EVOLUTION OF THE PHARMACEUTICAL INDUSTRY IN BANGLADESH, 1982 TO 2020

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ABSTRACT

Most developing countries depend on imports for the supply of essential medicines. Many developing countries have been finding it extremely difficult to promote local production. But despite being a Least Developed Country (LDC), Bangladesh has succeeded in developing a pharmaceutical industry. The rise of the pharmaceutical industry in Bangladesh is attributed to the Drug Ordinance of 1982. This created a market for the local firms for simple generic formulations which were earlier imported or manufactured by the foreign firms. Local firms grabbed the opportunity and dramatic growth of the industry led by local firms followed. But manufacturing of active pharmaceutical ingredients was neglected. This did not constrain the growth initially with the availability of cheap supplies from India and then China. But this has emerged as a critical bottleneck today. Bangladesh, as an LDC abolished product patent protection in pharmaceuticals in 2008 and what the 1982 Ordinance did for generic products, the change in the patent regime has been doing for patented products. Bangladesh has introduced to the market a number of patented products at very low prices. This is a significant development. But the traditional sources of APIs, viz., India and China cannot officially export patented APIs to Bangladesh unless permitted to do so. Due to the difficulty of sourcing patented APIs, Bangladesh is unable to enjoy the full benefits of the absence of product patent protection. Some steps have been initiated for the growth of the API sector. For the efforts to succeed, the government needs to be more directly involved in developing the technological base of the industry.

Keywords: TRIPS, product patent, pharmaceuticals, drugs, medicines, Bangladesh, India, industrialization, industrial policy.

JEL Classification: E64, F13, I18, L43, L52, L65, N85, O14, O25, O34, O38.
Introduction

Most developing countries depend on imports for the supply of essential medicines. Updating a typology used by Balance, Pogany and Forstner (1992), WHO (2004, p. 6) found that 42 countries had no pharmaceutical industry at all out of the 166 countries considered. Despite some improvements since then (UNCTAD 2011), most of the low and middle income countries (LMICs) still either have no pharmaceutical industry or are involved in relatively late stage manufacturing and packaging of finished products (WHO 2011, p. 24). Bangladesh is an exception in this regard. Many developing countries have been finding it extremely difficult to promote local production and reduce dependence on imported drugs. In countries such as Tanzania, local production share has been going down (UNDP 2016). But despite being one of the Least Developed Countries (LDCs), Bangladesh has succeeded in developing a pharmaceutical industry. In fact, the latter is more developed in Bangladesh than not only in other LDCs but also in some developing countries which are not LDCs such as Ghana. The success of the ready-made garments industry of Bangladesh is well known internationally. But the rise and growth of the pharmaceutical industry which is a modern technology intensive industry has attracted less attention. The basic objective of the paper is to trace the evolution of the industry in Bangladesh and understand the factors explaining the remarkable growth.

Product patent regime plays a very important role in industries such as pharmaceuticals. 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 replaced the British Act of 1911 by the Patents Act of 1970 and with effect from 1972, product patents in pharmaceuticals was abolished. This is considered as one of the major factors behind the rise and growth of the pharmaceutical industry in India. Pakistan and later Bangladesh had the same option before the TRIPS Agreement of the WTO came into effect in 1995. Even after 1995, Bangladesh, as an LDC had the option not to grant product patent in pharmaceuticals, initially till 2005, later extended to 2016 and then to 2033. But Bangladesh did not exercise this option before 2008. By then the industry had already made substantial progress. The rise of the industry in Bangladesh is attributed to the Drugs (Control) Ordinance, 1982, later converted into a law. We will analyse in the paper both the developments before 2008 and the substantial changes that have been taking place in the country after 2008 when product patenting was abolished.

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 only lately has started taking steps to diversify into API. This has been an important difference with India and a major weakness of the industry in Bangladesh and has implications for the international role that Bangladesh can play as an LDC supplying patented medicines to the world.

Current Status of the Pharmaceutical Industry in Bangladesh

The size of the pharmaceutical market in Bangladesh is estimated to be BDT 260.1 billion (USD 3.1 billion) in 2019. The market has been expanding rapidly with a compound annual rate of growth (CARG) of about 15% in recent years. The country is self-reliant in formulations, meeting about 97% of the local demand. While there are about 150
firms currently operating, the industry is highly concentrated with the top 20 firms accounting for about 85% of the market. Quite significantly, the local firms dominate the market with more than 90% market share. This is very rare in the world. All the top 10 firms, for example Square, Incepta, Beximco, Opsonin, Eskayef and Renata are local firms. The major MNCs operating in Bangladesh are Sanofi, Novo Nordisk, GlaxoSmithKline and Novartis. The market shares of these foreign companies, Sanofi, the largest (1.9 %), Novo Nordisk (1.8 %) are very small compared to large local firms – Square (18.7 %), Incepta (10.4 %).

Bangladesh manufactures more than 450 generic drugs for 5600 registered brands covering different therapeutic classes. About 3% of the local market for finished formulations for which the country is dependent on imports relate to technologically intensive products including biologics. But the local firms have also started manufacturing high tech products. The dosage forms include such technically advanced products such as lyophilized injectables, sterile ophthalmics, prefilled syringes, oral thin films and multi-layer tablets. The domestic market is essentially a branded generics market. Patented medicines account for about 7% of the market.

