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Pharmaceutical Patent Protection and Trips Challenges for Bangladesh: An Appraisal of Bangladesh's Patent Office and Department of Drug Administration

Abstract

This paper examines the TRIPS Agreement as it applies to Bangladesh in the context of pharmaceutical patents. An important aspect of the Agreement is ensuring that the regulatory agencies are ready and able to apply and interpret the new intellectual property regime that will be required by TRIPS. An appraisal of the capacity of Bangladesh's regulatory agencies, particularly the Department of Patent Design and Trademarks and the Directorate of Drug Administration, becomes even more important as Bangladesh is required to have a TRIPS compliant patent regime for the pharmaceutical sector from 1 January 2016.

Keywords

Bangladesh, TRIPS challenges, pharmaceutical patent protection

PHARMACEUTICAL PATENT PROTECTION AND TRIPS CHALLENGES FOR BANGLADESH: AN APPRAISAL OF BANGLADESH'S PATENT OFFICE AND DEPARTMENT OF DRUG ADMINISTRATION

MOHAMMAD MONIRUL AZAM* AND KRISTY RICHARDSON**

Abstract

This paper examines the TRIPS Agreement as it applies to Bangladesh in the context of pharmaceutical patents. An important aspect of the Agreement is ensuring that the regulatory agencies are ready and able to apply and interpret the new intellectual property regime that will be required by TRIPS. An appraisal of the capacity of Bangladesh's regulatory agencies, particularly the Department of Patent Design and Trademarks and the Directorate of Drug Administration, becomes even more important as Bangladesh is required to have a TRIPS compliant patent regime for the pharmaceutical sector from 1 January 2016.

Introduction

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) which is binding on all members of the World Trade Organization (WTO) aims at establishing strong minimum standards for intellectual property rights (IPRs) including patent protection for pharmaceuticals. As John E Giust has observed, 'intellectual property is now a key component of the multilateral trading system, the protection of intellectual property is one of the three pillars of the WTO, the other two being trade in goods (the area traditionally covered by the General Agreement on Tariffs and Trade (GATT)) and the Agreement on Trade in Services'.¹ Developing and Least Developed Countries (LDCs) are apprehensive of strong patent protection on the basis that such patent protection may be harmful to their nascent pharmaceutical industries and for the access to affordable medicines to their populations. To address these concerns the Doha Declaration, which was adopted by

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¹ John E. Giust, 'Non-compliance with TRIPs by Developed and Developing Countries: Is TRIPs Working?' (1997) *Indiana International and Comparative Law Review* 2.

the WTO Ministerial Conference, in Doha on 14 November 2001 further extended the transitional period for LDCs to introduce pharmaceutical patent protection to 1 January 2016. In implementing the TRIPS compliant patent regime in the pharmaceutical sector much will rest with Bangladesh's regulatory agencies; particularly the Department of Patent Design and Trademarks and the Directorate of Drug Administration. This paper explores the capacity of those regulatory agencies in anticipation of the changes to Bangladesh's intellectual property regime for 1 January 2016.

Trips: Background

The TRIPS Agreement was the brainchild of an industry coalition of developed nations including the United States of America, the European Union and Japan. The main impetus for the agreement came from the pharmaceutical, software and entertainment industries with the CEO of Pfizer playing a lead role as Chairman of the Intellectual Property Rights Committee (IPC).² The Committee was created during the Uruguay Round of negotiations with the goal of putting TRIPS firmly on the agenda.³ One of the arguments advanced by the developed countries for the adoption of TRIPS was that stronger IPRs would create an incentive for innovation and would stimulate the development of new technologies, such as patent protection for pharmaceuticals. This incentive for innovation would consequently encourage greater domestic and foreign investment in research into new pharmaceuticals and tropical diseases.⁴ The argument propounded was that the foreign investments and

² Sylvia Ostry, 'Intellectual Property Protection in the WTO: Issues in the Millennium Round' *Fraser institute conference Santiago, Chile* (April 19, 1999) 3.

³ John Madely, *Hungry for Trade* (Zed Books, 1st ed, 2000) 96.

