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Policy Space for Building Production Capabilities in the Pharmaceuticals Sector in Low- and Middle-Income Countries

EVIDENCE FROM BANGLADESH

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ABSTRACT

Over the past four decades Bangladesh has built enough domestic productive capacity in the pharmaceuticals and related industries to generate manufacturing capacity and employment to provide access to medicines in the country and to become a modest exporter of medicines as well. This paper traces the role played by government policy in fostering Bangladesh's burgeoning pharmaceuticals sector and then examines the extent to which such policies would have been permissible under World Trade Organization (WTO) rules and the rules of recent trade and investment treaties. Bangladesh has not had to adhere to such rules given its status as a Least Developed Country (LDC) but will face those rules as it may graduate from LDC status in the coming years. We find that a significant amount of Bangladesh's policies would not have been permitted under the WTO, and even more policy space would be constrained under other regional and bilateral trade and investment treaties. These findings reveal that Bangladesh will face a series of challenges as it graduates from LDC status in its efforts to build its domestic pharmaceutical industry moving forward. Our findings also pinpoint challenges for current WTO and other trade and investment treaty members who now seek to build domestic productive capacity in this sector in the wake of the COVID-19 pandemic.

Keywords: Bangladesh, pharmaceutical sector, industrial policy, health policy, policy space, LDC graduation, trade and investment treaties

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INTRODUCTION

The global medical supply chain is dominated by a handful of companies in China, India, the United States, and Europe—accounting for over 70 percent of the producers of Personal Protective Equipment (PPE) and Active Pharmaceutical Ingredients (API) related to COVID-19. Most of the firms are massive oligopolies and household names such as Honeywell, Dupont, and SunPharma for APIs. With respect to vaccines and medicines, production of APIs is concentrated in China and India (USP 2020). It is estimated that the top ten pharmaceutical companies' sales represent one third of the global sales (Barton 2020). The dangers of concentrating production and economic power within global health value chains have been exposed all too openly during the COVID-19 crisis.

Such a concentrated supply chain can pose serious bottlenecks. Both high-income and low- and middle-income countries have realized that protective equipment and pharmaceutical and diagnostic products, will need to be produced rapidly, and increasingly at home, either domestically or regionally, both to expand supply and to ensure access. To encourage domestic production and revive their economies, governments will need to provide subsidies, tax breaks, and preferential trade and investment treatment to domestic firms, and especially to their micro, small and medium enterprises.

Bangladesh is a unique example of a United Nations-designated least developed country that has managed to create a significant niche for itself in the global medicines supply chain. Understanding how Bangladesh developed this niche will be of great use to other countries looking to go down a similar path. However, the extent to which Bangladesh can further its trajectory using the same policy mix, or whether others may draw direct lessons from it under current global trade rules, is an open question.

Bangladesh developed these capabilities, in large part, because it has been able to enjoy market access to its fellow members of the WTO and, at the same time, has been exempt from the disciplines in a number of key agreements due to its status as a Least Developed Country (LDC) at the United Nations and the World Trade Organization (WTO). These agreements include the Agreements on Trade-Related Aspects of Intellectual Property (TRIPS agreement) and Trade-Related Investment Measures (TRIMs agreement), which have strict rules on intellectual property protection and the ability to regulate foreign investment. Bangladesh has also employed a variety of government policies to take advantage of this 'policy space' it had under the trade and investment regime. In this paper we ask to what extent Bangladesh would have been able to deploy their policy mix if the country was not exempt from these trade rules.

An examination of Bangladesh's trajectory will have implications for Bangladesh as well as the global value chain in general. At a crucial time when Bangladesh will need to maintain access to essential medicines and treatments, preserving the policy space it has may prove to be of urgent importance. Furthermore, tracing Bangladesh's trajectory will allow other low- and middle-income countries to understand the promise and pitfalls of attempting to establish their own production capabilities. Finally, such a study suggests important reforms necessary to the trade and investment regime in order to enable other countries to go down Bangladesh's path.

Following this short introduction (Part I), this paper has four additional parts. Part II provides an overview of the global pharmaceutical supply chain in the pharmaceutical sector and Bangladesh's niche. Part III traces the government policies that Bangladesh has deployed over the past four decades to build and bring its pharmaceutical industry to the place it holds now. Part IV is a legal analysis that examines the extent to which Bangladesh's policies would have been permissible under the global trade and investment treaty regime—and by association replicable by other members of the same regime. Part V summarizes our findings and draws lessons for further research and policy.

OVERVIEW OF GLOBAL PHARMACEUTICAL SUPPLY CHAIN AND MARKET CONCENTRATION

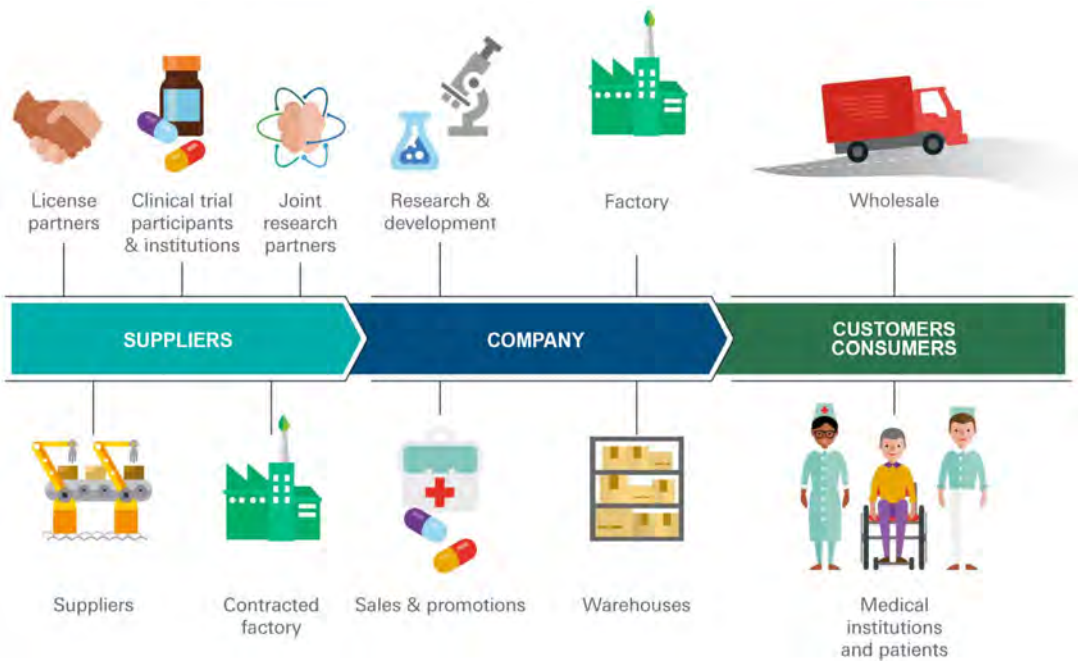
Global Market Scenario

The global market for pharmaceuticals is characterized by significantly high entry barriers compared to other traded goods. The barriers occur both in supply- and demand-side factors due to the high costs of building infrastructure, research and development (R&D) clinical trials, and continuous investments into quality assurance and compliance. For instance, using the data from 63 biologic agents approved by the United States Food and Drug Administration it has been estimated that the median capitalized research and development cost per product was US$ 985 million (Wouters, McKee, and Luyten 2020). Approval for generic medicines likewise faces a series of obstacles through domestic approval processes, legal uncertainties due to intellectual property protection, continuous investments into quality assurance and compliance and supply chain management (Morgan, Yau, and Lumpkin 2017; Ahonkhai et al. 2016). Not surprisingly, low- and middle-income countries, particularly LDCs, face formidable challenges in entering the global pharmaceutical market.

Privett and Gonsalvez identify ten global health pharmaceutical supply chain challenges as the most critical: (a) coordination; (b) inventory management; (c) demand information; (d) human resource dependency; (e) order management; (f) shortage avoidance; (g) expiration; (h) warehouse management; (i) temperature control and (j) shipment visibility. The list very well reveals the high complexity of the involved value chain (Privett and Gonsalvez 2014). This is also corroborated by Figure 1 which shows the pharmaceutical value chain to be highly resource-intensive, knowledge-embedded and complex in terms of approval process, production system, management and marketing.

Indeed, market analyses show an overwhelming presence of pharmaceutical companies from the high-income countries dominating the global pharmaceutical trade of finished products ("The World's Biggest Pharmaceutical Companies: Top Ten by Revenue" n.d.). In 2018, of global exports

Figure 1: Pharmaceuticals Value Chain



Source: Adapted from "Pharmaceuticals | JT Global Site", n.d..

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of pharmaceutical products worth US$ 587.0 billion, high-income country exports made up 89.9 percent. Indeed, the top ten exporting countries from among those high-income countries account for more than three-fourths of the global market. Meanwhile, exports from low- and middle-income countries accounted for only 10.02 percent, and that of LDCs was a mere 0.03 percent. The only LDC which was able to put a footprint worth mentioning was Bangladesh with exports of about US$ 113.0 million, accounting for about 58 percent of total export of the LDCs (ITC n.d.).

Table 1: Export of Pharmaceutical Products by Major Country-Groups (in billion US$)

Country Groups	2018	2001
High-income countries	528.00 (89.9%)	110.00 (93.8%)
Low- and middle-income countries	58.98 (10%)	7.30 (6.2%)
China	14.0	0.74
India	8.0	1.05
LDCs	0.19 (0.03%)	0.013 (0.01%)
Bangladesh	0.113	0.0039
Total Export	587.00	117.30

Source: ITC, n.d.[1]

Although the low- and middle- income countries have made some headway, the change has been marginal and slow over the last two decades. To compare, the global pharmaceutical export market in 2001 was US$ 117.3 billion, of which the share of high-income countries was about 94.0 percent. Only a few low- and middle-income countries have been able to make inroads into the export market, with India and China being the most noteworthy. It does credit to Bangladesh that it was the only LDC which was able to significantly enhance its exports in this period – from US$ 3.9 million in 2001 to US$ 113.0 million in 2018. To note, LDC imports (US$ 6.5 billion in 2018) far outweighed their export of pharmaceutical products (US$ 0.194 billion), resulting in a trade deficit of US$ 6.3 billion for LDCs in these products.

