

An Analysis of the Bangladesh Patent Act 2022: A Step Forward from an LDC to a Developing Country

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Abstract

Bangladesh is categorized as a Least Developed Country (LDC). It has a thriving pharmaceutical industry, which is unusual for an LDC. Because of its LDC status, Bangladesh has been enjoying several preferential treatments. For instance, according to the current Council's decision, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the most comprehensive multilateral agreement on intellectual property (IP), provides an extended transition period for LDCs until 2034. TRIPS also offers a special exemption for introducing an IPR system compatible with TRIPS in LDCs.

Currently, Bangladesh faces new challenges. The country will graduate from LDC status in 2026, partly due to the country's robust pharmaceutical industry. Once Bangladesh graduates from LDC status and becomes a developing country, it will no longer be eligible for these preferential treatments. The country will be required to introduce a patent law compatible with TRIPS. Bangladesh has been preparing diligently to become a developing country, and as part of that effort, it revised and enacted a new patent law, Patent Law 2022, in April 2022. This article examines the impacts of Bangladesh's graduation from LDC, as well as Bangladesh's future prospects after graduation.

Keywords: Bangladesh, Pharmaceutical Industry, Intellectual Property Rights, WTO/TRIPS, Business Model, Mega-Pharma, Access to Medicine

1 Introduction

Most developing and least developed countries (LDCs) lack a pharmaceutical industry. Bangladesh, on the other hand, is an LDC with a thriving pharmaceutical industry. Several factors contribute to the growth of the pharmaceutical industry in Bangladesh. The first is national drug policies. Under the military government of Hussain Muhammad Ershad, Bangladesh formulated its first drug policy, called the "National Drug Policy 1982 (NDP1982)." The NDP 1982 was a protectionist policy that prohibited foreign pharmaceutical companies from doing business in Bangladesh. Thus, the NDP 1982 enabled the rapid growth of the domestic pharmaceutical industry in Bangladesh.

In 2005, the country announced the second national drug policy, named National Drug Policy 2005 (NDP 2005). Unlike NDP 1982, NDP 2005 allowed certain foreign capital pharmaceutical firms to do business in Bangladesh.

The second factor contributing to the growth of the pharmaceutical industry in Bangladesh was the World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS requires all WTO members to introduce a patent law

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compatible with TRIPS. However, TRIPS provides a special exemption for LDCs, allowing them not to introduce product patents in the pharmaceutical field. Hence, in the absence of product patents, Bangladesh's pharmaceutical companies can copy patent-protected drugs and manufacture and sell them as "Generic Drugs."

Partly due to the rapid development of its pharmaceutical industry, Bangladesh will graduate from LDC in 2026. Graduation from LDC is positive news for Bangladesh and its people. However, Bangladesh will lose many preferential treatments that the country enjoys as an LDC upon graduation.

This study first examines both the benefits and challenges of graduating from LDC, followed by an analysis of the country's preparation for becoming a developing country, which includes the recently enacted Bangladesh patent law.

2 Bangladesh's Economic Status

Bangladesh enjoyed a decade of robust economic growth before the outbreak of the COVID-19 pandemic in the spring of 2020. In FY2019 (July 2018-June, 2019), the country's GDP grew at an all-time high of 8.15%. However, Bangladesh's economy grew by merely 3.80% in FY2020 due to the COVID-19 pandemic. Table 1 shows the economic indicators compiled by JETRO [1].

Table 1: Economic Indicators of Bangladesh

Year	2018	2019	2020
Real GDP Growth Ratio	7.86 (%)	8.15 (%)	3.80 (%)
Nominal GDP	273.3 (\$1 bil.)	302.4 (\$1 bil.)	329.1 (\$1 bil.)
Per Capita Nominal GDP	1,694 (\$)	1,855 (\$)	1,998 (\$)
CPI Growth Ratio	5.54 (%)	5.59 (%)	5.69 (%)
Exports	33,775 (\$1 mil.)	35,919 (\$1 mil.)	30,746 (\$1 mil.)
Imports	55,319 (\$1 mil.)	55,095 (\$1 mil.)	45,858 (\$1 mil.)

