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Product Patent Protection, the TRIPS LDC Exemption and the Bangladesh Pharmaceutical Industry

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1 Introduction

THE rise and growth of the pharmaceutical industry in Bangladesh is a remarkable story. Most developing countries depend on imports for the supply of essential medicines. As the experience of many developing countries shows, reducing import dependence by promoting local production has been extremely difficult. But Bangladesh has been able to do so. The last few decades have seen extraordinary growth of the pharmaceutical industry in Bangladesh.

Two major factors which have influenced the growth of the industry are the Drug (Control) Ordinance of 1982 and the exemption of product patent protection for pharmaceuticals in 2008.

The former laid the foundations for the industry and led to the growth of the generics sector. The Ordinance banned the manufacture and import of medicines identified by an Expert Committee (1982) as harmful, unnecessary and otherwise undesirable. Bangladesh also banned the marketing by multinational corporations (MNCs) of medicines manufactured on contract basis by local firms if the MNCs did not have any manufacturing plant in the country. This eliminated a significant part of the market of the MNCs since they dominated the industry and much of their activities were related to non-essential medicines. This effectively created for the local firms a market for simple generic formulations which had previously been imported or manufactured by MNCs. The local firms grabbed the opportunity and led the dramatic growth of the industry.[1]

[1] See Chowdhury (1995), Reich (1994), Sonobe, Mottaleb and Amin (2018), UNCTAD (2011, case study 2 on Bangladesh), Gehl Sampath (2019) and Chaudhuri (2019b) for a discussion on the 1982 policy and the impact on the growth of the industry.

Bangladesh basically focussed on simple formulation products in the initial stages. As the industry evolved, local firms started venturing into manufacturing of more complex formulation products including vaccines, monoclonal antibodies, biotech products and hormones.

The exemption of product patent protection in 2008 further stimulated such diversification. It has enabled the country to play an active role in the market for patented medicines, as will be discussed in this paper.

The product patent regime plays a critical role in the pharmaceutical industry. All the three countries of erstwhile British India – initially India and Pakistan from 1947 and then Bangladesh from 1971 – inherited the British Patents and Designs Act, 1911, which recognized product patent protection including in pharmaceuticals. India abolished product patent protection in pharmaceuticals in 1972 and that is considered to be one of the major factors behind the rise and growth of the Indian pharmaceutical industry. Bangladesh had the same option to abolish product patent protection before the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into effect in 1995, but this option was not exercised.

The TRIPS Agreement made it mandatory for all WTO members to make available patents for inventions in all fields of technology, including for pharmaceutical products. Developing-country members of the WTO were allowed to delay implementation of pharmaceutical product patents for up to 10 years, if such products were not patentable when the TRIPS Agreement took effect.[2] Accordingly, India had to reintroduce the pharmaceutical product patent system from 2005.

However, the least developed country (LDC) members of the WTO continue to enjoy a general exemption from TRIPS implementation (other than for Articles 3, 4 and 5 of the Agreement), pursuant to Article 66.1 of the Agreement. The exemption was initially for 10 years but has on LDCs' request

[2] See Articles 65.1, 65.2 and 65.3 of the TRIPS Agreement.

been renewed several times and is presently granted until 1 July 2034.[3] Overlapping with the general exemption is a specific TRIPS decision with respect to pharmaceutical products, whereby LDCs are not required to grant product patents till 1 January 2033.[4]

It is this option that Bangladesh, an LDC, utilized to exempt product patent protection in pharmaceuticals in 2008. Bangladesh did not replace or amend the Act of 1911 but simply issued a Notification in 2008 suspending the examination and processing of applications for product patents in pharmaceuticals (and agrochemicals). Further, since 2006, Bangladesh has maintained a "mailbox" to receive patent applications for pharmaceutical and agrochemical products. These applications would only be examined once Bangladesh allows patenting of pharmaceutical products. In 2015, the WTO waived the mailbox requirement at least until 2033,[5] but this waiver has yet to be implemented in Bangladesh.

The importance of Bangladesh lies in the fact that none of the other LDCs, even though they are not required to recognize product patent protection in pharmaceuticals, has significant manufacturing capacity in the pharmaceutical sector. And other developing countries which do have the capacity, such as India and China, have introduced product patent protection in pharmaceuticals in line with the TRIPS Agreement. Generic firms of these countries can no longer manufacture and sell patented medicines unless they obtain a voluntary licence from the patentees or a compulsory licence is issued by the government to override the patent barrier.

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3 The initial 10-year general transition period for LDCs ended in 2005. In 2005, the Council for TRIPS at the WTO renewed the general transition period until 1 July 2013 through decision IP/C/40; in 2013, the Council renewed the general transition period until 1 July 2021 through decision IP/C/64; and on 29 June 2021, it renewed the general transition period until 1 July 2034 through decision IP/C/88.

4 Specifically for pharmaceutical products, in 2001 the WTO granted LDCs exemption from patents and the protection of undisclosed data until 2016 through decision IP/C/25. In November 2015, this exemption was extended until 2033 through decision IP/C/73.

5 In 2015, the WTO General Council adopted decision WT/L/971 that waived the requirements for a "mailbox" and "exclusive marketing rights" until 2033 with respect to pharmaceutical products.

Thus, Bangladesh can do what other countries such as India cannot. In fact, in the COVID-19 pandemic, India granted product patents on the medicine remdesivir and so manufacturing was not possible until Indian generic firms obtained voluntary licences from the patentee, the pharmaceutical MNC Gilead, to manufacture it or a compulsory license was issued. But generic firms in Bangladesh could and did produce the medicine without any restrictions. Remdesivir has however not turned out to be as effective in treating COVID-19 as it was thought to be initially. But should effective patented medicines be developed for COVID-19 or, for that matter, for any other diseases, they can be manufactured in Bangladesh without facing a product patent barrier. This can benefit not only Bangladesh but also other countries, as discussed below.

Presently Bangladesh is set to graduate from LDC status in 2026.[6] A number of studies have been undertaken analyzing the possible impact on the pharmaceutical industry if Bangladesh loses its LDC status and is forced to reintroduce product patent protection in pharmaceuticals (see, for example, Gay (2018), Islam, Kaplan, Wirtz and Gallagher (2020), Razzaque, Rabi and Akib (2020), South Centre (2020), and Gay and Gallagher (2020)). The general consensus is that the impact will be negative. Hence the LDC Group of countries and a large number of international and national civil society organizations urged members of the WTO to extend the transition period for LDCs under Article 66.1 of the TRIPS Agreement, for an additional period of 12 years after a country graduates from LDC status.[7]

This paper specifically focusses on the market structure and prices of new medicines sold in Bangladesh. After providing a broad statistical picture of the structure and the growth of the pharmaceutical industry in Bangladesh in Chapter 2, we consider in Chapter 3 the new medicines which have been

6 http://ddnews.gov.in/international/un-body-recommends-bangladesh-graduation-ldc

7 See, for example, the LDC Group's communication to the Council for TRIPS in the WTO (WTO document IP/C/W/668) requesting extension of the TRIPS transition period; the LDC Group's proposal to the WTO General Council on "Smooth Transition in Favour of Countries Graduating from the LDC Category" (WT/GC/W/807); civil society letter with respect to extension of the LDC transition period, available at https://www.twn.my/announcement/signonletter/CSO_LetterToWTOMembers.pdf; and letter by experts in support of requested transition period, available at https://www.bu.edu/gdp/2021/04/22/letter-to-the-ustr-and-eu-trade-commissioner-support-pandemic-recovery-for-least-developed-countries/

developed from 2008 onwards. We compare the market structure and prices of the medicines introduced in India (which has reintroduced product patents) and in Bangladesh (which has exempted pharmaceutical product patents). Comparing these two countries provides a good case study of the impact of product patent protection on the market structure and prices. The basic objective is to analyze the contribution of the Bangladeshi pharmaceutical industry in introducing generic versions of medicines patented in other countries.

Pharmaceutical manufacturing has two technologically distinct components: (i) manufacturing of active pharmaceutical ingredients (APIs) and (ii) formulations manufacturing, i.e., processing of APIs into finished dosage forms such as tablets and injections. Bangladesh initially focussed on formulations manufacturing and has only lately started taking steps to diversify into APIs. Compared with the remarkable growth of formulations manufacturing and exports, APIs have lagged far behind. This has emerged as a major constraint on the further development of the pharmaceutical industry in Bangladesh. In Chapter 4, we focus on the need for industrial policy to enable Bangladesh to develop the API sector and to realize the potential it has in manufacturing and supplying patented medicines. In the final chapter, we summarize the findings and discuss the need for Bangladesh to continue to enjoy the transitional TRIPS waiver and be exempted from the introduction of product patent protection in pharmaceuticals.

