TRIPS Compliant Patent Law and Pharmaceutical Patent Protection: Options for Patent Law Reform in Bangladesh

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Certificate of Originality

I certify that the work in this thesis was carried out by me in accordance with the regulations of Central Queensland University. The work is original and no part of the thesis has been submitted for any other degree. Some parts of this thesis have already been published as peer-reviewed journal articles and conference presentations. All the materials and literature used during the preparation of this thesis are duly acknowledged.

Any views expressed in this thesis are those of the author and in no way represent those of Central Queensland University.

I declare that this thesis has not been presented to any other university for examination either in Australia or overseas.

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Abstract

Before the creation of the World Trade Organization (WTO) in 1995, individual countries were free to determine their own patent laws. This position has now changed. A WTO Agreement, the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement), which is binding on all members, aims at establishing strong minimum standards for intellectual property rights (IPRs). Such minimum standards include the implementation of patent protection for pharmaceuticals. Bangladesh is a member of the WTO and as a least-developed country (LDC) has been granted until 1 January 2016 to facilitate the introduction of pharmaceutical patents under the TRIPS Agreement into its national intellectual property legislative regime. This thesis analyses options for implementing TRIPS-compliant patent law in Bangladesh with a focus on pharmaceutical patents.

Brazil and India were in a similar position prior to becoming TRIPS compliant, so those countries' experiences become an important basis for the analysis of the transition to TRIPS-compliance in pre-compliant countries. This thesis combines doctrinal analysis, comparative reviews and a mixed-method research approach to answer the research questions as identified for the study.

The thesis examines two underlying research questions:

1. Using the experience of India and Brazil, what are the different options available to Bangladesh to change existing patent law to comply with TRIPS in the area of pharmaceutical patents?
2. Using the options identified, what changes to the Bangladeshi patent law will need to be made to balance both pharmaceutical innovation and access to medicines in Bangladesh?

To answer research question one, the thesis used doctrinal analysis and comparative reviews and then to answer research question two it used an original survey instrument and interviews to examine the views of identified stakeholders such as commercial entities in the pharmaceutical industry, relevant regulatory bodies in Bangladesh, public-health groups and academics.

This research makes an original contribution to the body of knowledge on TRIPS and intellectual property in four ways, as this thesis:

1. analyses the contemporary literature examining TRIPS and its impact upon access to medicines in developing countries and LDCs, particularly, India, Brazil and Bangladesh;
2. uses an original survey instrument to analyse and report on the responses of the pharmaceutical industry and their perceptions of TRIPS and its implementation in Bangladesh;
3. produces recommendations that may facilitate the introduction of TRIPS-compliant patent-law reforms in Bangladesh ready for 2016; and
4. identifies the further research that is required into the area of TRIPS-compliant patent-law reforms.

Dedication

This thesis is dedicated to my parents, my wife Tanya, my son Anas, my mother-in-law and to the memory of my late father-in-law, Golam Morshed, who will never see the outcome of this thesis.

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Preface

The journey towards a PhD degree is a long and lonely journey. I am fortunate to have had great support from my loving family members and my scholarly supervisor. My supervisor, Dr Kristy Maree Richardson, has been an excellent source of support, inspiration and advice throughout my difficult PhD process. I think if I had listened to her properly, this thesis would have been completed earlier. I am extremely sorry for being awkward at times and thank her for helping me through. I am grateful to Dr Imtiaz Omar for consenting to be my associate supervisor. I am also grateful to Jeni Richardson, FABIE, Central Queensland University (CQU) and Kerrie Thomson, Office of Research, CQU for their kind advice and encouragement during my difficult time. Thanks also to those who provided comments during my first-year confirmation process (Professor John Rolfe, Professor Kamal Puri and Professor Sheikh Rahman).

It would not have been possible to complete this study without financial assistance from CQU. I am indebted to CQU for providing me with the required funds to complete this study. I sincerely acknowledge the great cooperation of the CQU library, and more particularly, the document delivery services that provided me with access to all the important books and articles, as and when necessary, by way of lending and by photocopy requests to other universities and research institutions. I am grateful to officials at the Department of Patents, Designs and Trade Marks and the Directorate of Drug Administration in Bangladesh for their cooperation during field studies. I am also thankful to the pharmaceutical industries in Bangladesh and all other participants for their cooperation during the surveys and interviews in Bangladesh.

Finally, I am indebted to my loving family members for putting up with me during these difficult years of writing and travelling, particularly for the love and patience of my wife Tanya and my little angel Anas. I would like to thank my parents, brothers and sister and in-laws for their support and inspiration. I am also grateful to my colleagues for their kind cooperation.

A special thank you to my late father-in-law, who inspired me always to go for higher studies and always enquired about my progress: his sudden departure just after my confirmation process in October 2009 has left a huge void in our lives.

List of Publications and Presentations

Peer-reviewed Journal Publications and Presentations by the Candidate That Are Relevant to the Thesis

1. Mohammad Monirul Azam and Kristy Richardson, 'Pharmaceutical Patent Protection under the TRIPS Agreement and Pharmaceutical Industry in Bangladesh: Challenges and Opportunities' (2010) *LAWASIA Journal*, University of Queensland, Australia.