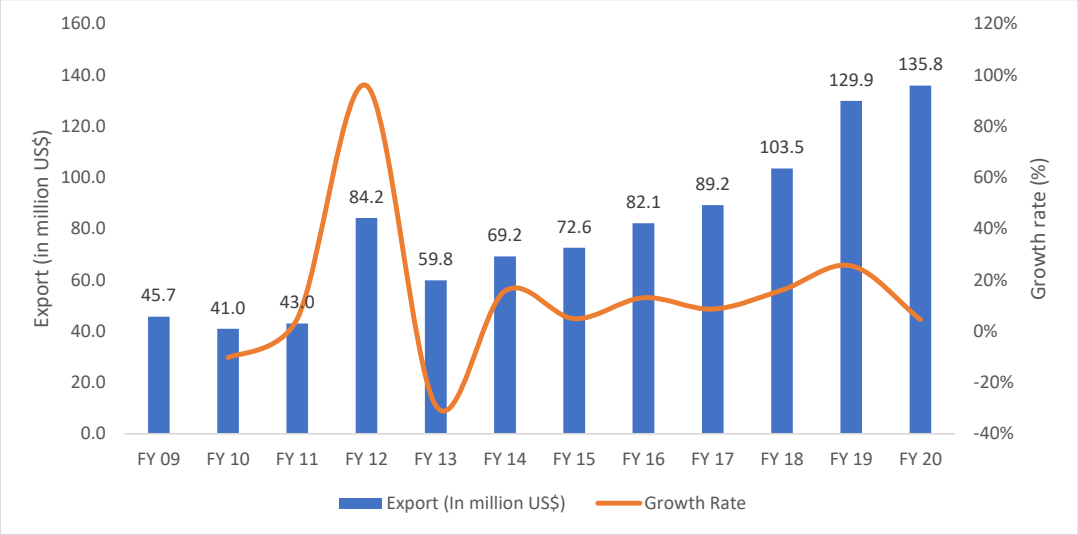
Bangladesh in the Global Pharmaceutical Market

Bangladesh's pharmaceutical exports have been growing at a remarkably fast pace in recent years. From US$ 41.0 million in FY 2010, exports rose to US$ 82.1 million in FY 2016, and again to US$ 135.8 million in FY 2020 (EPB, 2020).

Figure 2 shows export performance of pharmaceuticals and corresponding growth rates for the period between FY 2010 and FY 2020. However, even Bangladesh's export market is highly concentrated. As indicated by Figure 3, the top five countries accounted for more than half (56.7 percent) of Bangladesh's pharmaceutical exports in FY 2020. LDCs as a group made up a key market of Bangladesh's pharmaceutical exports: in FY 2020, out of the 118 export destinations 27 were LDCs, 29.6 percent of the country's total pharmaceutical exports. Notably, the U.S. has now emerged as the country's third most important export destination.

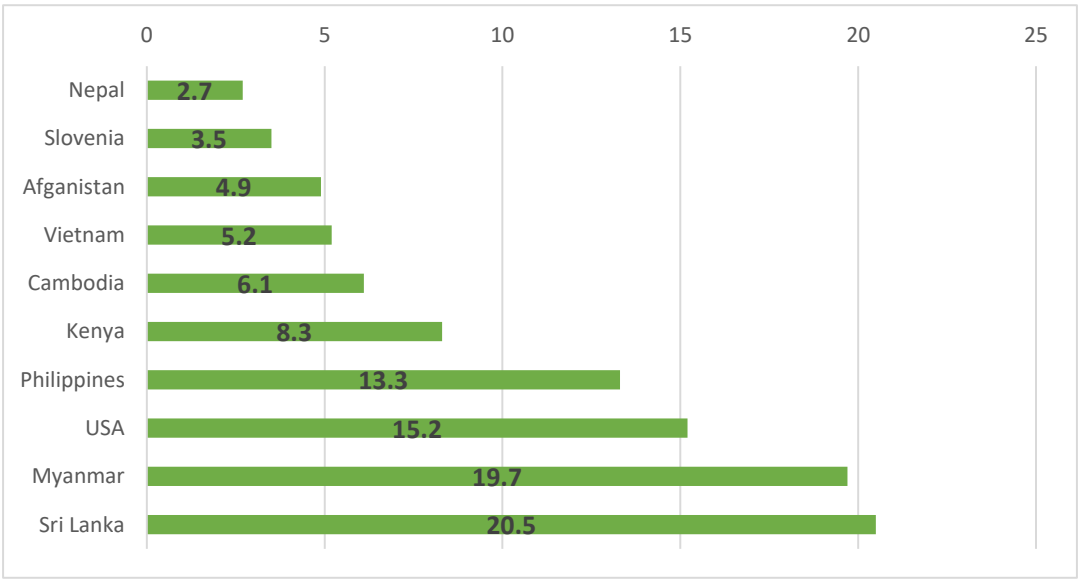
[1] Bangladesh's rank was 71st in the global pharma export market of US$ 635.0 billion in 2019. In Bangladesh, fiscal year indicates the period between July to June. In this connection it is to be noted that ITC and Comtrade corresponding data do not match Bangladesh's Export Promotion Bureau (EPB) data in part because ITC/Comtrade figures relate to calendar year whereas the EPB figures relate to the fiscal year (this, though, does not fully explain the discrepancy between the Bangladeshi data and ITC/Comtrade data).

Figure 2: Pharmaceutical Exports from Bangladesh and its Growth



Source: Based on Export Promotion Bureau, Bangladesh, n.d.

Figure 3: Top Ten Pharmaceutical Export Destinations of Bangladesh (million USD)

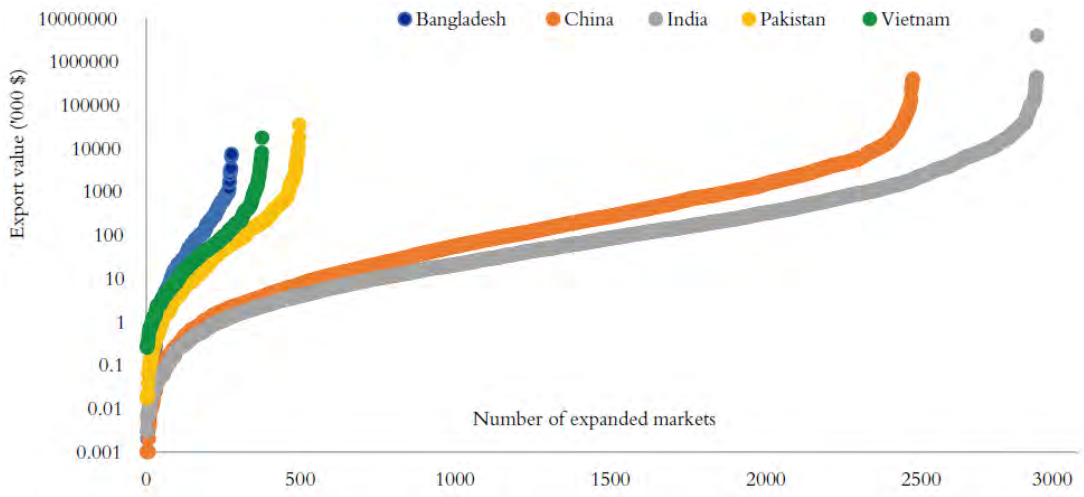


Source: Based on Export Promotion Bureau, Bangladesh, n.d.

As Annex Table 2 indicates, low- and middle-income countries (developing market economies) are key importers of Bangladesh's pharmaceutical exports, which suggests the potential for export expansion into those countries.[2] However, at present, Bangladesh lags significantly behind some of its major competitors in terms of pharmaceutical market diversification. The expanded market reach (EMR), a measure of market diversification, is calculated by the number of countries an exporting country has been able to reach for a certain medicine. As Figure 4 demonstrates, while Bangladesh was able to reach only 274 expanded export market destinations (which calculates all pharmaceutical items according to their 6-digit Harmonized System Code that were exported to various countries) the corresponding figures were 2,866 for India, 2,465 for China, 492 for Vietnam and 372 for

[2] Mainly India, Singapore, Israel, China, Mexico, UAE, Brazil, Saudi Arabia and South Korea.

Figure 4: Expanded Market Analysis: Bangladesh and Competitors (2018)



Source: Razzaque, Rabi, and Akib, 2020.

Pakistan. More recent estimates by the authors for 2020 indicate that the scenario has remained more or less unchanged for Bangladesh.

According to industry insiders, Bangladesh has a very high potential as a supplier of low-cost generic drugs and vaccines (Niti 2019). Bangladesh companies have also been trying to get World Health Organization (WHO) pre-qualification, which is an important step toward gaining entry into the global market. As of the time of this writing, 2 companies (Beximco Pharmaceutical and Incepta Pharmaceuticals Ltd.) have received WHO pre-qualification (World Health Organization (WHO) n.d.). In recent years leading Bangladesh pharmaceutical companies have been able to get market authorization from regulatory authorities in the UK, Canada, the EU and Australia, among others. Beximco, Square Pharmaceuticals and Renata have even received certification from the U.S. FDA (Hossain Ovi and Mahmud 2019; BIZDATA INSIGHTS 2020). In fact, Beximco, became the first to launch the generic version of remdesivir (under the brand name *Remsivir*), which has been exported to several countries.

