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'Towards an optimal trips-compliant industrial policy for the pharmaceutical industry in Bangladesh'

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TOWARDS AN OPTIMAL TRIPS-COMPLIANT INDUSTRIAL POLICY FOR THE PHARMACEUTICAL INDUSTRY IN BANGLADESH

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ABSTRACT

Since 1982, under a protective regulatory regime, Bangladesh has attained self-sufficiency in off-patent drugs. Of significance, all LDCs including Bangladesh need to implement the Agreement on Trade Related Intellectual Property Rights (TRIPS) of the WTO in 2016. This regulatory change warrants enhanced technology and R&D adoption to improve firms' competitiveness. Using data obtained from 94 pharmaceutical companies through a questionnaire survey, this study provides an empirical analysis of firm-level TRIPS-related vulnerability facing the Bangladeshi pharmaceutical sector. I find that R&D-related and international competitiveness-related vulnerabilities are the most important types of vulnerability. A vulnerability-based classification using cluster analysis reveals that the least vulnerable firms have comparatively higher involvement in independent and collaborative R&D activities. However, at the industry level, the inter-firm and firm-academia/institution collaboration is significantly low. The study underlines the importance of careful policy intervention to provide sustained institutional support to create incentives for multidimensional R&D collaboration, including public-private partnerships.

INTRODUCTION

All least developed countries (LDCs) including Bangladesh are obliged to implement the Agreement on Trade Related Intellectual Property Rights (TRIPS) of the World Trade Organisation (WTO) on the 1 January 2016. This means that like developing and developed countries, they will also be obliged to implement a strict patent regime.

Bangladesh is recognised as the most industrially advanced LDC that has also made considerable progress in the pharmaceutical sector, especially in the production of off-patent/generic drugs. Since the implementation of the Drug Policy in 1982, the industry has flourished under a protective regulatory regime. Currently domestic firms meet around 95% of the local demand for medicines. In 2011, the industry exported medicines worth USD 62 *million* (BRAC EPL 2012). Typical to a LDC setting, almost all pharmaceutical companies in

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Bangladesh are dependent on imported raw materials and technology (Sampath 2011; The World Bank 2008). There are a few R&D activities related to product development and quality assurance, but there is rarely any initiative to engage in any original research per se (Sampath 2007; The World Bank 2008).

As stated in the TRIPS Preamble and Article 66.2 of the Agreement, 49 LDCs were granted with an extended transition period for 10 years (beginning from 2005) to enable them 'to create a sound and viable technological base'. The WTO envisages that LDCs will be able to operate within a strict regulatory regime and shift their strategic focus from imitation to innovation by 2016. Also, the WTO has made an appeal to developed countries to transfer technology to LDCs. Therefore, there is a call from the WTO to encourage collaboration to promote innovation in the pharmaceutical industry in LDCs.

Nevertheless, Correa (2001) noted that although developed countries promised that TRIPS would enhance the flow of international technology transfer and increase domestic innovation, the promise was not likely to be kept as firms in the developing countries have been increasingly facing difficulties in taking advantage of superior technology. Hoekman et al. (2004) infer that TRIPS may expedite technology transfer from MNCs to only middle-income and a few leading developing countries but not in LDCs. MNCs undertake every means possible to protect their own interests (Glass and Saggi 2002). Therefore, the implementation of TRIPS may clear the path for MNCs to revert to their dominant market positions (Mueller, 2007).

Many scholars are apprehensive of the implementation of Article 66.2, and they still believe that TRIPS will eventually affect the growth of the pharmaceutical industry in many poor countries as the technical capability of pharmaceutical firms still remains very low (Artz et al. 2010; Moon 2011). Also there is a criticism of the effectiveness of the current monitoring mechanism of the WTO; the provision of an extended implementation period in the absence of the provision of resources may not be a meaningful approach (Correa 2007).

TRIPS has already affected the structure of the Indian and Chinese pharmaceutical industries; it has strengthened the position of large firms and at the same time has weakened the competitiveness of small ones lacking technical competence (Wendt 2007; Li 2008; Thomas

2009). The majority of Bangladeshi firms is small on a global scale, and therefore may face the same consequences as the small Indian and Chinese firms.

A wide range of literature suggests that to improve resilience to the potential impact of TRIPS-related exogenous shocks, firm-level adaptive capacity would need to adjust along with institutional-level adaptive capacity. Also, the optimal choice for LDCs may be to encourage industry-institution collaboration, which may necessitate designing a new industrial policy and specialised programs to strengthen existing institutions and establish new institutions and patterns/methods of collaboration (Correa 2007; Moon 2011).

It is in this respect that this paper addresses two important questions that have been widely debated in the TRIPS literature. First, what are the impacts of TRIPS on the pharmaceutical industry in LDCs? Second, what is the outline of an optimal TRIPS-compliant industrial policy for an LDC setting that can promote collaboration in terms of R&D/technology?

Accordingly, the empirical analysis begins by quantifying six dimensions of firm-level vulnerability, which is perceived as an impact of TRIPS experienced by Bangladeshi pharmaceutical firms since 2005. Six types of potential impact of TRIPS (sources of vulnerability) and the feasible adaptive strategies aligned with them were identified through a review of the current literature (Mani 2006; Chaudhuri 2007; Pradhan 2007; Wendt 2007; Chittoor et al. 2008; Li 2008; Rai 2009; Chadha 2009; Guennif & Ramani 2010; Basant 2011). As described later, a more extensive body of work which utilises the concept of vulnerability may be found in the climate change literature. In this study the definition of vulnerability and the methodological techniques used to measure vulnerability are drawn from the climate change literature.