2 Status of the Pharmaceutical Industry in Bangladesh

TABLE 1 gives a statistical picture of the pharmaceutical market in Bangladesh. Total pharmaceutical sales in 2019 amounted to US$3.08 billion. This was an increase from US$2.431 billion in 2016 with a compound annual rate of growth of about 15%. The market is estimated to grow to US$4.323 billion by 2024. Prescription medicines account for about 80% of the market and over-the-counter medicines (OTCs) the remaining 20%. Sales of medicines patented in other countries (referred to in this paper as "patented medicines") constituted about 7% of the total market in 2019. The forecast of Fitch Solutions (2020) is that the proportion will increase to 10% by 2024.

Table 1. Bangladesh Pharmaceutical Market Structure

	In US$ billion								
	2016	2017	2018	2019	2020f	2021f	2022f	2023f	2024f
Pharmaceutical sales (a + b)	2.431	2.637	2.832	3.08	3.312	3.538	3.79	4.047	4.323
a) Prescription medicine sales	1.921	2.088	2.248	2.414	2.644	2.832	3.043	3.26	3.494
Patented medicine sales	0.182	0.204	0.227	0.218	0.284	0.314	0.352	0.393	0.438
Generic medicine sales	1.739	1.884	2.021	2.196	2.359	2.518	2.691	2.867	3.056
b) OTC	0.510	0.549	0.584	0.666	0.669	0.706	0.747	0.787	0.829

Source: Fitch Solutions (2020).
Note: f: Fitch Solutions forecast.

The country is self-reliant, with local production accounting for 97% of the market for formulation products. Dependence on imports for the remaining 3% of the market mainly relates to technologically advanced products. But local firms have also started manufacturing high-tech products.[8]

While there are about 150 firms currently operating, the industry is highly concentrated, as Table 2 shows. Bangladesh is one of the few countries in the world where the local firms dominate. The market share of local firms is about 90% (in 2016). The top local firms, such as Square (18.8% market share in 2016), Incepta (10.2%), Beximco (8.5%), Opsonin (5.6%), Renata (5.1%) and Eskayef (4.5%), have a much larger share than the MNCs operating in Bangladesh such as Sanofi (2%), Novo Nordisk (1.8%), Novartis (1.3%) and GlaxoSmithKline (GSK) (1.2%).

Table 2. Market Share of Local Firms and MNCs, Bangladesh, 2016

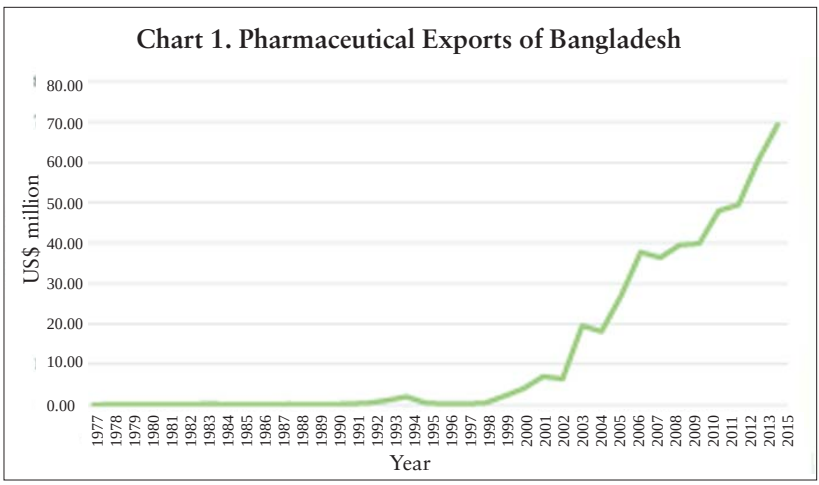
Firm	Market share (%)
Local firms (total)	89.5
Square	18.8
Incepta	10.2
Beximco	8.5
Opsonin	5.6
Renata	5.1
Eskayef	4.5
Aristo Pharmaceutical	4.4
ACI	4.3
Acme	3.9
Healthcare	3.8
Other local firms	20.4
MNCs (total)	10.5
Radiant	2
Sanofi	2
Novo Nordisk	1.8
Novartis	1.3
GSK	1.2
Other MNCs	2.2

Source: LR Global Research (2017, p. 2).

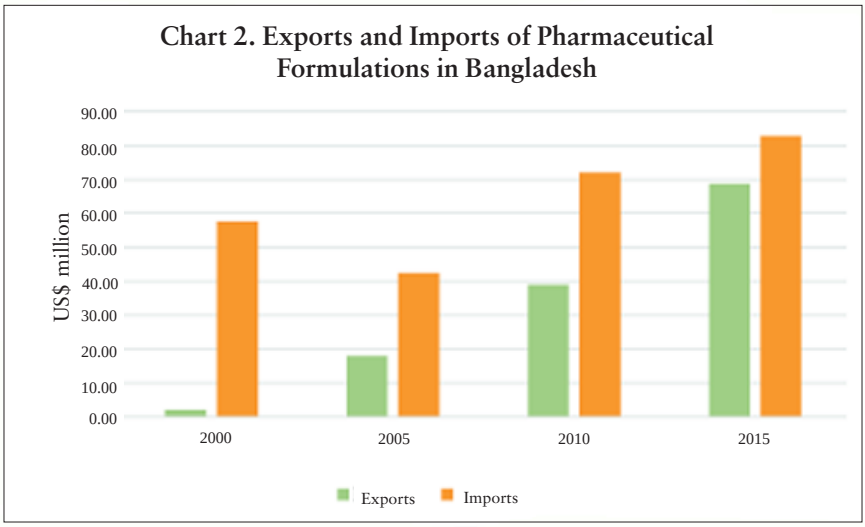
[8] For further details on the current status of the pharmaceutical industry in Bangladesh, see the website of the Bangladesh Association of Pharmaceutical Industries, http://www.bapi-bd.com/; Fitch Solutions (2020); EBL Securities (2019); LR Global Research (2017); Rahman and Farin (2018); and Azam (2016, Chapter 2).

Bangladesh has emerged as a major exporter of pharmaceutical products. As Chart 1 shows, exports were negligible till the late 1990s. Exports then increased from US$2.12 million in 2000 to US$18.18 million in 2005. From 2005 to 2015, exports grew at an annual compound rate of growth of about 16%. While some exports of APIs have started in recent years, the pharmaceutical exports of Bangladesh mainly consist of formulation products, which account for about 99% of total exports (in 2015). What is remarkable is that exports of formulation products have been increasing at a much faster rate than imports of formulations, resulting in a significant decline in the trade gap (Chart 2).

Chart 1. Pharmaceutical Exports of Bangladesh



Source: UN COMTRADE database (https://comtrade.un.org/) (accessed on 2-3 December 2020).
Note: In SITC, Rev 2 classification, data before 1977 and after 2015 are not available.



Source: Same as in Chart 1.

Note: Formulations: SITC, Rev 3 commodity code 542.

Bangladesh exports pharmaceutical products to more than 100 countries. It exports not only to nearby Asian countries such as Myanmar, Sri Lanka, the Philippines and Vietnam but also to African countries (such as Kenya and South Africa) and Latin American countries (such as Brazil and Ecuador) (Table 3). The country has also started entering the regulated markets of developed countries which have much stricter standards. Data for 2015 in Table 3 show that the UK, the Netherlands, Australia, France, Denmark and Canada are among the developed countries which import formulations from Bangladesh. Since then, some of the large local firms have obtained approvals for exporting medicines also to the USA.

Table 3. Major Destinations of Formulation Exports from Bangladesh, 2015

Country	Exports (US$)	Share in total exports
Myanmar	10829323	15.75
Sri Lanka	10328235	15.03
Philippines	5510888	8.02
Vietnam	4450310	6.47
Kenya	3606277	5.25
Afghanistan	3475866	5.06
Slovenia	3403000	4.95
South Africa	2534860	3.69
Cambodia	1642436	2.39
Ecuador	1323429	1.93
Somalia	1286322	1.87
Indonesia	1168380	1.70
United Kingdom	1102285	1.60
Costa Rica	959102	1.40
Nepal	951339	1.38
Nigeria	936979	1.36
Hong Kong	843484	1.23
Cuba	818958	1.19
Turkey	803333	1.17
Netherlands	799746	1.16
Brazil	775599	1.13
Ethiopia	774478	1.13
Malaysia	702569	1.02
Australia	689316	1.00
Mauritius	564608	0.82
Pakistan	521853	0.76
Fiji	460622	0.67
Jordan	395272	0.58
Thailand	377937	0.55
France	361295	0.53
Panama	345833	0.50
Denmark	345210	0.50
Canada	317784	0.46

Singapore	295027	0.43
Jamaica	294268	0.43
Uganda	274027	0.40
Colombia	266019	0.39
Ghana	264957	0.39
Sudan	260689	0.38
United Rep. of Tanzania	247638	0.36
Iraq	224967	0.33
Liberia	221981	0.32
Tokelau	175348	0.26
South Korea	165624	0.24
Mongolia	151413	0.22
Mauritania	145895	0.21
Timor-Leste	128821	0.19
Bhutan	123953	0.18
Maldives	122945	0.18
Germany	113451	0.17
Burundi	112382	0.16
Honduras	109908	0.16
Lao People's Dem. Rep.	101226	0.15
Other countries	1528612	2.22
	68736079	100.00

Source: Calculated from UN COMTRADE database (https://comtrade.un.org/) (accessed on 2-3 December 2020). 2015 is the latest year for which export data are available in the database.
Note: The table lists all countries with exports from Bangladesh exceeding US$100,000.

