, since the firms require access to know-how in addition to codified technology in order to build capacity.

On the question of intellectual property rights protection and access to technologies, the Baby Zinc tablet that is now being produced and marketed by Acme Pharmaceuticals makes an interesting case. This product, originally developed by the Centre for Health and Population Research (ICDDR,B) is the only zinc product that meets pharmaceutical GMP standards as prescribed by the WHO, and is used for the prevention of diarrhoea in children. ICDDR, B tried to negotiate the production of the tablets with local pharmaceutical firms within Bangladesh but Nutricet, a French firm holds the formulation patent that was needed to produce the drug. This necessitated an agreement between

Nutricet and the local firm in order to manufacture the tablets on a large scale. Square Pharmaceuticals, which first attempted to formulate the medicine for the local Bangladesh market on a commercial basis, withdrew its interest due to the high price it would have to pay to purchase the license for the formulation patent from the French company.[30] ICDDR, B intervened and negotiated the license with Nutricet on its own in 2005, and has now entered into an agreement with Healthcare Pharmaceuticals to produce the tablets.[31] This case although anecdotal, shows the problems inherent in negotiating commercial licenses for access to technologies.

5.6. Narrow focus on the domestic market

Most of the sales for even the largest firms accrue from the local market,[32] but the size of the local market is quite small.[33] The policy framework protects the local firms from imports of drugs that can be locally manufactured and the present marketing and sales incentives for firms (see next paragraph) are such that there seems to be very little incentive to enhance competitiveness (field interviews). The few firms that are in the process of expanding their range of activities to include API and reverse engineering skills are focusing on the export markets, and will need a lot of institutional support to achieve efficient results.

6. Firm-Level Competitiveness in Bangladesh's Pharmaceutical Sector and Access to Medicines

The previous section paints a rather ambivalent picture of the innovative capabilities of the local pharmaceutical firms in Bangladesh. How competitive are the local firms, given all the constraints that they face, and how well-placed are they to move up to more knowledge-intensive activities required for self-sufficient production of generic drugs? This section seeks to answer some of these questions by comparing some indicators of firm-level competitiveness between India and Bangladesh. The data used for Indian firms was collected by the author during a firm-level survey of 103 firms in the Indian

[30] Pers. Comm., Mohammadul haque, Director Marketing, Square Pharmaceuticals, 11 April 2007. According to Square, they were asked to pay a royalty of 200,000 Euros for the license by the French firm.
[31] Pers. Comm., David Sack, Executive Director, ICDDR. B, 10 April 2007.
[32] The first largest firm in the market, Square Pharmaceuticals is reported to be exporting only 3 per cent of its total production, and Beximco, another firm in the top five, exports only 2.7 per cent.
[33] According to World Bank Statistics (2007), Bangladesh reported a population of 141.8 million in 2005.

pharmaceutical sector in 2005.[34] The data used for Indian firms is from 2000-2004, whereas that for Bangladesh's pharmaceutical firms is from 2001-2005.

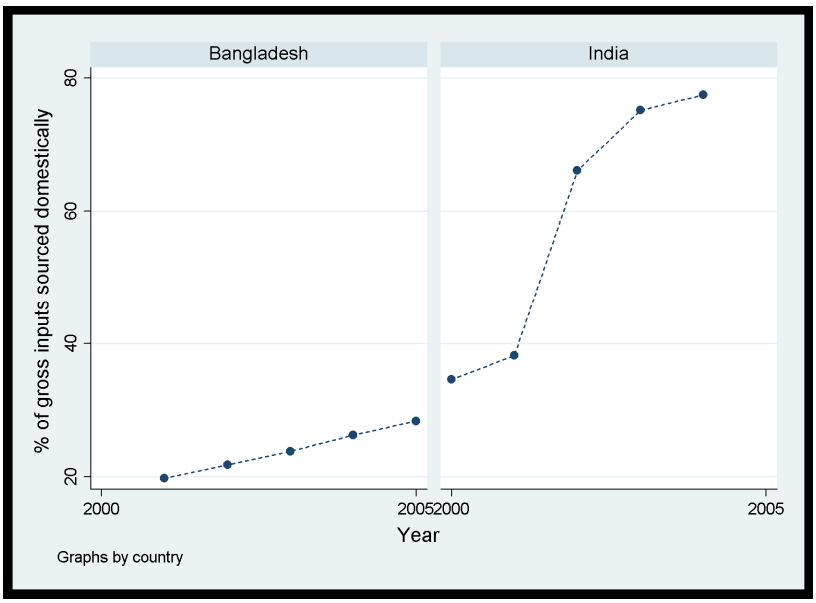
Apart from the evolution of the sector over time (policies and institutions as well as response of the main sector actors) which has been presented in the previous section, competitiveness of the firms is measured through indicators such as exports (manufacturing exports as a percentage of overall production of the firm), comparison among competences of different size classes (small, medium, large sized firms), observed rates of innovation, costs of production, including sources of machinery and production inputs (local and foreign) in this section.