Importantly, despite its success in producing and exporting medicines, Bangladesh remains overwhelmingly dependent on imported APIs, the key pharmaceutical ingredients. About 95 percent of the raw materials, worth about US$ 844.5 million in FY 2018-19, required for about 8 thousand generic drugs produced in Bangladesh (in 2019), are, at present, imported. Building domestic API capacity is seen by Bangladesh as a critically important strategy to raise competitiveness and ensure strengthened presence in the global pharmaceutical export market (see Section III, below).

THE ROLE AND IMPACT OF GOVERNMENT POLICY IN BANGLADESH'S PHARMACEUTICAL INDUSTRY

There is an extensive literature establishing that government intervention played a decisive role in the ability of 'latecomers' (described below) to the development process to build the endogenous productive capacity that led to their sustained growth (The World Bank 1993; Wade 2003; Amsden 2001). The case of Bangladesh is no exception. The most successful nations, first among them South Korea, Taiwan, Hong Kong and Singapore, and now of course China, followed by Malaysia, Thailand, India, and Indonesia, focused state support toward the development of specific technologies

or sectors in specific geographical regions—especially when facing significant market concentration within sectors dominated by the advanced economies.

While the toolkit was large and varied, the state broadly invested in an educated labor force, public R&D, tariff protection, and subsidized credit to support domestic firms until they could produce products at the global technological frontier. To attract and absorb foreign technology and skills, these nations encouraged joint venturing with technological transfer agreements with foreign firms to learn technological capabilities, and industrial clustering to generate agglomeration effects that accelerate productivity (Amsden 2001; Gallagher 2005). This section of the paper shows how Bangladesh followed and adapted the latecomer industrialization model in its pharmaceutical industry to build it to what it is today.

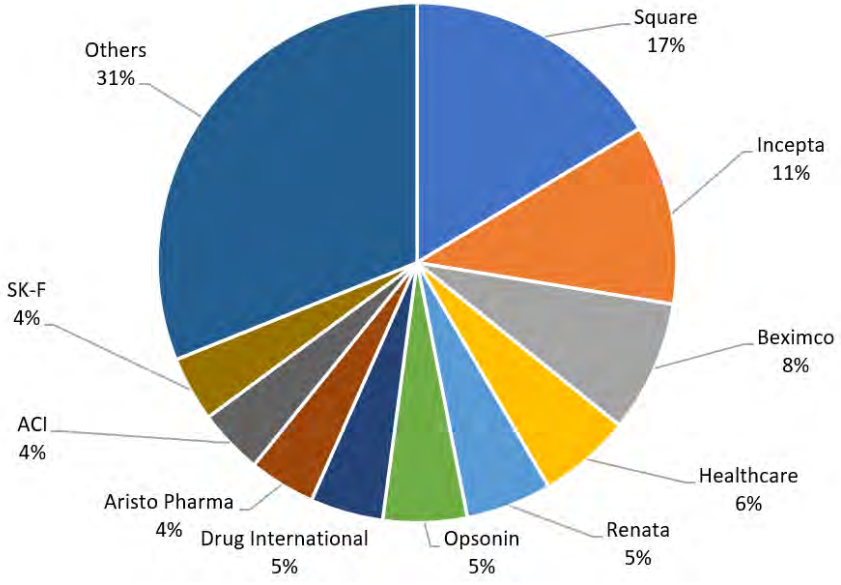
Market and Structure

After 40 years of fostering the sector, the pharmaceutical industry is the fourth, after apparel, textiles and food processing, among the major industrial sectors in Bangladesh (Rahman and Farin 2018). The industry caters primarily to the domestic market, where it meets about 97 percent of total demand. The domestic market for medicines has been growing at a fast pace: from about US$ 700.0 million in 2008 to about US$ 2.80 billion in 2019 (Munni 2019).

The Directorate General of Drug Administration (DGDA) is the designated organization responsible for overseeing the country's pharmaceutical industry. It is tasked with issuing licenses, market authorization, ensuring safety, quality and efficacy of drugs and API, undertaking pharmacovigilance, conducting bioequivalence trials, monitoring price and undertaking environmental risk assessments (DGDA 2017).

The number of registered pharmaceutical companies in Bangladesh stood at 273 in 2019 (DGDA 2019). Of about 5,600 brands of medicines produced in Bangladesh, about 20 percent are generic versions of patented drugs while the remaining 80 percent are (off-patent) branded generics. The top ten companies, all of which are local, account for more than two-thirds of the domestic sales (68.7 percent) (Figure 5).

Figure 5: Market Share of Top Ten Pharmaceutical Companies in Total Sales (%)



Source: Munni, 2019.

Bangladesh's market was not always dominated by domestic firms however. Before 1982, 75 percent of the market was dominated by multi-national corporations (MNCs), with about 133 local companies accounting for the rest (Mohiuddin 2019; Amin and Sonobe 2013). Within the country, there were 166 licensed manufacturers, eight of which were MNCs controlling 70 percent of the market, whilst the remaining 158 local companies had a market share of 30 percent (South Centre 2020). However, these two groups together were able to cater to only 35 percent of the domestic demand for drugs at the time. Even in 1985 all top ten firms were subsidiaries of MNCs. In contrast, by 2011 all the top ten firms were owned and operated by Bangladesh entrepreneurs and managers and this is still the case.

Today, the pharmaceutical market of Bangladesh is dominated by branded generic drug production, followed by generic versions of patented drugs, low-end generics and contract manufacturing, almost all of which are dependent on imported API (South Centre 2020). Where patented products have been manufactured with imported API, the prices are significantly lower than the branded product of the innovator company in countries such as the U.S. For example, the retail price of sofosbuvir in Bangladesh was US$ 6.0 (compared to US$ 1,000 abroad) and rosuvastatin was US$ 0.25 (compared to US$ 7.25) (South Centre 2020). Annex Table 3 provides detailed information on domestic and overseas price differentials. At the same time, the table shows that prices of the same drugs vary significantly within the local market. It is noteworthy that low prices of generic medicines in Bangladesh compared to innovative prices in the U.S. does not mean that the retail prices of medicines in Bangladesh are affordable to the population in Bangladesh.

The pharmaceutical industry is one of the very few capital intensive, skills-embedded and white-collar jobs-dependent manufacturing sectors in Bangladesh. The industry employs about 177,000 professionals and staff (Bangladesh Bureau of Statistics 2018). As Table 3 shows, in contrast with the rest of Bangladesh's manufacturing industries, the share of those holding managerial, professional and skill-endowed positions is quite high in the pharmaceutical sector.

Investment in the pharmaceutical industry is dominated by local players, with Foreign Direct Investment (FDI) playing only an insignificant role. As Table 4 shows, overall, Bangladesh's FDI stock and flows are rather small, and those concerning the pharma sector even smaller. As of December 31, 2019, the country's FDI stock was only US$ 17.8 billion (equivalent to 5.4 percent of GDP in the corresponding year). FDI in the pharmaceuticals sector, at US$ 261.0 million, was a mere 1.45 percent of the total FDI stock of the country.

Table 3: Employment Structure: Pharmaceutical Industry versus Overall Manufacturing Sector in Bangladesh (in percent)

Occupation	Pharmaceutical sub-sector	Overall Manufacturing Industry
Managerial and Supervisor position	15.0	3.0
Professional techniques and	38.2	1.6
Associate Professionals	11.8	3.3
Sub total	***65.0***	***7.9***
Workers	6.3	64.2
Others	28.7	27.9
All employees	***100.0***	***100.0***
(Number of employees)	***(0.177 million)***	***(8.77 million)***

Source: Estimated from Bangladesh Bureau of Statistics, 2018.

Table 4: FDI in Bangladesh's Pharmaceuticals and Chemicals Industry (in Million US$)

Indicator	2010	2015	2019	FDI Stock as of 31 Dec. 2019
Total FDI Inflow to Bangladesh	913.3	2235.9	2873.9	17,785.0
of which				
pharmaceuticals and chemicals	6.3	30.1	49.9	261.0
(share in total)	(0.69 %)	(1.34 %)	(1.74 %)	(1.47 %)
Share in Bangladesh FDI stock (as of 31 Dec 2019)	***United Kingdom: 47.2 % India: 11.0 % Japan: 3.5 %***			

Source: Bangladesh Bank, n.d.

One distinctive feature of the Bangladesh pharmaceutical industry is a lack of backward linkages, particularly in the production of raw materials. While a few local companies are producing APIs on a commercial scale, most don't have the capacity to synthesize complex formulations to meet the growing demand of local industries (South Centre 2020). In FY 2019 pharmaceutical industry imported APIs (HS 29) were worth about US$ 844.5 million (Table 5). Most of the APIs are imported from China and India.

Bangladesh's pharmaceutical industry is still lagging in many other areas as well, including quality infrastructure in bioequivalence testing and clinical research, as well as oversight and institutional enforcement by the DGDA (Razzaque, Rabi, and Akib 2020). A proposal was floated by concerned authorities in 2015 to set up Bangladesh Clinical Research Organization (CRO) with a budget of US$ 50 million (USAID 2019). However, as of this writing, no concrete progress has been made in this regard. Moreover, poor enforcement of laws and regulations penalizes well-governed firms, and in turn, acts against the interests of trying to access the global market.

In order to address the coming challenges, Bangladesh will need to significantly enhance its reverse engineering capacity. This requires investment in decoding formulation parameters of an innovative pharmaceutical product. It is a continuous process and involves significant upfront cost, and adequate government support in R&D. More time is required to consolidate and sustain the developments and address the emerging challenges (Gay and Gallagher 2020).

Table 5: Import of API (organic chemicals: HS 29) by Bangladesh (in Million US$) in FY 2018-19

	Import (In Million USD)	Percent of total
India	259.2	30.7
China	254.5	30.1
Malaysia	33.7	4.0
Korea	33.5	4.0
Singapore	32.8	3.9
Others	230.8	27.3
Total	*844.5*	*100.0*

Source: Based on Bangladesh Bank, n.d.