In many developing countries, manufacturers have been finding it very challenging to upgrade production facilities to conform to GMP standards. Local pharmaceutical companies in Bangladesh have developed the technical competence to set up and run GMP compliant manufacturing plants and to develop products meeting the regulatory requirements for getting marketing approvals in different countries. Bangladesh exports to more than 100 developing countries. It exports not only to nearby Asian countries such as Myanmar and Sri Lanka but also to African countries (such as Kenya and South Africa) and Latin American countries (such as Brazil and Ecuador). The country has also started entering the regulated markets of developed countries which
have much tougher standards. Some products of leading companies have been approved for marketing in the US, in Europe, UK, and Australia, among others.

Ready-made garments is the largest export sector in Bangladesh and with exports of US$ 27949 million, alone accounts for about 83% the total exports in 2019-20. In comparison, pharmaceuticals is a very small sector accounting for about 0.4% of total exports. But excluding readymade garments, textiles and traditional industries such as footwear and leather, pharmaceuticals with exports of US$ 136 million is the largest exporter among manufactured commodities. It is one of the fastest growing export sectors in the country with formulations exports expanding at CARG of 16% during 2005 to 2015. In terms of domestic production index, pharmaceuticals is the fourth largest with a weight of 8.2 after garments (34.8), textiles (14.1) and food products (10.4) (Rahman and Farin 2018, p. 11).

However, compared to the remarkable growth of formulations manufacturing and exports, APIs have lagged far behind. While some local firms are involved in manufacturing some APIs, the industry is primarily dependent on imported APIs. This has emerged as a major problem for Bangladesh as we will discuss below.

Drug Policy of 1982

Market Structure in the Early 1980s

Few MNCs and local firms started manufacturing pharmaceutical products in the 1950s in Bangladesh (Azam, p. 60). But it was since the 1980s that the industry started growing rapidly. In the early 1980s, the pharmaceutical market in Bangladesh was dominated by the MNCs. While there were 166 licensed manufacturers in the country, only 8 MNCs – Glaxo, Pfizer, Hoechst and others – accounted for 70% of the drug market. The country followed a very liberal policy towards the MNCs. There were no restrictions on their operations. They had the
technological, managerial and financial resources to play an active role in the development of the industry. But the MNCs were keen on importing and marketing rather than manufacturing from basic stages. Several local firms were operating on behalf of MNCs – selling imported products and manufacturing drugs on contract basis for the MNCs. MNCs were manufacturing only simple drug formulations and these were largely non-essential drugs. In fact, the Expert Committee (1982) found that nearly one third of medicines purchased were on “unnecessary and useless medicines such as vitamin mixtures, tonics, alkalisers, cough mixtures, digestive enzymes, palliatives, gripe water and hundreds of other similar products.” The MNCs were not involved in manufacturing of APIs and these were imported often at inflated prices.6

**Creation of Market for Local Firms**

Soon after it came into power in March 1982, the military government appointed an Expert Committee for the formulation of a national drug policy. The Expert Committee (1982) approached the problem both from the industrial policy objective of promoting local production of essential medicines and from the health policy objective of removing from the market non-essential products. Representatives from the industry dominated by the MNCs were deliberately kept out (Chowdhury 1995). It comprised of eight members drawn from the medical profession, drug administration and civil society.

The Expert Committee (1982) recommended policy intervention both for the formulations sector and the API sector. The government accepted the recommendations for the formulations sector and issued the Drugs (Control) Ordinance, 19827 in June 1982 to implement the following two steps:

- Manufacture, import and sales of drugs identified by the Expert Committee as harmful, unnecessary and otherwise undesirable drugs, were banned
Marketing of drugs by MNCs manufactured on contract basis for MNCs were banned if the MNCs did not have any manufacturing plant in the country and if these drugs or their substitutes were produced locally.

The 1982 policy transformed the formulations sector.\textsuperscript{8} The Ordinance eliminated a significant part of the market of the MNCs. This was a very radical step. There was a hostile reaction to the policy from the MNCs actively supported by foreign governments, particularly by the government of the United States. Pressure was put on the military government not to implement the policy, at least to postpone it. As a result, some concessions were provided but the basic thrust of the policy was not compromised with.\textsuperscript{9} Out of the 4340 registered drug products, about 1700 products were banned and withdrawn from the market in phases (Chowdhury 1995, pp. 53-58; also Reich 1994). The MNCs had the option to re-organize their manufacturing and marketing operations by focussing on essential drugs. After all, the Ordinance did not ban the operations of the MNCs as such. But the MNCs chose not to do so. Some of them, for example Squibb discontinued their operations in Bangladesh. Among those who remained, some continued to be active. But on the whole the MNCs were not prepared to re-structure their operations and play a major role in the growth of the industry in the new environment.

This effectively created for the local firms a market for simple generic formulations which were earlier imported or manufactured by MNCs.

\textit{Technology Factor}

But apart from market, another key factor for successful industrial development is access to relevant technologies. This often acts as a major constraint particularly in developing countries even in simpler products. The 1982 policy did not address the question of technology. But some favourable circumstances existed at Bangladesh at that time which enabled the local firms to actively utilize the space created for their growth.
The Department of Pharmacy of Dhaka University was set up in 1964 and played a very useful role. The MNCs used to recruit pharmacy students for their operations.\textsuperscript{10} These people who were trained in the MNCs constituted a pool of skilled manpower who could be and in fact were recruited by the local firms. As a survey found out, there was a massive shift of managers, engineers and skilled workers from MNCs to local firms after the 1982 policy (Amin and Sonobe 2013, pp 20-23; Sonobe, Mottaleb and Amin 2018, pp. 36-38). Local firms themselves 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, pp. 63). Without the creation of a pool of skilled personnel for formulations manufacturing, the desired outcome of drug policy of 1982 may not have been realized.