Figure 1 below shows the proportions of gross inputs sourced domestically in both countries, and figure 2 contains a further break up of inputs in terms of local production inputs and machinery. Pharmaceutical firms in Bangladesh mainly use process development technologies to manufacture generic formulations. The survey shows that the firms import between 75 to 100 per cent of their machinery and 50 to 100 per cent of all production inputs are imported from foreign sources. Active pharmaceutical ingredients are sourced from a range of countries including India, China, Italy, Spain, Germany, United Kingdom, France and the USA.[35] As figure 1 shows, local firms reported to sourcing a maximum of 30 per cent of inputs locally, which stands in stark contrast to approximately 80 per cent domestic inputs amongst pharmaceutical firms in India.

[34] The data was collected for a study commissioned by the WHO's Commission on Intellectual Property Rights, Innovation and Health. The 203 firms that participated in the survey were within the top 150 firms in 2005, based on annual turnover, R&D investments and exports.

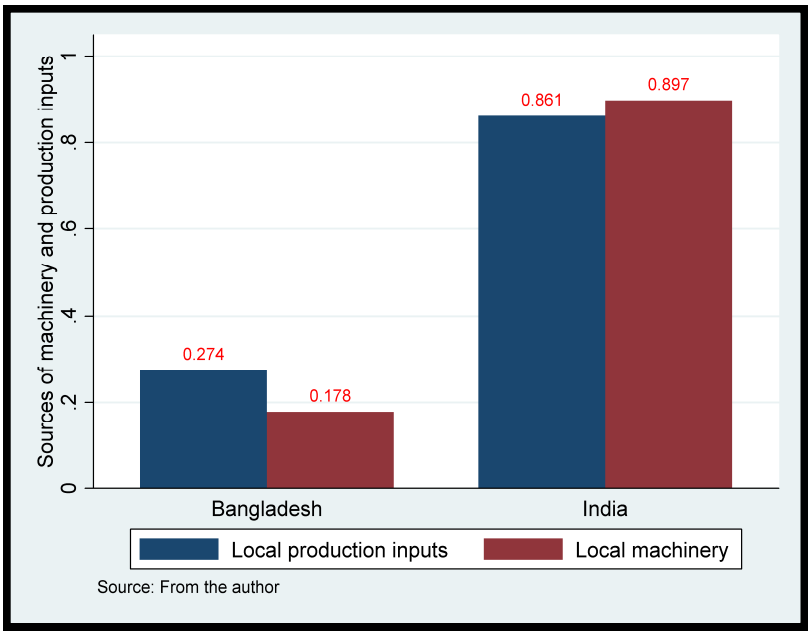
[35] Pers. Comm., Parvez Hashim, Executive Director Operations, Muhammadul Haque, Director Marketing and Md. Nawabur Rahman, Assistant General Manager, Square Pharmaceuticals, 9 April 2007; Amanullah Chowdhury, Executive Vice President and Habibur Rahman, Vice-President and Director, Rangs Pharma, 16 April 2007.

Figure 1: Percentage of gross inputs sourced domestically in India and Bangladesh, 2000-2005



Source: Author's survey of Indian and Bangladesh pharmaceutical sectors, 2005-2007