The quantification involves creating indices for individual firms for each type of vulnerability, by calculating the gap between the perceived impacts of TRIPS on them and their associated response or adaptive capacity. The analysis is then expanded to provide insights into which types of vulnerability may be considered more important than the others, such that they may warrant some form of policy intervention to help the Bangladeshi pharmaceutical industry's transition to a strict patent regime in 2016. Robustness checks were performed to ensure the reliability and validity of the vulnerability indices.

Additionally, a number of cluster analyses were performed to best determine the classification of firms, in terms of various types of vulnerability. From this, the paper explores the typical features and the adaptive strategies of particularly identified groups of firms to understand more fully what predominant characteristics lead to their individual differences in terms of TRIPS-related vulnerability, and whether collaboration has contributed to lower vulnerability. The paper ends with a discussion on the important implications of our findings for a post-TRIPS industrial policy for the pharmaceutical industry in Bangladesh, which can provide an appropriate supportive environment for promising firms.

This paper aims to make two specific contributions. First, to incorporate the climate change literature into the evolutionary economics domain and add new insights into the vulnerability of firms in a LDC economy facing a multilateral patent regime, such as TRIPS; and second, to provide empirical evidence on the ineffectiveness of TRIPS in enhancing inter-firm collaboration and developed countries-LDCs technology transfer.

The remainder of the paper contains five sections. The next section reviews the relevant literature on the concept of vulnerability, TRIPS and evolutionary economic policy and presents the theoretical framework. It is followed by a section devoted to a description of the Bangladeshi pharmaceutical industry, which is then followed by an outline of methodology, followed by the section presenting the results. The subsequent section discusses the results and their implications for the post-TRIPS industrial policy. The paper concludes with final comments on the role of the government in promoting collaborative R&D and innovation activities to support the Bangladeshi pharmaceutical industry to address TRIPS-related vulnerability.

LITERATURE REVIEW AND THEORETICAL FRAMEWORK

The concept of vulnerability

In the economics literature, TRIPS has been widely viewed as a source of uncertainty, especially for the developing and least developed countries (Danzon 2007; Guennif & Lalitha 2007; Abbott 2011; Yu 2011). In the pharmaceutical industry in Bangladesh, there is a serious lack of resources available to firms and institutions to invest in R&D, poor industry-institution collaboration, inadequate technology transfer and the absence of a well functioning industrial policy. This study considers how the Bangladeshi pharmaceutical industry is likely

to be vulnerable to TRIPS as it will impose considerable changes which could be potentially destabilising.

The concept of vulnerability is not commonly discussed in the economics literature, and measuring vulnerability represents a challenging task (O'Brien et al. 2004). In recent decades, there has been some effort to use the concept of vulnerability in economic studies, particularly in economic development, such as: the economic vulnerability of small states (Briguglio et al. 2004); the vulnerability of the Indian agricultural sector to globalization (O'Brien et al. 2004); construction of an economic vulnerability index (EVI) of countries (Guillaumont 2007); and the vulnerability of the industrial sector to production losses (Hiete and Merz 2009). However, in vulnerability-related economic studies, in most cases, the concept of vulnerability and the methodological techniques to quantify vulnerability are largely influenced by the climate change literature.

In the climate change literature, uncertainty is considered as being closely related to vulnerability. It is argued that a greater understanding of uncertainty can help in devising policies to reduce vulnerability (Patt et al. 2005). Vulnerability is a function of three components, namely exogenous shocks (observed or anticipated); the exposure to such shocks; and the adaptive capacity (resilience) to shocks (Smit & Wandel 2004; Guillaumont 2011). Thus, vulnerability is the gap between potential exogenous shocks and adaptive capacity that denotes helplessness or susceptibility to harm (Füssel & Klein 2006; Guillaumont 2011). In this study, we draw from the climate change literature to measure the post-TRIPS industrial vulnerability in terms of the following parameters (Smit & Wandel 2006; Gbetibouo and Ringer 2009; Guillaumont & Jeanneney 2011):

$$\text{Vulnerability (V)} = \text{Potential impact (I)} - \text{Adaptive actions (A)} \quad (1)$$

The potential impact (I) depends on exposure and sensitivity, and adaptability/adaptive capacity (A) is viewed as 'a function of wealth, technology, education, information, skills, infrastructure, access to resources, and stability and management capabilities' (McCarthy et al. 2001, p.8).

It is important to understand what adaptive strategies Bangladeshi pharmaceutical firms have adopted during the transition phase in the areas where they are more vulnerable. The adaptive

actions of individual firms will involve bringing about adjustments in resources, technologies and management techniques. While the strength of a firm's adaptive strategy will depend on internal resources, it can be augmented by external support, such as the initiatives and programmes undertaken by the government and knowledge transfer from developed countries.