The major sources of imports of formulations are the developed countries. As Table 4 shows, about three-fourths of formulation imports by Bangladesh are supplied by nine developed countries – Switzerland, Denmark, the USA, Germany, Belgium, France, the Netherlands, the UK and Australia. India, which is considered one of the most competitive sources of generic formulation products, supplies only 7% of the imports. Table 4 suggests that much of the formulation imports by Bangladesh relate to patented and technologically advanced products which are not being manufactured in the country and cannot be sourced from competitive sources such as India.

Table 4. Major Sources of Formulation Imports by Bangladesh, 2015

Country	Imports (US$)	Share in total imports
Switzerland	17483488	21.1
Denmark	12944013	15.6
USA	8288368	10.0
Germany	6052531	7.3
Belgium	5992370	7.2
India	5988540	7.2
France	4550356	5.5
Portugal	4382738	5.3
South Korea	3674282	4.4
Netherlands	2211921	2.7
United Kingdom	2140830	2.6
Singapore	1776691	2.1
Australia	1102193	1.3
Hungary	1028085	1.2
China	888355	1.1
Total	82742067	100.0

Source: Same as in Table 3.
Note: The table lists all countries with more than 1% import share.

Bangladesh is primarily dependent on imports for APIs and, as we will see below, this has emerged as a major constraint on the further development of its pharmaceutical industry. Table 5 shows that China and India account for almost half of API imports (2015). Among the developed countries, the major sources include Denmark (15.7% of imports in 2015), Belgium (5.4%), Germany (3.9%), France (2.9%) and the Netherlands (2.7%). The importance of developed countries as sources of APIs has drastically come down over the years. In 1990, seven developed countries – the USA, Canada, Germany, the UK, Belgium, Spain and France – accounted for more than 70% of supplies. India and China's share was less than 10% (Table 6). The combined share of these two countries increased to 39.5% in 2005 and 48% in 2015. The share of developed countries correspondingly declined. Most dramatic has been the decline of the USA as a source of APIs. In 1990, it alone accounted for about a third of the supplies. By 2005, the share of the USA had declined to 9.3% and by 2015 to 1.8% (Tables 5 and 6).

Table 5. Major Sources of API Imports by Bangladesh, 2015

Country	Imports (US$)	Share in total imports
China	70128281	25.1
India	64130806	22.9
Denmark	44038346	15.7
Belgium	15236488	5.4
Singapore	12029389	4.3
Germany	10833289	3.9
France	8214964	2.9
Netherlands	7467579	2.7
Switzerland	6747329	2.4
South Korea	6348500	2.3
Italy	6240250	2.2
USA	5152938	1.8
Austria	4810995	1.7
Spain	2920412	1.0
Total	279878854	100.0

Source: Same as in Table 3.
Note: The table lists all countries with 1% or more import share.

Table 6. Top Ten Sources of Imports of APIs by Bangladesh, 1990 to 2015

Country	Import share 1990 (%)	Country	Import share 2000 (%)	Country	Import share 2005 (%)	Country	Import share 2015 (%)
USA	32.1	Germany	15.0	India	27.7	China	25.1
Canada	13.3	India	10.9	China	11.8	India	22.9
Germany	9.8	Italy	9.8	USA	9.3	Denmark	15.7
UK	6.8	Denmark	8.6	Belgium	8.2	Belgium	5.4
Yugoslavia	4.7	Netherlands	7.1	Italy	5.6	Singapore	4.3
India	4.5	Belgium	6.9	Denmark	4.1	Germany	3.9
China	4.0	Canada	6.6	Germany	3.8	France	2.9
Belgium	3.9	UK	5.4	Spain	3.4	Netherlands	2.7
Spain	2.9	Switzerland	4.6	S. Korea	3.3	Switzerland	2.4
France	2.6	Spain	3.2	France	3.0	S. Korea	2.3
Total imports (US$)	17392987		82227362		105038755		279878854

Source: Same as in Table 3.

3 Post-TRIPS Market for New Medicines: Bangladesh and India

INDIA reintroduced product patent protection in pharmaceuticals in 2005 in accordance with the TRIPS Agreement, and Bangladesh abolished it in 2008 as permitted by TRIPS for LDCs. Thus, as we have mentioned above, generic firms in India can no longer manufacture and sell patented medicines (unless they are permitted to do so) but Bangladesh can. In the absence of patent barriers to entry of firms in Bangladesh, the market structure is expected to be more competitive and the prices more affordable. And if so, this can be considered to be a positive outcome of the absence of product patent protection in Bangladesh. But are new medicines manufactured and marketed in Bangladesh? Is the market really more competitive? And, are the medicines more affordable?

We do not have full information about the patent status of medicines approved and marketed in recent years. But the website of the United States Food and Drug Administration (USFDA) provides year-wise information on new medicines approved for marketing. We thus considered all the "New Molecular Entity (NME) Drug and New Biologic Approvals" by the USFDA from 2008 to 2018. Then we identified those which have been introduced for sale in Bangladesh and in India. For data for Bangladesh, we used the website of the Directorate General of Drug Administration (DGDA), the country's medicine regulatory authority, while for India we relied on the PharmaTrac database on sales audit data from AIOCD Pharmasofttech AWACS Pvt Ltd (henceforth AIOCD-AWACS). The Indian database provides information on sales for all the products sold. But the DGDA provides information on the marketing registration status only; it does not provide information on sales of products registered. Thus, we had to analyze the market structure in terms of the number of sellers rather than using market concentration ratios. With

regard to prices, again, the Indian database provides information on prices for all the products sold. But the DGDA provides information on prices for only some, not all, of the products. The price comparison below is subject to this limitation.

The list of 379 molecules approved for marketing by the USFDA from 2008 to 2018 and their sales status in Bangladesh and in India in 2019 are provided in the Appendix. As the summary table below shows: out of these 379 molecules, 263 were sold neither in Bangladesh nor in India in 2019, 61 were sold in both the countries, 36 were sold in India but not in Bangladesh, and 19 sold in Bangladesh but not in India.

Molecules	No. of molecules
Molecules approved by the USFDA, 2008 to 2018	379
Molecules sold in both India and Bangladesh	61
Molecules sold in Bangladesh but not in India	19
Molecules sold in India but not in Bangladesh	36
Molecules not sold in both India and Bangladesh	263

Source: See Appendix.

Market structure

If we focus on the 61 molecules available in both the countries, we find that in India, 18 molecules are sold by just either one or two firms. But at the other extreme, eight molecules are sold by five to 10 firms and 26 molecules by more than 10 firms in India. (The remaining nine molecules are sold by three to four firms in India.) The fact that there are multiple sellers for several new molecules in India suggests that not all new medicines face patent or other entry barriers.

Patents are territorial in nature. In general, the exclusive rights are applicable only in a country in which a patent has been filed and granted, in accordance with the applicable patent law of that country. Hence a medicine may be patented in one country but not in another. In a few cases, the patent holder may offer voluntary licences allowing specific manufacturers to manufacture and supply the product to a set of countries under certain terms and conditions which are often secretive and restrictive and undermine access to medicines.[9] For example, the hepatitis C medicine sofosbuvir is patented in India but 15 India-based firms sell the product under voluntary licensing arrangements with the patentee to a specified list of countries.

For all the 34 molecules sold by five or more firms in India, the number of sellers in India is higher than that in Bangladesh except for three molecules – prasugrel, artemether + lumefantrine, and secnidazole. India has a much larger market and the number of pharmaceutical firms is also significantly higher. Therefore, it is not a surprise that for molecules where there are no entry barriers, the number of sellers is typically higher in India than in Bangladesh. For example, desvenlafaxine, ivabradine and abiraterone acetate are among the molecules not patented in India (Chaudhuri 2019a). The number of firms selling desvenlafaxine is 30 in India and two in Bangladesh; ivabradine, 19 and six; and abiraterone acetate, 19 and two respectively.