⁴ Mansfield claims that 65 percent of pharmaceuticals and 30 percent of chemical inventions would not have taken place without patent protection; See E Mansfield, 'Intellectual Property Protection, Direct Investment and Technology Transfer: Germany, Japan and the United States' (1995) *IFC Discussion Paper no 27*, The World Bank and International Finance Corporation, Washington, DC; E Mansfield, 'Patents and Innovation: An Empirical Study' (February, 1986) *Management Science*, 173-181; Other studies reaching similar conclusions include Scherer et al (1959), Taylor and Silberston (1973), Arundel and van de Paal (1995) and Cohen et al (1997); see W M Cohen, R R Nelson, and J. Walsh, 'Appropriability Conditions and Why Firms Patent and Why They Do Not in the U.S. Manufacturing Sector (1997) *Working Paper*, Carnegie Mellon University, A Arundel, and G van de Paal, 'Innovation Strategies of Europe's Largest Industrial Firms' (1995) *Unpublished Manuscript*, MERIT; Taylor, C T and Z A Silberston, 'The Economic Impact of the Patent System' (1973) Cambridge University Press, Cambridge; F M Scherer, S E Herzstein, A W Dreyfoos, W G Whitney, O J Bachman, C P Pesek, C J Scott, T G Kelly, and J J Galvin, *Patents and the*

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technology transfer would, in turn, benefit developing and least developed countries.⁵

For the first time TRIPS established a global minimum standard of IPR protection. Hence it represents a major departure from the previous level of international IPR treaties/agreements, which aimed not to standardise IPR legislation between countries, but to guarantee non-discrimination in national IP systems.⁶ It is particularly distinctive from earlier international IPR conventions/treaties/agreements in three important ways. First, TRIPS makes it mandatory for WTO members to provide existing types of IPR protection which include patents, copyright, trademarks, trade secrets, industrial designs, layout designs of integrated circuits and geographical indications.⁷ Second, it specifies the substantive content of national IPR legislation, such as the extent of coverage, terms of protection, and mechanisms of enforcement. Third, it brings national IPR legislation under the coverage of the WTO's dispute settlement procedures, which includes the option of cross-retaliation in cases of non-compliance.⁸

Corporation: A Report on Industrial Technology under Changing Public Policy (1959), Harvard University.

- ⁵ However, the evidence linking IPRs to FDI and technology transfer is mixed. See Smarzynska, B, *The Composition of Foreign Direct Investment and Protection of Intellectual Property Rights: Evidence from Transition Economies*, 48 *European Economic Review*, 2004, pp 39-62. Branstetter, L G, Fisman, R and C F Foley. *Do Stronger Intellectual Property Rights Increase International Technology Transfer? Empirical Evidence from US Firm-Level Panel Data*. *World Bank Policy Research Working Paper no. 3305*, The World Bank, 2004, Primo-Braga, C A and C Fink, *The Relationship between Intellectual Property Rights and Foreign Direct Investment* (1998) 9 *Duke Journal of Comparative and International Law* 163-188 and Maskus, K E, Dougherty, S M and A Mertha, *Intellectual Property Rights and Economic Development in China*. In Fink, C and K E Maskus (eds), *Intellectual Property and Development: Lessons from Recent Economic Research* (2005), the World Bank / Oxford University Press.
- ⁶ Earlier IPR convention like Berne Convention 1886 and Paris Convention 1883 under the auspices of the World Intellectual Property Organization (WIPO) provides some general principles regarding copyright, related rights and industrial property but lacks effective enforcement mechanisms and there are no binding guidelines for making national intellectual property laws. See Mohammad Monirul Azam, *WTO, Intellectual Property and Bangladesh* (New Warsi Book Corporation, 1st ed, 2008).
- ⁷ The exceptions are utility models and plant breeders' rights, although TRIPS members are obliged to provide some kind of effective plant variety protection.
- ⁸ J J Simons, 'Cooperation and Coercion: The Protection of Intellectual Property in Developing Countries' (1999) 11(1) *Bond Law Review* 1.

