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A firm-level analysis of the vulnerability of the Bangladeshi pharmaceutical industry to the TRIPS Agreement: Implications for R&D capability and technology transfer

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Abstract

This study measures the different types of vulnerability experienced by Bangladeshi pharmaceutical firms since 2005, consequent upon the Agreement on Trade Related Intellectual Property Rights (TRIPS) of the World Trade Organisation (WTO). We find that that R&D-related vulnerability was the highest in the pharmaceutical sector in Bangladesh. Cluster analysis supports this proposition as 79.8% of the sampled firms had below average levels of innovativeness. We argue that the TRIPS transition period (which began in 2005 and is to end in 2015) has not been used effectively used by Bangladesh, the most technologically advanced LDC to create a strong technological platform for the pharmaceutical industry. Also, the expected process of transfer of technology has not taken place. We recommend that the post-TRIPS industrial policy for the pharmaceutical industry in Bangladesh should be designed and delivered with a key focus to improve the R&D and innovation capabilities of the domestic firms. Moreover, the WTO must evaluate the current mechanisms underpinning developed countries-LDCs technology transfer.

Keywords: **TRIPS; patent regime; vulnerability; Research and development; innovation; technology transfer**

1. Introduction

The Agreement on Trade Related Intellectual Property Rights (TRIPS) of the World Trade Organisation (WTO) has provided special consideration to the least developed countries (LDCs), including Bangladesh, by allowing an extended transition period for 10 years (beginning from 2005). Nevertheless, they are obliged to implement a strict patent regime on the 1 January 2016. As mentioned in the TRIPS Preamble as well as in Article 66.2, the WTO has also instructed its developed country members to transfer technology to LDCs enabling them 'to create a sound a viable technological base'. Interestingly, many scholars are apprehensive of the implementation of Article 66.2 and are critical of the effectiveness of the current monitoring mechanism of the WTO. They believe that the treaty will rather thwart the growth of the pharmaceutical industry in many countries (Correa 2007; Chaudhuri 2007; Danzon 2007; Artz et al. 2010; Abbott 2011; Moon 2011).

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Under a protective regulatory regime, the Bangladeshi pharmaceutical industry has made considerable progress since 1982. Over 95% of the local demand for medicines is met by domestic firms and medicines are exported to about 80 countries (BAPI Annual Report 2012). It is argued that in the context of an integrated global economy, the implementation of this multilateral trade-related treaty in developing countries in 2005 has since then had the potential to affect the growth of the pharmaceutical industry in LDCs (the spillover effects of stronger IP protection) (Yu 2009; Abbott 2012).

In this study, we have measured the different types of vulnerability facing Bangladeshi firms to the TRIPS Agreement since 2005 to see which type of vulnerability (negative impact) is the most important and warrants immediate intervention. A cluster analysis has helped us to identify two clusters of firms based on their degree of different types of vulnerability. We have found that the cluster of firms with a higher degree of vulnerability to the TRIPS Agreement has a lower level of innovativeness and vice versa. Thus, our findings, in addition to providing key insights into how the post-TRIPS industrial policy for the pharmaceutical industry in Bangladesh should be designed and delivered, also have important implications for other LDCs. Moreover, these findings can be used by the WTO to evaluate the current mechanism related to developed countries-LDCs technology transfer, and to review its TRIPS-related considerations for LDCs.

2. Theoretical framework

2.1. The Post TRIPS-regulatory transition and innovation

The TRIPS Agreement does not only involve regime shifting, but it has also triggered firm level changes in technical expertise and innovation to maintain competitiveness. According to Van Den Bergh (2007), evolutionary economics view of technical change is the most appropriate theoretical framework for the study of transitions and innovations. In the evolutionary economics, firm level innovation efforts involving changes in routine activities and the observed path dependency are studied concurrently (Coombs & Hull 1998). 'Path dependency' means that in the absence of a supportive technological regime, in response to unfavourable changes in the surrounding environment, a firm's change in routine (adaptation strategy) is based on its own path and history. Therefore, a firm's future technological change or dynamic capability depends on its past technological change, and the firm level technological change is cumulative in nature (Nelson & Winter 2002). Therefore, it is important to know that in the absence of any supportive technological regime, what adaptive strategies Bangladeshi pharmaceutical firms are adopting through bringing necessary changes in their routine in the areas where they are more vulnerable, and what sort of innovative efforts have individual firms begun, which will be augmented in the future to comply with the TRIPS Agreement.