2. Mohammad Monirul Azam and Kristy Richardson, 'Pharmaceutical Patent Protection and TRIPS Challenges for Bangladesh: An Appraisal of Bangladesh's Patent Office and Department of Drug Administration' (2010) 22(2) *Bond Law Review*, Australia.

3. Mohammad Monirul Azam and Kristy Richardson, 'Access to Medicines and Pharmaceutical Patent Protection under the TRIPS Agreement: A Review of Literature on the Challenges for Least Developed Countries' (2011) *IP Forum Journal, Journal of Intellectual Property Society of Australia and New Zealand*.

4. Mohammad Monirul Azam, 'Effectiveness of the Patent System in Bangladesh in the Context of the TRIPS Agreement: In Search of Balance between Pharmaceutical Innovation and Public Interest (peer-reviewed)' (Pacific Rim Conference**,** 22–23 January 2010, University of Melbourne, Australia).

5. Mohammad Monirul Azam, 'Journey towards WTO Legal System and the Experience of Bangladesh: The Context of Intellectual Property (peer-reviewed)' (Society of International Economic Law [SIEL] Conference, 7–8 July 2010 at the IELPO of the University of Barcelona, Spain).

6. Mohammad Monirul Azam, 'TRIPS Compliance Patent Law and Implications for the Pharmaceutical Regulation and Pricing of Drugs in the LDCs with Special Reference to Bangladesh (peer-reviewed)' (3rd International City Break Conferences**,** 16–19 October 2009, Athens Institute for Education and Research, Athens, Greece).

Additional Publications and Presentations by the Candidate in Related Areas

1. Mohammad Monirul Azam, 'Globalisation of Intellectual Property Law and Ethical Standards for Intellectual Property Lawyers: The Context of Bangladesh (peer-reviewed)' (International Legal Ethics Conference IV: 'The Legal

Profession in Times of Turbulence', 15 July 2010, Stanford University, USA).

2. Mohammad Monirul Azam and Abdul Hamid Chowdhury, 'Enforcement of Intellectual Property in Bangladesh and Singapore: A Comparative Study, (Book Chapter)' in Talwar Sabanna (ed.), *Intellectual Property Rights in WTO and Developing Countries*, ISBN: 9788183872607 (Serial Publications, India, 2009).

3. Mohammad Monirul Azam, 'Globalised Intellectual Property and Concern for LDCs' (5th Asian Law Institute Conference held in the National University of Singapore, 22–23 May 2008).

4. Mohammad Monirul Azam, *Intellectual Property, WTO and Bangladesh*, **(**New Warsi Book Corporation, 2008 [book]).

5. Mohammad Monirul Azam, 'Establishment of the WTO and Challenges for the Legal System of Bangladesh' (2006) 3 *Journal of Business Law*, Macquarie University, Australia.

6. Mohammad Monirul Azam, 'Effectiveness of the Enforcement Mechanisms of Intellectual Property Rights: The Context of Software Piracy' (Collection of Research Paper Series, WIPO Worldwide Academy, Geneva, Switzerland, 2006).

7. Mohammad Monirul Azam, 'Globalisation and Public Good: What Role for Intellectual Property Law?' (Globalisation and Environmental Justice Seminar, April 2005, Faculty of Law, Macquarie University, Australia).

8. Mohammad Monirul Azam, 'Accession to the WTO and Challenges for Legal and Institutional Reforms in Bangladesh' (2006) 5 *JATI Journal*, Dhaka, Bangladesh.

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Abbreviations

API	Active pharmaceutical ingredient
BAPI	Bangladesh Association of Pharmaceutical Industries
BIT	Bilateral investment treaties
DPDT	Department of Patents, Designs and Trade Marks
DDA	Directorate of Drug Administration
EU	European Union
FDA	Food and Drug Administration of USA.
GATT	General Agreement on Tariffs and Trade
GMP	Good Manufacturing Practices
HDI	Human Development Index
IP	Intellectual property
IPRs	Intellectual property rights
IPC	Intellectual Property Rights Committee
LDCs	Least-developed countries
MNCs	Multinational corporations
NGOs	Non-governmental organisations
R&D	Research and Development
TAC	Treatment action campaign
TNCs	Transnational national corporations
TRIPS	Trade-related aspects of intellectual property rights
UNDP	United Nations Development Program
USA/US	United States of America
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Common Terms

Generic drugs: cheaper pharmaceutical products that are marketed under a non-proprietary or approved name rather than under a proprietary name or brand name by a third party other than the original patent holder, and whose patent has either expired or is still valid. Generic drugs usually have the same effectiveness as brand-name drugs but are sold at a significantly cheaper price.

Reverse engineering: the process by which a drug is analysed so that its components are known and can be replicated. Reverse engineering was not a violation of agreements prior to TRIPS, as those agreements protected only the 'process' rather than the 'final product', which is now also protected under TRIPS.

TRIPS flexibilities: different Articles of the TRIPS Agreement that allow governments a certain latitude in the enforcement of the Agreement in order for them to account for national concerns and public-health needs such as by way of compulsory licenses, parallel imports and experimental exceptions.