Developing countries argue that western IP regulations are unsuited to the present stage of industrial and economic development in the developing and least developed countries.⁹ It is claimed that domestic generic pharmaceutical producers in developing countries like India, Turkey and Bangladesh will be prevented from continuing the production of generic pharmaceuticals. A potential consequence of the introduction of pharmaceutical patents being that drug prices will increase and the availability of cheap pharmaceuticals for poorer populations will decrease.¹⁰ Here the apprehension of the negative consequences of patent protection for pharmaceuticals is not only applicable for the LDCs that are WTO members, but may also place non-WTO member LDCs at a disadvantage given such countries dependence on being able to import cheap generic medicines.¹¹ Relevantly, almost fifty developing countries, which were not granted patent protection for pharmaceuticals during the Uruguay round, fiercely resisted including particular pharmaceuticals under the patent protection regime and claimed that vastly higher pharmaceutical prices would be associated with such patents.¹²

Historically product patent protection has been excluded in most developed countries.¹³ Given the advent of TRIPS, the argument being mounted is that these

⁹ See Vandana Shiva, *Protect or Plunder* (Zed Books, 1st ed, 2001).

¹⁰ Ma El Farag Balat and M H Loutifi, 'The TRIPS Agreement and Developing Countries: A Legal Analysis of the Impacts of the New IPR's Law on the Pharmaceutical Industry in Egypt' (2004) 2 Web JCILI 3.

¹¹ For example, after the introduction of patent protection for pharmaceuticals in India in compliance with the TRIPS Agreement, Bhutan a non WTO member LDC, faced problems with respect to the availability of affordable pharmaceuticals. See Dr. Tandi Dorji, 'Effects of TRIPS on Pricing, Affordability and Access to Essential Medicines in Bhutan' [2006] *Journal of Bhutan Studies*, 128.

¹² Jane O Lanjouw, 'The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?' [1997] Yale University and the NBER, Working Paper no 6366, 2.

¹³ The following countries are provided by way of example. In France product patent protection was prohibited under the law of 5 July 1844 and limited patent protection has been permitted since 2 January 1966. In Germany product patents were explicitly excluded under the law of 25 May 1877 but were then introduced from 4 September 1967. In Switzerland, product patents for pharmaceuticals were explicitly prohibited by the constitution and were only introduced in 1977. In Italy pharmaceutical patents were prohibited until 1978. In Spain, product patents were introduced in 1986 just after its accession to the European Economic Community (EEC) and the relevant laws given effect from 1992. The rationale behind the non-granting of product patent protection for pharmaceuticals in each of the example countries was to allow local pharmaceutical companies to imitate and produce patented medicines by using new processes. Over the

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countries are acting in a hypocritical way: they support the implementation of IP protection for pharmaceuticals only after bedding down their own pharmaceutical industries.¹⁴

Therefore, for LDCs the freedom to rely on imitated technology until such time as their pharmaceutical production is at a similar stage of development before the implementation of pharmaceutical patent protection is no longer an option¹⁵ given the obligation as a WTO member country to implement the TRIPS agreement. In that context the extension until 1 January 2016 to implement the pharmaceutical patent provisions of the TRIPS Agreement under the Doha declaration on TRIPS and Public Health¹⁶ is quite meaningless for those least developed countries which do not have the technological capabilities to produce generic pharmaceuticals.¹⁷ Whilst Bangladesh is an LDC, Bangladesh it is in a somewhat different position.

The position of Bangladesh

Among the 49 countries classified as an LDC (of which 32 are WTO members), Bangladesh is the only country with adequate pharmaceutical manufacturing capability and is nearly self-sufficient in pharmaceuticals.¹⁸ Bangladesh's

years these developed countries gained self-sufficiency and invested in research and development (R&D) which enabled and facilitated the transformation of their pharmaceutical industries into innovative and research based industries by using the imitated technology: See Xuan Li, 'The Impact of Higher Standards in Patent Protection for Pharmaceutical Industries under the TRIPS Agreement-A Comparative Study of China and India' (2008) *The World Economy* 1368.