Figure 2: Sources of machinery and production inputs

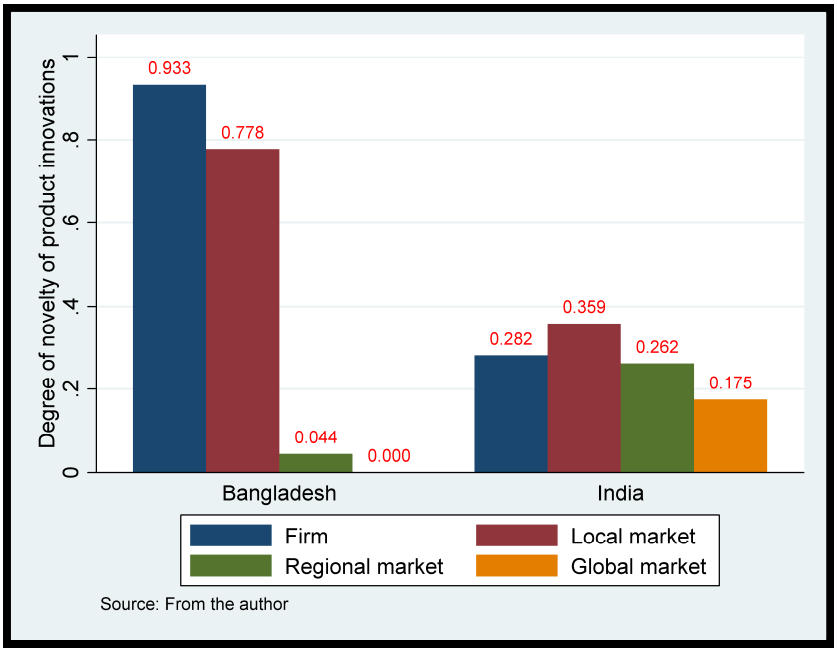


Source: Author's survey of Indian and Bangladesh pharmaceutical sectors, 2005-2007

Firms in both surveys were asked to report whether their innovations were (a) only new to the firm (b) new to the local market (c) new to the regional market, and (d) new to the global market. The response to this question, as shown in figure 3, captures the nature of

innovative activities at the firm level, and is also a clear indication of where a sector stands on the spectrum of innovative capacity for pharmaceutical innovation, as presented in the framework in section 2 of this study. Figure 3 below presents the survey response by firms in both countries. Whereas Indian firms reported to have innovations in all categories, with a sizeable amount of innovations reported to being new to the regional and global market, almost all the output of the pharmaceutical sector in Bangladesh is new to the firm or the local market only.

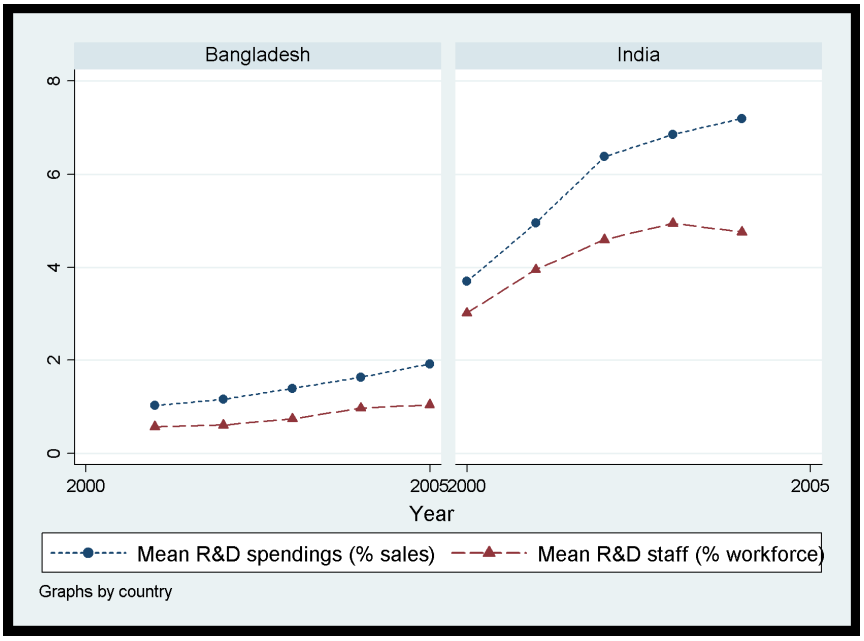
Figure 3: Degree of novelty of innovations



Source: Author's survey of Indian and Bangladesh pharmaceutical sectors, 2005-2007

Export intensity of local firms in Bangladesh is also quite low when compared to that of the Indian firms captured by both surveys. Even the biggest firms like Square and Beximco export 3 per cent and 2.7 per cent of their total output, whereas amongst the Indian firms, the exports can even account of over 70 per cent of total output (author's survey, 2005). Similarly, other key indicators of firm-level competitiveness such as total employment (full time equivalents), R&D investments, number of R&D personnel employed within firms, level of education of R&D personnel, all show that Bangladeshi firms are lagging far behind their Indian counterparts. A comparison of mean R&D spending (as a percentage of sales) and mean R&D staff employed (as a percentage of total workforce) amongst pharmaceutical firms in both countries is presented in Figure 4.