Compulsory licensing: the granting by a government of permission to produce patented drugs by a third party other than the original patent holder or his authorised agent so as to meet public-health needs in the country concerned.

Parallel importation: the importation of patented products from a third country where the products are cheaper.

Doha Declaration: a Declaration of the WTO member states on TRIPS and public health, reiterating flexibilities in TRIPS with regard to health.

Doha waiver: the waiver granted to the least-developed countries (LDCs) until 1 January 2016 for the introduction of pharmaceutical patents as agreed at the WTO Ministerial Conference in Doha, 2001.

TRIPS plus: provisions in the bilateral investment and trade agreements, usually with the United States of America or EU, that impose more or extended obligations that surpass TRIPS requirements.

Chapter 1: Chapter Synopsis and Background Information

1.1 Presentation of Thesis

This thesis is structured in seven chapters.

Chapter 1 presents a synopsis of the seven chapters of the thesis. Chapter 1 also includes a statement of the importance of this research regarding its contribution to knowledge, background information about trade-related aspects of intellectual property rights (TRIPS), an introduction to pharmaceutical patents and the research method adopted.

Chapter 2 presents the literature review and identifies the gaps present in the literature, which leads to the justification for the research. Chapter 2 concludes with the two research questions explored in this thesis.

Chapter 3 presents the research methods as chosen for this study, and details some key findings so as to provide a roadmap for the remainder of the thesis.

Chapter 4 uses the experience of India and Brazil to examine the options adopted by these countries in their progress to TRIPS compliance. This analysis forms the basis for exploring the possible options for Bangladesh to proceed to TRIPS compliance.

Chapter 5 focuses on the situation in Bangladesh and contains an overview of the current patent law and the pharmaceutical industry of Bangladesh. In focusing on Bangladesh, the perceptions of different stakeholders are presented in the context of the requirement for TRIPS-compliant patent laws from 1 January 2016.

Chapter 6 presents the recommendations arising from the research. There are three categories of recommendations. The first involves a focus on the potential legislative changes that may be required to the existing patent law of Bangladesh; the second category focuses on the potential governmental/policy interventions and discusses potential policy directions that may be needed and the third category examines infrastructure changes.

Chapter 7 concludes the thesis by discussing the infrastructure changes that are needed so that Bangladesh can move towards a successful TRIPS implementation. The chapter concludes by confirming the thesis' contribution to knowledge and the options for further research.

1.2 Introduction to TRIPS and Pharmaceutical Patents

The setting up of the WTO was agreed to by 125 countries on 15 April 1994 at a conference in Marrakesh, Morocco.[1] The creation of the WTO was intended to

[1] The Uruguay Round negotiations that led to the conclusion of the WTO Agreement lasted for seven and a half years, almost twice as long as the original schedule, which had foreseen the culmination of negotiations as coming in 1990. After preparatory discussions that began in 1982, the Uruguay Round

replace looser arrangements for the conduct of international trade originally embodied in the General Agreement on Tariffs and Trade of 1947 (GATT).[2] The WTO replaced GATT and came into effect on 1 January 1995 with the backing of at least 85 founding members, including Bangladesh.

The establishment of the WTO has been an important exercise in a number of ways. First, it represents an entirely new chapter in the jurisprudence of post-World War international organisation through the establishment of a multilateral trading system that provides a binding dispute-settlement mechanism for its members.[3] Second, the WTO has also taken unto itself the onerous task of evolving a binding law of international trade amongst the member countries.[4] Third, the WTO has in many ways displaced the internal sovereignty of the member countries.[5] This is because every member is required to adjust its domestic laws so that they conform to WTO Agreements.[6] Indeed, as a founding member, the legal system of Bangladesh has been subject to reorganisation to satisfy the requirements of the WTO.[7]

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began in September 1986 at Punta del Este, Uruguay. The negotiation agenda covered virtually every outstanding trade-policy issue. It extended into several new areas, notably trade in services and intellectual property, and also aimed to reform trade in the sensitive agriculture and textile sectors. These negotiations were larger than any other in the history of mankind. During a conference in Montreal in 1988, a package of early results was agreed upon, despite the existing difficulties in finding a general consensus. This included some concessions on market access for tropical goods and the creation of a dispute-settlement system. Further, the Trade Policy Review mechanism, which provided for the first comprehensive, systematic and regular reviews of national trade policies, and which examined the practices of GATT members, was agreed upon. Due to difficulties in reaching agreement on the agricultural sector, the first draft of the Final Act was only produced in December 1991. However, the negotiations were then completed on 15 December 1993 in Geneva, and on 15 April 1994, the Uruguay Round Final Act was signed by the representatives of the 125 participating countries at a meeting in Marrakesh. The Act contains about 30 agreements, plus more than 25 additional ministerial declarations that clarify the provisions of the agreements. See for Details, Petros C. Mavroidis and Alan O. Sykes (Eds.) The WTO and International Trade Law/Dispute Settlement (Edward Elgar Publishing Inc., 2005).

[2] GATT was an attempt by 23 developed and developing countries to make a decisive break with previous policies concerning international trade.