Source: JETRO

https://www.jetro.go.jp/world/asia/bd/basic_01.html

Bangladesh has made a strong economic recovery from the COVID-19 pandemic. However, the country's economic growth faces a new obstacle as global commodity prices have risen amid the uncertainty created by the war in Ukraine [2]. Under these circumstances, the World Bank has projected that Bangladesh's economy will grow by 6.6% in 2022 and 6.3% in 2023 [3].

3 Bangladesh Pharmaceutical Industry

A. Bangladesh Market After Independence

Bangladesh won its independence in 1971 following a two-year liberation war against Pakistan [4]. Bangladesh virtually had no pharmaceutical industry when it gained independence. The pharmaceutical market in Bangladesh was dominated by multinational enterprises (MNEs), or so-called mega-pharma. These MNEs did not manufacture pharmaceutical products in Bangladesh; instead, they imported them from their home countries. As a result, the Bangladeshi market was flooded with ineffective, substandard, and non-essential drugs [5].

B. National Drug Policy 1982

General Hussain Muhammad Ershad (the then Army Chief and politician) formulated the National Drug Policy 1982 shortly after seizing power in a bloodless coup. His NDP 1982 was a protectionist policy. An Expert Panel set up by General Ershad compiled guidelines consisting of 16 articles. Articles 12 to 16 (except Article 14) were protectionist policies and intended to protect Bangladeshi pharmaceutical firms from foreign capital companies [6].

Articles 12 to 16 (except Article 14) are listed below:

12. The importing of a drug which is the same or one produced in the country, or a close substitute for it, may not be imported, as a measure of protection for the local industry. However, if local production is far short of need, this condition may be relaxed in some cases.

13. A basic pharmaceutical raw material which is locally manufactured will be given protection by disallowing it or its substitute to be imported if sufficient quantity is not available in the country.

15. No foreign brands may be manufactured under license in any factory in Bangladesh if the same or similar products are available/manufactured in Bangladesh, as this leads to unnecessarily high prices and payment of royalties. In the light of this policy, all existing licensing agreements should be reviewed.

16. No multinational company without their own factory in Bangladesh will be allowed to market their products after manufacturing them in another factory in Bangladesh on a toll basis.

The NDP 1982 prohibited MNEs, or mega-pharma companies, from importing, manufacturing, and selling drugs in Bangladesh. Once the NDP 1982 was implemented in Bangladesh, MNEs, or mega-pharma companies, left the country. In the absence of Mega-pharma, the Bangladesh pharmaceutical industry has developed rapidly [7].

Bangladesh reaped substantial benefits from NDP 1982.

These are:

*Local production of drugs increased substantially.

*The availability of essential drugs also increased remarkably.

*Local companies' share of production increased from 30% in 1970 to more than 80% in 2002.

*Drug prices stabilized, increasing by only 20% compared to a 179% increase in the consumer price index.

*The quality of pharmaceutical products improved, and the proportion of substandard drugs fell from 35% in 1970 to 2% in 2002 [8].

C. National Drug Policy 2005

The Bangladesh government announced a new national drug policy in 2005, named "National Drug Policy 2005" (NDP 2005).

Unlike NDP 1982, which prohibited foreign capital firms from manufacturing, importing, and selling their pharmaceutical products in Bangladesh, NDP 2005 partially relaxed the restriction. For instance, one clause of the NDP 2005 stated that foreign and multinational companies would be allowed to invest and manufacture drugs in Bangladesh if at least three of their original brand-name drug products are registered in at least two of the following countries: the USA, UK,

Switzerland, Germany, France, Japan, and Australia.