Figure 4: R&D figures and personnel: Indian and Bangladesh pharmaceutical firms



Source: Author's survey of Indian and Bangladesh pharmaceutical sectors, 2005-2007

6.1 The case of HIV/AIDS drugs: The competitive advantages

Given these differences and the fact that economies of scale and reverse engineering skills are two critical factors in competitive supplies of drugs, what are the competitive advantages of Bangladesh's firms and how can they be harnessed?

India's TRIPS-compliant patent regime that came into force in 2005 contains some interesting clauses that protect local generic firms while at the same time catering to access to medicines in the international market. The most notable amongst these are a provision that exclude the patenting of polymorphs/salts and esters of already existing molecules on grounds of lack of novelty (Section 3), and a provision that states that for all molecules that are patented between 1995 and 2005, Indian firms that have already invested in reverse engineering and manufacturing of the drugs can continue to do so, subject to the payment of a reasonable royalty to the patent holder firm. The law does not define "reasonable royalty", and this is expected to be the cause of some litigation in the country (Grace, 2005). This means that Indian firms can still continue to produce several of 1st and 2nd line ARVs, despite the country's TRIP-compliant regime. Table 12 contains a discussion on the drugs.

Table 12: ARVs and the Indian Patent Regime

The fixed dose combination stavudine/lamivudine/nevirapine, comprises patents on the three individual drugs which were filed in 1987/1989 and 1990 and will expire in 2007/2009/2010 respectively. Since all the three products were patented before 1 January 1995 (irrespective of the launch date of the products), each drug can be freely marketed without any arrangement with the patent holder company, irrespective of the expiry date of the patent. Indian generic companies are also free to develop and patent their own fixed dose combinations based on these three products.
Combivir contains AZT (patented 1985) and lamivudine (patented 1987). Since both of these drugs are pre-1995, they are not individually eligible for patents in India. However, Combivir has a formulation (for the combination of the two in one tablet) patent with the priority date of 1997. Worldwide, no one can market this product until 2017 (2018 in the US). Indian drug firm, Cipla, which has been manufacturing Combivir for years already took GlaxoSmithkline to court in the UK on grounds of "lack of novelty" for its patent on Combivir (GB2235627), which Cipla claimed was a combination of its earlier two ARV products, AZT (patent expiry date 2005) ands Lamivudin (patent expiry date 2007). Cipla won the case in the UK in 2004. Within India, Cipla can challenge the validity of GSK's patent, asserting that the formulation should not be patentable.
The patent for Tenofovir has been issued in 1992, but the priority patent date for the ester/ salt on of the molecule, Tenofovir Disoproxil Fumerate, is 1997. Gilead filed a patent application in India, for which a pre-grant opposition was filed by MSF in 2006. Cipla launched 'Tenvir', its own brand of tenofovir disoproxil fumarate (TDF), in September 2005. Gilead came out with a statement in May 2006 stating that its patent application will not run counter to access to medicines goals and it is ready to grant voluntary licenses to all firms (within India and otherwise) for the manufacture of generic versions of the drug.

Source: Grace (2005); Gehl Sampath (2005)

Whether local firms in Bangladesh can compete with Indian firms already producing ARVs, by sourcing their APIs from them (see the box on Square's API productions in section 4) is unclear. The question that needs to be resolved in this context is whether Bangladesh's firms can compete with their Indian or other counterparts who have the advantage of sourcing their own APIs as well as demonstrate much higher technological sophistication, in addition to possessing the required economies of scale? The niche for firms in Bangladesh's pharmaceutical firms seems to be to focus on post-2005 molecules where Indian firms will have much difficulty gaining foothold for reverse-engineering and manufacture due to TRIPS requirements. It remains to be seen, however, if the new data protection regime in India will improve the prospects for Bangladesh's local firms. The main steps that should be taken to enable Bangladesh's firms to attain competitiveness to become potential suppliers of such drugs (as well as many others) are listed out in the next section.

7. CONCLUSIONS

The pharmaceutical sector in Bangladesh has received a lot of attention in the context of access to medicines and the TRIPS Agreement in recent times. With India becoming

TRIPS-compliant in 2005, the sector in Bangladesh could potentially fill the vacuum created by Indian firms, if the local firms are able to produce generic versions of important medicines at globally competitive rates. There are however, many reasons analyzed in this study, that may not work in favour of indigenous pharmaceutical firms in Bangladesh that are seeking to capitalize on the Doha extension until 2016.

