

WTO TRIPS Agreement- Current state of Pharmaceutical Industry and Policy Options for Bangladesh

Abstract

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires adoption of a minimum patent standard for all countries. It is often argued by developing countries that the introduction of a uniform (and minimum) patent standard for all countries irrespective of their level of development would prevent people from access to medicines. Moreover, in developing countries, the drug expenses are being paid out of pockets by the patients unlike developed countries where insurance companies bear the burden. In this regard an empirical study was conducted on pharmaceutical stakeholders consisting of leading pharmaceutical companies, drug administration of Bangladesh (the regulatory authority), leading experts on industrial pharmacy, academics and leaders of Bangladesh Association of Pharmaceutical Industries. The study finds that price of medicines will go up and access to health will be denied once Bangladesh enters the patent regime. The perceived impact on the industry however is mixed. The paper concludes with some policy considerations that the government and the industry should consider to ensuring that the patients have access to medicines at an affordable price.

Keywords: Patent, Compulsory Licensing, Drug, Parallel Importation, Active Pharmaceutical Ingredient (API), TRIPS

1. Introduction

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) entered into force on 1 January 1995. The introduction of the TRIPS Agreement has created immense debate among different stakeholders regarding its perceived consequences on several sectors especially on pharmaceutical and agriculture¹ sector. The debate mostly centred on its perceived severe consequences on people's access to medicines in developing countries (in the WTO parlance developing country also includes LDCs). Although there is a growing literature on the perceived consequences of TRIPS Agreement on access to health and pharmaceutical industry, no study has yet been done on Bangladesh. Bangladesh is a densely populated LDC country with strong pharmaceutical manufacturing base. It is therefore important to assess how the patent regime for medicine is going to impact both the access to health as well as the pharmaceutical industry in Bangladesh. This paper examines how the TRIPS agreement is going to impact people's access to health. This paper also attempts to assess the perceived consequences of the Agreement on the sustainability of the pharmaceutical companies as the sector has been performing reasonably well before the implementation of the patent regime.

This paper is organized in four sections. Section 2 provides a brief description of the TRIPS Agreement. Section 3 details Bangladesh Pharmaceutical Industry. Section 4 explains the methodology. In Section 5 are the findings and suggested policy options. The paper ends with a conclusion in Section 6.

2. The TRIPS Agreement

The agreement on Trade-Related Aspects of Intellectual Property Rights sets out the *minimum standards* of protection for Intellectual property(IP) areas such as copyrights, patents, trademarks, geographical indications, industrial designs, and undisclosed information etc. to be provided by each member. The agreement requires all WTO Members with few exceptions, to provide 20-year patents for any inventions, whether products or processes, in all fields of technology (including pharmaceuticals) without discrimination as to the place of invention, subject to the normal tests of novelty, inventiveness, and industrial applicability (Agreement on TRIPS: Article 27.1, Article 33). It is a minimum standard agreement as it allows members to provide more extensive protection of intellectual property if they so wish.

The TRIPS Agreement extends the scope of patent protection to both products and processes. Before TRIPS Agreement, many countries did provide only process- but not product patents. Product patent provide for absolute protection of the product, whereas process patents provide protection in respect of the technology and the process (method) of manufacture.

TRIPS - An Uneven Agreement!

Under TRIPS Agreement, both developed and developing countries are required to provide patent protection for all areas of IP although they are not at the similar level of development. The income levels of developing countries are much lower than that of developed countries. For example, (as shown in table 1) the major industrial countries (SL 1-4) adopted strong patent protection at high levels of real income (e.g., Japan’s GDP per capita \$24,043, Switzerland \$ 36,965), whereas, developing countries (SL 5-8) will be required to adopt similar standards at much lower income levels (e.g., Pakistan GDP per capita \$ 508) under the said agreement (Subramanian, 2004).

Table 1 Development level on adoption of pharmaceutical product patents

| | Year of adoption | GDP per capita |
|-------------|------------------|----------------|
| Japan | 1976 | 24043 |
| Switzerland | 1977 | 36965 |
| Denmark | 1983 | 28010 |
| Sweden | 1978 | 21896 |
| Canada | 1983 | 16296 |
| Brazil | 1996 | 4482 |
| Pakistan | 2005 | 508 |
| India | 2005 | 450 |
| China | 1992/93 | \$424 |
| Bangladesh | Future | \$435 |

Source: Lanjouw, J.(2002), “Intellectual Property and the Availability of pharmaceuticals in Poor Countries,” *Centre for Global Development Working Paper No. 5*, Washington Centre for Global Development in Subramanian,2004 and Bangladesh Bank.