The NDP2005 aimed to provide Bangladeshi citizens with access to advanced, high-quality medicines, such as breakthrough or first-in-class medicines, while protecting the country from harsh competition from generic drug-centric countries such as China and India [9].

D. The Current Pharmaceutical Drug Market in Bangladesh

Since the 1980s, the pharmaceutical industry in Bangladesh has been thriving [10]. Pharmaceutical production in Bangladesh reached 2.8 billion USD in 2018 and is estimated to reach 4.3 billion USD by 2024 [11].

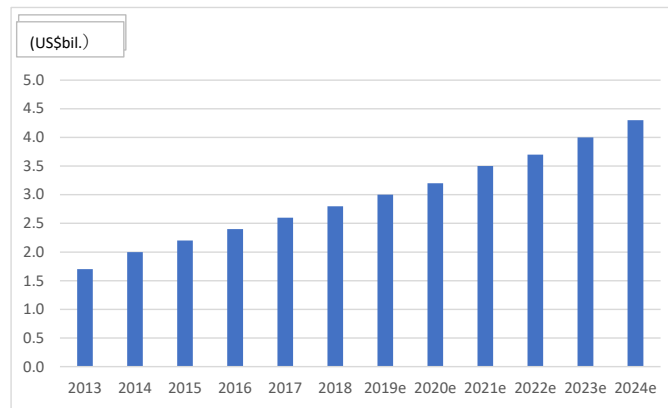


Figure 1: Bangladesh Pharmaceutical Market 2013–2024

Note: This figure shows the pharmaceutical market in Bangladesh from 2013 to 2024. (Figures between 2019–2024 are estimated figures)

Table 2: Top 10 pharmaceutical companies in Bangladesh

	Company Name	type	found ation	founder/CEO	market share(%)
1	Square	public	1958	Samson H Chowdhury	17.0
2	Incepta Pharma	private	1999	Abdul Muktedir	11.1
3	Beximco	public	1980	ASF Rahman & Salman F Rahman	8.3
4	Renata	public	1993	Sayed S Kaiser Kabir	5.2
5	Healthcare Pharma	private	1989	Suraya Bilkis	5.2
6	Opsonin Pharma	public	1956	Abdul Khaleque Khan	5.1
7	ACI	public	1968	M. Anis Ud Dowla	4.4
8	Eskayef	private	1990	Latifur Rahman	4.4
9	Aristopharma	private	1986	M.A. Hassan	4.1
10	Acme	public	1954	Hamidur Rahman Sinha	3.5

Note: This table lists Bangladesh's top 10 pharmaceutical companies.

Source: EBL Securities Ltd. [12]

The pharmaceutical industry in Bangladesh is highly concentrated, with the top ten firms controlling 70% of the market. The top 20 firms account for 80% of the market, while the top 3 firms (Square, Incepta, and Beximco) account for 36.3% [13].

4 Bangladesh Intellectual Property Structure and Enforcement

Bangladesh is a relatively young country. However, the nation has a long history of protecting intellectual property. Bangladesh was a British colony until 1947. Even after attaining independence in 1971, the country kept the “Patents and Designs Act, 1911,” which was drafted during British rule, in force until 2022. The Patents and Designs Act 1911 provided product patent protection in the pharmaceutical field [14].

Bangladesh has been a WTO member since the international organization’s inception in 1995 [15]. Since Bangladesh was designated as an LDC, it could scrap product patent protection in the pharmaceutical field under TRIPS. However, the country kept product patents in the pharmaceutical field until 2008. Since then, the country has set up a mailbox and keeps patent applications for pharmaceuticals in it. Figure 2 illustrates patents applied and patents granted in Bangladesh from 1995 to 2021 [16].