**Import Protection**

Another policy which is believed to have helped the local firms is that imports of products were restricted if these or close substitutes were manufactured locally. Any imports need to be approved by Directorate General of Drug Administration’s (DGDA’s) Standing Committee of importation of raw materials and finished products. This committee followed a directive that was issued in the mid-1990s by the Prime Minister’s Office to DGDA to discourage imports where local firms are involved in manufacturing.\textsuperscript{11} The criteria followed by the committee to restrict imports seem to have changed from time to time.\textsuperscript{12} But in any case in the highly competitive generic market for simple formulations, the industry could withstand import competition without protection for most products.

**Neglect of the API Sector**

The Expert Committee (1982) also recommended the abolition of product patent protection in pharmaceuticals and a policy for supporting
the development of API manufacturing. The Ordinance did not deal with this part of the recommendations. MNCs did not manufacture APIs. The local firms focussed on formulations and the API sector continued to be neglected. The underdevelopment of the API sector however did not constrain the growth of the formulation sector at that time. APIs for generic formulations production were readily available not only from developed countries but also from developing countries such as India and China. In fact, these two countries with very competitive API sector emerged as the main sources of supplies of APIs at low prices. Bangladesh found it cheaper to import APIs than to develop these in the country.

**Rise of the Industry Dominated by Local Firms**

The remarkable growth of the Bangladesh pharmaceutical industry that followed the 1982 policy has been summarized by the National Drug Policy 2005 as follows:

- Formulation production increased from BDT 1,730 in 1981 to BDT 41,000 in 2002
- Widely used essential drugs became more affordable
- Dependence on imports of drug formulations reduced dramatically. The country is estimated to have saved foreign exchange of USD 600 million every year
- From a drug importing country, the country emerged as a drug exporting country
- MNCs were dislodged from the position of dominance.

What contributed to the growth was not only expansion of firms such as Square and Beximco which all through have been locally owned. As the market situation and the strategy of MNCs changed, some of them divested their ownership in favour of local shareholders. As a
result, a number of MNCs became locally owned firms, for example Pfizer became Renata, Imperial Chemical Industry became Advanced Chemical Industries (ACI), SmithKline and French became Eskayef and Organon became Nuvista (Amin and Sonobe 2013; UNCTAD 2011). New local firms such as Incepta (1999) and Beacon (2006) also entered the industry.

Local firms focused on and started dominating the market segment for simple formulation products. MNCs manufacturing in Bangladesh, also basically operated in these markets. MNCs often found it difficult to match the prices charged by the local firms and to compete against them and started losing market shares. The MNCs were free to manufacture the technologically advanced and patented products. But they chose to cater to this small market through imports. As we will discuss below the local firms started manufacturing technologically advanced and patented products much later.

**Changes in Drug Policy of 1982**

*Contract Manufacturing for Exports*

With the growth of the industry, the local firms demonstrated their competence as manufacturers of quality formulation products at low cost. The in-house formulations technological capability of local firms improved. The local firms also used technical expertise from more advanced countries to supplement their efforts (UNCTAD 2011, p. 79). We mentioned above the historical importance of the Department of Pharmacy at Dhaka University. Not only did this department expand and diversify its activities and catered to the needs of the industry. As the pharmaceutical industry developed and the demand for skilled technical person persons increased, many more pharmacy institutions were set up. It is not only that skilled technical manpower is available in Bangladesh. It is cheaper too compared to other drug major manufacturing countries. It is estimated that labour cost is about 3 to 4
times cheaper compared to India and China. And gas based electric power is supplied in the country at about one-third of the cost in India.\textsuperscript{18}

This provided an opportunity to foreign firms to take advantage of such low cost of manufacturing in Bangladesh and sub-contract their manufacturing operations and market these in different countries. But the 1982 restriction on contract manufacturing meant that foreign firms which did not have any manufacturing operations in Bangladesh could not do so and as a result local firms too were denied the opportunity to enlarge their operations. This restriction was withdrawn in the \textit{National Drug Policy 2005} (NDP 2005) and the \textit{National Drug Policy 2016} (NDP 2016) for exports. This encouraged collaboration between foreign and local firms for mutual benefit. Following the policy change, a number of local firms have entered into arrangements with foreign companies to manufacture and export drugs.\textsuperscript{19} As we have mentioned above, between 2005 and 2015, formulation exports have increased at a compound annual rate of growth of 16\%. Mohiuddin (2019 p. 7) has reported that there are about 30 local firms involved in contract manufacturing for other firms including the MNCs. A number of local firms, for example Beximco and Eskayef with a history of partnerships and alliances with MNCs have been particularly active in such activities.