2.2. Measuring the post-TRIPS vulnerability of pharmaceutical firms

Although, in the economics literature, the TRIPS Agreement has been widely viewed as a source of uncertainty for the developing world (Danzon 2007; Abbott 2011; Yu 2011; Sampath 2012), there is no available empirical literature on measuring the vulnerability of an industrial sector in a LDC setting facing such a major regulatory change. Also, the quantification of vulnerability is a challenging task. However, the climate change literature is useful in understanding the methodological techniques used to measure vulnerability. Heltberg and Bonch-Osmolovskiy (2011) view vulnerability is 'a function of the risks, exposure and sensitivity to risks, and adaptive capacity' (p.5). As outlined by McCarthy et al. (2001), 'exposure' can be considered as a direct hazard or stressor, and 'sensitivity' refers to the degree of response to the hazard. Thus, the potential impact depends on exposure and sensitivity. McCarthy et al. (2001, p.8) have defined

adaptability as 'a function of wealth, technology, education, information, skills, infrastructure, access to resources, and stability and management capabilities'. Brooks (2003) terms adaptive capacity as 'the ability or capacity of a system to modify or change its characteristics or behaviour so as to cope better with existing or anticipated external stresses' (p.8). In this study, the conceptual framework for the post-TRIPS industrial vulnerability is based on the following relationship (Füssel and Klein 2006; Gbetibouo and Ringler 2009):

Vulnerability (V) = Potential impact (I) – Adaptive actions (A) *(1)*

3. Research methodology

3.1. Choice of variables for measuring vulnerability

A review of the recent literature suggests that the TRIPS Agreement is discriminatory to poor countries. Kanwar & Evenson (2003) studied the impact of stronger IP protection on research and development (R&D) spending in 85 countries, and found that unless a a stronger IP regime did not encourage innovation activities in poor countries. In general, some potential sources for concern for poor countries include unequal bargaining power; the resurgence of MNCs in the domestic market; increased price of raw materials and technology; increased imports of medicines; fall in the competitiveness of small firms (Kuanpoth 2006; Wendt 2007; Li 2008; Guzmán 2012; Kapczynski & Hall 2009; Yu 2011).

The development of technology and the manufacturing pharmaceutical raw materials, especially active pharmaceutical ingredients (APIs), requires high levels of engineering and chemistry skills, which are largely absent in LDCs including Bangladesh and thus pharmaceutical firms mostly depend on imported raw materials (Sampath 2007). In LDCs, most technologies are imported; however, increased imports are unlikely to result in technology transfer into countries with weaker absorptive capacity (Acharya & Keller 2009; Yang & Maskus 2009).

Currently, governments across countries insist that imported medicines should be produced following the WHO's current good manufacturing practices (cGMPs) guidelines (Bah-Traore 2012). Therefore, a higher regulation handling capability is more important than before for firms interested in export. In the post-TRIPS period, a large number of Indian pharmaceutical firms have adopted R&D-intensive business models to improve their regulation handling capability; currently, there are more than 100 Indian pharmaceutical firms with USFDA accreditation (Arora et al. 2008; Guennif & Ramani 2010). Unfortunately, to date, there is no pharmaceutical company in Bangladesh with USFDA accreditation. In the Bangladeshi pharmaceutical sector, R&D investments and the number of R&D personnel are much lower than in Indian firms; average annual R&D spending as a percentage of sales is only 1% (in India 7%), while the average R&D staff employed as a percentage of the total number of the employees is below 1% (in India the figure is around 5%) (Sampath 2007). Therefore, in export markets, Bangladeshi pharmaceutical firms face strong competition from the MNCs as well as from pharmaceutical firms in China, but the main threat is from Indian firms.