Role of Policies and Incentives in the Rise of Bangladesh's Pharmaceutical Industry

For an LDC such as Bangladesh, both geographical availability and affordability of health care and medicines are of crucial importance—and provide a double incentive to prioritize government policy toward building domestic capabilities. In retrospect, these concerns were already present when Bangladesh started its journey as an independent country in December 1971. Yet even now, budgetary allocation for healthcare in Bangladesh, equivalent to only about 0.9 percent of the GDP, is the lowest in South Asia, while out of pocket expenditure on health was the highest (73.9 percent of the total average health expenses of a citizen) (World Bank n.d.). With this backdrop, keeping prices of essential drugs affordable is an issue of heightened importance for Bangladesh. Many governments pursue the promotion of domestic production in an effort to acheive affordable medicines prices.

Without a doubt, the National Drug Policy (NDP) 1982, together with the Drugs (Control) Ordinance 1982, were the first policies to play a crucial role in setting the stage for the rise of Bangladesh's pharmaceutical industry. While the primary goal of these measures was to keep the prices of essential drugs affordable, this would not have been possible without sending strong positive signals to domestic producers. From this vantage point, both the 1982 Ordinance and the NDP of 1982 also served as an industrial policy aimed at removing cartelization by the MNCs in the country's pharmaceutical market and creating a conducive environment for domestic entrepreneurs and pharmaceutical companies to enter the market. The policies also incentivized investment in the sector through investment protection and the encouragement of import-substituting activities (*The Drugs (Control) Ordinance, 1982 (Ordinance No. VIII of 1982)* 1982; Ministry of Health and Family Welfare 2005, preamble).

In arguing what characterizes these measures as a successful industrial policy, Amin and Sonobe draw attention to three 'aggressive measures' in the policy that encouraged local companies to play an increasingly important role and incentivized investment in the sector. First, by keeping the MNCs from concentrating in areas of production and development of innovative, sophisticated and high-tech products (such as antibiotics), the NDP made space in the domestic market for new Bangladesh players. Second, by restricting imports of substitutes for the finished drugs and intermediate inputs that were produced by two or more local firms, the NDP created demand for those new domestically produced products. Third, by prohibiting the MNCs that did not have any local production facilities from marketing their products produced by other firms on a toll manufacturing basis, the NDP produced incentives for internationals companies to invest in the production of local facilities (Amin and Sonobe 2013). Moreover, the University of Dhaka opened a Pharmacy Department in 1964, which created an opportunity for growth in the supply of educated professionals for the industry (Alam and Al-Amin 2014).

Subsequently, a 1998 Executive order of the Prime Minister's office put an import ban on such drugs (in finished form) that were produced in 'sufficient quantity' by more than two local firms. This reinforced a protected domestic market for domestic firms to produce many of the drugs which they continue to enjoy to this day. Following the initial NDP in 1982, Bangladesh introduced new NDPs in 1985, 2005 and 2016 (Murshid and Haque 2019), all of which supported various fiscal-financial incentives that contributed to the growth of the sector (see Table 6). All these, taken together, in effect worked as a successful industrial policy that triggered the rise of Bangladesh's domestic and export market-oriented pharmaceutical industry as we see today.

The impact of the 1982 Ordinance and successive NDPs on the rise of Bangladesh's pharmaceutical industry was remarkable. Medicine prices in Bangladesh had gradually come down since the 1980s and were lower by between 5 percent and 1500 percent compared to, for example, those in India and Sri Lanka (Amin and Sonobe 2013). Keeping drug prices low was an issue of existential importance

to Bangladesh, given the low purchasing power and high out-of-pocket expenditure of its citizens (Mohiuddin 2019).[3]

In 2005, the 1982 Ordinance was amended to allow MNCs, which did not have manufacturing plants in Bangladesh, to manufacture drugs under licensing arrangements (South Centre 2020). While this subjected the industry to some new competition, it also afforded new opportunities for export and manufacturing of patented products for an industry that was proving its worth at a global scale. The groundwork for the rise of a domestically owned pharmaceutical industry had already been laid, thanks to the aforesaid policies.

In addition to industrial policy, Bangladesh has taken full advantage of the TRIPS waiver for pharmaceuticals by suspending examination and granting of patents in 2008 (South Centre 2020). The current intellectual property policy in force provides for a 16-year patent term as well as broad government discretion for granting compulsory licenses and relatively easy patent revocation and opposition procedures (*The Patent and Designs Act, 1911 (Act. No. II of 1911)* 1911). Each of these components preserves the policy space of the Bangladesh government to consider the public interest in its intellectual property enforcement. In 2006, Bangladesh drafted a new Patent Act, and in 2018, a new Intellectual Property policy, which extends the patent term to 20 years ("Intellectual Property Policy (Draft)" 2018). If it is enacted, however, it will not impact pharmaceutical patents unless the 2008 suspension is lifted.

Another policy aimed at affordable and available medicines is price regulation. The NDP 2016 stipulates that drug availability at affordable prices "will be ensured" through fixing prices of essential drugs (Ministry of Health and Family Welfare 2016, 3.6). There is a list of essential drugs approved by the DGDA (Annex Table 3), which also fixes maximum retail prices (MRP) of these drugs (DGDA 2016). Pharmaceutical companies producing such drugs must not exceed the MRP. For other non-essential drugs, prices vary considerably between those of MNCs and local firms (Annex Table 3).

The NDP 2016 also continues to emphasize the importance of reducing import dependence. It gives priority to local pharmaceutical industries "in providing all services and facilities... to ensure self-sufficiency in production of drugs and raw materials for drugs" (Ministry of Health and Family Welfare 2016, 2.3). Although import tariffs have been generally very low, in order to preserve affordability (World Trade Organization 2019), the import prices are generally negotiated with neighboring country prices serving as a reference. Notably, pharmaceutical companies contest this practice as irrational and unstructured, leaving customs officials with significant discretionary power.

The most recent iteration of Bangladesh's strategy, the National API and Laboratory Reagents Production and Export Policy 2018, sets the objective of developing a dedicated backward linkage industry in the pharmaceutical sector through production of API (Ministry of Commerce, Government of Bangladesh 2018). The proposed API industry is being geared to cater to both the domestic market as well as the export market. The policy sets concrete goals for the sector: reducing import dependence by 17 percent, attracting US$ 1 billion in foreign investment by 2022, increasing the number of domestically produced API molecules (from 41 to 370 over 12 years) and increasing API production to US$ 685 million. The Policy also envisages that while the sector will primarily aim at import substitution, Bangladesh will also gradually enter into the promising and lucrative export market for API products.

[3] As Islam et al. estimate in view of the anticipated jump in prices in Bangladesh after expiry of TRIPS flexibilities, welfare of households with diabetic patients will significantly decline, leading to increase in the poverty rate of such households from 20 percent to 36 percent, and of those needing insulin from 11 percent to 60 percent (Islam et al. 2020).

The National API and Laboratory Reagents Production and Export Policy seeks to meet these goals through a series of targeted interventions centered around an Industrial Park built up for that purpose. The interventions take three basic forms: (1) making it easier (financially and logistically) for them to import their inputs, (2) tax relief, deductions, and other breaks, and (3) facilitating access to finance for their business (see Table 6, below). Each of these incentives is contingent either on the location of production, domestic value added, or export performance. The above incentives are, however, to be gradually implemented with the support of concerned authorities such as the National Board of Revenue. A five-year corporate income tax holiday for pharma enterprises, for example, is already in place.[4]

Bangladesh has also taken several other steps towards raising the competitive strength of her pharmaceutical industry. Recently, the infrastructure of the National Control Laboratory (NCL) has been improved and modernized. It has received certification from the Bangladesh Accreditation Board (BAB) and from the American Accreditation Board (AAB). The NCL has also applied for WHO prequalification certification (DGDA 2019). Moreover, the capacity of the DGDA has been strengthened, which includes human resource expansion, strengthening of medical device registration and price control (DGDA 2019). Finally, a new law has been drafted (in Bangla) by consolidating the Drugs Act of 1940 and the Drugs Control Ordinance of 1982 which has been placed before the Ministry of Health for approval (DGDA 2019).

POLICY SPACE FOR REPLICATING BANGLADESH'S SUCCESS IN THE GLOBAL TRADE AND INVESTMENT REGIME

As the previous pages have shown, the Bangladesh government has gone to great lengths to protect and build up its domestic pharmaceutical industry to create a competitive, productive generic pharmaceutical sector that can both meet the health needs of its citizens and increase the country's export competitiveness. Key tools in their policy toolkit, described in more detail above, include intellectual property measures, such as suspending pharmaceutical patents, incorporating shortened patent protection terms, and rules allowing broad application of compulsory licensing and patent revocation, among others. The country has also adopted industrial policies – suspending or cancelling previously registered or licensed medicines, restricting imports, and offering many incentives for domestic and foreign firms to source their production locally or export a given percentage of the same. Parallel policies target investors by requiring foreign investors to either manufacture their licensed pharmaceuticals locally or enter into a licensing agreement with a domestic firm. Moreover, the country has offered various direct subsidies, tax incentives and special access to financing for firms willing to venture into the sector for active pharmaceutical ingredients (API) and reagents, inputs for medicine production.