With billions of dollars’ worth of drugs losing patent status every year, the local firms were able to participate more in the world generics market. Partnerships have also started keeping in mind the future generics market. A local firm for example has started collaborating with an Indian firm to manufacture products currently under patents. The local firm can sell these in Bangladesh and other LDCs with no patent protection. The motivation of the foreign partner is that after the patents expire in the US, which is the largest and the most lucrative market, it will be better prepared to enter the US market with ready supplies from Bangladesh.\textsuperscript{20}
Manufacturing of Technologically Advanced Products and Technology Transfer

In 1982 when the restriction was imposed on MNCs, they were primarily involved in marketing non-essential drugs. But the blanket restriction meant that contract manufacturing could not be done for essential drugs too. The result was that in the case of newly developed drugs, even when local firms did not have the capacity, they could not manufacture these under licensing from MNCs. As a result, the country had to rely on imports for these drugs. This was sought to be rectified by the NDP 2005. To encourage technology transfer and to ensure availability of newly developed drugs in the domestic market, the restriction was lifted provided the products were registered for marketing in the same brand names in at least two of the following developed countries: USA, UK, Switzerland, Germany, France, Japan and Australia. After the NDP 2016, the requirement is that these must be registered in at least one of these countries.

Such a requirement was imposed to avoid the situation in the early 1980s when the MNCs were marketing non-essential drugs in Bangladesh which were not sold in their home countries. For example, 22 out of the 56 drug products sold by Glaxo in Bangladesh in 1981-82 were vitamins and tonics and only three of these were marketed by it in Britain (Chowdhury 1995, p. 58).

The new drug policies also encouraged the MNCs to be more involved in direct manufacturing and in technology development and transfer. Again, to avoid the situation before the 1982 policy when the MNCs were mainly involved in importing and manufacturing non-essential drugs, NDP 2005 and NDP 2016 imposed the condition that foreign companies will be permitted to set up companies and manufacture drugs provided they manufacture at least three drugs which have been developed by them and are registered in at least two of the following countries: USA, UK, Switzerland, Germany, France, Japan and Australia.
Lack of MNC Interest in Manufacturing

But the progress in manufacturing of innovative products by MNCs either directly or through contract manufacturing has been slow.

Novo Nordisk is the world leader in diabetes care and the second largest MNC operating in Bangladesh and has been manufacturing human insulin in vials in partnership with the local firm, Eskayef since 2012. But pen-filled modern insulin products continued to be imported from Denmark. In January, 2018 Novo Nordisk signed a memorandum of understanding with Eskayef for technology transfer for manufacturing of advanced insulin. It is for the first time that such advanced technology will be used outside Denmark (Fitch Solutions 2019, pp. 52-53).

This is a significant development. But the general trend that is observed in Bangladesh is that MNCs are exiting from simpler formulations where they are finding it difficult to compete against the local firms and relying on imports of technologically advanced products which the local firms are finding difficult to manufacture. GSK has been operating in Bangladesh for decades. But in July 2018 it announced the decision to stop drug manufacturing in the country since it is incurring losses (but decided to retain its profitable consumer healthcare business) (Fitch Solutions 2020, p.48). Unable to compete against local firms in simple products, Sanofi, the largest MNC operating in Bangladesh is also planning to exit from drug manufacturing in the country and to focus on importing and marketing of advanced technology products (Fitch Solutions 2020, pp. 48, 58). Major MNCs such as AstraZeneca, Johnson & Johnson, Merck Sharp & Dohme and Roche are catering to the Bangladesh market through imports. In fact some of the foreign companies, for example Merck Sharp & Dohme, Allergan and Mylan have formed partnerships with local companies such as Healthcare Pharmaceuticals, Eskayef and Beximco respectively to distribute their products. 21 It is not surprising that the policy of encouraging the MNCs to invest in the country for the further development of the industry
has not yielded the expected results. Manufacturing of innovative products by MNCs was never discouraged. The 1982 policy put some restrictions on manufacturing and marketing of non-essential products only. MNCs were all through free to manufacture products for which local capability and capacity were yet to be developed. In fact, before 2008 they could get their products patented in the country and manufacture these without any competition. The problem with the 2005 and 2016 policies is that these did not introduce any new and concrete steps to induce or to compel the MNCs to change their behaviour.


The Expert Committee (1982) recommended the abolition of product patent protection in pharmaceuticals. But this was not done before 2008. Bangladesh did not replace or amend the British Act of 1911 which she inherited. She simply issued a Notification in 2008 that applications for product patents in pharmaceuticals (and agro-chemicals) will be suspended till 2016 (Azam 2016, p. 40).22 This suspension has continued with the extension of the LDC waiver from 2016 to 2033. But Bangladesh will be required to introduce product patent protection before that if she loses the LDC status. The Committee for Development Policy (CPD) of the UN Economic and Social Council determines the LDC status. The first review in 2018 shows that Bangladesh no longer satisfies the LDC criteria. Depending on the outcome of the review of Bangladesh’s progress in 2021, she may lose the LDC status in 2024 after the three-year transition period.23

The abolition of product patent protection in Bangladesh in 2008 has been another momentous event. What the 1982 Ordinance did for the generic products, the change in the patent regime has been doing for products patented elsewhere. But unlike in the earlier phase, the API constraint is preventing Bangladesh from realizing the full benefit.

Technological development takes place in stages and Bangladesh pharmaceutical industry is no exception to it. Local firms in Bangladesh
have been initially known for their proficiency in manufacturing simple generic formulation products. Technologically intensive products and patented products were primarily imported in the country. As the industry evolved, local firms started venturing into manufacturing of more complex formulation products and the abolition of product patent protection provided an opportunity and stimulated such diversification. Beacon Pharmaceuticals set up a manufacturing plant with the help of European consultants and has an agreement with Heber Biotec, Cuba for technology transfer. It is involved in manufacturing several innovative products. It was the first company to introduce anti-cancer drugs in 2009, biologics in 2011 and hepatitis C in 2015 (Beacon Pharmaceuticals, Annual Report 2019). Another example is Incepta. It is involved in manufacturing of human vaccines, monoclonal antibodies, biotech products and hormones. In 2012, Incepta introduced locally manufactured Hepatitis B vaccine for the first time in Bangladesh. 