But the fact that there are only one or two sellers in India for 18 out of the 61 molecules, points to the existence of patent or other barriers in that country. If there are patent barriers in India but not in Bangladesh, then what is expected is that the market for new medicines in Bangladesh will be less concentrated. And this is indeed what Table 7 demonstrates. In Table 7 we have listed the 18 molecules which are sold by just one or two firms in India and compared these with the number of firms selling the same products in Bangladesh. For only one product, regorafenib, are there more sellers in India (two firms) than in Bangladesh (one firm). For 13 molecules, the number of sellers in Bangladesh is higher than in India. For example, for eltrombopag,

[9] See "Voluntary Licenses and Access to Medicines" at https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf

there are five sellers in Bangladesh compared with one in India, and for ibrutinib, six sellers in Bangladesh and one in India. Another example is empagliflozin, for which there are 10 sellers in Bangladesh compared with two in India (Table 7).

Table 7. Number of Firms Selling Selected Molecules in Bangladesh and India, 2019

Molecule*	No. of firms in India	No. of firms in Bangladesh	Name of sellers in India	Product patent status in India
Afatinib	1	2	Boehringer Ingelheim	Patented
Apixaban	1	4	Pfizer	Patented
Axitinib	1	1	Pfizer	Patented
Crizotinib	1	4	Pfizer	Patented
Deferiprone	1	1	Cipla	Not patented
Eltrombopag	1	5	GSK	Patented
Empagliflozin	2	10	Boehringer Ingelheim and Lupin	Patented
Ibrutinib	1	6	Johnson & Johnson	?
Indacaterol	2	5	Novartis and Cipla	?
Linagliptin	2	30	Boehringer Ingelheim and Lupin	Patented
Nintedanib	1	1	Boehringer Ingelheim	?
Osimertinib	1	6	AstraZeneca	Patented
Palbociclib	1	3	Pfizer	Patented
Pertuzumab	1	2	Roche	Patented
Pitavastatin	2	6	Zydus Cadila and Wockhardt	?
Regorafenib	2	1	Bayer and Zydus Cadila	?
Rivaroxaban	2	7	Bayer and Zydus Cadila	Patented
Saxagliptin	2	2	AstraZeneca and Dr Reddy's	Patented

Sources: For columns 2 to 4: DGDA website and AIOCD-AWACS database (see sources in Appendix for details). For column 5: Chaudhuri (2019a).
Notes:
* The molecules with one or two sellers in India (see text).
? Patent status in India not known.

In Bangladesh, all the molecules are sold by local firms. But in India these are mostly patented and sold by the MNCs either solely – for example, osimertinib by AstraZeneca, pertuzumab by Roche, and crizotinib by Pfizer – or together with an Indian firm – for example, linagliptin by Boehringer Ingelheim and Lupin, and saxagliptin by AstraZeneca and Dr Reddy's. Both linagliptin and saxagliptin are patented and are sold by the Indian firms under licence from the MNCs (Chaudhuri 2019a).

Table 7 includes only the molecules which are sold by one or two firms in India. Besides these, there are other molecules for which the number of selling firms is higher in Bangladesh than in India. For example, for ticagrelor, there are three sellers in India but 11 in Bangladesh; for dapagliflozin, three and 10 firms respectively; and for besifloxacin, four and 10 firms respectively.

If we consider the 36 molecules sold in India but not in Bangladesh, we find that some have multiple sellers, for example, 11 sellers each for tolvaptan, edaravone and vilazodone. But the remaining medicines are patented and sold by the patentees alone in India, as the following shows:

Patented molecule	Name of the sole seller in India
Liraglutide	Abbott
Idarucizumab	Boehringer Ingelheim
Ramucirumab	Eli Lilly
Pazopanib	GSK
Daratumumab	Johnson & Johnson
Golimumab	Johnson & Johnson
Ruxolitinib	Novartis

Source for patent status: Chaudhuri (2019a, Appendix and Table 11).

Thus, there are medicines, including those which are patented in India, which are not sold in Bangladesh. The fact that despite the absence of patent barriers, some products are not available in Bangladesh, suggests there must be commercial, technological or other factors at work.

But significantly enough, 19 molecules are sold in Bangladesh but not in India (Table 8). While there is a single seller for some of these, for example, ceritinib and neratinib, there are multiple sellers for other molecules, for example, tofacitinib and lenvatinib. The fact that several sellers find it profitable to enter the market in Bangladesh but none of the generic firms manufacture these in India, suggests the presence of some entry barriers in India.

Table 8. Molecules Sold in Bangladesh but Not in India, 2019

Molecule*	No. of firms
Tofacitinib	12
Lenvatinib	5
Cabozantinib	3
Obeticholic acid	3
Brigatinib	3
Tedizolid phosphate	4
Olaparib	2
Ponatinib	2
Alectinib	2
Avanafil	1
Crisaborole	2
Larotrectinib	1
Miltefosine	1
Benzyl alcohol	1
Ceritinib	1
Lifitegrast	1
Neratinib	1
Niraparib	1
Sodium picosulfate	1

Sources: Same as in Table 7.
Note: * Among the molecules approved for marketing by the USFDA from 2008 to 2018, these are the ones sold in Bangladesh but not in India.

Price comparison

The ability of Bangladesh to supply medicines (patented in other countries) at low prices received international attention when local firm Incepta launched a generic version of the patented hepatitis C medicine sofosbuvir in 2015 at $10 compared with $1,000 per tablet in the United States.[10] Since then, prices have further declined in Bangladesh with the entry of additional firms. The price in 2019 varied between US$4.14 and 9.46 (400 mg tablet). In India the medicine is patented but several firms are manufacturing and selling it under voluntary licensing arrangements with the patentee. The price varies between US$4.24 and 28.51. The median price in Bangladesh is US$7.09 compared with US$9.60 in India.[11] Thus even in competitive markets, Bangladesh has been able to supply in general at lower prices.

Bangladesh is involved in selling several other patented medicines at lower prices. For price comparison, we focus on the 18 molecules sold by one or two firms in India (Table 7).

Deferiprone is sold by a single firm in both the countries. It is an iron chelating agent developed by the Indian firm Cipla, which is the only seller in India. In Bangladesh it is sold by a local firm Drug International. Cipla's price is in fact lower than that in Bangladesh. Another product sold by two firms in Bangladesh but for which price data are available for only a single firm is pertuzumab, which is used for the treatment of cancer. It is patented in India and the patentee, Roche, sells a single injection (420 mg/14 ml) at US$3,582.18. This is more than 300% higher than the price of US$827.68 at which it is sold in Bangladesh.

The remaining 10 molecules for which price data are available, are sold by several firms in Bangladesh. Prices vary depending on the firm and the product. In Table 9 we indicate the highest and the lowest prices for each molecule. If we consider the lowest prices, we see that prices are higher in India for each of the 10 molecules. The extent to which these are higher varies

[10] "$10 Sovaldi on Sale in Bangladesh", 12 March 2015 (http://www.pharmexec.com/10-sovaldi-sale-bangladesh).

[11] Sources of price data and foreign exchange rates are the same as in Table 9.

from 28% (for indacaterol) to 5,799% (for osimertinib). Osimertinib is a patented cancer medicine and in India it is sold by the patentee, AstraZeneca. In Bangladesh it is sold by six firms. Whereas the lowest price in Bangladesh is US$5.03 for one 80 mg tablet, it is sold in India by the patentee at US$296.73. For each of the remaining eight molecules listed in Table 9, the price differential exceeds 100% except for two (pitavastatin and saxagliptin). For example, ibrutinib is sold at US$5.91 in Bangladesh compared with US$49.44 in India for one 140 mg capsule; eltrombopag is sold at US$5.91 and US$15.75 (25 mg tablet); and apixaban is sold at US$0.30 and US$2.10 (5 mg tablet) respectively. Even if we consider not the lowest but the highest prices for each molecule, similar wide price differences are observed between the two countries.