[3] See, John H Jackson, *The Jurisprudence of GATT and the WTO* (Cambridge University Press, 2000).

[4] Member countries have undertaken to be bound by the commitments made by them under various agreements, which are part and parcel of the WTO legal regime, such as the principles of national treatment, the Most Favoured Nations clause being introduced so that there cannot be any discrimination between national and foreign goods and services; members have to introduce patent protection for pharmaceuticals under the WTO TRIPS Agreement.

[5] This has been the most important argument for the opponents of the WTO, as decision making on important issues of national interest has come within the WTO framework. See K C Reddy (ed.), *WTO and Implications for South Asia* (2006) 1.

[6] Membership of the WTO is conditional on the full acceptance—without reservation—of almost all WTO Agreements; See *General Agreement on Tariffs and Trade: Multilateral Trade Negotiations (The Uruguay Round): Final Act Embodying the Results of the Uruguay Round of Trade Negotiations* (15 December 1993), (1994) 33 I.L.M. 1 [referred as WTO Agreements]. The WTO Agreement has four Annexures, the first three of which are integral parts of the Agreement. Annexure 1 deals with substantive trade agreements on trade in goods, trade in services and trade-related aspects of IPRs. Annexure 2 deals with dispute resolution, with Annexure 3 providing for a process of multilateral surveillance of national trade policies. Only Annexure 4 deals with Agreements that are not necessarily binding on member states. Article XVI(4) of the WTO Agreement provides that "each Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements". See Michael J Trebilcock and Robert Howse, *The Regulation of International Trade* (Routledge, 2nd ed.,1999).

[7] Mohammad Monirul Azam, 'Establishment of the WTO and Challenges for the Legal System of Bangladesh' (2006) 3 *Macquarie Journal of Business Law* 23.

Therefore the situation before the creation of the WTO in 1995 was that individual countries were free to determine their own patent laws. This position has now changed. All the members of the WTO have to adopt TRIPS-compliant patent laws, including the implementation of patent protection for pharmaceuticals. The developed member countries of the WTO negotiated mandatory protection for pharmaceutical products and processes in the TRIPS Agreement on the basis that such mandatory protection will provide the necessary incentives for continued pharmaceutical innovation. In contrast, the developing and least-developed member countries of the WTO argued, and continue to argue, that enacting patent laws that comply with TRIPS may increase the price of pharmaceuticals to the point that pharmaceuticals may become inaccessible to their populations.

The implementation of the TRIPS Agreement will require a reorganisation and restructuring of Bangladesh's intellectual property regime. Given the extent of the reorganisation and the restructuring required, LDCs[8] (of which Bangladesh is one) were granted an initial transition period until 31 December 2005,[9] which was later extended to July 2013 to implement a TRIPS-compliant intellectual property regime within their domestic jurisdictions.[10] The extension was given after a request by the LDCs as a group, pursuant to Article 66.1 of the TRIPS Agreement. The group cited socio-economic, administrative and financial constraints and the need to create a viable technological base as reasons to justify the extension request. However, the extended transition period was not long enough and the Doha Declaration on the TRIPS Agreement and Public Health was adopted by the WTO Ministerial Conference of 2001 in Doha on 14 November 2001 which further extended the

[8] There are no WTO definitions of 'Developed', 'Developing' or 'Least Developed' countries. The WTO recognises as LDCs those countries which have been designated as such by the United Nations. There are currently 49 LDCs on the UN list, 32 of which to date have become WTO members. According to the United Nations, LDCs are countries that exhibit the lowest indicators of socioeconomic development, with the lowest HDI ratings of all countries in the world. A country is classified as an LDC if it meets three criteria based on low income (three-year average GNI per capita of less than US $750, which must exceed $900 to leave the list), human resources weakness (based on indicators of nutrition, health, education and adult literacy) and economic vulnerability (based on instability of agricultural production, instability of exports of goods and services, economic importance of non-traditional activities, merchandise export concentration, handicap of economic smallness and the percentage of population displaced by natural disasters). However, countries 'graduate' out of the LDC classification when indicators exceed these criteria.

[9] Article 65 of the TRIPS Agreement accounted for LDCs being in a weak stage of development and having no product patent system during the commencement of the TRIPS Agreement, and these LDCs were given a ten-year period (until 2005) in which to become TRIPS compliant.

[10] The initial transition period for LDCs ended on 31 December 2005. Later, by a decision of the TRIPS Council on Tuesday 29 November, 2005, LDC members as a group were granted an extension of the transitional period for 7.5 years to apply the provisions of the TRIPS Agreement; that is, 'until 1 July 2013, or until such a date on which they cease to be a least-developed country Member, whichever date is earlier'. The TRIPS Council took the decision following the request by the LDCs as a group, pursuant to Article 66.1 of the TRIPS Agreement, for a 15-year extension of the transition period in order for those LDCs to be able to apply the provisions of the Agreement. The group had cited socioeconomic, administrative and financial constraints and the need to create a viable technological base as reasons duly motivating the request. The Decision was negotiated between the LDCs and some key developed countries during informal consultations and was adopted by the formal TRIPS Council meeting on 29 November 2005. However, during the consultations, several developed country members, particularly the USA, insisted that each LDC member should request an extension on an individual basis and that extensions would be granted on a case-by-case basis.