(<http://www.cgdev.org/content/publications/detail/2785/>)

The above illustration confirms that TRIPS agreement requires providing patent irrespective of the level of GDP per capita. This creates an uneven playing field for developing countries. Furthermore, a large percentage of developing country population does not have access to medical insurance and more often than not pay for drugs themselves (WHO, 2001 in Cullet, 2003). Mazhar (2005) criticized the TRIPS agreement noting that 'the TRIPS agreement grants monopoly rights without having legislation to bound monopolies.

The Rationale for Patents

Intellectual property rights are justified on the ground that it would provide necessary incentives for research and technology development. Through patents, the inventor(s) is (are) given a time bound monopoly. This time bound monopoly gives the inventor the exclusive right to exploit the invention and prevent others from using the invention without his consent. Rewarding the inventor is the main rationale of patent system. This time bound monopoly is derogation from the concept of free trade. The proponents of the patent system argue that Pharmaceutical industry spends huge expenditures on R & D than any other industry. The patent system allows the inventor firms to charge prices more than the marginal cost of production and distribution of drugs. The monopoly right given by the patent and the scope to charge higher price than the marginal cost allows inventors/inventor firms to recoup the cost of developing the drug.

The developing countries view the patent regime from a different perspective. On public health ground a number of countries provided no patent protection or partial patent protection for pharmaceutical products before the Uruguay Round on the ground that health sector is concerned with basic need and therefore should be protected from full commercialization. India is a glaring example who vehemently endorsed this view. India did not recognize product patents on pharmaceuticals until very recent pastⁱⁱ(Cullet,2003).

Hughes, Moore, and Snyder (2002), in their paper titled "Napsterizing" argue that in the short term, consumers would be much better off if patents on drugs are eliminated, thereby allowing drug price to lower by increasing competition with generic products; however, in the long run we would all be worse off. This is because with lower revenues, pharmaceutical companies would not be able to dedicate much money into the research and development that is critical for the development of new products. So gradually the development of new drugs would decline, and fewer new life-saving and life-enhancing treatments would be available to future generations (Hughes, Moore, and Snyder, 2002 in Werhane & Gorman, 2005). Despite all these arguments in favour of intellectual property rights, the TRIPS Agreement has been subjected to severe criticism especially regarding its potential impact on medicine and access to health.

Concerns with TRIPS Agreement

Before the TRIPS agreement came into being, different countries could implement different systems to protect IP depending on their level of development. This allowed a number of countries not to have patents in any form for drug whereas many others dispensed only with patenting for therapeutic molecules in their IP laws. In this historical context of IP protection, the advent of TRIPS requiring uniform minimum standard for all countries, irrespective of their economic gap, has created antagonisms between developed and developing countries during Uruguay Round of negotiations. The main issue identified that created the debate between industrialized and developing countries was the perceived impact of the TRIPS Agreement on public health especially access to the generic drugs at low costs in developing countries. Developing countries argue that once they become TRIPS compliant, production of generic

drugs will be prohibited and price will go up. The debate, most often centred on the high price of HIV/AIDS treatmentⁱⁱⁱ thereby rendering HIV treatment impossible in southern countries where no health insurance system exists and patients have to pay out of pocket for medicines. The concerns that were raised about the implications of the TRIPS Agreement on public health were reflected in the adoption, upon the initiative of developing countries, of the "Doha Declaration on the TRIPS Agreement and Public Health" at the Fourth WTO Ministerial Conference (November 9-14, 2001). Recognizing the severity of the public health problems afflicting many developing and least-developed countries ("LDCs"), especially—but not limited to—those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics, the Declaration clearly states –“ the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all(Correa,2004)Another concern with patenting is the attempt by patent holder to “evergreen” the patent. Pharmaceutical companies sometimes apply to patent the new form of an old drug (known as ‘evergreening’^{iv}) and thus extending the life of a patent. In 2006, Chennai Patents Office rejected an application of Novartis for patenting a drug (Imatinib Mesylate under the brand name of Glivec)on the ground of evergreening. Novartis also lost the case challenging Chennai Patents Office decision in Chennai High Court (Srinivason, 2007)

Does Intellectual Property (IP) Stimulate Development of Drugs Related to the Needs of the Poor?