The impact of product patent abolition began to be felt since around 2015. Some of the patented products of recent years are technologically advanced. It takes time to understand the product characteristics, select the product keeping the market in mind, and develop the product for regulatory approval often with technical help from abroad. The local firms which have started manufacturing and marketing patented drugs include Incepta, Beacon, Square, Beximco, Eskayef and Renata. Some examples of products patented in India but approved for marketing by local firms in Bangladesh are: Sofosbuvir, Sitagliptin, Linagliptin, Dasatinib, Cetuximab, Eltrombopag, Axitinib, Pertuzumab, Osimertinib, Ibrutinib, Crizotinib, Nintedanib, Afatinib, Apixaban, Saxagliptin, Ramelteon, Empagliflozin. In the unprecedented situation arising out of the COVID-19 pandemic, the world is desperately looking for vaccines and medicines. One of the drugs which is being tried out is Remdesivir. In a significant development, Bangladesh has introduced this patented drug in the market.
A highly competitive market has developed for the patented products in Bangladesh. Companies need to inform DGDA in advance about their API import plan and hence business information about products to enter the market are easily available in advance. Once a company starts manufacturing a patented drug, other companies often follow soon. As a result of such competition, some patented products in Bangladesh are available at a fraction of the cost of the branded product of the innovator company. The local firm Incepta created quite a stir when it launched the generic version of the patented Hepatitis C drug, Sofosbuvir in 2015 at $10 compared to $1000 per tablet in the United States. It is now sold by 11 local firms and is available at a lower price.

India and Bangladesh are very good examples of the negative impact of re-introduction of product patents and the positive impact of abolition of product patents respectively. Before TRIPS, India was known for its ability to manufacture and sell patented products at low prices. But after the re-introduction of product patent protection, entry of generic firms in the market has been prevented and the MNCs taking advantage of the monopoly patented markets in India are charging exorbitant prices particularly for anti-cancer drugs. But because of the absence of such entry barriers in Bangladesh, markets are competitive and local firms there are able to supply some of these medicines at much cheaper prices. For example, Ibrutinib is sold at $331 in Bangladesh (compared to $6141 in India), Osimertinib at $63 ($2879), Crizotinib at $310 ($1497), Palbociclib at $96 ($1338) and Tofacitinib at $45 ($934).

To take advantage of such wide price differentials, products from Bangladesh have started entering the Indian market. Under the Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007, no penal action can be taken by customs authorities against goods contained in personal baggage or imported in small quantities intended
for personal use of the importer. It has been reported that such rules are being abused for commercial purposes and traders are involved in smuggling high-value, low volume drugs from Bangladesh to India. The Organisation of Pharmaceutical Producers of India (OPPI), representing the MNCs has taken up the matter with the government to find ways of stopping such imports of patented products.\textsuperscript{31}

With a share of 7.1\% in 2019, patented drug products constitute a small segment of the pharmaceutical market in Bangladesh (Fitch Solutions 2020, p. 18). The range of patented drugs manufactured and the volumes are low. The problem is not with formulation development. Despite some limitations, local firms are taking care of it. The problem is availability of APIs. Bangladesh is eligible to manufacture a much larger number of patented drugs and in larger volumes than she currently does. As the Managing Director of Active Fine Chemicals, a manufacturer of APIs said in an interview: “There are more than 100 patented drugs that we can manufacture and sell whereas China and India cannot manufacture them. But we failed to take the full advantage of it” (EBL Securities 2019, p. 39).

**Constraints Relating to API Manufacturing**

The Expert Committee (1982) realized the critical significance of the API sector and recommended the promotion of the sector with proper government support. But the government through the Ordinance of 1982 basically targeted the formulations sector. As the industry developed, the local firms on their own initiatives started manufacturing some APIs. But at present only few private sector companies such Square and Beximco manufacture simple APIs such as paracetamol, amoxicillin, ampicillin, cloxacillin on a limited scale. About 60\% of the APIs are in fact produced by Gonoshasthaya Pharmaceuticals, set up by Gonoshasthaya Kendra (People’s Health Centre), a charitable trust. Some large companies such as Incepta are not at all involved in API manufacturing. Local production caters to about 10\% of the demand
and hence the industry is primarily import dependent for APIs (Mohiuddin 2019, p. 4; Fitch Solutions 2020, p. 9).

The underdevelopment of the API sector in Bangladesh today is a major constraint because the local firms themselves are unable to manufacture much of the APIs required for new patented products. And unlike in the pre-TRIPS world, the traditional sources of APIs, viz., India and China recognize product patents protection and hence the generic firms from these countries cannot officially manufacture and sell patented APIs, (i.e., the APIs involved in patented products) to Bangladesh except under conditions consistent with the TRPS agreement. A possible way out is to tie up with the patentees. But as we have mentioned above, the MNCs are not keen to manufacture the patented drugs in Bangladesh either directly or through partnerships with local firms.

**Difficulties of Importing Patented APIs**

How does Bangladesh arrange for imports of patented APIs? Imports of APIs need to be approved by DGDA. DGDA asks for some information such as quantity and price but with the abolition of product patent in Bangladesh, DGDA is not required to and does not check whether the APIs are imported from countries satisfying TRIPS requirements. So, there is no difficulty from the Bangladesh side.