transitional period for LDCs to introduce pharmaceutical patent protection to 1 January 2016.[11]

1.3 Introduction to Bangladesh

Among the 49 countries classified as an LDC (of which 32 are WTO members), Bangladesh is the only country with an adequate pharmaceutical manufacturing capability and is nearly self-sufficient in pharmaceuticals.[12] Bangladesh's pharmaceutical industry now caters for ninety-seven per cent of the country's pharmaceutical needs (the remaining three per cent of the pharmaceutical needs includes Insulin, vaccines and high-end anti-cancer drugs, the production of which are very capital intensive and hence not economically feasible for Bangladesh) which amounts to about US $868 million.[13] Pharmaceuticals from Bangladesh are exported to 72 countries in Asia, Africa and Europe (in 2006–07 total exports were U$ 28.12 million with a growth rate of forty-seven per cent).[14]

Bangladesh can still produce generic versions of patented pharmaceuticals (here the word 'generic' is to be considered from a wide perspective and not only includes off-patent cheap drugs but also patented drugs produced by a different producer to that of the original patent owner either under voluntary license or compulsory license, or in LDCs as per the Doha waiver for pharmaceutical patents) so can still serve the pharmaceutical needs of other poorer countries with no or low manufacturing capacity by supplying cheap generic medicines of patented drugs.[15]

Given its position, it is important to explore how Bangladesh can exploit the opportunities available to it, whilst also considering how Bangladesh may initiate the processes to implement a TRIPS compliant patent law that balances the interests of pharmaceutical producers and the need to ensure access to drugs for local populations in anticipation of 2016.

This thesis therefore aims not only to be an original contribution to the body of knowledge on TRIPS, but also to produce recommendations that may facilitate the introduction of TRIPS compliant patent law reforms in Bangladesh ready for 2016.

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[11] As per the Decision of the TRIPS Council to implement paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, LDCs shall be free to disregard the TRIPS disciplines on patents, and undisclosed information, with respect to pharmaceutical products, until 2016. See the Decision of the Council for TRIPS on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, IP/C/25 of 27 June 2002.

[12] Mohammad Abu Yusuf and Qamrul Alam, 'WTO TRIPS Agreement: Current State of Pharmaceutical Industry and Policy Options for Bangladesh' (2008) 1(1) *International Business Research*.

[13] Mohammad Monirul Azam and Kristy Richardson, 'Trips Compliant Patent Law and the Pharmaceutical Industry in Bangladesh: Challenges and Opportunities' (2010) *LAWASIA Journal*.

[14] Ibid.

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

1.4 The Research

This research analyses the situation of India and Brazil regarding TRIPS compliant patent law and the use of different options to maintain a balance between pharmaceutical innovation and access to medicines. This thesis therefore used a research method that involved legal doctrinal analysis and a comparative review in order to analyse the patent law of India, Brazil and Bangladesh.

From that review, this thesis investigated the views of the stakeholders in the pharmaceutical industry in Bangladesh to gain and understanding of their strategies for TRIPS compliance. As participants in the research presented in this thesis, the stakeholders represented different categories of companies within the pharmaceutical industry operating in Bangladesh: multinationals and national pharmaceutical producers (small, medium and large). The thesis also investigates the perceptions of other identified stakeholders such as public-health groups, intellectual property and pharmaceutical academics, researchers and the national regulatory bodies: the Department of Patents, Designs and Trade Marks (DPDT) and Directorate of Drug Administration (DDA). To gather the necessary data, a mixed method of surveys and interviews was adopted, which helped to identify required changes to the existing patent law in comparison with the options used in Brazil and India.

The justification for the research method adopted by the research is further discussed in Chapter 3 of the thesis with details of both the research design and data analysis.

1.5 The Importance of This Research and Its Original Contribution to Knowledge

This thesis makes an original contribution to knowledge because it focuses on the pharmaceutical industry in Bangladesh and on identifying policy options required for an LDC such as Bangladesh to become TRIPS compliant. Developing countries such as India, China and Brazil, (who played very vital roles as producers and exporters of generic copies of brand-name patented products), can no longer produce generic of patented pharmaceuticals due to the introduction of TRIPS compliant patent regimes in their respective countries. Bangladesh is in a unique situation as it is the only LDC with sufficient capacity to produce and export generic pharmaceuticals, at least until 2016. Therefore, it has become an important research area to investigate whether Bangladesh's pharmaceutical sector can gradually evolve to provide low-cost substitutes for important patented drugs to other developing countries and LDCs, and whether it can contribute to the global access of cheap medicines. This thesis makes an original contribution to the existing knowledge in the field of global intellectual property law as:

a) This thesis analyses the impact of TRIPS-compliant patent law from the perspective of an LDC: Bangladesh.
b) The thesis evaluates the existing legislative and institutional framework in Bangladesh relating to pharmaceutical patents and the pharmaceutical industry and identifies required changes for when the pharmaceutical patent regime will be in place.
c) The thesis indicates future (and continuing) research directions to provide an on-going consideration of the policy options needed to reach the right balance

(and the management of that balance) between pharmaceutical innovation, access to affordable pharmaceuticals and TRIPS compliance.