The argument in favour of patent protection is that it provides incentives to inventors/private firms to undertake more Research and Development (R &D) in developing drugs for diseases more common in developing countries (Agarwal & Saibaba, 2001). This rationale of patent is often seen with scepticism on the ground that it is uncertain whether the redistribution of resources to the inventors/private sector firms actually results in development of more drugs for diseases more common in poor countries. This scepticism gets support from historical findings of WHO (World Health Organization) “of the 1223 new chemical entities developed between 1975 and 1996, only 11 were for the treatment of tropical diseases” (Cullet, 2003). In fact, patent does not stimulate R & D for development of drugs for poor people; rather firms concentrate on drugs that have got a big market. In this regard, it is important to cite the observation of the Commission on Intellectual Property Rights (CIPR)- ‘ all the evidence examined concerning the role that intellectual property protection plays in stimulating R & D on diseases prevalent in developing countries suggests that it hardly plays any role at all, except for those diseases where there is a large market in the developed world’(CIPR, 2002).

Flexibilities and Exceptions to Exclusive Patent Rights

The developing countries argue against TRIPS stating that the agreement is concerned mainly with the interests of IP right holders and ignores the needs of the poor people. A lot of debate was going on regarding the issue of access to medicines at affordable price, especially for the poor countries. On this issue, world renowned NGOs and donor organizations like Oxfam, USAID, TWN etc. started making lot of noise. They came up with arguments that due to TRIPS, price of necessary drugs will go up and access to medicines at affordable price will be at stake (Hasan, 2006). The strong opposition from developing countries as well as the controversies at the theoretical and practical levels regarding TRIPS led the policy makers to think for alternatives. As a result, in Year 2002, after lot of debate, the ‘*Doha Declaration*’ on TRIPS and Public Health (adopted at the Doha Ministerial meeting of the WTO in November 2001) came in to being.

The Declaration unambiguously states that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health”. According to the Paragraph 6 of Doha Declaration, all the LDCs were exempted from ‘Pharmaceutical Patent Protection’ until 1 January 2016. Article 66.1 also provides for the extensions of the transition period for LDCs upon request. Article 1.1 of the Agreement grants members the freedom to determine the “appropriate method of implementing the provisions of the TRIPS Agreement within their own legal system and practice.”

The Agreement also contains some exceptions to exclusive patent rights. Article 27.2 allows countries to restrict the patentability of inventions, if they pose a threat to human life or health. Article 30 permits Members to limit the exclusive privilege granted through patent rights. These general exceptions provided by article 27.2 and 30 are supplemented by article 31 which sets out regulatory framework to issue compulsory licensing (CL). Member States can allow CL on a case by case basis and subject to other conditions laid down in the agreement. WTO Members have the right to determine the grounds for the grant of compulsory licences (CL). Initially CL was restricted to producing pharmaceuticals ‘predominantly for the supply of the domestic market’(Article 31f). Members with insufficient or no manufacturing capacities in the pharmaceutical sector could not use CL as import was not permitted under CL and they could not resort to importation. Realizing this difficulty with CL, the General Council, on 30 August, 2003 waived the restrictions on export. After this interim waiver decision, a member is eligible to produce and export to eligible importing member^v(s). WTO members on 6 December 2005 approved changes to the WTO TRIPS Agreement making permanent the decision (the waiver of Article 31f) on patents and public health originally adopted in 2003. This will now be formally built into the TRIPS Agreement when two thirds of the WTO’s members have accepted the change.

Any WTO members (including the developed countries) may grant a CL to its domestic manufacturer to produce and export to the ‘eligible importing country’ under the scheme. The issuance of CL thus shall open the door to competition from generic pharmaceutical manufacturers (Fink, 2005). The person or agency obtaining the CL needs to pay compensation to the patent holder.

CL is a good weapon for developing countries to source cheaper generics. Some developing countries have successfully used the threat of resorting to such licence as a negotiating token in view of obtaining significant price cuts on essential drugs or voluntary licences(Eeckhaute,2002). There are evidences that issuance of CL to import generic drugs^{vi} resulted in drug price to drop. For example, in February, 2004, the Ministry of Health, Malaysia issued a contract to a local Malaysian company to import generic Zidovudine, Didanosine and a combination of Lamivudine and Zidovudine from Cipla(India). As a result, the average cost of Malaysian Ministry of Health(MOH) treatment per month per patient dropped from USD 315 to USD 58, equivalent to about an 81% reduction, when generic drugs were used. Patent holders also dropped their own prices when the government exercise its right of government use. This is evident from the table 2.