Graduation from LDC status, however, will considerably restrict Bangladesh's policy space to continue to build productive capacity in the pharmaceutical industry and to provide access to medicines for its population. Although Bangladesh has been a member of the WTO since 1995, as an LDC it has remained largely exempt from the associated rules. LDCs have the flexibility to impose import restrictions, make changes to their tariff rates, strategically subsidize exports, and suspend pharmaceutical patents in order to deploy policies which will grow and diversify their economy, sheltered from international competition for a time. Indeed, Bangladesh has taken a fair bit of an advantage of

[4] Other policies already in place include: (1) the VAT waiver is to remain effective till December 2025 on fulfilment of certain conditions: (a) the company must be registered in Bangladesh; (b) make at least five molecules every year; (c) domestic value addition of at least 60 percent; (d) must spend at least 1 percent of annual turnover on R & D among other conditions; (2) the API export incentive is equivalent to 20 percent of export value, with domestic value addition of at least 20 percent; (3) pharmaceutical export the incentive is 10 percent with minimum 30 percent local content requirement.

their LDC status, as noted above (See Section III).[5] For the first time in 2018, however, Bangladesh met all three criteria for graduation from LDC status and if it meets the graduation criteria for a second time at the next triennial review by the United Nations Committee for Development Policy in 2021, it is expected to graduate from LDC status in 2024. In that case, many of the WTO rules will begin to apply in new ways not yet determined.

Table 6 summarizes the overlap between Bangladesh's intellectual property policies and its commitments (both existing and potential) within the international trade regime. The WTO, in general, allows more policy flexibility than the provisions found in bilateral and regional agreements like the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP) and the Korea-United States Free Trade Agreement (KORUS). Bangladesh bilateral investment treaties (BITs), in contrast, have little to say directly about intellectual property policies, but do usually include non-discrimination rules which would preclude holding foreign and domestic firms to different standards (discussed below). The following paragraphs delve further into the ways that the WTO rules and bilateral, regional and mega-regional trade and investment treaties might conflict with Bangladesh policy, making graduation from LDC status more difficult for the country.

Table 6. Compliance of Bangladesh Intellectual Property Laws

Bangladesh Health, Industrial and IP Policies	WTO Compliant	CPTPP/KORUS Compliant	Bangladesh BIT compliant
Suspended pharmaceutical patents	No	No	N/A
Non-specific exclusionary rights for patent holders	No.	No.	N/A
Shortened patent term	No	No.	N/A
Compulsory licensing rules	Possible	Possible	N/A
Patent revocation rules; "working" requirement (4 years)	Possible	Probable	N/A

Source: Authors' analysis.

Evaluating Policy Space Against the TRIPS Agreement and TRIPS+ Commitments

One key area of health policy is in the protection of pharmaceutical patents and licensing. As noted above, Bangladesh has suspended pharmaceutical patents in response to the flexibilities granted to them under the TRIPS agreement (See Table 6), but would have to re-introduce them upon graduation. The Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council) has extended this flexibility for LDCs until January 1, 2033. In addition to this extension, LDCs are exempt from TRIPS notification requirements; and as a result, so far, Bangladesh has submitted very few notifications.

If Bangladesh graduates and re-introduces pharmaceutical patenting, however, its current intellectual property law (*The Patent and Designs Act, 1911 (Act. No. II of 1911)* 1911) may run afoul of TRIPS rules in a number of areas. In the first place, the term of protection for patents under the existing law is only 16 years (4 short of that mandated under TRIPS). In addition, the law is vague on the kinds of exclusionary rights actually conferred to patent owners. The TRIPS agreement, on the other hand, explicitly stipulates what those typical rights of exclusion must be: third parties cannot, unless

[5] Bangladesh is also a member of the APTA (previously known as the Bangkok Agreement, 1975), the oldest preferential RTA in the Asia-Pacific region, with China, India, Lao PDR, the Republic of Korea, and Sri Lanka . In addition to its trading arrangements, Bangladesh is party to 32 bilateral investment treaties (BITS) aimed at the promotion and protection of investments (World Trade Organization 2019). According to the WTO, Bangladesh's trade policy appears to be primarily influenced by "... considerations of revenue and assistance to local industries rather than trade competitiveness." Approximately 80 to 88 percent of government revenue comes from [trade?] taxes (World Trade Organization 2019, 59).

otherwise stipulated, make, use, offer for sale, sell, or import a patented product (World Trade Organization 1994, 28).

Existing patent revocation procedures may also violate the terms of the TRIPS agreement. Under Bangladesh's current law, a petition for revocation can be based entirely on the fact that "any trade or industry in Bangladesh is unfairly prejudiced by the conditions" of the patent (*The Patent and Designs Act, 1911 (Act. No. II of 1911)* 1911, 22(5)(b)). Moreover, a "working requirement" demands that a patentee manufacture or import their patented product in Bangladesh within 4 years of receiving patent protection (*The Patent and Designs Act, 1911 (Act. No. II of 1911)* 1911, 23). Both of these provisions give priority to domestic industry in a way that is likely to violate the non-discrimination principles in the TRIPS agreement and the WTO more broadly. In fact, the U.S. challenged a similar working requirement enacted in Brazil on the basis of inconsistency with Articles 27 and 28 of the TRIPS agreement and Article III of the General Agreement on Tariffs and Trade (GATT) (national treatment). Ultimately, the parties negotiated a mutually agreeable solution, so consistency of such a measure with TRIPS is uncertain.

Finally, Bangladesh's rules governing compulsory licensing may be problematic as well. Although TRIPS allows compulsory licensing in circumstances where the patentee and licensing country cannot agree on voluntary licensing terms, the patent right holder is still owed "adequate remuneration" for the license (World Trade Organization 1994, 31(h)). Bangladesh's law, however, does not specify such payment, nor does it allow the rights holder to challenge such a license, which is required under TRIPS article 32.

Outside of the WTO, many bilateral, regional and mega-regional treaties contain language that would further constrain policymaking and make it harder for Bangladesh's generic pharmaceutical industry to thrive. Treaties like the CPTPP, KORUS and others include extremely high levels of intellectual property protection (TRIPS-plus) (Canada-Australia-Brunei-Chile-Japan-Malaysia-Mexico-New Zealand-Peru-Singapore-Viet Nam 2018; U.S.-South Korea 2019). Table 7 describes TRIPS-plus measures, as found in various treaties, and summarizes their impact. This includes longer patent protection with extensions, the availability of secondary patents, data exclusivity for 6-12 years, patent/registration linkage and others.

Indeed, there are potential TRIPS-plus measures in the existing Bangladesh IP Law. For example, a patent can be opposed only if the invention was found in a Bangladesh patent application or known or used beforehand in Bangladesh (*The Patent and Designs Act, 1911 (Act. No. II of 1911)* 1911, 9). This limits the grounds for patent opposition to domestic activities only and is arguably a TRIPS-plus standard. Furthermore, patent extensions can be given for *any* reason, including that the patent "has not been sufficiently remunerative," which is even broader than many patent extension provisions, which are allowed in the case of unreasonable marketing or registration delays. As noted above, the Bangladesh patent law has been suspended for pharmaceuticals since 2008, so that none of these provisions have had an obvious impact, but if pharmaceutical patenting is once more introduced, those existing measures may stymie growth in that sector.

Even more important, if Bangladesh were to enter into regional trade agreements with neighboring countries, in particular those who are already members of the CPTPP or similar arrangements, its new IP laws will have to introduce even more protection for pharmaceutical innovators. This leaves less room for Bangladesh to put limits on patentability, allow liberal patent revocation, and make the protected data associated with patented medicines available to generic producers as they prepare for entry into the market. Moreover, TRIPS-plus treaty provisions often require increased enforcement through both civil and criminal remedies, as well as strict border measures to provide additional protection to patent holders.

Table 7. TRIPS+ Measures with Implications for Access to Medicines

MEASURES	MECHANISM OF IMPACTING ACCESS
Eased standards of patentability	Requires patents on: (1) new uses or methods of use of known medicines, and (2) new forms for known substances regardless of therapeutic efficacy. Lowers standards on novelty, inventive step (changed to "obviousness") and industrial applicability (changed to "usefulness"- both terms as used in the US).
Limitations on Patent revocation/opposition	Limited grounds for patent opposition/revocation by government.
Weakened limited exceptions for patent use	Restriction on the use by non-patent holder of early working/Bolar provisions in obtaining third-market registration. No exception or weak exception for non-commercial and commercial research and educational use of patented technology. No exception permitted for prior use of patented technology.
Patent term extension	Extensions for delays in processing patent applications, medicines registration and marketing and other regulatory delays.
Elimination of patent exceptions	Requires patents on diagnostic, therapeutic and surgical methods for treatment of humans
Patent registration linkage	Restricts the medicine regulatory authority's ability to register a generic medicine whenever an originator merely claims that a patent would be infringed
Data exclusivity	Gives exclusive rights to regulatory data to the patent holder and prohibits medicine regulator's reliance on, or reference to, innovator's submission data in reviewing registration applications of generics. Includes the possibility of extending data exclusivity upon submission of additional clinical data not available at the time of the original submission.
Increased civil and border measures remedies	Deterrent civil remedies, such as damages based on average retail price. Requires seizure of goods in transit, mandatory destruction and allows third-party enforcement.
Broadened criminal remedies	Criminal sanctions for patent violations (beyond TRIPS requirement for criminal trademark counterfeiting and copyright piracy only)
Investor-state dispute settlement provisions	Inclusion of IPRs as covered investment, which permits ISDS claims based on patent decisions.

Source: (Gleeson et al. 2019).[6]

Evaluating Policy Space Against Trade and Investment Commitments Outside of TRIPS

While some policy constraints are found within the TRIPS agreement and intellectual property rules in bilateral and regional free trade agreements, the major constraints to Bangladesh policy space will occur under other parts of the trade regime. Under the WTO, for example, there are various rules governing the non-discriminatory treatment of foreign products, quantitative restrictions, and prohibited investment and subsidies measures. Each of these, in turn, present problems for Bangladesh's past and current pharmaceutical policies (see Table 8).