Table 9 lists six other products which are sold in India by just one or two firms, and high prices are charged for a single tablet/capsule, for example, afatinib at US$33.93, crizotinib (US$25.71), nintedanib (US$35.36), palbociclib (US$65.66) and axitinib (US$43.27). Unlike with the other products listed in Table 9, price data for Bangladesh are not available for these products from the DGDA source. But a newspaper article reported that wide price differentials exist between the two countries, for example, for crizotinib and palbociclib.[12]

[12] https://timesofindia.indiatimes.com/business/india-business/illegal-cancer-drugs-frombdesh-flood-local-market/articleshow/72100024.cms

Table 9. Prices in Bangladesh and in India for Selected Molecules, 2019

			Bangladesh	Bangladesh	India	India
Molecule	No. of firms in Bangladesh	Unit*	Highest price (US$)	Lowest price (US$)	Highest price (US$)	Lowest price (US$)
Linagliptin	30	5 mg tablet	0.26	0.08	0.71	0.71
Empagliflozin	10	10 mg tablet	0.3	0.18	0.68	0.68
Rivaroxaban	7	10 mg tablet	0.3	0.3	2.1	2
Osimertinib	6	80 mg tablet	5.91	5.03	296.73	296.73
Pitavastatin	6	2 mg tablet	0.12	0.12	0.22	0.2
Ibrutinib	6	140 mg capsule	7.09	5.91	49.44	49.44
Eltrombopag	5	25 mg tablet	7.09	5.91	15.75	15.75
Indacaterol	5	300 mcg rotacap	0.77	0.77	0.98	0.98
Apixaban	4	5 mg tablet	0.3	0.3	2.1	2.1
Saxagliptin	2	5 mg tablet	0.41	0.35	0.63	0.63
Pertuzumab	1**	420 mg/14 ml injection	827.68	827.68	3582.18	3582.18
Deferiprone	1	500 mg tablet	0.21	0.21	0.12	0.12
Afatinib	2	50 mg tablet	NA	NA	33.93	33.93
Crizotinib	4	250 mg capsule	NA	NA	25.71	25.71
Nintedanib	1	150 mg capsule	NA	NA	35.36	35.36
Palbociclib	3	100 mg capsule	NA	NA	65.66	65.66
Axitinib	1	5 mg tablet	NA	NA	43.27	43.27
Regorafenib	1	40 mg tablet	NA	NA	30.74	30.74

Sources: Price data for Bangladesh from DGDA website and price data for India from AIOCD-AWACS – see sources in Appendix for more details. For foreign exchange rates: https://www.xe.com/currencytables/?from=BDT&date=2019-07-01.

Notes:

* The unit in which most stock-keeping units (SKUs) are sold in Bangladesh. The same molecule sold in different forms such as tablets and syrups and in different strengths such as 5 mg and 10 mg and by different firms are considered as separate SKUs. We have considered the SKUs of plain molecules only, not combination products.

** Pertuzumab is sold by two firms in Bangladesh but price data are available for only one firm. Prices in Bangladesh in mid-2019 in Bangladeshi taka have been converted to US$ using the exchange rate in July 2019 (US$ per BDT = 0.011824). Similarly, prices in India in mid-2019 in Indian rupee have been converted using the exchange rate in July 2019 (US$ per INR = 0.014515).

The discussion above demonstrates the positive impact of the absence of product patent protection on accessibility and affordability of medicines in Bangladesh. But the share of patented medicines in the country's pharmaceutical market is only about 7% in 2019 (Table 1). Bangladesh manufactures and sells a limited range of patented medicines, as we have seen above. The problem is not with formulation development; despite some limitations, local firms are taking care of it. The main constraint is the availability of APIs.

The Bangladeshi pharmaceutical industry is primarily dependent on imports for the supply of APIs. Local production of APIs caters to only about 10% of the demand (Mohiuddin 2019, p. 4; Fitch Solutions 2020, p. 9). Only a few private sector companies such as Square and Beximco manufacture APIs and that too, simple ones such as paracetamol, amoxicillin, ampicillin and cloxacillin on a limited scale. Some large companies such as Incepta are not at all involved in API manufacturing.

The underdevelopment of the API sector did not constrain the development of the formulations sector in the pre-TRIPS world. Bangladesh could import not only from developed countries but also from developing countries such as India and China. In fact, availability of APIs at competitive prices from India and China acted as a disincentive for Bangladesh to develop its own API sector. But after TRIPS, generic firms from India and China which recognize product patent protection can no longer officially manufacture and sell patented APIs to Bangladesh except under conditions consistent with the TRIPS Agreement. Of course, Bangladesh can import the APIs from the patentees. But as we have seen above, all the patented medicines in Bangladesh are manufactured and sold by the local firms. MNCs are not keen to manufacture patented products or to export patented APIs to Bangladesh. Thus, developing the API sector is critically important for Bangladesh.

4 Need for Industrial Policy to Promote API Sector in Bangladesh

THE Drug (Control) Ordinance of 1982 which played such an important role in the development of the formulations sector in Bangladesh was based on the recommendations of an Expert Committee (1982). The latter also made several other recommendations including the abolition of product patent protection and development of the API (bulk medicines) sector through government support. To quote from the Report of the Committee:

"Local production of basic pharmaceuticals in bulk shall be promoted to attain self-reliance. To encourage such production, special benefits and protection will be provided to private investors. The public industrial sector shall also take appropriate measures for the local production of essential basic pharmaceuticals in bulk including vital antibiotics" (p. 5).

But these recommendations were not implemented at that time. It was only in 2008 that product patent protection in pharmaceuticals was abolished. Concrete steps also began to be taken for the development of the API sector from 2008 onwards. In 2008 the government approved the construction of an API park with infrastructural facilities on 200 acres of land in Munshiganj near Dhaka. After considerable delay, 42 plots were handed over to 28 local firms in 2017. It will take some more time for the park to be fully operational.

In May 2018, the government announced a series of incentives for promoting local production of APIs, including:[13]

- 100% tax holiday for all API manufacturers for the first five years from 2016-17 to 2021-22
- Beyond the first five years, 100% tax holiday to continue till 2032 for those who manufacture at least five molecules per year. For those manufacturing at least three molecules, 75% tax holiday will be provided during the same period
- Waiving of value-added tax (VAT) and VAT deduction at source for API manufacturers on purchase and sales of APIs, raw materials and machinery parts
- Exemption from advance income tax and tax deduction at source till 2023
- 20% tax incentives for export of APIs
- Financial facilities such as loans from offshore funds; longer tenure of 12 years instead of six years for term loans for factories and equipment; back-to-back letter of credit etc
- Priority in getting land in industrial estates and economic zones.

These are important steps in the right direction. But much more needs to be done if Bangladesh is to properly develop the API sector and to take full advantage of the absence of pharmaceutical product patents.[14]

To develop an industry, it is important to coordinate all the three important factors of market, finance and technology. The removal of pharmaceutical product patents has created a market for local firms. The government has also offered tax and other financial incentives. What is further required is proper support for technology development. In the case of formulations, some

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13 "National API (Active Pharmaceutical Ingredients) and Laboratory Reagents Production and Export Policy." The text of the Policy is available in Bengali at the Bangladesh Commerce Ministry website (https://mincom.gov.bd/sites/default/files/files/mincom.portal.gov.bd/policies/275863ac_df4b_4050_a9db_9e5451689cd4/API_10(10.5.18).pdf), accessed 8 March 2019. See also Jasim Uddin, "Pharma ingredient-makers to get corporate tax holiday till 2032: Govt publishes first-ever policy on API production and export", New Age Business, 24 May 2018 (http://www.newagebd.net/article/41935/pharma-ingredient-makers-to-get-corporate-tax-holiday-till-2032), accessed 8 March 2019.

14 This part of the discussion relies on Chaudhuri (2019b, pp. 23-27).

favourable circumstances existed in Bangladesh and hence the lack of specific government support for technology did not act as a constraint. The MNCs which dominated the industry before the 1980s were involved in manufacturing formulations. The Department of Pharmacy of Dhaka University set up in 1964 also played a very useful role. The MNCs used to recruit pharmacy students for their operations. These people who were trained in the MNCs constituted a pool of skilled manpower. Local firms too were involved in manufacturing and marketing operations on behalf of the MNCs. This also provided the local firms the opportunity to learn about technology and management of manufacturing and marketing operations (UNCTAD 2011, p. 63).

The MNCs did not manufacture APIs and unlike in India, there were no public sector plants or government laboratories involved in pharmaceutical research and development (R&D).[15] The local firms in Bangladesh focussed on formulations and the API sector remained neglected with easy availability of APIs from India, China and other countries. As mentioned above, the underdevelopment of the API sector did not constrain the growth of the formulations sector before TRIPS but has emerged as a critical factor after TRIPS.

While a number of local firms are producing a number of APIs, these are for simple products and only penultimate steps in the process of manufacturing are done in the country.[16] What is also needed is the development of API manufacturing technologies from basic stages for new and more complex products. The steps taken by the government for the development of the API sector are necessary but not sufficient. Firms can benefit from tax and other incentives only if they are willing and able to manufacture and sell APIs in the first place. The API park reduces the costs of API investment and manufacturing but by itself does not equip the firms to manufacture APIs.