How do exporting countries sell patented APIs to Bangladesh without violating TRIPS? There are of course some official channels that can be used but these are unlikely to be major sources of supplies. TRIPS permits some exemptions from patentability and exceptions to patent rights. Article 30 of TRIPS allows for limited exceptions. One such exception relates to the use of the patented products for research and experimental use (Musungu and Oh 2005, pp. 31-32). Firms can export to Bangladesh patented APIs citing such an exception as the official purpose. Small volumes even when actually used for commercial
purposes can go unnoticed. But large volumes are likely to invite scrutiny and be accused for violating TRIPS. Again, under Article 27 (1) of TRIPS, patents are required to be provided for inventions which are “new, involve an inventive step and are capable of industrial application”. The agreement, however, does not define these terms. This provides some flexibility for countries to interpret these terms and adopt different patentability standards. For importing the APIs, Bangladesh can choose countries where these are not patented. But most of the post TRIPS molecules are likely to be patented in the major pharmaceutical manufacturing countries and hence such opportunities are in all probability limited. Another possible way in which the TRIPS restrictions may be avoided is to import the APIs at penultimate stages and complete the last stage or the last few stages in Bangladesh. But even this requires proper plants and technical skills and as we have mentioned above these are not yet widely available in the country.

According to knowledgeable persons,33 while some APIs may find their way to the country through above channels, patented APIs are primarily imported from China and to some extent from India unofficially. We have mentioned above how patented medicines are imported into India under personal consumption category. Similar channels are being used in Bangladesh for importing most of the patented APIs.

Even when sources of APIs are identified, prices quoted can be high. When foreign suppliers realize that Bangladesh does not have too many options and are dependent on them, they naturally try to take advantage of the situation and charge high prices. APIs constitute a major component of the cost of production of formulations. Depending on the product, when local firms are able to get APIs at reasonable prices, the prices of finished formulations can be low as in some of the examples cited above. Otherwise the prices are high.
Implication of Patented API Import Dependence

Both the difficulty of sourcing APIs and the price uncertainty act as major barriers. Bangladesh (and also other countries) may not be able to enjoy the full benefits of the absence of product patent protection unless the API sector is developed. Take for example the AIDS and COVID-19 pandemics. During the AIDS pandemic, the world benefitted from the absence of product patent protection in pharmaceuticals in India. After supplies from India started, the prices of an effective patented AIDS drug combination crashed leading to significant scaling up of treatment. India became the dominant source of AIDS drugs for the vast majority of the people in LMICs.\textsuperscript{34}India was able to do this because India succeeded in developing the industry from basic stages. Indian generic firms developed manufacturing capacities to manufacture both APIs and formulations and to supply the drugs in large volumes for HIV/AIDS patients around the world.\textsuperscript{35}

As and when new medical products for COVID-19 are developed, if these are patented, India will not be able to play a similar role with the introduction of product patents in India since 2005. But Bangladesh has the potential to do so. In fact, Bangladesh has introduced in the market the patented drug Remdesivir which is being experimented with for COVID-19 patients. This is a significant development. But Bangladesh may not have the same impact as India had during the AIDS pandemic because of her inability to control either the volume of production or the prices.\textsuperscript{36}

It is fundamentally important to develop the API sector to realize the potential that Bangladesh has to be a major international player not only for patented COVID-19 medical products but also for other essential drugs.

Policies for the Development of the API Sector

The need for a strong and competitive API sector has been realized and some policies have been introduced and some action has been initiated in that direction.
Following the NDP 2005, the government approved in 2008 the construction of an API Park with all infrastructural facilities on 200 acres of land in Munshiganj near Dhaka through the Bangladesh Small & Cottage Industries Corporation under the Ministry of Industry. Work started in the same year but after considerable delay, 42 plots have been handed over to 28 local firms in 2017. It will take some more time for all the facilities to be in place and the park to be fully operational. Bangladesh Association of Pharmaceutical Industries has taken the responsibility for establishing the common effluent treatment plant and waste dumping yard (Hossain, 2018). In the NDP 2016, the government has declared its intention to reduce the country’s import dependence on raw materials by providing facilities and incentives. In January 2018, pharmaceuticals was declared as the “Product of the Year” by the Prime Minister. In May 2018, the “National API (Active Pharmaceutical Ingredients) and Laboratory Reagents Production and Export Policy” was announced. The major incentives to be provided for production of APIs and laboratory Reagents (henceforth referred to as only APIs) are as follows:\textsuperscript{37}

- 100% tax holiday for all API manufacturers for the first five years
- 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 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
- Providing 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.

The Budget for financial year 2019 has also proposed exemptions and reduction of customs duty for a number of raw materials (Rahman, 2019).

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 product patent abolition in pharmaceuticals.