The survey, most importantly, points out to the link between incentives for learning and competitiveness of the sector as a whole. As the analysis in this section shows, a protective local policy regime that was initially intended to boost local manufacture of drugs and enhance access to medicines in the local market, seems to be creating disincentives for the local firms to technologically upgrade their production and enhance competitiveness. The local pharmaceutical sector is presently focusing extensively on retaining the gains that accrue from their dominant position in the domestic market. This narrow focus, attenuated by the policy environment, fails to create appropriate incentives for firms to strategically invest in acquiring reverse engineering skills required for production of APIs. Apart from protecting local firms from extensive foreign competition, there is a lack of scientific and physical infrastructure support, which can also be traced to insufficient policy emphasis, and the relatively small domestic market does not provide the requisite economies of scale, which are all important factors for API skills development. If the local firms are to transition gradually into a competitive sector even within the highly competitive global generics market, their acquisition of such skills is essential. Industrial policy for the sector will need to resolve this paradox of creating appropriate incentives for technological upgrading within firms, failing which merely extending the TRIPS deadline will not help realize the potential of the sector.

A sectoral lens allows for in-depth investigation of general concepts (Evans, 1995), and the disaggregated sector characteristics elaborated in this study create an important basis for thinking about the relevance of institutional incentives within the pharmaceutical sector in Bangladesh. Institutions play a key role in production efficiency and hence, there is a need to address the pre-eminence of learning institutions for creating sustained mid-term or long-term economic growth. These institutions, as laid out in the introduction of this study, can either be formal or informal, coded in terms of unofficial attitudes (Rodrik, 2003) and pre-existing cultural and social arrangements that shape the behavior of agents in the absence of good formal institutions for exchange.

Modest changes in institutional arrangements and official attitudes towards the economy can often produce large payoffs (Rodrik, 2003, p. 16). But these changes are contextual and flow from the specific needs of the knowledge system in consideration. In the case of Bangladesh, an analysis of the institutional incentives for pharmaceutical innovation, as conducted by this study drives home two essential points. Firstly, it endorses the point on weak or ineffective domestic knowledge systems in least developed countries, the disjuncture between public sector research and commercialization of products and stresses the relevance of concerted policy effort to build science, technology and innovation institutions for economic development. Secondly, and more importantly though, it raises a larger question regarding the institutional framework in Bangladesh, which can perhaps be extended to other LDCs as well. This relates to the role of market incentives in the normally export-oriented, pharmaceutical sector. Why are competitive pressures of global exports not fostering these linkages locally, despite the obvious gains? Competitive market pressures do not seem to work in the case of Bangladesh due to the institutional setting, where even well-intended policy and market incentives fail to enhance patterns of interaction and learning needed for innovation. Firms seem to be more interested in retaining their incumbent advantages by lobbying for static policies, rather than pushing concertedly for dynamic growth-oriented models. Mistrust and lack of representation of consumer welfare are key features of interpersonal interactions and the policy landscape. Most of these factors inhibit even the role of competitive market pressures in fostering welfare-maximizing collaborations, and can be summed up as 'negative' institutions (Evans, 1995; North 1990). The informal and (the few) formal institutions for innovation in the country create ample scope for capture by a few, to the detriment of the larger population. The survey found numerous instances where firms work around well-intentioned policies to find informal mechanisms that help them to retain their profits, to the detriment of the economy and technological progress at large. This is a key finding for national policy bodies and international agencies trying to build innovation capacity in Bangladesh. This implies, for example, that within the current policy landscape, direct industry support to the pharmaceutical sector will not help to reduce the negative public health impacts, in the absence of other policy interventions that target unfair business models and doctor-pharmacy-industry linkages. Donor agencies and international bodies need to focus on how policy-relevant interventions can minimize the inefficiencies of the informal institutional structures that promote such rent-seeking, to move towards increased production efficiency and consumer welfare.

In the main, strategic policy support that targets consumer welfare (in terms of greater access to medicines both locally and globally) is key to enhancing the performance of the pharmaceutical sector. Incremental innovation that will make the local firms competitive within the global generics sector will require technological upgrading activities and investment in the creation of API skills. Important policy-relevant recommendations to boost the competitiveness of the sector can be broken up into three main fields-regulatory framework, innovation capacity and common services- and these are provided below.