- ¹⁴ S Srinivasan, How TRIPS benefits Indian Industry and how it may not benefit the Indian People (April-June 2008) V(2) *Indian Journal of Medical Ethics* 68.
- ¹⁵ In a case study of UNCTAD in Bangladesh (2007) it is revealed that without imitation learning will be made extremely difficult for countries with low technological capabilities. See for details, Sampath Gehl, 'Intellectual Property in Least Developed Countries: pharmaceutical, agro-processing, and textiles and RMG in Bangladesh' Study prepared for UNCTAD as a background paper for The Least Developed Countries Report 2007, UNCTAD, Geneva, Switzerland.
- ¹⁶ Paragraph 7 of the Declaration on the TRIPS agreement and Public Health, adopted 14 November, 2001.
- ¹⁷ Padmashree Gehl Sampath, 'Innovation and Competitive Capacity in Bangladesh's Pharmaceutical Sector' (September 2007) United Nations University-Maastricht Economic and Social Research and Training Centre (UNU-MERIT) Working Paper series#2007-031, 3.
- ¹⁸ Mohammad Abu Yusuf and Qamrul Alam, 'WTO TRIPS Agreement-Current state of Pharmaceutical Industry and Policy Options for Bangladesh' (2008) 1(1) *Journal of International Business Research* 12, 12-15.

pharmaceutical industry now caters to 96 percent of the country's pharmaceutical needs. It is worth noting that Bangladesh now exports a wide range of pharmaceutical products (therapeutic class and dosage forms) to 72 countries¹⁹ in Asia, Africa and Europe and in 2006-2007 total exports were US\$28.12 million with a growth rate of some 47 percent.²⁰ Bangladesh is also exporting specialized products like HFA inhalers, suppositories, hormones, steroids, oncology and immunosuppressant products, nasal sprays, injectibles and IV infusions.²¹ Many of the bigger firms in Bangladesh are now venturing into the production of anti-cancer drugs, anti retroviral drugs for the treatment of HIV/AIDS²² and anti-Bird-Flu drugs. Some of the most stringent regulatory authorities in the world have approved Bangladeshi pharmaceutical companies for export.²³

It is also remarkable that now pharmaceutical market in Bangladesh mostly dominated by local players. Out of top 10 players, 9 are local and only 1 is MNC (Sanofi-Aventis).²⁴ Top 10 companies represent 64% and top 20 companies represent 82% of total pharmaceutical market in Bangladesh.²⁵

Considering the thriving local pharmaceutical industry and considerable exports over the years, Bangladesh can still produce generic versions of patented medications so can still serve the pharmaceutical needs of other poorer countries with no or low manufacturing capacity by supplying cheap generic medicines of patented pharmaceuticals.²⁶

¹⁹ Directorate of Drug Administration, Bangladesh, (10 June 2010)

<http://www.ddabd.org/exporting_country.htm>.

²⁰ Nazmul Hasan, *Bangladesh-An Emerging Country for Generics* (12 June, 2010)

<<http://www.jacobfleming.com/buxus/docs/downloads/case-study-smgenerics-nazmul-hassan-finalapproed.pdf>>.

²¹ Ibid.

²² Ibid.

²³ Such as the Gulf Central Committee for Drug Registration, the Therapeutic Goods Administration of Australia, the Medicines and Healthcare products Regulatory Agency (MHRA) of UK, and Food and Drug Administration of USA have already issued Good Manufacturing Clearance (GMP) clearance to many local pharmaceutical companies in Bangladesh.

²⁴ IMS Health Data 2008-2009.

²⁵ Ibid.

²⁶ Anne St Martin, 'The Impact of Trade Related aspects of Intellectual Property Rights (TRIPS) on Access to Essential Medicines in the Developing World' [May 1, 2006] (a research project report submitted to Worcester Polytechnic Institute) 2.

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However, the ability to produce generic pharmaceuticals is reliant upon a country's particular legal and regulatory environment. Also important is the country's overall political will and leadership. Government policies and regulatory agencies have a significant impact on pharmaceutical innovation. In Bangladesh two of the relevant regulatory agencies are the Department of Patent Design and Trademarks and Directorate of Drug Administration (DDA).

The Department of Patents, Designs and Trademarks

The present patent protection regime in Bangladesh based on the century old *Patents and Designs Act* of 1911 and the *Patent and Design Rules* of 1933. Bangladesh inherited its patent law from the then British Government in India, and continues with (essentially) the same law. A few minor amendments have been enacted such as the establishment of Department of Patent Design and Trademarks. The Department is charged with determining patent applications.