It needs to be noted that this thesis does not deal with the issue of traditional medicine. Although the thesis does not cover traditional medicine, it is an important aspect that needs to be considered. It was also not possible to examine the socio-legal impact of the TRIPS-compliant patent law and pharmaceutical patents comprehensively. Options for further research are addressed in Chapter 7 of this study.

1.6 Conclusion and Introduction to Chapter 2

This chapter has provided a summary of different chapters making up the thesis and an introduction to the research area. It also mentioned the importance of this research and its original contribution to current knowledge. Chapter 2 examines the relevant literature and identifies research gaps that lead to the research questions investigated in this thesis.

Chapter 2: Literature Review

2.1 Background

The TRIPS Agreement established a global minimum standard of intellectual property rights (IPR) protection. Hence, it represents a major departure from the previous level of international IPR treaties and agreements, which aimed not to standardise IPR legislation between countries, but to guarantee non-discrimination in national IP systems.[16] It is particularly distinctive from earlier international IPR conventions/treaties/agreements in three important ways. Firstly, TRIPS makes it mandatory for WTO members to provide existing types of IPR protection that include patents, copyright, trademarks, trade secrets, industrial designs, layout designs of integrated circuits and geographical indications.[17] Secondly, it specifies the substantive content of national IPR legislation, such as the extent of coverage, the terms of protection and the mechanisms for enforcement. Thirdly, 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.[18]

The TRIPS Agreement was the brainchild of an industry coalition of developed nations including the United States, the EU 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).[19] The Committee was created during the Uruguay Round of negotiations with the goal of putting TRIPS firmly on the agenda.[20] 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.[21] The

[16] Earlier IPR conventions such as the Berne Convention of 1886 and the Paris Convention of 1883 under the auspices of the World Intellectual Property Organization (WIPO) provided some general principles regarding copyright, related rights and industrial property, but lacked effective enforcement mechanisms and there were no binding guidelines for making national intellectual property laws. See Mohammad Monirul Azam, *WTO, Intellectual Property and Bangladesh* (New Warsi Book Corporation, 2008).

[17] The exceptions are utility models and plant breeders' rights, although TRIPS members are obliged to provide some kind of effective plant variety protection.

[18] J J Simons, 'Cooperation and Coercion: The Protection of Intellectual Property in Developing Countries' (1999) 11(1) *Bond Law Review* 1.

[19] Sylvia Ostry, 'Intellectual Property Protection in the WTO: Misuses in the Millennium Round' *Fraser Institute Conference Santiago, Chile* (April 19, 1999) 3.

[20] John Madely, *Hungry for Trade* (Zed Books, 2000) 96–7.

[21] Mansfield claimed that sixty-five per cent of pharmaceuticals and thirty per cent 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' (IFC Discussion Paper No 27, 1995, The World Bank and International Finance Corporation); E Mansfield, 'Patents and Innovation: An Empirical Study' (February, 1986) 32(2) *Management Science*, 173–81; 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' (Working Paper, 1997, Carnegie Mellon University); A Arundel and G

argument propounded was that the foreign investment and technology transfer would, in turn, benefit developing countries and LDCs.[22] In contrast, developing countries argue that Western IP regulations are unsuited to the present stage of industrial and economic development in the developing countries and LDCs.[23]

Developing countries and LDCs are apprehensive of strong patent protection on the basis that such patent protection may be harmful to the nascent stage of their pharmaceutical industries and may have severe negative consequences for their citizens.[24] A potential consequence of the introduction of pharmaceutical patents being that prices of pharmaceuticals will increase and the availability of cheap pharmaceuticals for poorer citizens will diminish.[25] 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.[26] Relevantly, almost 50 developing countries, which were not

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van de Paal, 'Innovation Strategies of Europe's Largest Industrial Firms' (Unpublished Manuscript, MERIT, 1995); Taylor, C T and Z A Silberston, *The Economic Impact of the Patent System* (Cambridge University Press, 1973); F M Scherer et al., *Patents and the Corporation: A Report on Industrial Technology under Changing Public Policy* (Harvard University, 1959).