1. Policy assistance that seeks to enhance the competitiveness of the sector needs to focus on:
    a. An integrated approach to innovation and design of sectoral initiatives that promote human skills development of relevance to the sector, as well as improved coordination between the various components (especially public research and industry) in the domestic knowledge system;
    b. Reducing the dependencies (which are also the cause for major inefficiencies) between medical practice, research and product commercialization in the pharmaceutical sector (that presently extend well into the performance of the health sector);
    c. Helping Bangladesh develop concrete innovation incentives for the sector that could work hand-in-hand with IPRs to reduce its potential negative impacts on access to technologies for the sector;
    d. Help enhance capacity of the local intellectual property office, in order to be able to document data on patent applications and grants transparently and accountably; and lastly,
    e. Help forge liaisons between local and foreign firms that focus on technological upgrading and innovative capacity of the sector.

2. Policy assistance on the regulatory framework should focus on:
    a. Assisting the formulation of GMP compliant standards for the pharmaceutical sector and establishment of bioequivalence facilities within the country;
    b. Enhancing the capacity and performance of the Drug Directorate both for regulatory compliance and for other services such as price control;
    c. Technical assistance to evolve a system of price control and price setting to enhance access to medicines in the local market;

d. Assisting in the creation of appropriate university accreditation system as well as help design academic and vocational courses to produce the right mix of skilled manpower for the sector;
e. Separating the pharmaceutical sector regulations from the Ministry of Health functions, and on improving the recruitment patterns of the Ministry of Health.

3. Policy assistance to set up common industry infrastructure should focus on:
   a. Assisting in the setting up of the API park;
   b. Accompanied by other policy efforts that aim to create common facilities for the sector that could function on a 'pay-and-use' basis, such as a central bioequivalence laboratory for firms wanting to branch out their exports to regulated and semi-regulated markets.

A key lesson for private sector approaches to building capacity from the analysis seems to be the relevance of operating within a broader framework of reforms that target sector-level capacity building that also tackles the several pharmaceutical and health sector interfaces in the country. In the absence of such a holistic perspective, targeting individual firms' for capacity building may not serve the long term goals of enhanced access to medicines both in the domestic and international markets.

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ANNEXES

ANNEX I: Pharmaceutical Biotechnology: Firms Surveyed

Bangladeshi Pharmaceutical Firms Surveyed	
1. ACI Ltd	26. Rangs Pharmaceuticals Ltd
2. Ambee Pharmaceuticals Ltd	27. Pharmdesh Laboratories Ltd
3. Orion Infusion Ltd	28. Rephco Pharmaceuticals Ltd
4. Somatec Pharmaceuticals Ltd	29. Apex Pharma Ltd
5. Square Pharmaceuticals Ltd	30. Aristo Pharma Ltd
6. Beximco Pharmaceuticals Ltd	31. Seema Pharmaceuticals Ltd
7. Incepta Pharmaceuticals Ltd	32. Sky Lab Ltd
8. Opsonin Pharma Limited	33. Medimet Pharmaceuticals Ltd
9. The ACME Laboratories Ltd	34. Popular Pharma Ltd
10. Sanofi Aventis	35. Edruc Ltd
11. Eskayef Ltd	36. Tropical Pharmaceuticals Ltd
12. General Pharmaceutical Ltd	37. Peoples Pharma Ltd
13. Healthcare Pharmaceutical Ltd	38. Ethical Drugs Ltd
14. Globe Pharmaceuticals Ltd	39. APC Pharmaceuticals Ltd
15. Pacific Pharmaceuticals Ltd	40. Supreme Pharmaceutical Ltd
16. Delta Pharma Ltd	41. Marks Man Pharmaceuticals
17. Biopharma Laboratories Ltd	42. Orion Infusion Ltd
18. Navana Pharmaceuticals Ltd	43. Amico Laboratories Ltd
19. The Ibn Sina Pharmaceuticals Ltd	44. Renata Limited
20. Jayson Pharmaceuticals Ltd	45. Chemist Laboratories
21. Ziska Pharmaceuticals Ltd	
22. Chemico Laboratories Ltd	
23. Nipa Pharmaceuticals Ltd	
24. Proteety Pharmaceuticals Ltd	
25. Doctor’s Chemical Works Ltd	