Although not directly specified the patent laws of Bangladesh, Bangladesh does follow other countries by applying a criterion of novelty, inventive step and industrial application for patentability.²⁷ A patent application is required to be accompanied with either a complete²⁸ or provisional²⁹ specification. If an applicant applies with a provisional specification, a complete specification is required to be submitted within nine months. If not, after a period of ten months the application is deemed to have been abandoned. A complete specification is required to include following particulars, such as:

- The name and address of the inventor,
- The title of the invention,
- An abstract or summary of the invention,
- A description of the invention,
- The process of invention with drawings and
- A claim or claims defining the scope of the invention for which protection is sought.

²⁷ See for details, Azam, Mohammad Monirul, 'Intellectual Property, WTO and Bangladesh' (New Warsi Book Corporation 1st ed 2008).

²⁸ As per section 4 of the Act, a complete specification must particularly describe and ascertain the nature of the invention and manner in which the same is to be performed.

²⁹ *Patents and Designs Act, 1911* (Bangladesh) s 4A.

The application is then sent to an examiner for examination. The examination will trigger one of three outcomes: (1) the specification is correct and the invention is patent-worthy or (2) the specification is not reflected any new invention and is rejected (3) the specification is accepted with modification or amendment.

If the examiner raises no objections, the specification is published in the Gazette. Interested parties may raise objections within four months.³⁰ The allowance for pre-grant opposition is an important way to assist and encourage public interest groups and local generic pharmaceutical companies to oppose attempts by others to seek a patent.

In Bangladesh the pre-grant objection is limited by two conditions. The first is that the objection must be made within four months of the advertisement of the acceptance of application and the second is that the objection can only be based on the statutory grounds provided by section 9(1) of the Act. If defects in the patent application are revealed or identified after the four month period, no objection can be raised against the patent application. In other words, the existing legislative regime does not permit any type of post-grant opposition.³¹

Arguably, the existing Bangladeshi pre-grant opposition regime is not sufficient and should be amended to include more extensive pre-grant heads of objection and include a process for post-grant opposition as well. In taking such a legislative step, it is suggested that the heads of objection should be as wide as possible so that the twin

³⁰ *Patents and Designs Act, 1911*(Bangladesh) s 9. This kind of objection months of advertisement is called pre-grant opposition. The TRIPS Agreement does not prescribe a specific type of opposition system, and many WTO Members, such as Canada, Australia and Japan, allow pre-grant opposition: See for details, Will the lifeline of affordable medicines for poor countries be cut? (1 October, 2010) <<http://www.who.int/hiv/amds/MSFopinion.pdf>>.

³¹ This is in contrast to the legislative equivalent in India which not only contains eleven grounds for pre-grant opposition but also permits post-grant opposition to be made. The Indian grounds for post-grant opposition are broad enough to challenge novelty, inventive step, and process of industrial application, best method, claims, and disclosure of origin and even use of indigenous or local knowledge. This provides Indian pharmaceutical firms, which make most of their revenues and profits from the manufacture of generic, pharmaceuticals can oppose the unsubstantiated claims made by the multinational patent holder without going to court of law or infringing the patent, both of which are expensive options. Again quality of patents granted in India would also be improved through this meaningful approach: See Post Grant Opposition Becomes Popular in Indian Pharma Industry, (5 October, 2010) <<http://www.lexorbis.com/post-grant-opposition.html>>.

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aims of ensuring access to medicine with the aim of promoting innovation within the pharmaceutical industry are not hampered.

Importantly however, in 2008 the Department of Patents, Designs and Trademarks suspended the patenting of pharmaceuticals in Bangladesh until 1 January 2016 in accordance with the Doha Declaration.³² The Department's notification provides that applications relating to patents for medicines and agricultural chemicals will be preserved in a 'mail box' and will be considered after January 2016.

Prior to the suspension, the available information indicates that between 1998-2007 patent applications and patents granted in Bangladesh doubled in number, and 90 percent of those patents were owned by multinational corporations.³³ In 2007, the Department of Patents, Designs and Trademarks registered 269 foreign patent applications of which 50 percent related to multinational pharmaceutical formulas.³⁴ Table 1 depicts the number and type of patents granted in Bangladesh between 1995-2009. It is suggested that nearly 50 percent of the patents were pharmaceutical patents.³⁵

³² Jashim Uddin Khan, *New Patent rights of Drug suspended*, (The Daily Star, March 14, 2008, Dhaka, Bangladesh) (28 September 2009)

<<http://www.thedailystar.net/story.php?nid=27621>>.