*Need for Technology Policy*

For developing an industry, all the three factors of market, finance and technology need to be properly coordinated. Product patent abolition has created a market for local firms. The API policy provides some financial incentives. What is lacking is proper support for technology development. The API policy does provide incentives for API production, for example tax and export incentives. But firms can benefit from these incentives only when they are able to sell and export APIs. If in the first place, firms do not have the capability and capacity to produce APIs, then these incentives will not be realizable. While as mentioned above, a number of 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 (Gehl Sampath, 2007, p. 20). The API park is an important initiative. It reduces the cost of API investment and manufacturing. What is also needed is the development of API manufacturing technologies from basic stages for the new and more complex products. To do so, investment in R&D is required. But it is well known that especially in nascent stages, private firms are neither able to nor willing to invest in R&D for technology development. The private sector is yet to invest significantly on R&D. Beximco Pharma is
one of the major spenders. It spent 1.25% of its revenue on R&D \textit{(Annual Report, 2018-19)}. Others spend much less. The largest pharmaceutical firm, Square Pharmaceuticals, for example spent only 0.27% of its revenue on R&D \textit{(Annual Report, 2018-19)}. The government needs to intervene to support the private sector. Going by the experiences in other countries, effective steps that are needed have often taken the forms of government directly initiating R&D and supporting R&D in the private sector by providing funds and other benefits. Direct government involvement in R&D in Bangladesh is conspicuous by its absence. There are also no government incentives in place to support and promote R&D in the pharmaceutical sector (Azam 2016, p. 72).

The NDP 2016 talked about the need for more R&D by firms and universities and promoting FDI for technology transfer. But unlike the API incentives mentioned above, no concrete steps have been proposed to incentivize R&D.

Here a comparison with India is relevant to draw policy lessons. Unlike India, Bangladesh was able to weed out irrational and non-essential products. India is still grappling with this issue. But unlike Bangladesh, India stressed the development of the industry from basic stages. With respect to API manufacturing the situation that Bangladesh faces today is similar to what India faced in the 1950s and 1960s. Like in Bangladesh today, local firms in India then were not in a position to undertake API production on any significant scale. Both countries stressed the importance of technology transfer through foreign companies. But foreign companies were not keen to invest for manufacturing APIs. It was because of these reasons that the government in India intervened to develop the industry. The foundations for technological development and the growth of the API sector 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.38

Bangladesh never had any large public investments in pharmaceutical manufacturing. Similar to India’s CSIR, Bangladesh has the Bangladesh Council of Scientific and Industrial Research. Bangladesh also has a number of medical R&D institutions such as Bangladesh Medical Research Council, Bangladesh National Research Council, National Institute of Cancer Research and Hospital etc (Gehl Sampath 2007, p. 23; Annex II). But these organizations have never been involved in the development of drug manufacturing technologies.39

If Bangladesh wants to take full advantage of the absence of pharmaceutical product patents, it is important for the government in Bangladesh to be directly involved in developing the technological base of the industry. Setting up a large public sector unit in Bangladesh may not be a feasible option now. But the government can and should play an active role in re-organizing the R&D infrastructure in the country and also be directly involved in funding pharmaceutical R&D not only in government laboratories but also in pharmaceutical firms and universities and other R&D organizations.

**Discussion and Conclusions**

Most developing countries want to develop pharmaceutical industries to reduce dependence on imports of essential medicines. But most of these countries in Africa and elsewhere also find it extremely difficult to implement a set of effective policies to achieve self-sufficiency.

The unfavourable conditions under which the local industry operates evoke a lot of pessimism. To start with, the local firms are obviously disadvantaged both technologically and financially compared to firms from countries with more advanced industries. The
apprehension that is commonly expressed is that if local firms are promoted to develop the industry then even though some economic benefits such as less foreign exchange spending and more employment may follow, the country will suffer from high costs and prices and the industry will not be able to sustain against more efficient firms from abroad. Attracting foreign firms to invest in the country is considered as a better option and most countries follow very liberal FDI policies and hope that foreign firms will help the country to develop the industry. It is also politically difficult to implement policies which support local firms but have a significant adverse effect on foreign firms. Countries are hesitant to adopt policies which may result in non-cooperation and even retaliation by foreign governments.

But if liberal policies towards foreign companies do not lead to the desired outcomes, then governments have no option other than to intervene if they really want to develop the industry.

That is what Bangladesh did. It intervened in favour of local firms and against foreign firms. The 1982 policy eliminated a significant part of the MNC market and provided a space for the local firms to grow. This obviously went against the interests of the MNCs and there was a hostile reaction to the policy from the MNCs and foreign governments and pressure was put on the government not to go ahead. The political leadership did not succumb to these pressures and demonstrated the political will to continue with the policy. It is very important for policy planners to be convinced that local industry needs support and that if supported, efficient industry can develop and the country can gain. In Bangladesh too doubts were expressed about the viability and sustainability of local industry. In fact, stories started appearing in newspapers how the drug policy will lead to closure of factories (Chowdhury 1995, p. 69). But Bangladesh did not fall prey to such negativism.
These are important lessons for countries trying to develop pharmaceutical industries. Countries need not be pessimistic about prospects. Countries need not be hesitant to support local enterprise. If the countries have the political will to act then viable and competitive industries can be developed even in small countries. Many African countries are similar to Bangladesh in economic aspects.

Bangladesh has successfully developed the formulations sector. That by itself is a great achievement. But as the industry developed, it starting facing the constraints of an under developed API sector. The 1982 and 2008 policies were very effective in creating the market for local firms. But it did not involve any financial outlay. The government hardly provided any other support such as export assistance or R&D funding which are particularly important in nascent stages. It is really creditable that local firms made so much progress without any other assistance. Absence of technological support did not matter so much for formulations. The local firms benefitted from some favourable initial conditions and also developed competencies through in-house efforts and also use of services of foreign technical persons. But the API sector was neglected with the private sector not in a position to invest in any significant scale. This did not constrain the growth of the formulations industry in the pre-TRIPS days due to availability of cheaper supplies from India and China. But in the product patent regime under TRIPS, Bangladesh is finding it extremely difficult to source patented APIs and this is preventing the country from taking full advantage of absence of product patents in Bangladesh.