ANNEX II: Universities and Public Research Institutes Surveyed

Bangladeshi Universities and Public Research Institutes Surveyed	
1. Dept. of Pharmacy, Rajshahi University	21. Prime Asia University
2. Dept. of Genetic Engineering & Biotechnology, Rajshahi University	22. North South University
3. Khulna Medical College Hospital	23. Dept. of Biotechnology, Khulna University
4. Dept. of Biochemistry, Rajshahi University	24. Pharmacy Discipline, Khulna University
5. Manarat International University	25. Dept. of Biotechnology, Islamic University. Kushtia
6. Dept. of Pharmacy, The University of Asia Pacific	26. Dept. of Pharmaceutical Chemistry, Dhaka University
7. Northern University Bangladesh	27. Dept. of Community Medicine, Gono Bishwabiddalaya
8. Dept. of Clinical Pharmacy & Pharmacology, Dhaka University	28. Dept. of Pharmacy R&D, Gono Bishwabiddalaya
9. Northern University of Bangladesh	29. Dept. of Pharmacy, Jahangir Nagar University
10. Northern International Medical College	30. Dept. of Microbiology, Gono Bishwabiddalaya
11. Dept. of Pharmaceutical Technology, Dhaka University	31. Dept. of Biochemistry, Gono Bishwabiddalaya
12. Marks Institute of Medical Technology	32. National Institute of Cancer Research Clinic
13. Govt. Unani Ayurvedic Medical College and Hospital	33. Dinajpur Medical Hospital
14. Federal Homoeopathic Medical College and Hospital	34. James P. Grant School of Public Health, BRAC University
15. Rangpur Medical College and Hospital	35. Bangladesh University
16. Ziaur Rahman Medical College	36. Marie Stopes
17. Dept. of Biochemistry & Molecular Science, Dhaka University	37. Dhaka Ahsania Mission Cancer Hospital
18. Sylhet M.A.G. Osmani College	38. National Heart Foundation
19. Dept. of Chemistry, Shahjalal University	39. International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B)
20. Dept. of Genetic Engineering & Biotechnology, Dhaka University	

ANNEX III: Hospitals Surveyed

Bangladeshi Hospitals Surveyed	
1. Badda General Hospital	26. Al-Fateh Medical and Consultation Service
2. Japan Bangladesh Friendship Hospital	27. City General Hospital and Diagnostic Center
3. Naz-E-Noor Hospital Pvt. Ltd.	28. Health and Hope Ltd.
4. Ahmad Medical Center Ltd.	29. Pedi Hope Hospital for Sick Children
5. Confirm Diagnostic Ltd.	30. Popular Diagnostic Center Ltd.
6. Meghna Diagnostic Pvt. Ltd	31. Delta Medical Center Ltd.
7. Ahsania Mission Cancer Hospital	32. Green Life Hospital Ltd.
8. National Heart Foundation Hospital and Research Institute	33. Medi Aid Hospital Ltd.
9. Dr. Azmal Hospital Ltd.	34. South Asia Hospital Ltd.
10. Gulshan Maa O Shishu Clinic Ltd.	35. Millennium Diagnostic Center Ltd.
11. Asia Medical Services Ltd.	36. Comfort Nursing Home (p) Ltd.
12. ICH of Shishu Hospital Shishu Sasthya Foundation	37. Dhaka Renal Center and General Hospital
13. Dhaka Dental College and Hospital	38. Hitech Multicare Hospital Ltd.
14. Rohima Maternity Hospital	39. MARKS Hospital and SARC Health Care Center
15. Mirpur Adhunic Hospital Ltd.	40. Pan Pacific Hospital
16. Al-Rajhi Hospital Pvt. Ltd.	41. Lab Aid Cardiac Hospital
17. Upasham Health Complex Pvt. Ltd.	42. General Medical Hospital
18. Al-Sami Hospital Pvt. Ltd.	43. Euro Bangla Heart Hospital Ltd.
19. Module General Hospital	44. National Chest Diseases Hospital
20. National Institute of Cancer Research and Hospital	45. Medinova Medical Service Ltd.
21. Brighton Hospital and Diagnostic Center	46. Salvation Specialized Hospital and Research Ltd.
22. Nirupom Hospital	47. Mirpur General Hospital Pvt. Ltd.
23. Asian Cardiac and General Hospital	48. Parkway General Hospital Ltd.
24. Samorita Hospital Ltd.	49. Marie Stopes
25. Gastro Liver Hospital and Research Institute Ltd.	50. ICDDR, B