³³ Nazmul Hasan, General Secretary, Bangladesh Association of Pharmaceuticals Industries General Secretary, (published in the daily star, 14 March 2008) 28 September 2009

<<http://www.thedailystar.net/story.php?nid=27621>>.

³⁴ Ibid.

³⁵ See Jashim Uddin Khan, *New Patent rights of Drug suspended*, The Daily Star, 14 March 2008, Dhaka, Bangladesh, (28 September

2009)<<http://www.thedailystar.net/story.php?nid=27621>>; Mohammad Monirul Azam and Yacouba Sabere Mounkoro, *Intellectual Property Protection for the Pharmaceuticals: An Economic and Legal Impacts Study with special reference to Bangladesh and Mali*, a course paper submitted as a partial requirements for the Legal and Economic Foundations of Capitalism, MS in Law, Economics and Finance, IUC, (December 2008), (28 September, 2009) <http://www.afriblog.com/blog.asp?code=Yacou&no_msg=8705>.

Table 1: Patents applications and granted in Bangladesh (1995-2009)

Year	Patent Applied			Patent Accepted		
	Local	Foreign	Total	Local	Foreign	Total
1995	70	156	226	6	74	80
1996	22	131	153	18	52	70
1997	46	119	165	15	61	76
1998	32	184	216	14	126	140
1999	49	200	249	26	122	148
2000	70	248	318	4	138	142
2001	59	236	295	21	185	206
2002	43	246	289	24	233	257
2003	58	260	318	14	208	222
2004	48	268	316	28	202	230
2005	50	294	344	21	161	182
2006	22	288	310	16	146	162
2007	29	270	299	27	269	296
2008	60	278	338	01	36	37
2009	55	275	330	28	103	131

Source: Department of Patents, Designs and Trademarks, Dhaka, Bangladesh, 2010.

Table 1 highlights that patent applications in Bangladesh increased significantly from 1998. The trend continued until the suspension against granting pharmaceutical patents in 2008. Most of the applications filed belong to the foreigners and multinational companies.³⁶

The reason behind the lower number of patent applications from local (ie Bangladeshi) researchers and research institutions in Bangladesh is directly related to the low level of research conducted in Bangladesh, the lack of technical and financial resources to do innovative research, the low priority given over to research and patenting by both research institutions and the Government and a low level of awareness about the benefits of patents among the researchers, research institutions

³⁶ Md Farhad Hossain Khan and Yoshitoshi Tanaka, IP Administration and Enforcement System Towards Modernization of IP Protection in Bangladesh and a Comparison of IP Situation between Japan and Bangladesh, (2004) 2 *IP Management Review* 1, 1-2.

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and industry.³⁷ In terms of capacity to effect any change, the Department of Patents, Designs and Trademarks is yet to be able to accept online applications (relying on paper copies and the manual processing of applications) and the (single) office is located in the capital city of Bangladesh, Dhaka. Consequently, any researchers or research institutions working outside Dhaka have limited or no access to the Department. The Directorate of Drug Administration also has a role to play and will need to capacity build in anticipation of 1 January 2016.

The Directorate of Drug Administration (DDA)

The Manufacturing of pharmaceutical products is regulated by international standards. International standards are a pre-condition for worldwide trade with pharmaceutical products. National Drug Regulatory Authorities (DRAs) are responsible for licensing the production of medicines, controlling ongoing production and if necessary, the withdrawal of licenses. International standards include the Good Manufacturing Practices (GMP)³⁸ for medicinal products of the EU, the Code of Federal Regulations of the American Food and Drug Administration³⁹ and the Pharmaceutical Inspection Convention⁴⁰ which are aims at maintaining quality and efficacy of medicines worldwide.

³⁷ Mohammad Monirul Azam, interview with officials of Patent Office in Bangladesh (requested for non-disclosure of names), Dhaka, September 22-24, 2010.

³⁸ The WHO defines Good Manufacturing Practices (GMP) as 'that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization'. GMP is a regulatory framework to ensure the correct manufacturing of pharmaceutical products.

³⁹ Title 21 of the US Code is the portion of the Code of Federal Regulations that governs food and drugs within the United States for the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), and the Office of National Drug Control Policy (ONDCP).