Table 1 provides a list of six types of vulnerability, the potential impacts of the TRIPS Agreement and the adaptive actions undertaken to minimize those impacts which have been supported by current literature on the TRIPS Agreement (Hati 2006; Mani 2006; Chaudhuri 2007; Pradhan 2007; Wendt 2007; Chittoor et al. 2008; Li 2008;; Rai 2009; Guennif & Ramani 2010; Basant 2011; Nielsen et al. 2011). A positive (+) sign after each potential impact variable (IV) indicates the expectation of a positive functional relationship with vulnerability and a negative (−) sign indicates inverse functional relationship.

Table 1. Types of TRIPS-related vulnerability and related impact variables (IVs) and adaptive action sub-variables (AVs)

Types of Vulnerability	Impact variables (IVs)	Adaptive action sub-variables (AVs)
Raw materials-related vulnerability (V_1)	IV_1: Difficulty in obtaining raw materials from abroad (+)	AV_{11}: Strategic partnership with raw material suppliers from abroad (−) AV_{12}: Upstream vertical integration (merger/acquisition) with overseas raw material suppliers (−) AV_{13}: Increasing investment in in-house production of raw materials (−) AV_{14}: Using substitute ingredients for some drugs (−)
Technology-related vulnerability (V_2)	IV_2: Difficulty in obtaining the latest technologies (+)	AV_{21}: Increased investment in developing own technological capabilities (−) AV_{22}: Technology collaboration with domestic firms (−) AV_{23}: Technology collaboration with foreign firms/licensing technology (−) AV_{24}: Obtaining technology through licensing agreement(s) with foreign firms (−)
Quality and regulatory compliance-related vulnerability (V_3)	IV_3: Conformity to higher quality and regulatory standards (+)	AV_{31}: Increased investment to improve quality (−) AV_{32} : Employing highly skilled/scientific workforce from home or overseas (−) AV_{33} : Increasing investment in on-the-job training (−)
R&D-related vulnerability (V_4)	IV_4: Higher investment required in R&D and innovation activities (+)	AV_{41}: Raising venture capital or debt finance (−) AV_{42}: Access to government R&D support funds (−) AV_{43}: Joint R&D activities with public/private research institutes/universities (−) AV_{44}: R&D collaboration with foreign firms/MNCs/ international organisations (−)
Domestic competition-related vulnerability (V_5)	IV_5: Increased competition from MNCs and imports in the domestic market (+)	AV_{51}: Downstream vertical integration to access more distribution channels (−) AV_{52}: Strategic partnerships with domestic customers, e.g. private/public hospitals, public organisations/NGOs (−) AV_{53}: Undertaking cost-reduction programs (−) AV_{54}: Expanding production capacity and product range(−) AV_{55}: Increasing investment in market promotion (−) AV_{56}: Building strategic alliances with foreign firms and MNCs (e.g. contract manufacturing) (−) AV_{57}: Obtaining 'compulsory licences' from the government to produce on-patent drugs under legal cover (−)
International competitiveness-related vulnerability (V_6)	IV_6: Increased competition from the MNCs and foreign firms in the export market (+)	AV_{61}: Obtaining accreditation from developed countries (e.g. USFDA, UKMHRA, TGA) (−) AV_{62}: Developing niche market strategies (focusing on essential drugs, drugs for neglected diseases, and herbal products) (−) AV_{63}: Establishing extensive sales and distribution networks abroad (−) AV_{64}: Strategic partnerships with customers abroad (e.g. hospitals, NGOs and international organisations) (−) AV_{65}: Entering into joint ventures with foreign companies (−)

3.2. Choice of variables for measuring the innovativeness of firms

The term 'innovativeness' refers to a firm's dynamic capability, which is measured in two ways: firstly, in terms of inputs, such as annual R&D expenditure/R&D intensity and in terms of output, such as the number new products introduced in a year, product diversity and the number of patents (Hollenstein 1996; Damanpour 2010). In addition, a firm's innovativeness has been found to be correlated with its size (Pla- Barber & Alegre 2007). Accordingly, given the availability of the relevant data, in this study a Bangladeshi pharmaceutical firm's innovativeness is measured using the following conceptual framework:

Innovativeness = f (firm size, product introduction, product diversity, market focus, export success) *(2)*

Table 2 provides a list of ordered categorical variables used in this study to measure innovativeness.