TRIPS as a source of vulnerability

Outwardly, TRIPS might emphasize minimum intellectual rights protection by the WTO member countries, but it is likely to have an important impact on the performance of firms, governments' relationships with industries, multilateral trade and technology transfer. While innovation by firms is a prerequisite for firms to survive in a stringent regulatory regime, many scholars have expressed pessimism while analysing the impact of TRIPS on LDCs. As argued by Maskus (2000), Azmi and Alavi (2001) and Correa (2001), a TRIPS-styled stringent intellectual property regime is ineffective in stimulating R&D, domestic innovation, foreign direct investment (FDI) and technology transfer as firms in LDCs have been increasingly facing difficulties in taking advantage of superior technology.

A large number of empirical studies suggest that domestic investors in developing countries rarely support a stringent IPR regime as they are vulnerable to stronger competition from the affiliates of the MNCs in possession of advanced technology (Simonetti et al. 2007). Referring to a large increase in the export earnings of IPR-sensitive industries in the developed countries in recent years, Ivus (2008) argues that since its introduction, TRIPS remains widely controversial as the ultimate beneficiaries of the multilateral agreement seem to be the developed countries. Malik and Kotabe (2009) view that unless government industrial policy promotes organizational learning and improve the supply of inputs; the performance of firms is less unlikely to be improved by any other measures, such as a strong IP regime.

Evolutionary economic policy: innovation through collaboration

Evolutionary economics view of technical change is recognised as the most suitable theoretical framework for the study of innovation and technical change (Van Den Bergh 2007). 'Path dependency' is an important concept within the evolutionary perspective, which is related to the notion that a firm's future adaptive capacity to an exogenous shock is largely

determined by its present innovativeness and technological capability (Coombs & Hull 1998). A firm's dynamic capability is cumulative in nature (Nelson & Winter 2002).

Therefore, an understanding of the current level of innovativeness of Bangladeshi pharmaceutical firms will provide insights into their future capability to cope with the post-TRIPS regime. Innovation is the basis of core competence and dynamic capabilities for firms trying to deal with exogenous shocks (Belliveau et al. 2006).

Pharmaceutical innovation can take various forms, ranging from incremental innovation to the discovery of new raw materials (Guennif and Ramani 2010). However, Mascus (2000) and Matthews (2010) argue that it is a difficult task to define innovation in the context of poor countries given their resource constraints and inability to invest resources in innovation. At a moderate level of economic development, they can develop some abilities to innovative/invent that incorporates adaptation, imitation and modification of existing technologies.

Product and process development for manufacturing even off-patent drugs involves a huge cost, and the research for new drug discovery is far more expensive. Therefore, collaboration in R&D among firms, universities and publicly-funded research organisations tends to be more common in the pharmaceutical sector than most other industries (Johnson 2008). Although TRIPS has not resulted in higher R&D expenditure for new pharmaceutical products in emerging economies like India and China, it has influenced collaborative research activities in the area of off-patent medicines (Chaudhuri 2007; Thomas 2009).

At the core of industry policy shaped by an evolutionary perspective, firms are viewed as a part of a system that consists of both business firms as well as non-business or non-market institutions (Nelson & Winter 1982; Nelson 2008). The cornerstones from a system perspective are (Fransman 1995; Freeman 1995; OECD 2002): bridging between users and producers of technology; promoting mutually beneficial collaboration between the private and public sectors and the creation of spillovers. The system perspective is proactive in encouraging firms and institutions to engage in collaboration to develop dynamic capabilities (Nelson 2008).

Traditionally, the culture of cooperation between enterprises, the government and scientific communities is absent in most of the poor developing countries (Forero-Pineda 2006). Technological innovation requires investment capital, entrepreneurial vision, a trained scientific/technical workforce, research laboratories, and research programs (Johnson 2008). Thus, considering the importance of a systematic approach in addressing TRIPS-related challenges, it is important to investigate the collaborative activities undertaken by Bangladeshi pharmaceutical firms.

In the post-2005 period, among the fast-growing countries in Asia like India and China, the state has played an important role in designing and implementing pro-pharmaceutical policies and programmes, which have acted as a catalyst in the development of the R&D capabilities of pharmaceutical and biotech firms and has led to innovation (Thomas 2009). Under current circumstances, Bangladeshi pharmaceutical firms mostly depend on their limited financial, physical and organizational capital (typical of many LDCs); consequently, they have limited innovation capabilities (Sampath 2007; The World Bank 2008). However, by being part of an innovation system, firms can benefit from institutional support, technological policy and other complementary policies, such as education policy and competition policy (Malerba & Mani 2009).

In the absence of any supportive technological regime, the reliance of Bangladeshi firms on their own research activities solely as a source of knowledge and skills may not reduce their vulnerability in the post-TRIPS regulatory regime. A dynamic system of innovation approach to industrial policy has the potential to facilitate a mechanism for Bangladeshi pharmaceutical firms to gain access to the necessary strategic resources to build up capabilities to survive in the post-TRIPS period.

RESEARCH SETTING —THE BANGLADESHI PHARMACEUTICAL INDUSTRY

Most of the Bangladeshi pharmaceutical firms are engaged in the production of generic medicines and imitation drugs using almost 100 percent imported technology and around 95 percent imported raw materials. The industry is currently characterized by a very low level of R&D activities. The industry has a medium level of seller concentration. In 2011 the top 5 companies held 46.8% of the USD 1.13 *billion* market, the top 10 held 67.7%, the top 15 held 77.7% and the top 20 companies held 84.9% market share (BRAC EPL 2012). Only four of

the top 10 firms were publicly listed companies, collectively holding 36.7% of the market (BRAC EPL 2012). There is a very low level of FDI in the pharmaceutical sector in Bangladesh.