Table 2: Price Reduction Resulting from Issuance of CL.

| | 2001 prices(USD) | 2004 prices(USD) | % drop in price |
|--------------------------|------------------|------------------|-----------------|
| Combivir (60 tablets) | 286.28 | 57.99 | 80% |
| AZT(100 tablets) | 77.58 | 36.08 | 53% |
| 3TC(60 tablets) | 141.75 | 46.39 | 67% |

(Source: Ling, 2005 cited in Smith, 2005)

The Agreement also allows Members to authorize use for public non-commercial purposes (government use) without the authorization of the patent owner. WTO Members are also free to establish its own regime of exhaustion (national or international) of IP rights. This means that Members can adopt international exhaustion in their patent act with a view to allowing parallel importation of patented goods that have been put on a third market by the patent holder or with his authorization(Eeckhaute,2002). These flexibilities and exceptions could be good alternatives for countries that are in need of medicines at affordable price.

To assess the perceived impact/consequences of the TRIPS Agreement on Bangladesh, it is pertinent to present a brief picture of the present state of Bangladesh Pharmaceutical Industry. The next section depicts a brief sketch of Bangladesh Pharmaceutical Industry.

3. Bangladesh Pharmaceutical Industry

Before 1982, Bangladesh was largely dependent on imported raw materials/API and finished products. The local production was dominated mostly by multinational companies (eight MNCs) who produced about 75% of the value of production. The national Drug Policy (NDP) i.e. Drug Control (Ordinance) 1982 aimed to remove medicines considered harmful, useless and unnecessary from the market (by banning 1707 brands) and ensure supply of essential drugs of all levels at affordable price helped national companies increase their market share from 35 in 1981 to 60 percent in 1990 and by 1991 the top three firms in terms of sales were from locally owned (Rovira, 2004; Islam & Faroque, 2007). Pharmaceutical industry has grown in the last two decades at a considerable rate. At present the size of the industry is estimated to be US\$482 million. With an annual growth rate of about 10%, Bangladesh Pharmaceutical Industry is now heading towards self-sufficiency in meeting the local demand..Bangladesh Pharmaceutical industry is now the largest white-collar intensive employment sector of the country (Hassan, 2005). At present 225 registered pharmaceutical companies are operating in the pharmaceutical sector (Smith, 2005; Shafiuzzaman, 2005). Out of this about 200 have their own manufacturing facilities of which 5 are multinationals (Chowdhury,2005).Pharmaceutical manufacturers in Bangladesh together now produce 95% of the demand for the country (Smith, 2005, Yusuf 2006). Bangladesh lacks capacity in producing APIs(Yusuf,2006a) and the industry depends on the imports (of raw materials, API and Machinery) from India, China, UK and few other European countries(Rovira,2004).

Bangladeshi pharmaceutical companies produce only 15 Active Pharmaceutical Ingredients (API) The market size of the market amount to US\$520 million with double digit growth rate The pharmaceutical manufacturers of Bangladesh exports pharmaceutical products(such as all major therapeutic classes and dosage forms like Tablets, Capsules & Syrups and specialized products like Inhalers, Suppositories, Nasal Sprays, Injectables and Infusions) to 62 countries in the world(Hassan,2006). The major pharmaceutical companies in Bangladesh comply with WHO cGMP (Current Good Manufacturing Practice). With an aim to enter the regulated markets

like US, EU countries, they are putting up manufacturing facilities of US FDA (Food and Drug Administration) and UK MHRA standards (Chowdhury, 2005)

The pharmaceutical industry is however, beset with some problems. The Directorate of Drug Administration is not adequately equipped with expert manpower to carry its monitoring role functions (The Daily Ittefaq, February 2, 2006) effectively. The drug testing laboratories (one in Dhaka and other in Chittagong) are not well equipped to carry out drug testing functions. Moreover there is no independent drug testing laboratory. The most important bottleneck lies in the absence of bio-equivalence test laboratory (Rahman ,Drug Administration, 2006). Availability of substandard medicines said to produce by unlicensed companies (*The Daily Inqilab*, 18 February, 2006) is a matter of great concern for the regulatory authority and a threat to human health.