Table 2. Innovation variables used in calculating the innovativeness indices of Bangladeshi pharmaceutical firms.

Innovation variable	Proxy variables
Firm size	The number of employees; the number of finished products
Product introduction	The average number of new products introduced by the company annually
Product diversity	Whether a firm is a finished product manufacturer, raw material producer or both; Whether a firm produces herbal products; Whether a firm produces animal products
Market focus	Whether a firm focuses mainly on the domestic market, foreign markets or equally both
Export success	Whether a firm has no plan to export soon, is going to export soon, exports occasionally or exports regularly; The number of export destinations

3.3. Multivariate analysis to assess construct validity of sub-variables

To establish the validity of the measurement procedure (construct validity) and to get rid of less important (redundant) variables in measuring different types of vulnerability facing firms and their innovativeness, we used a widely acceptable multivariate statistical analysis technique for the reliability analysis, called Cronbach's Alpha. Cronbach's Alpha is the average correlation co-efficient of each of the variables belonging to an underlying factor, which is widely used to develop composite indices through simple arithmetic averaging (Cooksey 2007; Field 2009). Generally, the minimum acceptable value of Cronbach's alpha is expected to be 0.7 (internal consistency reliability is 70%); however in the literature, with low number of variables, 0.5 is considered to be the minimum acceptable number (George & Mallery 2003).

3.4. 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 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 capacity 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*. Also, demographic and general information was sought to measure innovativeness of firms.

3.5. Measuring vulnerability and innovativeness using indices

In this study, six types of vulnerability to the TRIPS Agreement facing the sampled Bangladeshi pharmaceutical firms as well as their innovativeness were measured through six composite indices. A composite index is obtained from compiling a set of related variables (Nardo et al. 2005).A composite index representing a firm's certain type of vulnerability (e.g. vulnerability related to raw materials) has been created using two variables, i.e. one impact variable and one adaptive capacity variable (average of the adaptive capacity sub-variables). The vulnerability index has taken values between 0 and 1 where 0 indicates no vulnerability and 1 indicates extreme vulnerability.

In recent decades, composite indices have been increasingly used for comparing country performance in terms of human development, competitiveness, sustainability and industrialization and to divide them into

various groups or clusters (Nardo et al. 2005). For example, Guillaumont (2007) has used a structural economic vulnerability index (EVI) to determine which countries can be labelled as LDCs.

Based on the methodology developed by the UNDP in constructing a Human Development Index (HDI), to develop composite indices, variable scores have been normalized (so that all values are between 0 and 1) (Anand & Sen 1994; Nardo et al. 2005). In line with the conceptual framework for calculating vulnerability, following the notable work of Anand & Sen (1994), the impact variables (with a positive functional relationship) and adaptive action variables (with a negative functional relationship0 have been normalized using the following formulae 3 and 4, where IV^*_{ij} is the standardized score of impact variable (IV) *i* of firm *j* (the higher the value of IV^*_{ij}, the higher is the vulnerability) and AV^*_{ij} is the standardized score of aggregate adaptive action variable (AV) *i* of firm *j* (the higher the value of AV^*_{ij}, the lower is the vulnerability).

$$IV_{ij}^{*} = \frac{IV_{ij} - Min(IV_i)}{Max(IV_i) - Min(IV_i)} \tag{3}$$

$$. AV^*_{ij} = \frac{Max(AV_i) - AV_{ij}}{Max(AV_i) - Min(AV_i)} \tag{4}$$

Given the absence of any reliable weighing methods of the sub-variables, in most cases composite indices are obtained by calculating an un-weighted average of the constituent variables ((Anand & Sen 1994; Nardo et al. 2005; Patnaik & Narayanan 2009). The composite index (V_{ij}) of an individual firm *j* for a particular type of vulnerability *i* has been calculated with the formula 5 where, IV^*_{ij} is the standardized score of impact variable (IV) and AV^*_{ij} is the standardized score of the average of adaptive action sub-variables (AV) of firm *j*.