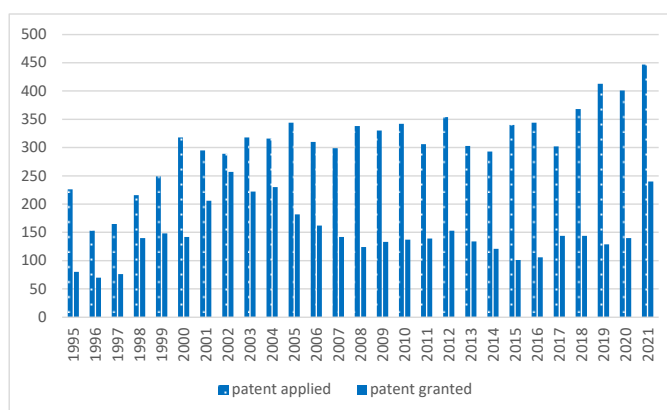


Figure 2: Patent Applied and Granted in Bangladesh

Note. This figure illustrates patents applied and patents granted in Bangladesh from 1995 to 2021.

The number of patents applied for and granted has fluctuated over time. Approximately 150-450 applications were filed each year, with 50-250 being granted. When applicants are divided into Bangladeshi and foreigners, foreigners constitute the majority (81%). Also, when Bangladeshi and foreigners who are granted patents are compared, foreigners make up the majority (88%) [15].

5 Graduation from LDC

A. Transition from an LDC to a developing country

In part due to Bangladesh’s robust pharmaceutical industry, the country’s economy has grown rapidly over the past decade. In 2021, Bangladesh was decided to graduate from LDC by 2026 [17]. In order to graduate from LDC, a country must meet three criteria (gross national income per capita, human assets index, and economic vulnerability index) at two consecutive triennial inspections conducted by the Committee for Development Policy (CDP) of the United Nations. In 2018, Bangladesh cleared the first round of inspection. In 2021, the country passed the second round of inspection by CDP [18].

Table 3: Bangladesh’s scores in the 2021 evaluation by CDP

	Bangladesh's score	Threshold
GNI Per Capita	\$1,827	>\$1,222
Human Assets Index (HAI)	75.3	>66
Economic and Environmental Vulnerability Index (EVI)	27.2	<32

Note: This table displays Bangladesh’s scores for the 2021 inspection as well as the graduation thresholds set by the Committee for Development Policy (CDP) of the United Nations.

Source: The Committee for Development Policy (CDP) of the United Nations

B. Challenges and Benefits of Graduation from LDC

Graduation from the LDC status will bring both challenges and opportunities to Bangladesh.

*Opportunities and benefits from graduation:

- improve Bangladesh’s global image
- enhance the confidence of international financial actors
- will give the country a better credit rating
- assist in reducing the cost of international borrowing from the international financial market
- attract FDI
- instill psychological values

*Challenges from graduation

Disappearing of a wide ranges of LDC specific international support measures (ISMs), which include:

- ODA
- concessional loans
- preferential market access
- special and differential treatments under WTO

In the pharmaceutical industry/market, LDCs are granted special exemption from patent protection and licensing requirements for pharmaceutical products until 2033.

Once Bangladesh graduates from LDC, it will no longer be eligible for the aforementioned benefits and will instead face these challenges [19].

C. Preparation for Graduation from LDC

Bangladesh initiated a range of policies, strategies, and programs to prepare for LDC graduation.

Bangladesh’s government established the National Committee on LDC Graduation (NCG), chaired by the Principal Secretary to the Prime Minister. Under the NCG, seven subcommittees were set up. One of the seven committees is responsible for Intellectual Property Rights (IPRs), and another is responsible for WTO-related issues (other than market access & TRIPS) [20].

The Economic Relations Division (ERD) formed the Joint Task Team (JTT), which serves as a consultative mechanism involving all relevant stakeholders and provides technical support for preparing a smooth transition strategy (STS).

The JTT comprises four representatives from Bangladesh’s development partners (UNDP, EU, FCDO-USAID, and ADB); four representatives from the Bangladesh government (Economic Relations Division (ERD), General Economic Division (GED), Ministry of Commerce, and Ministry of Foreign Affairs); and three representatives from the private sector (Bangladesh Garment Manufacturers and Exporters Association (BGMEA), Bangladesh Association of Pharmaceutical Industries (BAPI), and Federation of Bangladesh Chambers of Commerce and Industries) [20].