Bangladesh has started to take some steps to develop the API sector. This would require much deeper intervention by the government including direct involvement in developing the technological base of the industry.
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Notes

1 Information on the current status unless otherwise mentioned, has been obtained mainly from 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).


3 GMP comprises of a set of safeguards and procedures to ensure that the product manufactured is effective and safe. Quality control and assurance are required to be done not only for the final products but also for raw materials and products at different stages in the production chain. Based on the GMP prescribed by the World Health Organization (WHO GMP), countries have formulating their own GMP standards. Developed countries follow tougher standards.

4 “Export performance (Goods) for FY 2019-20 July-June,” Export Promotion Bureau, Bangladesh (http://epb.gov.bd/site/view/epb_export_data/-).


6 The discussion on the situation of the pharmaceutical industry in early 1980s is based on Expert Committee (1982) and Chowdhury 1995 (chapter 3).


8 See the discussion on the 1982 policy by Zafrullah Chowdhury in Chapter 3 of Chowdhury 1995. Chowdhury was one of the members of the Expert Committee and played a key role in the deliberations and implementation of the policy (Reich 1994). For an account of the impact of the 1982 policy, see Reich 1994; Sonobe, Mottaleb and Amin 2018 (chapter 2) and UNCTAD 2011 (Case study 2 on Bangladesh).

9 Reich (1994, pp 133-35) and Chowdhury (1995, Chapter 4) discuss the opposition that the Bangladesh government faced from different quarters. It is possible that the government was dissuaded from implementing the other recommendations of the Expert Committee relating to API and product patent abolition because of the hostile reaction and the pressure exerted.

10 According to Chairman of a large company we interviewed (on 5 March, 2019 in Dhaka), some MNCs decided to locate their manufacturing operations more in East Pakistan (now Bangladesh) than in West Pakistan because of the availability of such skilled persons.

11 Source: according to the Managing Directors of two companies interviewed on 5 and 6 March, 2019 in Dhaka.

12 According to UNCTAD (2011, p. 70), government restricted the imports of products or close substitutes if these are produced in the country. But according to Sonobe, Mottaleb and Amin (2018, p. 37), import restrictions are applicable if the products are locally manufactured by two or more firms in the country and according to Fitch Solutions (2020, p. 9), by four or more firms.
‘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).


Retail prices of most of the locally produced drugs declined between 1981 and 1991 or remained static – see Chowdhury 1995, Table 5.4 for 30 widely used drug products.

As the Managing Director of one of the largest pharmaceutical companies in Bangladesh said in an interview (on 5 March, 2019 in Dhaka), pricing policy followed by the local management of the MNCs was not very flexible. Even when the local firms started charging lower prices, they were not able to reduce their prices.

There are 12 public universities and 31 private universities in Bangladesh offering degree programmes and 50 colleges/institutes offering diploma programmes (Mosharraf et al. 2019, p. 90).


As the Managing Director of a large pharmaceutical company in Bangladesh said in an interview (on 5 March, 2019 in Dhaka), contract manufacturing for MNCs provide a huge opportunity and is more profitable than domestic sales.

Interview with the Managing Director of a large company on 5 March, 2019 in Dhaka,


Though this is not a requirement of TRIPS, Bangladesh decided to preserve these applications in a “mailbox” to be taken up for examination for grant of patents after the expiration of the waiver period.

The three criteria used are GNI per capita, Human Asset Index and Economic Vulnerability Index (EBL Securities 2019, p. 22).


According to the Deputy Managing Director of a company, while China is a better source for APIs supplied, India is a preferred source for formulation technology. Local firms have started taking help from Indian firms and consultants to develop products (interview on 6 March, 2019 in Dhaka).

Information on product patent status in India was obtained from Chaudhuri (2019) and marketing status in Bangladesh from the website of Directorate General of Drug Administration, https://dgda.gov.bd (accessed 30 August, 2019).

‘Bangladesh Pharmaceutical Industry: Opportunities in Global Generics’, Kaiser Kabir, CEO, Renata Ltd and Vice President, Bangladesh Association of Pharmaceutical Industries.

The price for a 400 mg tablet varies between BDT 350 and 800 (https://dgda.gov.bd, accessed 30 August, 2019).

The prices in INR reported in Mukherjee (2019) have been converted to USD using the average exchange rate of INR 71 in November 2019.


Some local firms, for example Beximco has started manufacturing APIs for patented drugs in small scale (Beximco Pharma, Annual Report 2018-19). But that is too small given the requirements.

This discussion on how patented APIs can be or are imported into Bangladesh is based on interviews with the Deputy Managing Director and Head of International Business respectively of two large firms and with the Managing Director of a medium size firm. The interviews were conducted on 5 and 6 March, 2019 in Dhaka.

Unlike in the past, India is now dependent on China for much of API supplies especially those required in large volumes. But unlike Bangladesh, this happened after India had developed the capability and capacity for manufacturing APIs. India has a large API sector and India is particularly competitive in manufacturing technologically advanced APIs.

For an analysis of the differences between the role that India played during the AIDS pandemic and what Bangladesh can do in the COVID-19 pandemic, see Chaudhuri 2020.


For an account of how India developed the pharmaceutical industry, see Chaudhuri 2005, chapters 2 and 4.

Interview with the Chairman of a company on 5 March, 2019 in Dhaka.
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