[22] However, the evidence linking IPRs to FDI and technology transfer is mixed. Stronger IPR protection has been found to encourage FDI and technology transfer in certain industries, most notably in chemicals and pharmaceuticals. As with trade, IPRs may play less of a role in high-tech industries due to the difficulty in imitating these industries' products, while in low-tech industries other factors such as market size, cheap labour and political stability may be more important in determining FDI flows than IPRs; Smarzynska (2004) finds that weak IPR regimes deter FDI in high-tech sectors (i.e. drugs, cosmetics and health-care products, chemicals, machinery and equipment and electrical equipment), with some evidence suggesting that FDI is deterred in other industries also. She also finds evidence to suggest that stronger IPR protection encourages firms to set up local production facilities rather than focusing solely on distribution networks; Branstetter et al. (2004) suggest that technology transfer is higher following IPR reforms, with an increase in technology transfer, as measured by intra-firm royalty payments from parent firms to affiliates located in IPR reforming countries; see for details, B Smarzynska, 'The Composition of Foreign Direct Investment and Protection of Intellectual Property Rights: Evidence from Transition Economies' (2004) 48 *European Economic Review* 39–62; L G Branstetter, R Fisman and C F Foley, 'Do Stronger Intellectual Property Rights Increase International Technology Transfer? Empirical Evidence from U.S. Firm-Level Panel Data' (World Bank Policy Research Working Paper No 3305, The World Bank, 2004). But Primo Braga and Fink (1998) found no evidence of a relationship between FDI flows and IPR protection and Maskus et al. (2005) argued that strong IPR protection is not a necessary condition for firms to invest in particular countries. If it were, then large countries with high growth rates but weak IPR regimes, such as Brazil and China, would not have received the large foreign-investment inflows that they have; see for details, C A Primo-Braga and C Fink, 'The Relationship between Intellectual Property Rights and Foreign Direct Investment' (1998) 9 *Duke Journal of Comparative and International Law* 163–88 and K E Maskus, S M Dougherty and A Mertha, 'Intellectual Property Rights and Economic Development in China' in C Fink and K E Maskus (eds.), *Intellectual Property and Development: Lessons from Recent Economic Research* (The World Bank/Oxford University Press, 2005).

[23] See Vandana Shiva, *Protect or Plunder* (Zed Books Ltd., 2001).

[24] Martin Khor, 'Rethinking Intellectual Property Rights and TRIPS' in Peter Drahos and Ruth Mayne (eds.), *Global Intellectual Property Rights Knowledge, Access and Development* (Palgrave Macmillan, 2002) 201–13.

[25] 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, 2 Web JCILI, 2004, 3.

[26] For example, after the introduction of patent protection for pharmaceuticals in India in line with the TRIPS Agreement, Bhutan, which is a non-WTO member LDC, is now facing problems of cheap

granted patent protection for pharmaceuticals during the Uruguay Round, fiercely resisted including pharmaceuticals under the patent regime, claiming that vastly higher drug prices would be associated with such patents.[27]

Historically, product patent protection has been excluded in most developed countries.[28] For 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.[29] In Germany, product patents were explicitly excluded under the law of 25 May 1877 but were then introduced from 4 September 1967.[30] In Switzerland, product patents for pharmaceuticals were explicitly prohibited by the Constitution and were only introduced in 1977.[31] In Italy, pharmaceutical patents were prohibited until 1978.[32] In Spain, product patents were introduced in 1986 just after its accession to the European Economic Community (EEC) and the relevant laws came into effect from 1992.[33] 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.[34] Over the years, these developed countries gained self-sufficiency in pharmaceutical manufacturing and invested in R&D,[35] which enabled and facilitated the transformation of their pharmaceutical industries into innovative and research-based industries by using imitated technology.[36] Now, given the advent of TRIPS, the argument being mounted is that these countries are acting in a hypocritical way: they are supporting the implementation of IP protection for pharmaceuticals only after having bedded down their own pharmaceutical industries.[37]

For LDCs, the freedom to rely on imitated technology until such time as pharmaceutical production is at a similar stage of development before the implementation of pharmaceutical patent protection is no longer an option,[38] given the *immediate* obligation as WTO member countries to implement the TRIPS

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availability of drugs. See Dr Tandi Dorji, 'Effects of TRIPS on Pricing, Affordability and Access to Essential Medicines in Bhutan' (Summer 2007) 16 *Journal of Bhutan Studies*, 128–41.

[27] Jane O Lanjouw, 'The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of the Poor and Suffering"?' (Yale University and the NBER, Working Paper No 6366, 26 August 1997), 2.

[28] Xuan Li, 'The Impact of Higher Standards in Patent Protection for Pharmaceutical Industries under the TRIPS Agreement: A Comparative Study of China and India' (The World Economy 1368, 2008).

[29] Ibid.

[30] Ibid.

[31] Ibid.

[32] Ibid.

[33] M Boldrin and D K Levine, *Against Intellectual Monopoly* (Cambridge University Press, 2008) 212–42.

[34] Edwin Cameron and Jonathan Berger, 'Patents and Public Health: Principle, Politics and Paradox' (December 2004) 1(4) *SCRIPT-ed* 532.

[35] Sanjaya Lall, 'Indicators of the Relative Importance of IPRs in Developing Countries' (June 2003) UNCTAD-ICTSD Project on IPRs and Sustainable Development at 1.

[36] J O Lanjouw, 'The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?' (NBER Working Paper No 6366, 1998).

[37] S Srinivasan, 'How TRIPS Benefits Indian Industry and How It May Not Benefit the Indian People' (2008) 2 *Indian Journal of Medical Ethics* 68.

[38] In a case study of UNCTAD in Bangladesh (2007), it was revealed that without imitation, learning would 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.

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 Health[39] is quite meaningless for those countries that do not have the technological capabilities to produce generic pharmaceuticals.[40] Whilst Bangladesh is an LDC, Bangladesh is in a somewhat different position.