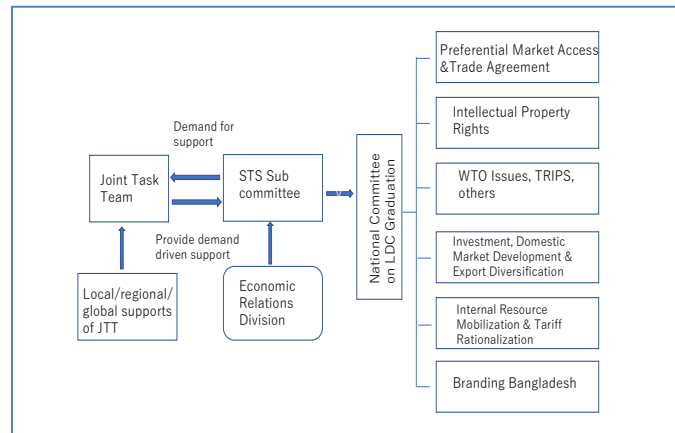


Figure 4: JTT and network for preparation of STS and framing of a consultative mechanism

Note: This figure shows JTT and the network preparing the STS and framing a consultative mechanism.

Source: Bangladesh Preparing for Sustainable Graduation, Annual Monitoring Report 2021 submitted to UN-CDP, the Economic Relations Division, Ministry of Finance, Government of the People’s Republic of Bangladesh, Nov. 2021

D. Revision of Bangladesh Patent Law

Bangladesh will be required to revise its patent law (The Patents and Designs Act, 1911) and to have a TRIPS-compatible patent law upon graduation from LDC status. The government of Bangladesh drafted a revision bill called the “Patent Law 2021 Bill,” which was approved by the Parliament in April 2022 [21], [22], [23], [24].

The following are the major revisions to the old “Patents and Designs Act, 1911” and included in the “Bangladesh Patents Act 2022”:

- The law extended the validity period of patents from 16 to 20 years.
- The new law stipulates that any technological product containing something novel would be patentable.
- The new law excludes from patent inventions, scientific theories and mathematical methods, business methods, rules or methods of performing purely mental work or sports, as well as any such computer programs.

Enacting the new patent law was a crucial first step in the Bangladesh government’s preparation for graduation from LDC status. However, the government must clear a backlog of other jobs to ensure smooth graduation from LDC.

6 Conclusion

Bangladesh, the LDC with the largest economy, is scheduled to graduate from LDC status in 2026.

Bangladesh is unique among LDCs in that its private sector, particularly its manufacturing sector, plays a significant role in the development of the economy. The ready-made garment (RMG) industry is vital to the country's economic success. However, the pharmaceutical industry also plays a significant role in the country's rapid development. The country has already passed a two-round test for graduation from LDC conducted by UN-CDP and is scheduled to graduate in 2026. To implement a smooth transition strategy, the government of Bangladesh set up a National Committee on Graduation, a Subcommittee on Smooth Transition Strategy (STS), and a Joint Task Team (JTT).

As soon as the country no longer qualifies as an LDC, it will lose the special exemption for LDCs offered by TRIPS. The country will be obliged to have a TRIPS-compliant patent system in terms of intellectual property.

Bangladesh revised its patent law in April 2022 to meet this requirement. The Patents and Designs Act, 1911 was replaced with the new Bangladesh Patent Act 2022. This revision of the country's patent law was only a first step toward graduating from LDC. Before Bangladesh can successfully change its status, it must deal with hundreds of tasks such as restructuring the governmental sector, negotiating with international and internal bodies, working with the private sector, and collaborating with its trade partners.

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Conflict of Interest

The author has no conflicts of interest directly relevant to the content of this article.

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