Pharmaceutical firms in a developing country or LDC setting concentrate either on raw materials, such as active pharmaceutical ingredients (APIs), or finished products, or both. However, the production of APIs demands a higher level of technological capability (especially, re-engineering skills) (Sampath 2006; Guenniff & Ramani 2010). Although Bangladeshi pharmaceutical firms have been protected by a weak patent regime for more than three decades, they have not been able to excel in API production mainly because of financial and infrastructural resource constraints and a lack of the necessary economies of scale (Sampath 2012).

Sampath (2007) suggests that the rate of annual new product introduction (generic formulations) is very low in the Bangladeshi pharmaceutical sector compared to India, mainly due to a low level of R&D activities. She estimates that in 2005-07 Bangladeshi pharmaceutical firms spent around 1% of sales on R&D (in India, this figure was 7%), while the workforce included only 1% R&D staff (in India, this figure was 5%). In 2012, the R&D intensity of the two largest publicly listed companies (combined market share is 27.5%) was below 1%.

In 1985 Bangladesh's pharmaceutical exports were only USD 0.4 *million* (the value of ready-made garments (RMG) exports was USD 116.2 *million*). However, over the years pharmaceutical exports from Bangladesh have grown steadily but their value is still significantly low. In 2011, total pharmaceutical exports were only US\$ 46 *million* (less than 0.2% of Bangladeshi exports). In India in 2010-11 the value of pharmaceutical exports was around USD 10.560 *billion* (share in total exports-4.2%), and the export intensity (exports as % of net sales) at the industry level for India was 45.31% (DOP 2012). It is important to note that a large proportion of Bangladesh's pharmaceutical exports is done by Novartis/Sandoz, an MNC operating in the country (the Bangladesh branch of the company sends its products to other branches across countries). For example, in 2011 the company exported products worth USD 9.89 *million* (21.5% of the total exports by the industry) (DGDA 2012). Overall, this indicates an overall poor export performance by the pharmaceutical sector, considering the size of the industry. Sampath (2012) observes that the lack of export focus by

Bangladeshi pharmaceutical firms is linked to a lack of the technical capabilities required for API production that stems from low R&D.

In the light of the above discussion, it can be argued that the pharmaceutical industry in Bangladesh is vulnerable to the substantial regulatory changes triggered by TRIPS.

METHODOLOGY

Research method

This study measures firm-level vulnerability using the concepts adapted from the climate change literature. As shown in equation (1), I seek to quantify the firm-level vulnerability experienced by Bangladeshi pharmaceutical firms since 2005. In particular, I have developed indices of TRIPS-related vulnerability of Bangladeshi pharmaceutical firms that involves gauging the adequacy of their adaptive capacity in six broad areas of vulnerability derived from the empirical literature. These are:

- Raw materials-related vulnerability (V_1);
- Technology-related vulnerability (V_2);
- Quality and regulatory compliance-related vulnerability (V_3);
- R&D and innovation-related vulnerability (V_4);
- Domestic competition-related vulnerability (V_5); and
- International competitiveness-related vulnerability (V_6)

As illustrated in equation (1), to construct a vulnerability index (any of the 6 types), we need an impact variable (IV) and an adaptive action variable (AV). A vulnerability score of 1 indicates full vulnerability, and 0 indicates no vulnerability. An extensive literature review was conducted to identify the most relevant strategies related to Bangladeshi firms' adaptive strategies to deal with the perceived TRIPS-related impacts. Thus I identified a set of AV sub-variables related to each type of impact variable (IV_1 to IV_6). Additionally, an appropriate multivariate statistical analysis (Cronbach's alpha) was performed to establish the validity of the measurement procedure (construct validity) and to identify the most compatible sub-variables belonging to individual adaptive action variables. The values of composite indices for AV_1 to AV_6 were obtained using the arithmetic average of their related sub-variables.

In developing the indices, I have followed Anand and Sen (1994), Nardo et al. (2005) and Patnaik and Narayanan (2009). The composite index (V_{ij}) of an individual firm j for a particular type of vulnerability i is calculated through using a simple arithmetic average of the standardized score of impact variable (IV) i and adaptive action variable (AV) i of firm j . As the values for the standardized scores IV_{ij}^* and AV_{ij}^* were determined on the basis of the functional relationship of impact variables (IVs) and adaptive action variable (AVs) with vulnerability, a standardised impact variable and adaptive action variable related to a particular type of vulnerability can be meaningfully combined to create a composite score/index (Cordina & Farrugia 2005; Jones & Andrey 2007). Following Saisana et al. (2002), Saisana et al. (2005) and Nardo et al. (2005), four additional sets of composite indices (for all six types of vulnerability) were constructed in this study to check the robustness of the results and to improve transparency (alternative weighting schemes).²

Also, I classified the sampled firms according to their degree of exposure to different types of vulnerability to gain a deeper understanding of the typical characteristics of different groups. To ensure an optimal classification of the sampled firms, I employed a technique that involved the use of cluster analysis. In this approach, a two-step (hierarchical) cluster analysis was performed for each of the weighting methods. Thus five different sets of vulnerability scores (one base case and 4 alternative cases) were generated. All firms were rank-ordered according to their vulnerability under alternative cluster analyses. Firms in the least vulnerable clusters were compared to see whether there was common membership across the 5 weighting schemes. Furthermore, I also examined the hypothesized linkage between vulnerability and collaboration. In particular, I have compared the mean scores of the three identified groups for four adaptive strategies that involve collaboration.