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15 The foundations for technological development and the growth of the API sector in India were laid by the setting up of large public sector manufacturing plants and a number of government R&D laboratories under the Council of Scientific and Industrial Research (CSIR). The result was that when product patent protection in pharmaceuticals was abolished in India in the early 1970s, the Indian firms were technologically ready to take advantage of the opportunities. For an account of how India developed the pharmaceutical industry, see Chaudhuri (2005, Chapters 2 and 4).

16 As reported by Gehl Sampath (2007, p. 20). The situation has not significantly changed since then.

What is lacking is proper support for technology development. It is well known that especially in nascent stages, private firms are neither able nor willing to invest in R&D for technology development. Bangladesh is no exception. The private sector there is yet to invest significantly in R&D. The largest pharmaceutical firm in Bangladesh, Square Pharmaceuticals, and the third largest, Beximco Pharma, spent respectively only 0.27% and 1.25% of their revenue on R&D (Annual Reports, 2018-19).

Bangladesh never had any large public investments in pharmaceutical manufacturing. Similar to India's Council of Scientific and Industrial Research (CSIR), Bangladesh has the Bangladesh Council of Scientific and Industrial Research. It also has a number of medical R&D institutions such as the Bangladesh Medical Research Council, Bangladesh National Research Council, National Institute of Cancer Research and Hospital etc (Gehl Sampath 2007, p. 23 and Annex II). But these organizations have never been involved in the development of medicine manufacturing technologies. There are also no government incentives in place to support and promote R&D in the pharmaceutical sector (Azam 2016, p. 72).

If Bangladesh wants to take full advantage of the absence of pharmaceutical product patents, it is important for the government to be directly involved in developing the technological base of the industry. The government can and should be directly involved in funding pharmaceutical R&D not only in government laboratories but also in local pharmaceutical firms, universities and other local R&D organizations.

5 Discussion and Conclusion

IN the absence of patent barriers to entry of firms in Bangladesh, the market structure in the country is expected to be more competitive and the prices more affordable. But are new medicines actually manufactured and marketed in Bangladesh? Are the markets more competitive? And are the medicines more affordable? Our discussion on the market structure and prices of new medicines introduced in India (where product patents were reintroduced in 2005) and in Bangladesh (where product patent protection was exempted for pharmaceuticals in 2008) shows that:

- When there are no entry barriers, the number of firms is higher in India than in Bangladesh.
- But the absence of product patent protection in Bangladesh has removed a major entry barrier for manufacture and sale of new medicines. For several new medicines, the market in India is more concentrated than in Bangladesh. And not only is the number of firms in the market higher in Bangladesh, but the products sold in the country are also more affordable.
- Some of the new medicines have been introduced in Bangladesh but are not available in India.

This demonstrates the positive impact of the absence of product patent protection in pharmaceuticals in Bangladesh. And this can benefit not only Bangladesh but also other countries. Other LDCs where product patent protection is not recognized can import these medicines from Bangladesh. Countries which do recognize product patents can also import these medicines from Bangladesh through compulsory licensing or other measures consistent with the TRIPS Agreement.

In fact, Bangladesh can play a very critical role in facilitating access to essential medicines in countries which do not have adequate manufacturing capacities, as the example of remdesivir shows (Chaudhuri 2020). The medicine is patented by Gilead in many countries, including India. When it initially showed promise for the treatment of COVID-19, Gilead entered into non-exclusive voluntary licensing agreements with a few generic firms to manufacture and distribute remdesivir in 127 countries. More than 70 countries, accounting for nearly half the world's population, were left out. Under the terms of the voluntary licensing agreements, Indian firms were not permitted to export the medicine to these countries. Of course, these countries could manufacture the medicine themselves, including by issuing compulsory licences if patents are a barrier, but this option is not available to those with limited or no manufacturing capacity. These countries could however import the medicine from Bangladesh, including by using compulsory licences to overcome the patents, if they have been granted. Unlike in India, firms in Bangladesh do not require any licences from the patentee. Bangladesh started manufacturing the medicine with no restrictions applicable for domestic sales or for exports. Countries with limited or no manufacturing capacity can thus import COVID-19 or other patented medicines from Bangladesh and avoid being at the mercy of patentees as far as supplies and prices are concerned.

The Preamble of the TRIPS Agreement acknowledges the importance of "maximum flexibility in the domestic implementation of laws and regulations" in view of the "special needs" of LDCs and to enable LDCs "to create a sound and viable technological base". Accordingly, Article 66.1 of the Agreement provided LDCs the option of exemption from implementation of the Agreement, including patent protection with respect to pharmaceutical products, "in view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base".

Bangladesh has amply justified this special flexibility for LDCs. It has made remarkable progress in formulations manufacturing. It is yet to "create a viable technological base" for the API sector but efforts are underway for its development, as we have discussed above. In view of its past record and current initiatives, there is every possibility that Bangladesh will be able to

develop the API sector as well. On its part, the government must intervene more directly to develop the industry, particularly the API sector.

COVID-19 has shown the importance of supporting countries with manufacturing capacity. If Bangladesh is required to introduce product patent protection, then much of the promising work the industry is doing will be derailed. Development of any industry requires adequate time and proper conditions. Bangladesh deserves to be given some more time and permitted to delay the introduction of product patent protection, even after it graduates from LDC status. It should also fully utilize all flexibilities available to it as an LDC, including the mailbox waiver, for as long as it is possible. Further, Bangladesh should learn from the experiences of developing countries in fully implementing other TRIPS flexibilities once it is required to implement TRIPS provisions with respect to pharmaceutical products. Building awareness and capacity among policymakers, the patent office, the generic industry and civil society on the implications of TRIPS for Bangladesh's pharmaceutical sector and on the role of TRIPS flexibilities in the development of the industry and access to medicines should also be a priority.

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Appendix

Molecules Approved for Marketing by the USFDA from 2008 to 2018 and Sales Status in Bangladesh and India in 2019

Sr. No.	Molecule	Sold in Bangladesh	Sold in India
1	ABALOPARATIDE	No	No
2	ABEMACICLIB	No	No
3	ABIRATERONE ACETATE	Yes	Yes
4	ABOBOTULINUMTOXINA	No	No
5	ACALABRUTINIB	No	No
6	ACLIDINIUM BROMIDE	No	No
7	AFATINIB	Yes	Yes
8	AFLIBERCEPT	No	Yes
9	ALBIGLUTIDE	No	No
10	ALECTINIB	Yes	No
11	ALGLUCOSIDASE ALFA2	No	No
12	ALIROCUMAB	No	No
13	ALOGLIPTIN	No	No
14	ALVIMOPAN	No	No
15	AMIFAMPRIDINE	No	No
16	ANGIOTENSIN II	No	No
17	APALUTAMIDE	No	No
18	APIXABAN	Yes	Yes
19	APREMILAST	Yes	Yes
20	ARIPIPRAZOLE LAUROXIL	No	No
21	ARTEMETHER 20MG + LUMEFANTRINE 120MG	Yes	Yes
22	ASENAPINE	No	Yes
23	ASFOTASE ALFA	No	No
24	ASPARAGINASE ERWINIA CHRYSANTHEMI	No	Yes
25	ATEZOLIZUMAB	No	No
26	AVANAFIL	Yes	No
27	AVATROMBOPAG	No	No
28	AVELUMAB	No	No

29	AXITINIB	Yes	Yes
30	AZILSARTAN MEDOXOMIL	Yes	Yes
31	BALOXAVIR MARBOXIL	No	No
32	BARICITINIB	No	No
33	BEDAQUILINE	No	No
34	BELATACEPT	No	No
35	BELIMUMAB	No	No
36	BELINOSTAT	No	No
37	BENDAMUSTINE HYDROCHLORIDE	Yes	Yes
38	BENRALIZUMAB	No	No
39	BENZNIDAZOLE	No	No
40	BENZYL ALCOHOL	Yes	No
41	BEPOTASTINE BESILATE	Yes	Yes
42	BESIFLOXACIN	Yes	Yes
43	BETRIXABAN	No	No
44	BEZLOTOXUMAB	No	No
45	BICTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE	No	No
46	BINIMETINIB	No	No
47	BLINATUMOMAB	No	No
48	BOCEPREVIR	No	No
49	BOSUTINIB	No	No
50	BRENTUXIMAB VEDOTIN	No	No
51	BREXPIPRAZOLE	No	No
52	BRIGATINIB	Yes	No
53	BRIVARACETAM	No	Yes
54	BRODALUMAB	No	No
55	BUROSUMAB	No	No
56	CABAZITAXEL	No	Yes
57	CABOZANTINIB	Yes	No
58	CALASPARGASE PEGOL	No	No
59	CANAGLIFLOZIN	Yes	Yes
60	CANAKINUMAB	No	No
61	CANGRELOR	No	No
62	CANNABIDIOL	No	No