$$V_{ij} = \frac{IV^*_{ij} + AV^*_{ij}}{2} \tag{5}$$

Finally, different types of vulnerability across the sector ($\mathbf{V^s_i}$) have been determined from the following equations, where V_{ij} is the composite index of an individual firm *j* for a particular type of vulnerability *i*:

$$V^s_i = \frac{\sum V_{ij}}{j} \tag{6}$$

Following Hollenstein (1996), first, the composite innovativeness index of a firm *j* ($\mathrm{INNOV^c_j}$) has been obtained using the following equation 7, where $\mathrm{X^*_{1j\ to}\ X^*_{1j}}$ are the standardized N retained variables of firm j obtained through the reliability analysis (Cronbach's alpha) and then each firm's innovativeness index has been expressed using Z-scores with a mean value of 0 and standard deviation of so that firms can be classified as below (<0) and above average (>0) in relation to innovativeness.

$$\mathrm{INNOV^c_j} = (\mathrm{X^*_{1j}} + \mathrm{X^*_{2j}} + \ldots.. + \mathrm{X^*_{Nj}})/\mathrm{N} \tag{7}$$

3.6. The use of the vulnerability and innovativeness indices and other statistical techniques

In this study, first, the mean values of the different types of vulnerability indices across the sector have been compared to see which type of vulnerability is the highest. Second, one-way repeated measures ANOVA was performed to examine whether the individual differences of firms in the degree of different types of vulnerability was statistically significant. Third, a two-step cluster analysis was performed to classify firms into groups according to various levels of vulnerability. Finally, a one-way ANOVA was performed to see whether the mean values of various clusters are different from each other in terms of different types of vulnerability.

4. Empirical results

In this study, the data were analysed in a number of stages using SPSS. Cronbach's alpha value for the items included in the different types of vulnerability indices were 0.564, 0.767, 0.723, 0.697, 0.718 and 0.828 respectively. Although the value 0.564 (related to raw-material related vulnerability) was low it is acceptable for two reasons: first, the number of variables is only three and the minimum corrected item-total correlation was 0.397, which indicates that the items form a reliable scale (Field 2009). However, Cronbach's alpha for the innovativeness index sub-variables was 0.834, which indicates a high level of consistency and reliability of the innovativeness scale; 5 out of 9 original sub-variables were retained to obtain the highest alpha value.

Next, following equation 3 to 6, six types of vulnerability indices across the sector were calculated. The mean value and the standard deviation of the different types of vulnerability are shown in Table 3 in terms of their importance.

Table 3. The mean and standard deviation of different types of vulnerability

Type of vulnerability	Mean	Standard deviation
R&D-related vulnerability (V_4)	0.8722	0. 1364
International competitiveness-related vulnerability (V_6)	0.7848	0.1491
Raw materials-related vulnerability (V_1)	0.6831	0.1725
Technology-related vulnerability (V_2)	0.6817	0.2007
Quality and regulatory compliance-related vulnerability (V_3)	0.5790	0.1135
Domestic competition-related vulnerability (V_5)	0.2770	0.1364

Table 3 shows that the R&D-related vulnerability (V_4) is the most important type of vulnerability (0.8722) facing the Bangladeshi pharmaceutical firms followed by international competitiveness-related vulnerability (V_6) with the value of 0.7848, where 0 indicates no vulnerability and 1 indicates full vulnerability. However, the least important type of vulnerability is the domestic competition-related vulnerability (V_5) with the value 0.2770.

One-way repeated measures ANOVA indicated that there was a significant difference between firms in the degree of three types of vulnerability, namely R&D-related vulnerability, international competitiveness-related vulnerability and quality and regulatory-related vulnerability, $F(4, 372) = 71.789$, $p<.001$. Machly's test for sphericity was not violated ($p>.094$), thus the result of the one-way repeated measures ANOVA test is highly reliable. Moreover, a two-step cluster analysis was used to classify the sampled firms in terms of their

innovativeness scores and the overall vulnerability scores. Two clusters were obtained (Figure 2). Cluster one comprised 17 firms (18.1%) and cluster two comprised 77 firms (81.9%). Finally, a one-way ANOVA indicated that there was a significant difference in terms of innovativeness and various types of vulnerability between the members of the two clusters except for in terms of domestic competition-related vulnerability. The test results are F (1, 92) = 18.24, $p<0.05$; F (1, 92) = 59.16, $p<0.05$; F (1, 92) = 96.71, $p<0.05$; F (1, 92) = 8.11, $p<0.05$; F (1, 92) = 36.20, $p<0.05$; F (1, 92) = 0.85, $p>0.05$; and F (1, 92) = 55.48, $p<0.05$. Table 4 illustrates how the firms in each of the two clusters differ in terms of vulnerability, innovativeness and demographic characteristics.