[6] Although this table is quite comprehensive in terms of the IP and investment provisions that directly impact access to medicines, it lacks additional IP rules that might affect delivery of medicines including trade secrets and in some cases trademark. It also does not include a much broader set of treaty provisions that have potential impacts on core pharmaceutical policy objectives, which include such provisions as procedural requirements for national pharmaceutical pricing and reimbursement, government procurement rules, rules on state-owned enterprises and designated monopolies, among others. For a detailed discussion of these aspects of trade agreements, see (Gleeson et al. 2019)

Table 8. Compliance of Bangladesh Industrial and Investment Policies

Bangladesh Health, Industrial and IP Policies	WTO Compliant	CPTPP/KORUS Compliant	Bangladesh BIT compliant
Strategic cancellation or suspension of medicine registration/licensing	No.	No.	No.
Import bans on strategic products	No.	No.	Yes.
Local manufacturing and joint venture requirements (1982)	Yes.	No.	Yes.
Administrative rules providing government review of licensing agreements, supervision by local personnel, and strict enforcement of unlicensed imports (1982)	Possible	No.	Yes.
Export performance requirements for foreign manufacturers	No.	No.	No.
Government use licensing carve-out for emergencies (2016)	Possible	No.	Yes.
Required donations to local research and development organizations/institutions (or tax benefits contingent on those donations) (2016, 2018)	Yes.	Yes.	Yes.
Tax benefits and cash incentives contingent on domestic value added (2018)	Possible	Possible	Yes.
Access to preferred finance for API and reagent producers	Yes, but challengeable	Yes.	Yes.
Removal of red tape for API and Reagent producers	Yes, but challengeable	Yes.	Yes.
Priority plot allocation in special economic zones for API and reagent producers	Yes, but challengeable	Yes.	Yes.

Source: Authors' analysis.

As noted above in Table 8, Bangladesh's strategy of cancelling medicine registrations and licenses, which it deployed in 1982 in order to eliminate poor quality medicines and restart the domestic industry from scratch, as well as its policy of banning imports that compete with domestically produced medicines, both would have (if deployed today) violated GATT Article XI on quantitative restrictions ("General Agreement on Tariffs and Trade (GATT)" 1947, XI). Its policies requiring either local manufacturing or a joint venture with a domestic firm would have violated national treatment rules by imposing a greater burden on foreign products compared with their domestically produced competitors ("General Agreement on Tariffs and Trade (GATT)" 1947, III). Moreover, certain administrative requirements (government review of all licensing agreements and required oversight by domestic personnel), though facially neutral, may have imposed a *de facto* burden on foreign firms which exceeds those on domestic competitors.

These rules on quantitative restrictions and national treatment are folded into the TRIMs agreement and apply there to investment measures which have the effect of restricting imports or discriminating against foreign investors ("Agreement on Trade-Related Investment Measures" 1994). The TRIMs agreement does not allow members to apply investment measures inconsistent with Articles III (national treatment) and XI (prohibition of quantitative restrictions) of the GATT. Prohibited TRIMs, include measures that require particular levels of local procurement by an enterprise ("local content

requirements") or which restrict the volume or value of imports that an enterprise can purchase or use to an amount related to the level of the products it exports ("trade balancing requirements").[7]

Finally, Bangladesh's incentive programs, in particular those aimed at building backward linkages in the pharmaceutical sector by establishing a new API Industrial Park would likely run afoul of rules on subsidies. The Agreement on Subsidies and Countervailing Measures (SCM agreement) prohibits subsidies which are contingent on either local content of inputs or export requirements (Art. 3) – both of which are present under current Bangladesh law ("Agreement on Subsidies and Countervailing Measures" 1994). API producers receive a 20 percent rate of subsidy/cash incentive with a 20 percent minimum local content requirement (Ministry of Commerce, Government of Bangladesh 2018). In addition, foreign firms manufacturing under a license agreement are generally restricted to the export market and not allowed to sell the products locally (Ministry of Health and Family Welfare 2016).

Subsidies that are not explicitly prohibited may still be subject to challenge before the Dispute Settlement Body (DSB) as "actionable" subsidies ("Agreement on Subsidies and Countervailing Measures" 1994, 5). These are subsidies which target specific sub-sectors or geographic areas and injure the business of foreign competitive industries. In this way, the special duty and tax concessions, including project loans at reduced interest rates on a priority basis, and duty-free imports of equipment for setting up compliant industry all could result in a complaint by a neighboring country for the injury to their domestic firms.

The LDCs have enjoyed special treatment under the SCM agreement with respect to these subsidies. The SCM agreement also prohibits the use of export subsidies for non-agricultural products, a prohibition from which LDCs are also exempt. Upon graduation, however, they will not be allowed to enjoy this benefit. Export incentives provided currently, and those contemplated under Bangladesh's Export Policy 2018-21, to stimulate production and export of pharmaceuticals could come under question after she graduates in 2024.

The *India-Export Related Measures* case at the WTO illuminates standards under the SCM agreement, which would be analogous to the Bangladesh situation (India - Export Related Measures 2019). In that case, the United States challenged a comprehensive set of export incentive measures which India had in place to promote export performance and build up India's manufacturing competitiveness. These measures included exemptions of customs duties, indirect taxes and central excise duties, as well as deductions of the same – all contingent on various measures of trade balancing, foreign exchange earnings and general export performance. India's primary argument was that these measures were still protected by certain provisions granting transitions times to countries which had not yet graduated to a certain level of development.

In a ground-breaking decision, the panel stated that the 8-year transition time extended to low- and middle-income countries only until 2003 (8 years from entry into force of the Uruguay Round Agreements), and those countries initially exempt from the commitments of the SCM agreement altogether do not receive an additional 8 years after graduating from such status. Given that India exceeded the development indicator ($1000 income per capita) in 2017, they do not receive an additional 8 years, but must immediately phase out prohibited subsidies under the agreement. This has

[7] Despite the fact that these trade-balancing and local content requirements are clearly prohibited under the WTO rules, they are also widely in use for various purposes. Most recently, many countries' industrial policies aimed at their renewable energy sector came under fire in a series of dispute settlement cases. In each instances, the Member state did not even attempt to argue the measure was consistent with GATT Article III or the TRIMS agreement. Instead, they argued (unsuccessfully) that the policies were part of a government procurement program in energy. See (Canada - Certain Measures Affecting the Renewable Energy Generation Sector - Report of the Appellate Body 2013; India - Certain Measure Relating to Solar Cells and Solar Modules 2016; United States - Certain Measures Relating to the Renewable Energy Sector - Report of the Panel 2019).

immediate implications for Bangladesh. Given that their graduation from LDC status is imminent, it is clear that the SCM agreement will be interpreted to not grant any additional transition time to come into compliance with the agreement. Moreover, the measures challenged in the India case, are substantially similar to those in Bangladesh supporting the new API and Reagent Industrial Park, such that many of those measures, despite being relatively new, would have to be phased out almost immediately, before having their full effect.

Some policies are still permitted, however, and could be expanded. For example, Bangladesh's rules requiring that API and reagent producers donate 1 percent of their profits to organizations and institutions engaged in research and development is a permitted policy. Moreover, it seems like an effective way to support R&D in a context where the government does not have much fiscal room to move.

Bangladesh's health, industrial and investment policies would be even further endangered if Bangladesh were to enter into a bilateral and regional agreements similar to the CPTPP or KORUS. As shown in Table 8, many of the industrial and investment policies would not only run up against rules prohibiting import bans and discriminating against foreign products, but would also definitely violate rules which prohibit imposing performance requirements on domestic producers or foreign investors. In this case, performance requirements include not only export performance and local content requirements (by percent), but also foreign exchange and trade balancing, technology transfer, local hiring, local manufacturing and joint venture requirements (Canada-Australia-Brunei-Chile-Japan-Malaysia-Mexico-New Zealand-Peru-Singapore-Viet Nam 2018, 2.5, 9.5, 9.10).

In addition to the higher standards of treatment and more specific rules, treaties like the CPTPP include investor-state dispute settlement (ISDS), providing enforcement "teeth" to support these international commitments. As of this writing only one pharmaceutical case has come before an ISDS tribunal – *Eli Lilly v. Canada* – in which Canada had revoked two of Eli Lilly's new-use patents (Baker and Geddes 2017). In that case, the tribunal ultimately reject Eli-Lilly's claim, but did not foreclose the possibility that future intellectual property claims could be brought before a similar tribunal. Indeed, investment treaties and investment chapters in treaties like the CPTPP universally include intellectual property as a protected investment. That fact alone could subject Bangladesh to future claims for its industrial policies aimed at the API and pharmaceutical sectors which seek to promote exports and build up manufacturing capacity.

Bangladesh is already party to a number of investment treaties (See Annex II, Table 3). Although those treaties largely adopt the same language as the CPTPP and KORUS investment chapters, they are marked by three key distinctions. First of all, none of Bangladesh's BITs extend the right of establishment to foreign pharmaceutical firms. In that way, Bangladesh can still act as gatekeeper to keep out foreign firms that may threaten the competitiveness of their domestic firms. Second, none of Bangladesh's BITs contain commitments on performance requirements, so that non-discriminatory requirements for export performance, local manufacturing, local hiring and technology transfer are likely to be permitted. Finally, in at least two of these BITs, the treaty contained no national treatment commitment at all (UK (1980) and Thailand (2005), the latter which is not currently in force). Although that does not keep Bangladesh from the reach of the national treatment commitments under the WTO, it does preclude ISDS claims on the basis of national treatment under those treaties.