63	CAPSAICIN PATCH 8%	No	No
64	CARFILZOMIB	No	Yes
65	CARGLUMIC ACID	No	No
66	CARIPRAZINE	No	No
67	CEFTAROLINE FOSAMIL	No	No
68	CEFTAZIDIME-AVIBACTAM	No	No
69	CEFTOLOZANE/TAZOBACTAM	No	No
70	CEMIPLIMAB-RWLC	No	No
71	CENEGERMIN-BKBJ	No	No
72	CERITINIB	Yes	No
73	CERLIPONASE ALFA	No	No
74	CERTOLIZUMAB PEGOL	No	No
75	CHOLIC ACID	No	No
76	CHOLINE C 11	No	No
77	CLEVIDIPINE BUTYRATE	No	No
78	CLOBAZAM	Yes	Yes
79	CLOSTRIDIAL COLLAGENASE	No	No
80	COBIMETINIB	No	No
81	CONJUGATED ESTROGENS/BAZEDOXIFENE	No	No
82	COPANLISIB	No	No
83	CRISABOROLE	Yes	No
84	CRIZOTINIB	Yes	Yes
85	CROFELEMER	No	No
86	CYCLOSILICATE	No	No
87	DABIGATRAN ETEXILATE MESYLATE	Yes	Yes
88	DABRAFENIB	No	No
89	DACLATASVIR	Yes	Yes
90	DACLIZUMAB	No	No
91	DACOMITINIB	No	No
92	DALBAVANCIN	No	No
93	DALFAMPRIDINE	No	Yes
94	DAPAGLIFLOZIN	Yes	Yes
95	DARATUMUMAB	No	Yes
96	DEFERIPRONE	Yes	Yes
97	DEFIBROTIDE SODIUM	No	No

98	DEFLAZACORT	Yes	Yes
99	DEGARELIX	No	Yes
100	DELAFLOXACIN	No	No
101	DENOSUMAB	Yes	Yes
102	DEOXYCHOLIC ACID	No	No
103	DESVENLAFAXINE SUCCINATE	Yes	Yes
104	DEUTETRABENAZINE	No	No
105	DIFLUPREDNATE	Yes	Yes
106	DIMETHYL FUMARATE	No	Yes
107	DINUTUXIMAB	No	No
108	DOLUTEGRAVIR	No	Yes
109	DORAVIRINE	No	No
110	DRONEDARONE HCL	No	Yes
111	DROXIDOPA	No	No
112	DULAGLUTIDE	No	Yes
113	DUPILUMAB	No	No
114	DURVALUMAB	No	No
115	DUVELISIB	No	No
116	ECALLANTIDE	No	No
117	EDARAVONE	No	Yes
118	EDOXABAN TOSYLATE	No	No
119	EFINACONAZOLE	No	No
120	ELAGOLIX SODIUM	No	No
121	ELAPEGADEMASE-LVLR	No	No
122	ELIGLUSTAT	No	No
123	ELOSULFASE ALFA	No	No
124	ELOTUZUMAB	No	No
125	ELTROMBOPAG OLAMINE	Yes	Yes
126	ELUXADOLINE	No	No
127	ELVITEGRAVIR, COBICISTAT, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE	No	No
128	ELVITEGRAVIR/COBICISTAT/ EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE	No	No

129	EMAPALUMAB-LZSG	No	No
130	EMICIZUMAB-KXWH	No	No
131	EMPAGLIFLOZIN	Yes	Yes
132	ENASIDENIB	No	No
133	ENCORAFENIB	No	No
134	ENZALUTAMIDE	No	Yes
135	ERAVACYCLINE	No	No
136	ERENUMAB-AOOE	No	No
137	ERIBULIN MESYLATE	No	No
138	ERTUGLIFLOZIN	No	No
139	ESLICARBAZEPINE ACETATE	Yes	Yes
140	ESTRADIAL VALERATE/DIENOGEST	No	No
141	ETELCALCETIDE	No	No
142	ETEPLIRSEN	No	No
143	ETHINYL ESTRADIOL VAGINAL SYSTEM	No	No
144	ETRAVIRINE	No	No
145	EVEROLIMUS	Yes	Yes
146	EVOLOCUMAB	No	No
147	EZOGABINE	No	No
148	FEBUXOSTAT	Yes	Yes
149	FESOTERODINE FUMARATE	No	No
150	FIDAXOMICIN	No	No
151	FILGRASTIM	Yes	Yes
152	FINAFLOXACIN	No	No
153	FINGOLIMOD HCL	No	No
154	FISH OIL TRIGLYCERIDES	No	No
155	FLIBANSERIN	No	No
156	FLORBETABEN	No	No
157	FLORBETAPIR F18	No	No
158	FLUCICLOVINE F18	No	No
159	FLUTEMETAMOL F18	No	No
160	FLUTICASONE FUROATE AND VILANTEROL TRIFENATATE	Yes	Yes
161	FOSNETUPITANT AND PALONOSETRON	No	No
162	FOSPROPOFOL DISODIUM	No	No

163	FOSTAMATINIB	No	No
164	FREMANEZUMAB-VFRM	No	No
165	GABAPENTIN ENACARBIL	Yes	Yes
166	GADOBUTROL	No	Yes
167	GADOFOSVESET TRISODIUM	No	No
168	GADOTERATE MEGLUMINE	No	No
169	GADOXETATE DISODIUM	No	No
170	GALCANEZUMAB-GNLM	No	No
171	GILTERITINIB	No	No
172	GLASDEGIB	No	No
173	GLECAPREVIR AND PIBRENTASVIR	No	No
174	GLUCARPIDASE	No	No
175	GOLIMUMAB	No	Yes
176	GRAZOPREVIR AND ELBASVIR	No	No
177	GUSELKUMAB	No	No
178	IBALIZUMAB - UIYK	No	No
179	IBRUTINIB	Yes	Yes
180	ICATIBANT ACETATE	No	No
181	IDARUCIZUMAB	No	Yes
182	IDELALISIB	No	No
183	ILOPERIDONE	Yes	Yes
184	INCOBOTULINUMTOXINA	No	No
185	INDACATEROL MALEATE	Yes	Yes
186	INGENOL MEBUTATE	No	No
187	INOTERSEN	No	No
188	INOTUZUMAB OZOGAMICIN	No	No
189	INSULIN DEGLUDEC INJECTION	No	Yes
190	IOBENUANE	No	No
191	IOFLUPANE 1-123	No	No
192	IPILIMUMAB	No	No
193	ISAVUCONAZONIUM SULFATE	No	No
194	IVABRADINE	Yes	Yes
195	IVACAFTOR	No	No
196	IVOSIDENIB	No	No
197	IXAZOMIB	No	No

198	IXEKIZUMAB	No	No
199	KIT FOR THE PREPARATION OF GALLIUM GA 68 DOTATATE INJECTION	No	No
200	LACOSAMIDE	Yes	Yes
201	LANADELUMAB-FLYO	No	No
202	LAROTRECTINIB	Yes	No
203	LATANOPROSTENE BUNOD OPHTHALMIC SOLUTION	No	No
204	LEDIPASVIR AND SOFOSBUVIR	Yes	Yes
205	LENVATINIB	Yes	No
206	LESINURAD	No	No
207	LETERMOVIR	No	No
208	LIFITEGRAST OPHTHALMIC SOLUTION	Yes	No
209	LINACLOTIDE	No	No
210	LINAGLIPTIN	Yes	Yes
211	LIRAGLUTIDE	No	Yes
212	LIXISENATIDE	No	Yes
213	LOFEXIDINE	No	No
214	LOMITAPIDE	No	No
215	LORCASERIN HYDROCHLORIDE	No	No
216	LORLATINIB	No	No
217	LUCINACTANT	No	No
218	LULICONAZOLE	Yes	Yes
219	LUMACAFTOR/IVACAFTOR	No	No
220	LURASIDONE HCL	Yes	Yes
221	LUSUTROMBOPAG	No	No
222	LUTETIUM LU 177 DOTATATE	No	No
223	MACIMORELIN ACETATE	No	No
224	MACITENTAN	No	Yes
225	MEPOLIZUMAB	No	No
226	MEROPENEM AND VABORBACTAM	No	No
227	METHYLNALTREXONE BROMIDE	No	No
228	METRELEPTIN	No	No
229	MIDOSTAURIN	No	No
230	MIGALASTAT	No	No