4. Methodology

This paper is based on both primary and secondary data. The primary data is based on interview findings. Pharmaceutical owners and senior level executives of 10 renowned pharmaceutical companies of Bangladesh were selected using the industry database in Bangladesh. In addition to the pharmaceutical owners and executives, the director of the Drug Administration of Bangladesh(the regulator), two academics from the pharmacy department of the University of Dhaka and two key leaders of the Association of Bangladesh Pharmaceutical Industry were also selected. The academics were selected considering their academic background and linkage with the pharmaceutical industry. The drug regulator has been selected considering his official policy making position and long experience as an academic. Before conducting the interview, the researcher(s) contacted the CEOs/directors of pharmaceutical companies, the drug regulator, concerned academics and industry leaders, explained the study and gained their consent . Timing of interview was fixed by mutual discussion that best suits the interviewee. A face to face interview was conducted using a questionnaire (arranged like a likert scale- table 1) among leading 10 pharmaceutical companies, drug regulator, industry leaders and academics. Table 1 summarizes the responses found through interview survey which focused on the consequences of TRIPS, state of Bangladesh pharmaceutical industry and policy options for the industry as well the government. Follow up interviews were conducted over telephone to clarify policy and trade issues. Secondary materials were extensively used to identify critical factors affecting the pharmaceutical industry in developing countries and to use those factors to construct an analytical framework for the study. The sources of secondary data include published articles from various journals, working papers, WTO website, published interviews, TWN (Third World Network) briefing paper, conference papers on TRIPS, newspapers and other e-sources.

Table 1

Stakeholders' Perception about impact of TRIPS Agreement on Bangladesh

| | Strongly agree | Agree | Not sure | Disagree | Strongly disagree |
|----------------------|----------------|-------|----------|----------|-------------------|
| | % | % | % | % | % |
| a. Implementation of | 10 | 70 | 10 | 10 | 0 |

| | | | | | |
|---|----|----|----|----|----|
| TRIPS agreement will result in significant price increase of medicine | | | | | |
| b. TRIPS gives Bangladesh a unique opportunity to capitalize by exporting medicines to eligible importing countries during the transition period of upto 1.1.2016 | 10 | 70 | 10 | 10 | 0 |
| c. Small pharmaceutical companies will face difficult situation in the patent regime | 20 | 70 | 10 | 0 | 0 |
| d. Bangladesh does have the research capacity to produce raw materials for drugs | 0 | 20 | 0 | 70 | 10 |
| e. Bangladesh Pharmaceutical industry needs to invest in R & D | 70 | 30 | 0 | 0 | 0 |
| f. Pharmaceutical companies should form joint collaboration with global companies to benefit from their skills, R & D and enjoy synergy | 10 | 50 | 20 | 20 | 0 |
| g. To face the challenge of post 2016 challenge i.e. patent regime Challenge, Bangladesh have enough preparation | 0 | 10 | 0 | 30 | 60 |

4. Findings /Perceived Consequences of TRIPS Agreement on access to medicine and on the industry

The situation for Bangladesh pharmaceutical industry as well as for drug consumers is expected to change after 1.1.2016 when Bangladesh would enter the patent regime. In this regard,

VanDuzer (2003) told in a seminar that implementation of TRIPS mean that prices will increase, generic drug producers will be hurt, and the access to medicines will be impeded.. Moreover, once TRIPS become mandatory for all countries, export market of Bangladesh pharmaceutical producers will be confined to eligible importing countries only.

Historically, developing country consumers had to pay higher prices for patented goods than generic alternatives. For example, the US price of 3TC (Lamivudine) marketed by Glaxo is USD 3,271 (per patient per year) whilst Indian generic manufacturers, Cipla Ltd. and Hetero Drugs Limited, offer their generic versions for USD190 and USD98, respectively (TWN, 2001). Where alternative medicines are available, a branded product is usually sold at lower price than the price the same brand will sell in countries where there is no competition. The same brand Zantac was sold cheaply in India (\$2 for 100 tablets) as there it faced competition from generics. It was sold \$3 in Nepal, \$9 in Bangladesh, \$30 in Vietnam, \$37 in Thailand, \$61 in Sri Lanka and \$183 in Mongolia, \$ 23 in Australia, \$77 in Canada and \$150 in South Africa(Health Action International 1998). The similar sort of consequences is widely perceived in the case of Bangladesh. 80% of the respondents interviewed told that price of medicines would go up (although they could not tell the extent of price rise precisely) once TRIPS Agreement is implemented. 10% interviewee could not tell what would happen on price once the country would enter the patent regime. It is easy to understand that 20 years of monopoly (article 33) over a pharmaceutical product would enable the right holder to charge higher price for medicines during the patent period as generic equivalents would not be able to come to the market.