Sample and data collection

The population to be surveyed is the 149 member firms of the Bangladesh Association of Pharmaceutical Industries (BAPI) as listed in the BAPI Annual Report (2010). The data for this study were collected between October and December 2012 from the owners/high level

² The weighting technique mainly involved the use of sector means (consisting of 94 firms) of each of the sub-variables related to an index to calculate their relative weights (Saisana et al. 2005). Also, an investigation of the stability of the results was performed placing various arbitrary but feasible weights of the standardized score of impact variable (IV) and adaptive action variable (AV) (Nardo et al. 2005). For example, first, IV_{ij}^* was multiplied by 1/3 and AV_{ij}^* was multiplied by 2/3; and then, IV_{ij}^* was multiplied by 2/3 and AV_{ij}^* was multiplied by 1/3.

managers of these firms through a self-administered questionnaire. A total of 94 completed questionnaires were obtained. The perception survey questionnaire measured six types of impact variables and their corresponding adaptive action variables using a five-point closed order Likert scale, where 1 indicates that the variable is *not important at all* and 5 is *very important*. This study captured a large representative sample of Bangladeshi pharmaceutical firms, with 94 firms completed questionnaires, representing about 63% of the pharmaceutical market in Bangladesh.

RESULTS

As shown in Table 1, in broad terms, all the vulnerability scores that were calculated are significantly different from zero, where 0 indicates no vulnerability and 1 indicates full vulnerability.

Table 1: The standardised mean and standard deviation of different types of base case vulnerability indices in terms of their importance (N=94)

Type of vulnerability	Mean (M)	Standard deviation (SD)
R&D and innovation-related vulnerability (V ₄)	0.87	0.14
International competitiveness-related vulnerability (V ₆)	0.79	0.15
Raw materials-related vulnerability (V ₁)	0.69	0.17
Technology-related vulnerability (V ₂)	0.68	0.20
Quality and regulatory compliance-related vulnerability (V ₃)	0.58	0.11
Domestic competition-related vulnerability (V ₅)	0.28	0.19

The results demonstrate that the R&D and innovation-related vulnerability is the most important type of vulnerability facing Bangladeshi pharmaceutical firms, followed by international competitiveness-related vulnerability, while domestic competition-related vulnerability was the lowest. In both cases, the spread in scores around the mean is small, which indicates that the responses related to both perceived impact and adaptive strategies (preparedness) were reasonably consistent. The results suggest that most of the sampled firms are faced with TRIPS-related challenges associated with R&D and innovation and international competitiveness. The gap between the impact and adaptive capacity related to R&D and innovation-related vulnerability (V₄) and international-competitiveness-related vulnerability (V₆) is much wider than that related to other types of vulnerability. The findings

reflect the growing need for Bangladeshi pharmaceutical firms' to develop R&D and innovative related dynamic capabilities in order to adjust to the post-TRIPS universal strict patent regime. Also, as expected, given the low level of R&D-intensity of the majority of Bangladeshi pharmaceutical firms, they have a low level of regulation-handling capability and export competitiveness.

Following Cooksey (2007), a one-way repeated measures ANOVA was performed to confirm whether the firms' differences in degrees of exposure to various types of vulnerability was statistically significant, $F(5, 465) = 193.35, p < 0.001$. Nevertheless, it can be argued that most Bangladeshi pharmaceutical firms are highly vulnerable across all categories with the exception of domestic competition-related vulnerability.

When alternative weighting schemes were applied in all four robustness checks, near equal vulnerability scores were obtained relative to the base case. Also, in each case, the ranking of different types of vulnerability in terms of their importance remained virtually unchanged.

Using a two-step (hierarchical) cluster analysis, with the five different sets of vulnerability scores (one base case and 4 alternative cases), each time two clusters were obtained; Cluster 1 consisted of firms with comparatively lower average vulnerability scores (in all types of vulnerability), while Cluster 2 was comprised of firms with comparatively higher average vulnerability scores (in all types). On the basis of the cluster membership pattern, there is a logical basis for classifying the sampled firms into three groups: *Least Vulnerable* consisting of 9 comparatively Least Vulnerable firms and better prospects of adjusting to a post-TRIPS regime; *Medium Vulnerable* consisting of 14 firms with some potential to adjust to the post-TRIPS regime through improving their existing capabilities, and *Most Vulnerable* consisting of 71 firms awaiting an uncertain future and have the lowest prospects of adjusting under the TRIPS regime. Table 2 illustrates how the cluster membership pattern was used in grouping the sampled firms. A one way ANOVA procedure confirmed that means of groups were significantly different from each other.

I found that there were no significant between-group differences at conventional levels in terms of firm location, years of operation, legal status and raw materials (APIs) production. However, the *Least Vulnerable* group was significantly superior than the others in term of the

number of employees, product portfolio, new product introduction (generic formulations), producing animal drugs, and export performance.