Table 4. Between-clusters differences for vulnerability and innovativeness measures and in terms of demographic characteristics

	Cluster one (17 firms; 18.1% of the total 94 firms)						Cluster two (77 firms; 81.9% of the total 94 firms)					
Mean vulnerability score	V1	V2	V3	V4	V5	V6	V1	V2	V3	V4	V5	V6
	0.46	0.38	0.51	0.72	0.26	0.59	0.73	0.75	0.59	0.91	0.28	0.83
Standard deviation	0.1385	0.2022	0.0772	0.1678	0.1839	0.1256	0.0152	0.0142	0.0131	0.0116	0.0222	0.0133
Average innovativeness index	0.68						-0.15					
Age more than 10 years	88.24% (15 out of 17 firms)						62.34% (48 out of 77 firms)					
No. of employees more than 1000	82.35% (14 firms)						24.68% (19 firms)					
No. of finished products 250 and above	52.94% (9 firms)						11.69% (9 firms)					
Producing raw-materials	17.65% (3 firms)						6.49% (5 firms)					
Producing herbal drugs	11.76% (2 firms)						19.485 (15 firms)					
Producing vet products	47.06% (8 firms)						23.38% (18 firms)					
Focusing on only domestic market	52.94% (9 firms)						71.42% (55 firms)					
Focusing on both domestic and export markets	47.06% (8 firms)						25.97% (20 firms)					
Exports regularly	64.71% (11 firms)						32.47% (25 firms)					
Exported to more than 10 countries in 2011	52.94% (9 firms)						7.79% (6 firms)					

5. Discussion, conclusions and policy implications

The empirical results in this study have a number of policy implications. It was found that the R&D-related vulnerability was the highest across the pharmaceutical sector in Bangladesh (0.8722) followed by international competitiveness-related vulnerability (0.7848). If 0 indicates that the vulnerability is nil and 1 is the highest, this points to the fact that Bangladeshi pharmaceutical firms have not been able to develop considerable technical and scientific capability as well as a higher level of regulation handling capability. The cluster analysis supports this proposition as only 18.1% of the sampled firms have an above average level of innovativeness (mean is 0.68). As the innovativeness indices are expressed as z-scores, the value 0.68 indicates that even in cluster one (the group with lower level of vulnerability than the other) only a few firms have satisfactory level of innovativeness. The mean values for R&D-related vulnerability and international competitiveness-related vulnerability of cluster one are 0.72 and 0.59 respectively, which indicate that unless they improve their R&D and innovation capacity as well as regulation handling capabilities, their competitiveness in domestic and export markets are likely to be negatively affected by the implementation of

the TRIPS Agreement in 2016. Conversely, cluster two includes 77 firms (81.9% of the sampled firms). The mean score for their innovativeness is -0.15; these firms have a below average level of innovativeness. They have a higher average level of vulnerability in all categories than those in cluster one. From Table 4, it can be deduced that the number of employees (the pharmaceutical sector mostly employs knowledge workers), product diversity and export performance are important determinants of firms' adaptive capacity (to reduce vulnerability) as well as innovativeness.

Finally, it can be argued that the TRIPS transition period has not been used effectively by the Bangladeshi pharmaceutical sector to create a strong technological platform for the industry and the expected process of transfer of technology has not taken place. The post-TRIPS industrial policy for the pharmaceutical industry in Bangladesh should be designed and delivered with a key focus on improving the R&D and innovation capabilities of the domestic firms. Moreover, the WTO should evaluate the current mechanisms related to developed countries-LDCs technology transfer, and should review its trade-related considerations for LDCs.

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