Of the respondents, 80% told that the transition period of up to 1 January 2016^{vii}, for LDCs in providing patent protection for pharmaceuticals comes as a blessing in disguise for Bangladesh. During this time, Bangladesh (as an LDC) would be able to freely manufacture and sell patented drugs(patented elsewhere) in its domestic market as well as export more to ‘eligible importing Member^{viii}’ because among LDCs,she has the strongest manufacturing capability to produce drugs. There are as good as 16 LDCs (Annexure 1 List of 16 LDCs) which do not have any pharmaceutical manufacturing capabilities where others have very limited or insufficient manufacturing capabilities (Annex-2 Import based countries). This holds out opportunities for the pharmaceutical manufacturers of Bangladesh to capitalize the post 2005 opportunities through exporting drugs to these countries. Realizing this opportunity, several leading Indian generic drug manufacturers are considering relocating their operations to Bangladesh to take advantage of the least developed country status and benefit from associated longer transitional periods that Bangladesh enjoys (Matthews, 2004). It is reasonably expected that in the absence of any competition from India and China, Bangladesh Pharmaceutical Industry will be able to sell the patented products to the LDCs at a price which could be 50% of the originator brand (Hassan, 2005) and strengthen its foothold in LDC markets.

This export potential is not without uncertainly. In Hassan’s view, “post 2004 scenario is not at all that clear. We are still not sure which products India cannot produce after 2004. Moreover, a lot will depend on their capability to produce bulk drugs for products which will be under patent regime during that time” (Hassan, 2004). However, one important risk is associated with this transition process. If Bangladesh is graduated from LDC to developing country group before 2016, all the TRIPS flexibilities allowed for LDCs will disappear. Most respondents stated that Bangladesh does not have research capacity and ability to produce raw materials/molecules for drugs.

Most respondents opins that Bangladesh lacks R & D to produce raw materials for medicines and therefore, the industry should invest in R & D.Although Bangladesh manufactures 95 percent of its total demand for formulation products, its bulk industry (also known as molecules/API) is still in its infancy. For API and excipients, Bangladesh heavily depends on imported ones. It is estimated that at least 80 percent of total demand for pharmaceutical raw materials come from

abroad. Bangladesh source most of its raw materials/API mostly from India and China. With the introduction of patent for pharmaceutical product in these source countries (developing countries were to put patent regime in place since 2005), the price of these bulk drugs/raw materials will naturally go up as royalty for patent use adds up to the cost of molecules/APIs. This will enhance the manufacturing cost of pharmaceutical producers leading to an erosion of their competitiveness in the world market. This might also result in reduced turnover resulting from enhanced price of drugs.

The majority (90%) respondents opined that the patent regime would especially put the smaller pharmaceutical companies in great disadvantageous position who are unable to conform to the cGMP standards and depend mostly on generic drugs. They are not expected to get toll or licence manufacturing order from renowned drug companies which has been allowed in the Bangladesh National Drug Policy, 2005.

The perceived impact from the empirical study shows that access to medicines would be expensive and be somehow impeded. The perceived impact on the industry is however mixed. The pharmaceutical companies have got the unique opportunity to increase their exports to eligible importing countries during the transition period of upto January 1,2016. However, the small pharmaceutical companies might face difficult situation once the country enters the mandatory patent regime under WTO TRIPS agreement. The study also reveals that the pharmaceutical companies should form joint collaboration with global companies to benefit from their skills and technology. One concern for the industry is that Bangladesh lacks enough preparation to face the post- 2016 challenges.

Policy Options to Facilitate Better Access to Medicines

There is important rationale behind TRIPS Agreement. It is also largely held view that the patent regime would result in increased drug price. To strike a balance between access to medicine and incentives for innovators, TRIPS Agreement contains some alternatives and exceptions that Members are allowed to exploit. The following are some important policy options for Bangladesh to ensure access to health at affordable price.

Amendment of the Patent Law

Although, Bangladesh has been exempted from pharmaceutical patent up to 2016, its existing patent act provides provision for pharmaceutical patents. It is therefore necessary to amend the national patent law to make it WTO compliant incorporating all TRIPS agreement flexibilities and safeguards. The patent laws should enable the country to provide CL, government use orders and parallel importing in simple and effective ways. The existing Patent Act provides for compulsory licensing but it needs to be amended in line with the TRIPS conditions These flexibilities and associated requirements to exploit them are shown Table 3.