CONCLUSIONS AND POLICY RECOMMENDATIONS

Despite a highly concentrated and hard to penetrate global pharmaceutical market that is enabled and protected by a tight web of intellectual property and other protections, government strategy and policy in Bangladesh over a forty-year period allowed Bangladesh to carve out a small but significant

niche in the global pharmaceutical value chain, and a large one in the Bangladesh market itself. Globally, Bangladesh's experience also plays a small but relevant role in promoting access to generic medicines in other lower- and middle-income countries such as Myanmar, Sri Lanka, the Philippines and Kenya that have less domestic pharmaceutical production than Bangladesh. If Bangladesh were to follow its previous policy trajectories that have propelled the country to this point, over the next decades Bangladesh will hit major roadblocks as it graduates from LDC status and has to adhere to the rules of the WTO, in addition to other regional and bilateral trade and investment treaties that it might join. LDC graduation for the country would commence in the wake of the COVID-19 pandemic, when low- and middle-income and Least Developed Countries have experienced significant shortages of medical products, including diagnostics (UNDESA 2020), and are likely to continue to face shortages of new treatments and vaccines as they become available (Tabacek 2020).

The Bangladesh case has implications far beyond itself and even South Asia. As other low- and middle-income countries across the world witnessed the seizure of availability of medical products and medicines during the COVID-19 epidemic due to export controls, supply bottlenecks, and patent walls, many are considering measures to develop manufacturing capabilities on their own shores moving forward. Unfortunately, emerging market and low- and middle-income countries will find it difficult to replicate Bangladesh's efforts going forward due to the constraining nature of global, regional, and bilateral trade and investment treaties. In pinpointing the types of measures that have been deemed successful this paper can serve as a guide for other low- and middle-income countries. While beyond the scope of this particular case study, this work begs the larger question of whether it is still possible for governments to build a vibrant domestic healthcare industry in the face of the daunting protection of health technology monopolies of the 21st century, and thus whether the policies that are now so constraining to do so should be reformed given the current context of pressing global health and economic challenges.

Bangladesh is unique among those LDCs under the TRIPS Article 66.1 waiver in having an exceedingly robust domestic pharmaceutical industry. Their current industrial and IP policies, specifically designed to incentivize local industry, are in tension with the rules governing international trade and investment. Trade and investment treaties constrain policymaking. This truth is particularly poignant in Bangladesh where its trade and investment commitments will change upon graduation such that Bangladesh will be susceptible to the loss of the majority of its current policy space for building up and protecting its API and Reagents sector.

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ANNEX TABLES

Annex Table 1: Export of Pharmaceutical Products for July-June 2019-2020

Export items at 8-digit level	Value (In Million USD)	% share
Total	135.8	100.0%
30049099: Other(excl.anti-malaria, anti-TB, anti-leprosy....and kidney dialysis solution	68.2	50.2%
30049010: Oth.Medicaments Of Mixe...Containing More Than 15% Of Absolute Alcohol	21.5	15.8%
30032000: Medicaments Containing Other Antibiotics, ...Not For Retail Sale	11.3	8.3%
30041000: Medicaments Of Penicillins... Or Streptomycins..., For Retail Sale	8.7	6.4%
30042090: Other than Mycophenolate mofetil, mycophenolate sodium, ciclosporin	8.5	6.2%
30043910: Anti-malaria-TB-cancer-leprosy,crdvsclr/anti-hepatic encephal opathy drugs/Kidney dls	5.6	4.1%
30039099: Other medicaments with >=2 constituents, not for retail sale, nes	3.2	2.4%
30039091: Other Anti-Malaria,Anti-Tb,A.-Leprosy Cardiovascular & A.-Hepatic Encep...	3.1	2.3%
30067000: Gel preparation designed to be used in human or vete...Medical instruments	1.2	0.9%
30042010: Mycophenolate mofetil, mycophenolate sodium, ciclosporin	1.0	0.7%
Others	3.6	2.6%

Source: Export Promotion Bureau, n.d.

Annex Table 2: Bangladesh Top Five Export and Developing Countries Export Values of those Top Five Items

Top Exporters of 300490: Other medicaments of mixed or unmixed products, for retail sale, nes	Export Value in 2018 (In Million USD)	% share
World	282913.5	100.0%
Developing Market Economies Aggregation	33270.0	11.8%
India	10783.0	3.8%
Singapore	4689.8	1.7%
Israel	4469.1	1.6%
China	2781.9	1.0%
Mexico	972.3	0.3%

Top Exporters of 300320: Medicaments of other antibiotics, not for retail sale	Export Value in 2018 (In Million USD)	% share
World	952.8	100.0%
Developing Market Economies Aggregation	532.4	55.9%
China	339.1	35.6%
Saudi Arabia	95.6	10.0%
Hong Kong, China	40.3	4.2%
Korea, Republic of	10.4	1.1%
Thailand	9.9	1.0%

Top Exporters of 300420: Medicaments of other antibiotics, for retail sale	Export Value in 2018 (In Million USD)	% share
World	15,142.6	100.0%
Developing Market Economies Aggregation	2,597.8	17.2%
India	1,010.1	6.7%
China	365.2	2.4%
United Arab Emirates	127.6	0.8%
Korea, Republic of	124.2	0.8%
Brazil	105.7	0.7%

Top Exporters of 300410: Medicaments of penicillins... or streptomycins..., for retail sale	Export Value in 2018 (In Million USD)	% share
World	3667.7	100.0%
Developing Market Economies Aggregation	1066.7	29.1%
India	497.3	13.6%
China	194.6	5.3%
Indonesia	76.6	2.1%
Hong Kong, China	63.0	1.7%
Korea, Republic of	28.5	0.8%

Top Exporters of 300390: Other medicaments with >=2 constituents, not for retail sale, nes	Export Value in 2018 (In Million USD)	% share
World	15966.3	100.0%
Developing Market Economies Aggregation	2166.8	13.6%
Israel	801.2	5.0%
Singapore	324.3	2.0%
India	314.4	2.0%
China	312.4	2.0%
Jordan	207.1	1.3%

Source: Estimated from ITC, n.d.

Annex Table 3: Price Comparison Between Original Drugs in Overseas Market and Generic Drugs in Bangladesh and Price Differentials within Bangladesh

Class	Name of the Manufacturer	Brand Name	Generic Name	Strength	Dosage Description	Price	Diff (%) High vs Low at local market	DAR	API	Remarks
Antibiotic	Pfizer	Zithromax 500mg	Azithromycin	500 mg	Tablet	792.00 Tk		USA	Original	Not available in Bangladesh
	Radiant Pharmaceuticals Ltd.	Acos 500mg	Azithromycin	500 mg	Tablet	55.17 Tk	345%	355-0074-023	Copy	
	Sanofi Bangladesh Ltd.	Curazith 500 mg	Azithromycin	500 mg	Tablet	35.11 Tk		143-0372-023	Copy	
	Square Pharmaceuticals Ltd. Gazipur	Zimax 500	Azithromycin	500 mg	Tablet	35.11 Tk		326-0066-023	Copy	
	EDCL (Dhaka)	Azithromycin	Azithromycin	500 mg	Tablet	18.28 Tk		296-0028-023	Copy	
	Medicon Pharmaceuticals Ltd.	Zitrex 500	Azithromycin	500 mg	Tablet	16.00 Tk		052-0056-023	Copy	
Hyperlipidaemia	AstraZeneca	Crestor	Rosuvastatin	20 mg	Tablet	736.00 Tk		USA	Original	Not available in Bangladesh
	Square Pharmaceuticals Ltd. Pabna	Rosuva 21	Rosuvastatin	21 mg	Tablet	30.10 Tk	376%	386-0020-061		
	The ACME Laboratories Ltd.	Rostab 20	Rosuvastatin	20 mg	Tablet	25.08 Tk		278-0103-061	Copy	
	Drug International Ltd.	Rostatin 20	Rosuvastatin	20 mg	Tablet	10.00 Tk		267-0261-061	Copy	
	Delta Pharma Limited	RTV 20	Rosuvastatin	20 mg	Tablet	8.00 Tk		005-0938-061	Copy	
Type 2 Diabetes	Novartis AG Switzerland	Galvus 50 mg	Vildagliptin	50 mg	Tablet	137.00 Tk		USA	Original	Not available in Bangladesh
	Novartis (Bangladesh) Ltd.	Galvus 50 mg	Vildagliptin	50 mg	Tablet	32.00 Tk	267%	005-1093-016	Original	
	Square Pharmaceuticals Ltd. Pabna	Viglita 50	Vildagliptin	50 mg	Tablet	20.06 Tk		143-0537-015	Copy	
	The ACME Laboratories Ltd.	Vildapin 50	Vildagliptin	50 mg	Tablet	15.04 Tk		336-0558-015	Copy	
	Concord Pharmaceuticals Ltd.	Vildaglip	Vildagliptin	50 mg	Tablet	12.00 Tk		360-0130-015	Copy	

Class	Name of the Manufacturer	Brand Name	Generic Name	Strength	Dosage Description	Price	Diff (%) High vs Low at local market	DAR	API	Remarks
Type 2 Diabetes	Novartis AG Switzerland	Galvus 50/850 mg	Metformin Hydrochloride + Vildagliptin	850 mg + 50 mg	Tablet	121.00 Tk		Canada	Original	
	Novartis (Bangla-desh) Ltd.	Galvus 50/850 mg	Metformin Hydrochloride + Vildagliptin	850 mg + 50 mg	Tablet	32.00 Tk	160%	005-1093-016	Original	
	Healthcare Pharma-ceuticals Ltd.	Redia-M 50/850 mg	Metformin Hydrochloride + Vildagliptin	850 mg + 50 mg	Tablet	24.00 Tk		015-0478-071	Copy	
	Eskayef Pharma-ceuticals Ltd., Tongi,Gazipur	Vigmet 50/500	Metformin Hydrochloride + Vildagliptin	500 mg + 50 mg	Tablet	20.00 Tk		083-0245-023	Copy	
	Sunman-Birdem Pharma Ltd.	SB-Metvilda 500/50	Metformin Hydrochloride + Vildagliptin	500 mg + 50 mg	Tablet	17.00 Tk		239-0101-062	Copy	
	NIPRO JMI Pharma Limited	Viltab Plus	Metformin Hydrochloride + Vildagliptin	500 mg + 50 mg	Tablet	15.00 Tk		116-0581-041	Copy	
Type 2 Diabetes	Sanofi Bangladesh Ltd.	Amaryl 2	Glimepiride	2 mg	Tablet	88.00 Tk		USA	Original	Not available in Bangladesh
	Sanofi Bangladesh Ltd.	Amaryl 2	Glimepiride	2 mg	Tablet	12.94 Tk	324%	264-0013-023	Copy	
	Beximco Pharmaceu-ticals Ltd.	Diaryl 2	Glimepiride	2 mg	Tablet	9.00 Tk		005-0539-064	Copy	
	The ACME Laborato-ries Ltd.	Dactus 2	Glimepiride	2 mg	Tablet	6.50 Tk		326-0042-031	Copy	
	Healthcare Pharma-ceuticals Ltd.	Glemep 2	Glimepiride	2 mg	Tablet	4.00 Tk		210-0226-042	Copy	