Table 2: Classification of the sampled firms (relative to other firms in the industry) on the basis of vulnerability using cluster membership pattern (N=94)

Group	No. of firms	Membership of Cluster 1	Mean V ₁ (SD)	Mean V ₂ (SD)	Mean V ₃ (SD)	Mean V ₄ (SD)	Mean V ₅ (SD)	Mean V ₆ (SD)
<i>Least Vulnerable</i>	9 (10%)	5 times	0.37 (0.11)	0.26 (0.20)	0.49 (0.10)	0.71 (0.21)	0.17 (0.16)	0.59 (0.16)
<i>Medium Vulnerable</i>	14 (15%)	2-4 times	0.60 (0.14)	0.55 (0.13)	0.51 (0.09)	0.73 (0.11)	0.35 (0.19)	0.67 (0.14)
<i>Most Vulnerable</i>	71 (75%)	0-1 time	0.74 (0.12)	0.76 (0.12)	0.60 (0.11)	0.92 (0.09)	0.28 (0.19)	0.83 (0.12)
F(2, 91)			40.01	70.29	8.02	27.21	2.72	22.58
ρ			<0.001	<0.001	0.001	<0.001	0.071	<0.001

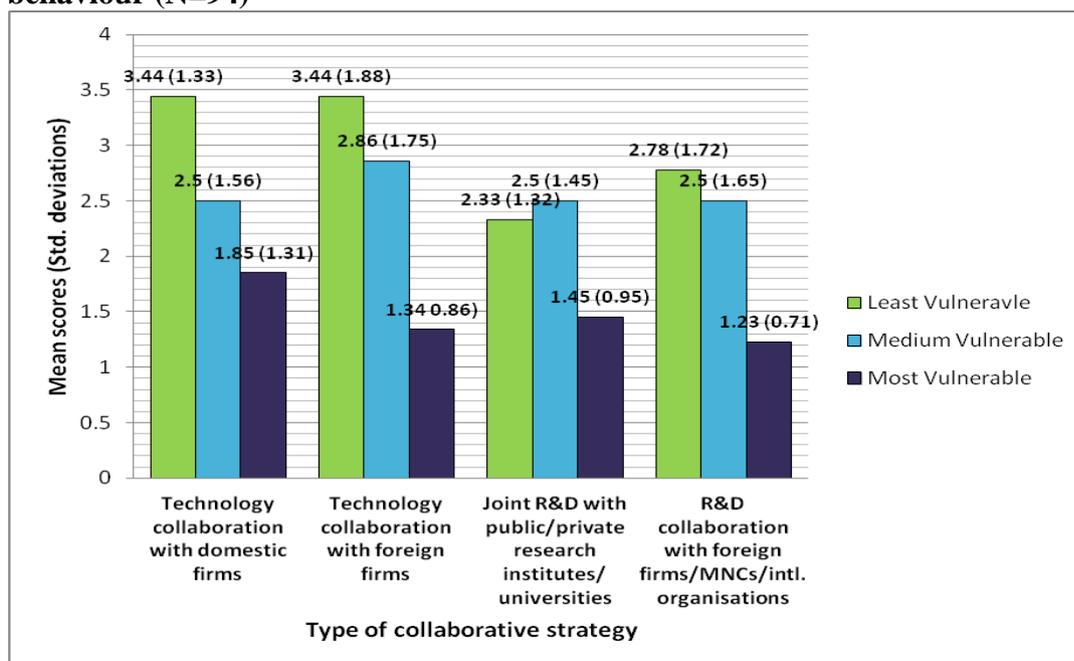
Although none of the groups demonstrated any significant capability in developing in-house API capability, in general, the majority of the *Least Vulnerable* firms are comparatively more successful than their counterparts in the *Medium Vulnerable* and *Most Vulnerable* groups in forming strategic partnerships with foreign raw material suppliers to deal with raw materials-related vulnerability. They were also distinctly different in terms of their capability to invest in developing technology, and demonstrated a significant superiority in terms of technology collaboration with both local and foreign firms.

All the groups emphasized on the quality of their products to meet quality and regulatory compliances but the *Least Vulnerable* firms had comparatively more capability in terms of investment in training. Nevertheless, similar to other groups, R&D and innovation-related vulnerability appeared as the most important type of vulnerability facing the *Least Vulnerable* firms. Importantly also, they did not have significant collaboration with local institutions/academia, but were more likely to engage in joint R&D with foreign firms to benefit from higher levels of scientific/technological knowledge possessed by foreign firms/institutions.

Conversely, domestic competition-related vulnerability was not an important dimension of TRIPS-vulnerability faced by any of the three groups, thanks to the strength of their distribution channels, production capacity of less R&D-intensive generic formulations, and investment in market promotion. However, the firms belonging to the *Least Vulnerable* and *Medium Vulnerable* groups dominate in the domestic market characterized by off-patent generics, and their limited exports are mostly directed to low value unregulated markets. Both these groups face a high level of R&D and innovation-related vulnerability as well as international competition-related vulnerability. The two main adaptive strategies related to international competitiveness approaches adopted by the majority of the *Least Vulnerable* firms and a few of the *Medium Vulnerable* firms include obtaining accreditation from developed countries and developing niche market strategies. Only a few firms had the ability to form strategic partnerships and enter into joint ventures with foreign firms.