Table 3: Flexibilities and Associated Requirements

| Policy measure | | Requirements |
|-----------------------------|--|---|
| <i>1.Importing the drug</i> | | |
| a.Compulsory licensing (CL) | A country can import generic version of the patented product by issuing a CL. Member states have the freedom to determine the grounds(except in the case of semi-conductor technology) upon which such licences are given. The | The applicant has to firstly negotiate to obtain a voluntary licence from the patent holder, and if that fails, then a CL can be granted. Adequate compensation has to be paid to |

| | | |
|--------------------------------------|--|--|
| | imported drug can be from a country where the drug is not patented or in which the drug is patented(in which case the exporting country has also to issue a CL) (Srinivas,2003) | the patent holder. |
| b. Government use | A generic version of the patented drug can also be imported for 'public, non-commercial use' by the government. This is designed and facilitating the government to use the imported drug. | Under this 'government use' procedure, the prior consent of or negotiations with the patent holder are not required, but adequate compensation has to be paid. |
| c.Parallel importation ^{ix} | Patented product (not the generic version) can be imported form another country where the same patented product is being sold at a lower price than in the importing country. This is allowed under Article 6 of the TRIPS Agreement on exhaustion of rights. Doha declaration affirms this by stating that each WTO member is 'free to establish its own regime for such exhaustion without challenge.' | There is no need for an importer to obtain a CL or pay compensation to the patent holder. |
| <i>Local Manufacture of Generics</i> | | |
| a. Compulsory licensing | If a drug is patented in a country, generic version of the drug can be locally manufactured by a local company or by an agency (including government agency) that has been granted CL by the government. | The applicant has to negotiate to obtain a voluntary licence from the patent holder, and if that fails, then a CL can be granted. This requirement, however, does not apply if the CL is issued on grounds of public non commercial use, for national emergency or to remedy anticompetitive practices. Compensation has to be paid. |
| b.Government use | The government can assign to a public or private agency the right to locally manufacture a patented product without the consent of the patent holder, provided the drugs are used for a public non-commercial purpose | The prior consent or negotiation with the patent holder is not required. Compensation has to be paid. |
| <i>Exporting</i> | A local producer of generic version of patented drugs under a CL or government-use provision may export of its output to countries with no or inadequate manufacturing capacity. | The importing country has to notify the WTO of the quantities of the drug required, confirm it has insufficient or no manufacturing capacities and that it intends to grant a CL. It also has to prevent re-exportation of the patented products. |

(Adapted from Smith, 2005)

Investment in R & D

In Bangladesh, universities lack R & D facility to support for pharmaceutical industry. In India and China, some selected universities are involved in pharmaceutical R & D. Bangladesh needs to invest in R & D for reverse-engineering of patented drugs. Investment in R & D facilities would also enable the pharmaceutical sector to develop its own molecule/API once the transition period is over. Leading pharmaceutical companies could explore this R & D facility. However research process for new drugs is not advisable for smaller companies as it is very expensive to develop new drugs. The estimated total capitalized R & D costs per new drug is US \$802 million to develop (and the out of pocket cost per approved new drug is US\$403 million) while the corresponding generic costs less than \$2 million (DiMasi, Hansen & Grabowski, 2003; Rahim, 2006). Development time for a new drug averages over 15 years (Rahim, 2006). The smaller companies could explore the possibility of forming consortium with the leading pharmaceutical companies to exploit the R & D result of renowned big companies and gain synergy from the joint collaboration (Rahman, 2006 personal interview)

Upgrade of the Pharmaceutical Sector

The pharmaceutical industry of Bangladesh needs to be upgraded in all respects including proper documentation, bioequivalence laboratory facility, strict compliance with the requirement of the cGMP, capacity building to produce API, quality control and proper supervision by regulatory authority. Establishment of bio-equivalence facility and conforming to cGMP would help the industry to enter into more regulated drug markets abroad (Rahman in an interview on January 1, 2006). Other developing countries with inadequate or no manufacturing capacities could resort to CL and Parallel Importation to provide access to medicines at reasonable price.

6. Conclusion

The Doha Declaration and the subsequent amendment of the TRIPS agreement has made the Agreement more balanced and acceptable. Bringing the amendment to article 31(f) of the Agreement and through Doha Declaration, the TRIPS Council has done a paramount job (Eeckhaute, 2002). Now it is up to Bangladesh and other developing countries to make use of the flexibilities and exceptions to their advantage to help access to medicine in the short term. This would require necessary regulatory changes to make the national patent Act WTO compliant. Moreover, Bangladesh needs to make long term strategic decisions to develop pharmaceutical manufacturing base through drug discovery/R&D. The other option is to make strategic alliance with renowned pharmaceutical companies as CL and parallel importations are not permanent solutions. As the pharmaceutical sector of Bangladesh suffers from some structural weaknesses (such as inability to produce drug molecules/API) and resource constraints to invest in R&D to develop new drugs, there is no substitute but to strengthen the technological, economic and commercial development of the sector through transfer of technology in alliance with highly technology driven successful companies.