Class	Name of the Manufacturer	Brand Name	Generic Name	Strength	Dosage Description	Price	Diff (%) High vs Low at local market	DAR	API	Remarks
Type 2 Diabetes	Novartis AG Switzerland	Diovan 80	Valsartan	80 mg	Tablet	83.00 Tk		USA	Original	Not available in Bangladesh
	Novartis (Bangladesh) Ltd.	Diovan 80	Valsartan	80 mg	Tablet	40.00 Tk	667%	048-0235-043	Original	
	Eskayef Pharmaceuticals Ltd., Tongi,Gazipur	Cardovan 80	Valsartan	80 mg	Tablet	10.00 Tk		143-0262-078	Copy	
	Concord Pharmaceuticals Ltd.	Valosan 80	Valsartan	80 mg	Tablet	7.00 Tk		238-0167-018	Copy	
	Incepta Pharmaceuticals Ltd.	Valsartil 80	Valsartan	80 mg	Tablet	6.00 Tk		193-0007-062	Copy	

Annex Table 4. Expanded Policy Toolkit Table

Bangladesh Health, Industrial and IP Policies	WTO Compliant	CPTPP/KORUS Compliant	Bangladesh BIT compliant
Suspended pharmaceutical patents (2008)	No. After graduation, pharmaceutical patents would be required	No.	N/A
Rights conferred by a patent (1911 Patent Law)	No. No indication of what rights are actually conferred (compare TRIPS Art. 28)	No.	N/A
Shortened patent term (16 years) (1911 Patent Law	No. 20 year patent term from filing date (TRIPS, Article 33)	No.	N/A
Compulsory licensing rules (1911 Patent Law) – does not require adequate remuneration	No. Violation of TRIPS article 31(h) which requires adequate remuneration		
Patent revocation on that basis of: "if any trade or industry in Bangladesh is unfairly prejudiced by the conditions" of the patent.	Possible As a de facto violation of national treatment, if it eliminates/ hinders the ability of a foreign entity to obtain a competitive market position inside Bangladesh	No. Each Party shall provide that a patent may be revoked only on grounds that would have justified a refusal to grant the patent.	N/A
Patent "working requirement" of 4 years	Possible. Articles 27 and 28 on patent rights conferred and rules on national treatment may be violated	No. Korus: 18.8(4): Each Party shall provide that a patent may be revoked only on grounds that would have justified a refusal to grant the patent.	N/A

Bangladesh Health, Industrial and IP Policies	WTO Compliant	CPTPP/KORUS Compliant	Bangladesh BIT compliant
Strategic cancellation or suspension of medicine registration/licensing in accordance with national interest (1982)	No; As an import restriction/ban for foreign medicines (Art. XI);	No; CPTPP Art. 9.8 (Expropriation, if the medicines were manufactured by foreign pharma companies); Art. 9.6 (minimum standard of treatment, if the medicines manufactured by foreign pharma companies); Art. 2.10 (prohibition on import restrictions)	No; Bangladesh BITs all include rules against expropriation including indirect expropriation
Import bans on strategic products (those competitive with local industry or already produced locally) (1982, 2005, 2016)	No; As an import restriction/ban (Art. XI); as a violation of national treatment (Art. III)	No; CPTPP Art. 2.10 (prohibition on import restrictions); Art. 2.3 (national treatment incorporating standards of GATT Art. III)	Possible, depending on whether the import bans unduly impact foreign investors
Local manufacturing and Joint venture requirements (1982)	Possible; As a *de facto* violation of national treatment, if it puts a larger burden on foreign manufacturers than domestic manufacturers	No; CPTPP Art. 2.10 (No party shall, as a condition for engaging in importation or for the importation of a good, require a person of another party to establish or maintain a contractual or other relationship with a distributor in its territory); Art. 9.4 (national treatment for foreign investors)	Possible; Bangladesh BITs do not include prohibitions on performance requirements, but most contain national treatment standards
Government review of licensing agreements (1982)	Possible; As a *de facto* violation of national treatment, if it puts a larger burden on foreign manufacturers than domestic manufacturers; Also transparency and notification rules of the Import Licensing Agreement (ILA)	No; CPTPP Art. 2.3 (national treatment due to differential treatment for foreign concerns as opposed to national companies); Art. 9.4 (national treatment in investment commitments); Art. 9.6, 9.8 (minimum standard of treatment and expropriation if the manufacturing license is cancelled) (possible, Art. 2.12 on incorporating standards of Import Licensing Agreement of WTO)	Possible; As a de facto violation of national treatment, putting a larger burden on foreign pharma firms than local ones
Requirement of supervision by local personnel (1982)	Possible; As a *de facto* violation of national treatment, if it puts a larger burden on foreign manufacturers than domestic manufacturers; Also transparency and notification rules of the ILA	No; CPTPP Art. 2.3 (national treatment due to differential impact on foreign concerns as opposed to national companies); Art. 9.4 (national treatment in investment commitments)	Possible; As a de facto violation of national treatment, putting a larger burden on foreign pharma firms than local ones
Stringent enforcement for unlicensed imports (1982)	Possible; As a *de facto* violation of national treatment, if it puts a larger burden on foreign manufacturers than domestic manufacturers	No; Art. 2.3 (national treatment due to differential treatment for foreign concerns as opposed to national companies); Art. 9.4 (national treatment in investment commitments); Art. 9.6, 9.8 (minimum standard of treatment and expropriation if the drug or API are forfeited to the government);	

Bangladesh Health, Industrial and IP Policies	WTO Compliant	CPTPP/KORUS Compliant	Bangladesh BIT compliant
possible; Art. 2.12 on incorporating standards of Import Licensing Agreement of WTO	Possible; As a de facto violation of national treatment, putting a larger burden on foreign pharma firms than local ones		
Export performance requirements (e.g., foreign pharmaceutical industries without manufacturing factories may only manufacture by contract for *export*) (2016)	No; As a violation of national treatment (Art. III) by differential treatment of foreign pharmaceutical industries	No; Art. 2.3, (national treatment due to differential treatment for foreign industries as opposed to domestic ones); Art. 9.4 (national treatment for investors/ investments)	No; as a violation of national treatment, included in most Bangladesh BITS
Government use carve-out for emergencies (2016)	Possible; Employs the government use carve out but without a requirement to compensate the manufacturers a certain amount	Government use exception in CPTPP?	Yes.
Required donations to local research and development organizations/institutions (or tax benefits contingent on those donations) (2016, 2018)	Yes	Yes	Yes.
Tax benefits and cash incentives contingent on domestic value added (2018)	Possible; depending on whether domestic value added is linked to domestic content or inputs (Art. III, SCM Art. 3)	Possible; depending on whether domestic value added is linked to domestic content or inputs (9.10 performance requirements, if they apply to foreign investors)	Yes; Bangladesh BITs do not include a prohibition on performance requirements.
Access to preferred finance for API and reagent producers (e.g., loans allowed from offshore funds, longer terms to settle letters of credit, longer-term loans (12 years) for setting up shop and importing machinery) (2018)	Yes; but it would count as a "specific" subsidies which could be challengeable ("actionable") under the WTO DSB (SCM Art. 5)	Yes.	Yes.
Removal of red tape for API and Reagent producers (government fast-track) (2018)	Yes; but it would count as a "specific" subsidies which could be challengeable ("actionable") under the WTO DSB (SCM Art. 5)	Yes.	Yes.
Priority plot allocation in special economic zones for API and reagent producers (2018)	Yes; but it would count as a "specific" subsidies which could be challengeable ("actionable") under the WTO DSB (SCM Art. 5)	Yes.	Yes.

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Annex Table 5. Bangladesh BIT Provisions

	Turkey (2012)	Denmark (2013)	India (2011)	Vietnam (2005)	UK (1980)	US (1989)	Thailand (2002)
Establishment	N/A	N/A	N/A	N/A	N/A	N/A	N/A
IP: protected Investment	1.1(d)	1.1(d)	1(b)(iv)	1(iv)	1(a)(iv)	I(c)(iv)	1.3(d)
Ind. Exprop.	6	5.1	5.1	5(1)	5(1)	III(1)	4.1
FET	2.2	3.2	3.2	2.2	2.2	II(3)	2.2
Free Transfers	8	7	7	6(1)	6 (ltd)	V(1)	6.1
ISDS	10	9	9	7	8(1)	VII(2)	9.2
Perf. Reqts	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NO NT	N/A	N/A	N/A	see art. 3	see art. 3	N/A	N/A

Sources: Bangladesh-Turkey 2012; Bangladesh-Vietnam 2005; Bangladesh-UK 1980; Bangladesh-U.S. 1989; Bangladesh-Denmark 2013; Bangladesh-India 2011; Bangladesh-Thailand 2002.