231	MILNACIPRAN TABLETS	Yes	Yes
232	MILTEFOSINE	Yes	No
233	MIPOMERSEN SODIUM	No	No
234	MIRABEGRON	Yes	Yes
235	MOGAMULIZUMAB	No	No
236	MOXETUMOMAB PASUDOTOX-TD	No	No
237	MOXIDECTIN	No	No
238	NALDEMEDINE	No	No
239	NALOXEGOL	No	No
240	NECITUMUMAB	No	No
241	NERATINIB MALEATE	Yes	No
242	NETARSUDIL OPHTHALMIC SOLUTION	No	No
243	NETUPITANT AND PALONOSETRON	No	No
244	NINTEDANIB	Yes	Yes
245	NIRAPARIB	Yes	No
246	NIVOLUMAB	No	No
247	NUSINERSEN	No	No
248	OBETICHOLIC ACID	Yes	No
249	OBILTOXAXIMAB	No	No
250	OBINUTUZUMAB	No	No
251	OCRELIZUMAB	No	No
252	OCRIPLASMIN	No	No
253	OFATUMUMAB	No	No
254	OLAPARIB	Yes	No
255	OLARATUMAB	No	No
256	OLODATEROL	No	No
257	OMACETAXINE MEPESUCCINATE	No	No
258	OMADACYCLINE	No	No
259	OMBITASVIR, PARITAPREVIR, RITONAVIR, DASABUVIR	No	No
260	ORITAVANCIN DIPHOSPHATE	No	No
261	OSIMERTINIB	Yes	Yes
262	OSPEMIFENE	No	No
263	OZENOXACIN	No	No
264	PALBOCICLIB	Yes	Yes

265	PANOBINOSTAT	No	No
266	PARATHYROID HORMONE	No	No
267	PASIREOTIDE DIASPARTATE	No	No
268	PATIROMER	No	No
269	PATISIRAN	No	No
270	PAZOPANIB	No	Yes
271	PEGINESATIDE	No	No
272	PEGINTERFERON BETA-1A	No	No
273	PEGLOTICASE	No	No
274	PEGVALIASE-PQPZ	No	No
275	PEMBROLIZUMAB	No	No
276	PERAMIVIR	No	No
277	PERAMPANEL	No	Yes
278	PERTUZUMAB	Yes	Yes
279	PIMAVANSERIN	No	No
280	PIRFENIDONE	Yes	Yes
281	PITAVASTATIN	Yes	Yes
282	PLAZOMICIN	No	No
283	PLECANATIDE	No	No
284	PLERIXAFOR	No	Yes
285	POLIDOCANOL	No	Yes
286	POMALIDOMIDE	No	Yes
287	PONATINIB	Yes	No
288	PRALATREXATE	No	No
289	PRASUGREL	Yes	Yes
290	PRUCALOPRIDE	Yes	Yes
291	RADIUM-223 DICHLORIDE	No	No
292	RAMUCIRUMAB	No	Yes
293	RAVULIZUMAB	No	No
294	RAXIBACUMAB	No	No
295	REGADENOSON	No	No
296	REGORAFENIB	Yes	Yes
297	RESLIZUMAB	No	No
298	REVEFENACIN	No	No
299	RIBOCICLIB	No	No

300	RIFAMYCIN	No	No
301	RILONACEPT	No	No
302	RILPIVIRINE	No	No
303	RIOCIGUAT	No	Yes
304	RIVAROXABAN	Yes	Yes
305	ROFLUMILAST	Yes	Yes
306	ROLAPITANT	No	No
307	ROMIDEPSIN	No	No
308	ROMIPLOSTIM	No	No
309	RUCAPARIB	No	No
310	RUFINAMIDE	No	No
311	RUXOLITINIB	No	Yes
312	SACUBITRIL/VALSARTAN	Yes	Yes
313	SAFINAMIDE	No	No
314	SARECYCLINE	No	No
315	SARILUMAB	No	No
316	SAXAGLIPTIN	Yes	Yes
317	SEBELIPASE ALFA	No	No
318	SECNIDAZOLE	Yes	Yes
319	SECUKINUMAB	No	No
320	SELEXIPAG	No	No
321	SEMAGLUTIDE	No	No
322	SILODOSIN	Yes	Yes
323	SILTUXIMAB	No	No
324	SIMEPREVIR	No	No
325	SODIUM PICOSULFATE/MAGNESIUM OXIDE/CITRIC ACID	Yes	No
326	SOFOSBUVIR	Yes	Yes
327	SOFOSBUVIR AND VELPATASVIR	Yes	Yes
328	SOFOSBUVIR, VELPATASVIR, AND VOXILAPREVIR	No	No
329	SONIDEGIB	No	No
330	SPINOSAD	No	No
331	STIRIPENTOL	No	No
332	SUGAMMADEX	No	No

333	SULFUR HEXAFLUORIDE LIPIDTYPE A MICROSPHERES	No	No
334	SUVOREXANT MK-4305	No	No
335	TAFENOQUINE	No	No
336	TAFLUPROST OPHTHALMIC	No	Yes
337	TAGRAXOFUSP-ERZS	No	No
338	TALAZOPARIB	No	No
339	TALIGLUCERASE ALFA	No	No
340	TAPENTADOL	Yes	Yes
341	TASIMELTEON	No	No
342	TAVABOROLE	No	No
343	TECOVIRIMAT	No	No
344	TEDIZOLID PHOSPHATE	Yes	No
345	TEDUGLUTIDE	No	No
346	TELAPREVIR	No	No
347	TELAVANCIN	No	No
348	TELOTRISTAT ETHYL	No	No
349	TERIFLUNOMIDE	No	Yes
350	TESAMORELIN	No	No
351	TETRABENAZINE	Yes	Yes
352	TEZACAFTOR/IVACAFTOR	No	No
353	TICAGRELOR	Yes	Yes
354	TILDRAKIZUMAB - ASMN	No	No
355	TILMANOCEPT	No	No
356	TOCILIZUMAB	No	No
357	TOFACITINIB	Yes	No
358	TOLVAPTAN	No	Yes
359	TRABECTEDIN	No	Yes
360	TRAMETINIB	No	No
361	TRIFLURIDINE AND TIPIRACIL	No	No
362	ULIPRISTAL ACETATE	Yes	Yes
363	UMECLIDINIUM/VILANTEROL	No	No
364	URIDINE TRIACETATE	No	No
365	USTEKINUMAB	No	No
366	VALBENAZINE	No	No

367	VANDETANIB	No	No
368	VEDOLIZUMAB	No	No
369	VEGABATRIN	No	No
370	VELAGLUCERASE ALFA	No	No
371	VEMURAFENIB	No	No
372	VENETOCLAX	No	No
373	VESTRONIDASE ALFA	No	No
374	VILASTA	No	No
375	VILAZODONE HCL	No	Yes
376	VISMODEGIB	No	No
377	VORAPAXAR	No	No
378	VORTIOXETINE	No	Yes
379	ZIV-AFLIBERCEPT	No	No

Sources and notes:

1) For molecules approved for marketing by the USFDA: "New Molecular Entity (NME) Drug and New Biologic Approvals", accessed on 4 December 2020 from the USFDA website, https://www.fda.gov/drugs/nda-and-bla-approvals/new-molecular-entity-nme-drug-and-new-biologic-approvals. This provides year-wise information on the new medicines approved.

2) For molecules sold in Bangladesh from among those approved by the USFDA: Website of the Directorate General of Drug Administration, https://dgda.gov.bd, accessed on 30 August 2019. This provides product-wise information on the medicines registered for marketing in Bangladesh. For molecules sold in India: PharmaTrac database on sales audit data from AIOCD Pharmasofttech AWACS Pvt Ltd. This provides information on the products sold by firms through stockists to the retail market and to institutions. It does not provide information on products directly sold by firms to hospitals and other institutional purchasers.

PRODUCT PATENT PROTECTION, THE TRIPS LDC EXEMPTION AND THE BANGLADESH PHARMACEUTICAL INDUSTRY

As a least developed country (LDC), Bangladesh is currently exempted from the requirements under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to grant patent protection for pharmaceutical products. Consequently, there is scope for the country's pharmaceutical industry to manufacture and sell medicines whose production would otherwise be controlled by a patent-holding firm.

This paper finds that this opportunity has been made use of to positive effect: in comparison with neighbouring India where pharmaceutical product patenting is in force, the market for several new pharmaceuticals in Bangladesh is more competitive and the medicines more affordable. Not only has this benefitted patients domestically, but Bangladesh has also played a key role in supplying essential medicines to other countries.

For this potential to be fully realized, however, the Bangladesh government needs to support the technological development of its industry, particularly the active pharmaceutical ingredients (API) sector. In addition, Bangladesh should maximize the use of TRIPS flexibilities for the freedom to operate in the pharmaceutical sector, which, as this paper shows, has had significant favourable impact thus far.

SUDIP CHAUDHURI *retired as a Professor of Economics from the Indian Institute of Management Calcutta after serving there for the last several decades. His research interests include intellectual property rights regimes and the pharmaceutical industry, industrialization and economic development in developing countries, and the role of the state in economic change.*

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