Since the study has mainly focused on the stakeholders' perception in regard to the access to medicine and sustainability of the pharmaceutical sector after 2016, the actual consequences will depend on how the government formulates policy to face the challenges of patent regime. In this context it can also be said that the sustainability of the pharmaceutical industry will also depend on how competition under the TRIPS conditionality evolves.

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Annexure -1 : LDCs with no pharmaceutical Manufacturing Base

1. Bhutan
2. Burkina-Faso
3. Burundi
4. Central African Rep
5. Chad
6. Comoros
7. Djibouti
8. Equatorial Guinea
9. Guinea
10. Guinea-Bissau
11. Maldives
12. Mauritania
13. Rwanda
14. Sao Tome & Principe
15. Senegal
16. Togo

Annexure2: Pharmaceutical Import based Countries(with very limited or insufficient manufacturing capabilities)

1. Afghanistan
2. Benin
3. Cambodia
4. Ethiopia
5. Lao People's DR
6. Liberia
7. Malawi
8. Mozambique
9. Myanmar
10. Nepal
11. Sierra Leone
12. Somalia
13. Sudan
14. Uganda
15. Yemen
16. Zambia
17. Kenya(Non LDC)
18. Sri Lanka(Non LDC)
19. Tanzania(Non LDC)
20. Vietnam(Non LDC)

(Source; Hassan, 2006)

ⁱ In the agriculture sector, there are growing opposition in the developing countries to the granting of IPRs for agricultural crops. Concerns of developing countries include environmental safety and food security (Ganakas, 2002). Moreover, there are also concerns regarding the restrictions on farmers' right to save, use, exchange and sell farm saved seeds (article 27.3b of the TRIPS agreement requires protection of plant variety. There is direct and indirect pressure on the developing and least developed countries (LDCs) to establish UPOV-like plant variety protection regimes that are designed to protect the interest of corporate plant breeders, and not farmers. Since farmers traditionally re-use the seed from their harvests, they are considered direct competitors of breeders who develop plant varieties for commercial interests and then seek legal protection for the exclusive market exploitation of their varieties. Such a regime takes away the traditional and community-centred control over seed conservation and use, which has been the regular practice of farming communities in developing countries (*the Hindu Business Line*, March 12, 2004). As a legal agreement, TRIPS creates a system of proprietary knowledge enforceable to a greater or lesser degree worldwide, expanding the site of surplus extraction in agriculture by restricting the traditional right of farmers to save seed. As a result of the dual nature of seed/grain as both means of production and product, after purchasing one generation of seed, farmers are subsequently able to propagate open-pollinated seed for many seasons without any significant loss of yield potential or characteristics. The restrictions on the use of seeds(although modern varieties of seeds are built upon the efforts of farmers whose knowledge and work is embodied in the seed) and the commodification of seeds thereof through TRIPS (27.3b) would invariably undermine the informal seed networks, the most important source of seed for small-scale farmers who produce the majority of food consumed in the region, by making it more difficult and expensive for farmers to save seed, and making it illegal to trade seed with neighbours. Given the importance of informal seed networks in southern Africa, any attempt to undermine traditional practices of saving and exchanging seed therefore represents a serious threat to regional, national and local food security(Zerbe,2001)

ⁱⁱ See India Patents Act, 1970.

ⁱⁱⁱ For example, before generic antiretroviral (ARVs) came into the market, the price of highly active ARV therapy was around US \$ 10,000 to US \$ 12,000 per person per year.

^{iv} 'Evergreening' is the process of interminably extending the life of a patent- 20 years as per Indian Patent law for drugs - by inventing new uses, indications or even dosages and/or by trivially modifying the structure of the drug' (Srinivas,2007 p.3688)

^v "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer(WTO website)

^{vi} A generic drug is a non-branded copy of a branded drug, and is supposed to be an identical, or 'bio-equivalent' copy. It is allowed to be produced and marketed after the brand name drug's patent expired or in circumstances where the drug patent does not apply (e.g. the exception to exclusive rights via a compulsory licence), or has been waived by the patent holder.

^{vii} After the inclusion of Doha Declaration in TRIPS Agreement (Article 66 and the associated extension of the deadline in the Doha Declaration on the TRIPS Agreement and public Health), LDC countries now under no obligation to provide for pharmaceutical product patent until 1.1.2016.

^{viii} 'Eligible Importing Member' means any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer.

^{ix} Parallel importation refers to the importation and resale in a country, without the consent of the patent holder, of a patented product that has been legally marketed in the exporting country, thus allowing one to "shop around" for a good price and enabling competition (Reinhardt, 2006)