With regard to the hypothesized linkage between vulnerability and collaboration, I can conclude that collaboration could contribute to lower vulnerability for Bangladeshi pharmaceutical firms. Figure 1 shows that the *Least Vulnerable* group demonstrates a higher level of collaborative attitude than the others, especially in dealing with technology-related vulnerability (V_2).

Figure 1: Comparison between the *Least Vulnerable*, *Medium Vulnerable* and *Most Vulnerable* firms in terms of Adaptive Vulnerabilities (AV) associated with collaborative behaviour (N=94)



Likert scale range: 1= Not important at all and 5= Very important

Although the overall level of collaboration to date is not encouraging, however, a closer look at the observed collaborative behaviour and the main areas of collaboration reveals that the *Least Vulnerable* firms had an equal preference for technology collaboration with domestic firms and foreign firms but in terms of R&D, they chose to collaborate more with foreign firms. This reflects their enhanced focus on benefitting from scientific knowledge/technology transfer from R&D-intensive foreign firms/MNCs.

DISCUSSION AND IMPLICATIONS FOR THE POST-TRIPS INDUSTRIAL POLICY

In this study, I have identified that among all six types of TRIPS-related vulnerability, R&D-related and international competitiveness-related vulnerabilities are the most important types of vulnerability faced by all firms in the Bangladeshi pharmaceutical industry. A pattern of a lack of willingness as well as opportunities for upgrading technical/scientific capability is evident across the industry and poses a significant threat to the sector. Additionally, an important potential consequence is the threat to access to affordable medicines. Given the pending TRIPS environment, these empirical findings would suggest there is a pressing need to develop an appropriate industrial policy, with special focus being given to reducing Bangladeshi firms' R&D and international competitiveness-related vulnerability exposure.

It was expected that Bangladesh would utilise the ten-year transition period (2005 to 2015) to improve pharmaceutical firms' R&D capabilities, innovativeness and international competitiveness. For an industry such as pharmaceuticals, which typically operates in a dynamic and technologically and knowledge-intensive market environment, it is critical to upgrade technological capability and innovation over time to maintain competitiveness both in domestic and international markets (Correa 2007; Malhotra 2008; Bruche 2012). Given Bangladesh's increasing commitment to integrate itself into the global economy, there are significant risks to pharmaceutical firms if they fail to adequately engage in such activities. Also, it is not clear whether during the TRIPS regime, the government will be able to provide sufficient support for indigenous firms from technologically dominant foreign companies.

Nevertheless, the *Least Vulnerable* firms (as well as some *Medium Vulnerable* firms) demonstrate some innovation potential at different levels - for example, in new product introduction (generic formulations) and in obtaining accreditation from abroad. Although

significant innovation by the firms belonging to the *Least Vulnerable* group lies in the future, to develop the required re-engineering/processing capability even for off-patent generic drugs, they are in need of financial resources as well as new scientific/technological knowledge. However, under the current circumstances, they have lacked institutional support. For example, they have no access to government R&D support funds, venture capital or debt finance for R&D projects. Additionally, they do not derive any benefits from academic research activities or programs undertaken by public/private research institutions. These findings are consistent with the current literature. In her study, Sampath (2012, p. 312) points to ‘extreme disparities in firm sizes and capabilities, as far as innovation as well as marketing capabilities is concerned’. She also argues that there are only some 6 highly established pharmaceutical firms in Bangladesh in possession of considerable R&D skills and scientific infrastructure.

For the majority of Bangladeshi firms the focus has been confined to the low value end of the domestic pharmaceutical sector in Bangladesh. During the transition period, most firms in the *Medium Vulnerable* and *Most Vulnerable* groups have not been able to advance their technological capability sufficiently to meet the challenges faced in the new post-TRIPS institutional context. They have relied on developing core competencies to ensure a reasonable share of the domestic market, but have been unable to undertake innovative strategic initiatives that would mitigate TRIPS-related vulnerabilities.

This research has been guided by a system perspective grounded in the evolutionary economics framework, and accordingly I have inferred that collaboration can promote mutual benefits for the collaborating parties and thus reduce vulnerability. The empirical evidence in the study supports this claim and proposes that linking firms with institutions (academia and public sector research organisations) can promote the adaptive capacity of dynamic firms. Drawing on insights from the analysis of the characteristics of vulnerability-based groups, I have found that there are convincing reasons for the post-TRIPS industrial policy in Bangladesh to provide a supportive environment for the *Least Vulnerable* firms and *Medium Vulnerable* firms through promoting their access to complementary resources and knowledge. Whilst it is envisaged that those firms in the *Least Vulnerable* group have a demonstrated capacity to benefit from such a supporting collaborative environment, if such support were to be available sector-wide it would enable those firms that are sufficiently capable within the *Medium Vulnerable* groups as well as some in the *Most Vulnerable* groups to develop. This

would particularly be the case for firms that are actively seeking opportunities to upgrade their R&D and technological capability, and those which are willing to collaborate to improve their processes, products and export performance.

It is evident from the findings that all the sampled firms including those from the *Least Vulnerable* group had very limited engagement with public research institutions and academia, and preferred R&D collaboration with foreign firms/MNCs/international organisations. It is obvious, however, that a firm's choice of collaborative partner is largely determined by the perceived benefit/risk underlying the collaborative relationship. In particular, the firm wants to maximize the potential for upgrading its existing knowledge through such interaction. This raises a set of important questions: do the local institutions (linked to the pharmaceutical sector) possess superior knowledge than the *Least Vulnerable* firms? If so, what are the factors that are hindering broader institutional collaboration, mutual dependence and trust? How should the government address such firm-level and institutional-level weaknesses?