ANNEX IV. Field Research Interviewees

Category and Company/Institution Name	Department/Faculty
INDUSTRY	
- Chemical	
- Advanced Chemical Industries Ltd.	- M. Mohibuz Zaman, *Chief Operating Officer, Pharma*
- BASF	- Masudur Rashid, *Manager*
- Fine & Intermediate Chemicals	- Saria Sadique, *Chairman & Managing Director*
- Pharmaceutical	
- Aristopharma, Ltd.	- M. A. Hassan, *Chairman & Managing Director*
- Delta Pharma, Ltd.	- Dr. M. Omar Faruque, *Managing Director*
- Eskayef Bangladesh Ltd.	- Mohammad Mostafa Hassan, *Business Planning & Procurement Manager*
- Healthcare Pharmaceuticals Ltd.	- Md. Halimuzzaman, *Executive Director*
- Jayson Pharmaceuticals Ltd.	- Md. Salimullah, *Managing Director*
- Rangs Pharmaceuticals Ltd.	- A. S. M. Habibur Rahman, *Vice President & Director*
- Production Operations	- Amanullah Chowdhury, *Executive Vice President*
- Square Pharmaceuticals Ltd.	- Md. Nawabur Rahman, *Assistant General Manager*
	- Parvez Hashim, *Executive Director Operations*
- Quality Operations	- Jayanta Datta Gupta, *Manager*
	- Muhammadul Haque, *Director Marketing*
	- Mir Mijanur Rahman, *Senior Executive Pesticide*
- The ACME Laboratories Ltd.	- Md. Lutf-e-Khoda, *Assistant Sales Manager*
PROFESSIONAL ASSOCIATIONS	
BAPI	
UNIVERSITIES AND PRIVATE RESEARCH INSTITUTIONS (PRIS)	
- BRAC University	
- James P. Grant School of Public Health	- Dr. Shahaduz Zaman, Ph.D., *Programme Coordinator, MPH Programme*
	- Nasima Selim, *Research Associate*
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	- Mohammed A. Salam, *Director Clinical Sciences Division*

- External Relations & Institutional Development ERID	- Armana Ahmed, MBA, *Fund & Institutional Development Officer* - Mohsena Hassan, *Public Relations Officer*
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OTHERS	
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- Traditional Knowledge Division & Life Sciences Programme	- Antony Taubman, *Director & Head Global IP Issues Division*

Annex V. Suggestions by the Faculty of Pharmacy to improve Quality of Education,

University of Dhaka, Bangladesh

Submitted to author by Faculty on 20 April 2007

1. Establishment of National Institute of Pharmaceutical Biotechnology: This will play a key role for the development and formulation of vaccines, protein and peptide drugs, oligoneucleotides (e.g. antisense) and other biotech products.

2. Establishment of a Referral / Appellate Drug Testing Laboratory: A central drug testing laboratory should be established following WHO framed guidelines where *in vitro* and *in vivo* tests for different formulations will be conducted.

3. Establishment of Pharmacokinetic and Bioequivalence Laboratory: Pharmacokinetic as well as bioequivalent data [Area under the curve (AUC), Time to reach maximum plasma concentration (t_{max}), Maximum plasma concentration (C_{max}), Elimination half life ($t_{1/2}$), Elimination rate constant (K_{el}), Mean residence time (MRT) and other statistical analysis for bioequivalence and pharmacokinetic studies] will help Bangladeshi pharmaceutical companies to export their finished products in developed countries by meeting regulatory requirements of the respective Drug Administration of that country. Furthermore, this type of work will enrich our technological know-how and develop a national pharmacokinetic research laboratory for conducting pharmacokinetic and bioequivalence tests not only to meet the local requirement but also for exporting pharmaceuticals to different countries.

4. Setting up Food and Nutraceuticals Testing Laboratory: This will ensure the quality and safety profiles of foods, food supplements and nutraceuticals as well as healthy population.

5. Exchange Program: Joint/collaborative research/training among different universities should be conducted which will help develop technology transfer and enrichment of know-how. Through this program both faculty and students will be benefited.

6. Establishment of Clinical Research Organization (CRO). CRO not only will conduct clinical trials but also will ensure clinical data management, quality assurance, regulatory affairs, medical monitoring, investigator recruitment and contract, grant management, central

randomization, patient recruitment, and statistics/report writing on behalf of different national and multinational pharmaceutical companies or academic institutions with their collaborations.

7. Laboratory Infrastructure Development: Development of biotechnology laboratory and ensuring instrumental facilities in pharmacy faculty will promote biotechnology research in Bangladesh.

8. Establishment of National Herbal Research Centre: This will ensure standardization, validation and evaluation of safety and efficacy of herbal drugs and formulations. As Bangladesh is a good repository of medicinal plants the proposed center will benefit not only the mass population of our country but also will attract international collaboration.

9. Workshop or Training Program: Workshops as well as training program should be conducted with the support of donor agencies to help develop know-how of pharmacy graduates in Bangladesh.

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