⁴⁰ The Pharmaceutical Inspection Convention (PIC) aims at the mutual recognition of inspections, harmonisation of GMP requirements, uniform inspection systems, training of inspectors, exchange of information and mutual confidence. The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP.

DRA in developing countries are often described as weak and inefficient, sometimes even corrupt.⁴¹ The same description is affected to the DDA in Bangladesh. In Bangladesh the DDA is the national drug regulative authority, it regulates pharmaceutical manufacture, pharmaceutical importation and the quality control of pharmaceuticals in Bangladesh. The DDA sits within the Ministry of Health and Family Welfare.

The DDA is responsible for the registration of pharmaceuticals as well as for inspection of premises, and for licensing medicines for the Bangladesh market and exporting to overseas. The DDA also issues licenses for import of raw materials for different pharmaceuticals and packed pharmaceuticals. It also monitors quality control parameters of marketed pharmaceuticals through an agency called the Drug Testing Laboratory, which is located in the Institute of Public Health at Mohakhali, Dhaka and is equipped with standard testing facilities.

The DDA in Bangladesh shadows the workings of Australian Therapeutic Goods Administration as it has the specific role of maintaining the quality, safety and efficacy of pharmaceuticals produced and imported in Bangladesh. The Therapeutic Goods Administration (TGA) which is a unit of the Australian Government Department of Health and Ageing empowered by the Therapeutic Goods Act 1989⁴² is responsible to ensure the quality, safety and efficacy of medicines and ensure the quality, safety and performance of medical devices. The regulatory framework is based on a risk management approach designed to ensure public health and safety, while at the same time freeing industry from any unnecessary regulatory burden for administering the provisions of the legislation. This role is different to the broad scope given to the United States' Federal Drug Administration.

In the United States the Food and Drug Administration (FDA or USFDA) is the responsible body for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceuticals (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), veterinary products, and cosmetics. It is an agency of the United States Department of Health and Human Services, which regulates almost every facet of

⁴¹ See for details, *The Viability of Local Pharmaceutical Production in Tanzania* (2007) <<http://www2.gtz.de/dokumente/bib/07-0300.pdf>>.

⁴² The objective of the *Therapeutic Goods Act 1989*, which came into effect on 15 February 1991, is to provide a national framework for the regulation of therapeutic goods in Australia to ensure the quality, safety and efficacy of medicines and ensure the quality, safety and performance of medical devices.

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prescription pharmaceuticals, including testing, manufacturing, labelling, advertising, marketing, efficacy and safety. The DDA however has limited resources.

In order to monitor and control over the production of pharmaceuticals and pharmacies all over Bangladesh, the DDA needs to have sufficient technical staff. The DDA itself has acknowledged that it does not have sufficient staff to monitor all domestic manufacturers.⁴³ In 2009 Government of Bangladesh reorganised DDA to have more financial and technical resources and more administrative power so that it can work more efficiently. To some, these promises are yet to materialise.⁴⁴ There are similar issues with respect to the Department of Patents, Designs and Trademarks.

It is expected that the Department of Patents, Designs and Trade marks function will change after the implementation of the TRIPS compliant patent regime. As the Department of Patent, Design and Trade marks will be responsible for ensuring that an invention is absolutely and truly new and not similar to any previously granted patent, it must be equipped with adequate technical resources and professionals working in the relevant field. The present workforce in the Department of Patent, Design and Trade marks is not adequate. The Department of Patent, Design and Trademarks is made up of one Registrar, four Deputy Registrars, nine Assistant Registrars, 25 Examiners and 73 support staff : a total number of 112 staff.⁴⁵

Among the 112 officials, less than 50% officials work in the field of patent. Arguably, the present number of examiners is not sufficient to ensure timely disposal of patent applications and even existing examiners also lack proper training and technical facilities to deal with complex applications in the field of pharmaceuticals.⁴⁶

Relevantly, neither the present patent law nor the proposed patent law deals with the human resources issues of the patent office. However fortunately the need to modernize the Department of Patents, Designs and Trademarks has been recognised. Currently, two projects has been implemented using the technical and financial

⁴³ Bangladesh Pharmaceutical Market, Q 2, 2010(Espicom Business Intelligence, 2010).