Considerable uncertainty exists in terms of appropriate policy interventions to enhancing learning, innovative performance and competitiveness of pharmaceutical firms in LDCs including Bangladesh under the TRIPS regime. I have identified some areas that may be highlighted to address TRIPS-related challenges, such as:

1. The post-TRIPS industrial policy may play an important role in promoting firm-institution collaboration in innovation through establishing a market-based and incentive-based collaborative network. First and foremost the new policy needs to focus on upgrading national institutions, including academia and other related research institutions, to facilitate mutually beneficial and commercializable knowledge-creating activities within the sector. Nevertheless, upgrading knowledge-based institutions warrants a long-term strategic plan and credible commitments of resources. Improving the competence of public research organisations should be reflected in the quality and quantity of their outputs as well as by their ability to diffuse new knowledge through collaborative arrangements.

Inter-firm R&D collaboration can be promoted through introducing collaborative projects involving public research institutions working with multiple domestic firms.

Such closer engagement between public research institutions and industry can act as a catalyst to enhance scientific/technological knowledge, thereby enabling firms and the industry as a whole to advance their technological capabilities. Also, this type of policy arrangement is likely to promote a culture of R&D collaboration in the pharmaceutical industry in Bangladesh.

Furthermore, to promote domestic firm-foreign firms/MNCs collaboration, the post-TRIPS industrial policy may create incentives for foreign firms/MNCs, such as protecting their IP rights and commercial interests; encouraging public institutions to be a party in the collaborative projects; providing infrastructural support; and granting subsidies.

2. Firms are in need of greater access to financial resources to improve their investment in producing raw materials, developing their own technological capabilities, enhancing R&D activities, and entering into new export markets. There is a need to improve institutional arrangements to enable most capable firms to access financial capital. Bangladesh can follow the Indian strategy in promoting the innovative output of pharmaceutical firms. As reported by Mani (2010), in the post-liberalization era (since 1995), Indian pharmaceutical industry was given the highest priority in providing financial incentives to enhance R&D activities, such as grants and loans, venture capital and tax incentives. However, Mani infers that financial incentives should be targeted to allow firms to grow larger so that they develop higher capability to invest in R&D.

In post-2005 India many large pharmaceutical firms separated their R&D units from the main firm and raised venture capital for risky projects (Athreya et al. 2009; Chadha 2009). Generally, dedicated R&D units attract risk-loving investors. Thus, there is a need to encourage mergers and for firms to be publicly-listed through providing incentives, such as tax-benefits. Furthermore, private-public partnerships can also improve the investment capability of firms by sharing ownership of risky R&D projects that can yield either a profit or a loss.

3. One of the most important reasons for the low level of innovativeness of Bangladeshi pharmaceutical firms is that the degree of product differentiation is very low (firms

mostly compete with identical generic formulations), which does not create adequate incentives for experimentation by firms. Most firms are pre-occupied with such low-level activities whilst ignoring more technologically intensive and more complex activities necessary to survive in a post-TRIPS environment. But looking at the post-2005 scenario in the Indian pharmaceutical industry, it can be predicted that only those Bangladeshi firms actively exploring and exploiting more knowledge-intensive activities and opportunities will be able to withstand the post 2016 environment (Chittoor et al. 2008; Kale & Wield 2008). Some of the *Least Vulnerable* firms have already begun to do this, but this is not enough to increase their capability and competitiveness; they are in need of additional support from a proactive industrial policy. Importantly also, IP policy should create conditions which facilitate higher-level activities, such that those firms which can take advantage of such opportunities will improve their likelihood of surviving and growing.

4. Finally, the industry needs to improve its regulation-handling capabilities critical for competing in highly regulated and high value markets in developed countries, and moderately regulated markets in developing countries/LDCs. To support this, the post-TRIPS industrial policy can also provide strategic and financial support (such as grants and export subsidies) towards firms' internationalization activities.

CONCLUSION

This study is guided by the system perspective supported in evolutionary economics that emphasizes on developing proactive industrial policy or innovation policy through linking industry with academia and public research institutions. Promoting mutually beneficial collaboration between pharmaceutical firms and institutions can be an optimal choice for resource-poor LDCs to address various TRIPS-related challenges as this can be a cost-effective way to influence their innovative capabilities. This study proposes that bridging firms with institutions through establishing a market-based and incentive-based collaborative network can promote the adaptive capacity of dynamic firms in Bangladeshi pharmaceutical sector, such as those in the *Least Vulnerable* and *Medium Vulnerable* groups (and of course, some in the *Most Vulnerable* group) which may have the capacity to adapt to a post-TRIPS environment.

It is worth pointing out a cautionary note. The purpose of this study is not to recommend policies to support those specific firms in the *Least Vulnerable* group. Rather the classification was aimed at identifying the major current problems/vulnerabilities facing the industry and to determine which type of policy support and institutional development would foster collaborative R &D and innovative activities. In principle, any firm should be able to take advantage of the post-TRIPS IP framework and industrial policy to upgrade its existing capability and hence reduce its TRIPS-related vulnerability.

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