⁴⁴ Mohammad Monirul Azam, interview with a staff of DDA (like to be unidentified), Dhaka, Sep 16, 2010.

⁴⁵ Mohammad Monirul Azam, interview with a deputy director of patent office of Bangladesh (anonymous), Dhaka, September 27, 2010.

⁴⁶ Mohammad Monirul Azam, interview with a patent examiner (anonymous), Dhaka, September 27, 2010.

assistance of WIPO.⁴⁷ In addition to these projects there are some steps which could be considered to build the capacity of the DDA and the Department of Patents, Designs and Trademarks.

Towards capacity building

There are number of steps that can be taken to capacity build within the regulatory agencies of the Department of Patent, Design and Trademarks and the DDA so that Bangladesh might cope with the challenges of post-TRIPS regime. Those steps include the development of a data base for recording patent application and granted patents, the introduction of an online application system, the development of an institutional framework for facilitating implementation of IPR in Bangladesh, the establishment of an Information Centre and support policies for the small and medium enterprises should be adopted. Further, given its workforce and technical resource issues in the patent area Bangladesh should consider joining the Patent Cooperation Treaty 1970 (PCT) so as to outsource patent examinations. This would enable Bangladesh to extend the patent protection of local inventions all over the world and also to pave the way for the foreigners to apply in Bangladesh through the international application system used under the PCT.⁴⁸ The advantage of relying on PCT preliminary examination reports to determine whether to award a national patent (as opposed to relying on foreign patent proxies under a re-registration scheme) is that developing countries are assured access to the underlying analysis on which the patentability was determined as well as the relevant body of prior art that was considered. An additional matter that should be considered is that University-Industry-Government collaboration should be strengthened to support IP creation and technology transfer.

University-Industry-Government collaboration

Despite lack of investment in basic Research and Development by the Government and pharmaceutical companies in Bangladesh, one positive aspect is that there is a continuous supply of fresh graduates in relevant fields from the local Universities in

⁴⁷ The projects being the Modernization and Strengthening of Patents & Designs System in Bangladesh and the Nationally Focused Action Plan (NFAP) for the Government of Bangladesh for Modernization of Patent Office.

⁴⁸ The PCT is a WIPO administered treaty concluded in 1970, which provides patent applicants with the opportunity of filing an international patent application. Instead of filing separate applications in different countries, the applicant can file a PCT application with the International Bureau (WIPO) or any national or regional patent office. The date of this international filing is deemed as the date of filing in all national offices.

PHARMACEUTICAL PATENT PROTECTION AND TRIPS CHALLENGES FOR
BANGLADESH: AN APPRAISAL OF BANGLADESH'S PATENT OFFICE AND
DEPARTMENT OF DRUG ADMINISTRATION

Bangladesh. Six public and 16 private universities in Bangladesh offer Bachelors of Science and Masters of Science courses relevant to the pharmaceutical sector. The total number of graduates each year in each discipline is pharmacy: 660 graduates, chemistry: 1560 graduates, microbiology: 250 graduates, applied chemistry: 150 graduates and chemical engineering: 250 graduates.⁴⁹ The job opportunities for graduates are only increasing so that more and more universities are offering relevant degrees.

While there are more graduates, necessary steps should be taken to ensure that they are recruited, deployed, trained and retained in the pharmaceutical sector. If graduates are given proper training and opportunity for research under the supervision of qualified and experienced experts, it would be an important step in the right direction for the transition of pharmaceutical industries in Bangladesh beyond 2016. Bangladesh has great potential in this regard as infrastructure and labour costs are substantially lower than those in compare China or India.

Conclusion

The implementation of the TRIPS Agreement in Bangladesh is inevitable. The 'how' of implementation is yet to be finalised. What is certain is that there will be a need for the regulatory agencies in Bangladesh to be ready, willing and able to facilitate the processing, granting and regulation of pharmaceutical patents. At the moment, there is concern that the current regulatory agencies, the Department of Patents, Designs and Trademarks and the DDA lack capacity to deal with post-TRIPS challenges. This paper has indicated some of the shortcomings and provided some suggestions for capacity building in anticipation of TRIPS compliance for pharmaceutical patent from 1 January 2016.

⁴⁹ See for details, www.boi.bd.com and report of University Grants Commission of Bangladesh-2005-2009.