Bangladesh has a considerable number of generic producers who can reduce the price of pharmaceuticals utilising the freedom of imitation. Bangladesh also exports to the less regulated markets of Asia and Africa and to some countries in Europe. However, the apprehension is that after the introduction of pharmaceutical patents, as required by TRIPS, the local pharmaceutical industry will face the issue of survival. If the industry fails, there will be an impact upon the access to pharmaceuticals. So, multinationals and other large pharmaceutical companies in Bangladesh consider that by having lowered protection for pharmaceuticals, Bangladesh has missed out on the opportunity to encourage an innovative and R&D-based pharmaceutical industry.

Thus, the debate centres around how to reach a balance between meeting the high costs of pharmaceutical R&D and creating incentives to stimulate access to those pharmaceuticals in developing countries and LDCs. This study will contribute to the debate by providing a better understanding of the implications of a TRIPS-compliant patent regime on pharmaceutical patents for an LDC by focusing on Bangladesh.

2.2 The Requirements of TRIPS

The existing patent law of Bangladesh is a century old law having essentially been inherited from the British during the colonial period.[41] It needs to be amended and updated to conform to the TRIPS Agreement's requirements. Specifically, in the context of pharmaceutical patents, Bangladesh will have to consider the following provisions of the TRIPS Agreement when amending its patent law:

i. To ensure that the patent is available and enjoyed without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced
ii. Patents for both the products and processes[42]
iii. To incorporate patentability requirements such as novelty, inventive steps and industrial application considering national developmental goals and provisions of the TRIPS Agreement

[39] Paragraph 7 of the Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001.
[40] Padmashree Gehl Sampath, 'Innovation and Competitive Capacity in Bangladesh's Pharmaceutical Sector' (Working Paper series#2007-031at 3, September 2007) United Nations University-Maastricht Economic and Social Research and Training Centre (UNU-MERIT), The Netherlands.
[41] The law relating to patents in Bangladesh is the Patents and Designs Act 1911, with some minor amendments to date.
[42] Although patents were always issued to protect the product production process, without patent restrictions on products, pharmaceutical companies were still able to use reverse-engineering techniques on needed medicines to uncover their molecular structure and thus develop new ways to build the pharmaceuticals that were needed. These compounds produced through alternate processes were then sold as 'generic' versions of the original pharamaceuticals, and drove down the price of the original product through market competition. However, if product patent is granted, within the duration of patent protection, even if making an alternative process, other companies cannot introduce generic products onto the market and, hence, the monopolised price of the patent holder is protected.

iv. The status/exclusion of pharmaceutical patents during the waiver period until 1 January 2016 and the likely provision for a 'mailbox' during the transitional period
v. Utilisation of flexibilities such as exceptions for government use, compulsory licenses, parallel imports, experimental use and public interest
vi. Provisions for the use of patents without the authorization of patent holders, but with a number of conditions and limitations
vii. Minimum 20-year term for patent protection.[43]

The amending legislation will necessarily require a consideration of the competing interests of a variety of stakeholders, including domestic generic-medicine producers, the domestic R&D community, foreign multinational pharmaceutical companies and citizens of Bangladesh to ensure that the move towards TRIPS compliance is effective without affecting Bangladesh's national interests.

2.3 TRIPS Flexibilities

In exploring the legislative requirements for TRIPS-compliant patent law there is a need to consider the flexibilities available under the TRIPS agreement. The TRIPS Agreement provides flexibility for members to determine their own approach regarding the relationship between IPRs and access to pharmaceuticals in a number of ways. The Agreement permits WTO members to:

- Define the nature of invention and to regulate the criteria of patentability within the broad framework of TRIPS Agreement rules
- Establish exceptions to patent rights
- Grant government use and compulsory licenses
- Have recourse to a range of options with respect to the protection of data submitted for regulatory purposes
- Determine country-based policies with respect to exhaustion of rights and to allow parallel importation of medicines
- Utilising the 'unfair commercial use' option of 'protection of undisclosed test data' can be restricted and limited to promote generic competition and reduce price.[44]

The use of these flexibilities forms the basis of the recommendations that result from the research. However there is a significant body of literature that addresses the issues of the TRIPS Agreement and experience of other countries regarding use of flexibilities. In the next section the literature is examined to identify the gap which justifies this research.

[43] See Article 33 of the TRIPS Agreement.
[44] Article 39.3 of the TRIPS Agreement requires member countries to establish protection for submitted test data. However, this requirement is in fact narrowly drawn, and countries maintain substantial flexibility in implementation. The public interest in limiting protection for data is to promote competition and to ensure that data protection does not become the means to block the timely entrance of generic competitors to off-patent drugs because generic competitors drive down price, thereby promoting greater accessibility to medicines. See Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (South Centre, 2002).

2.4 The Literature

The academic literature covering the WTO and multilateral trading system can be divided into three categories:

a) literature examining economic issues;[45]
b) literature examining trade policy and associated legal and governmental policy measures such as investment, imports and exports, textiles and clothing and intellectual property;[46]
c) literature examining the issues associated with the TRIPS Agreement and the domestic pharmaceutical industry.[47]

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[45] Major literature relating to the economic dimension of the multilateral trading system from the perspectives of Bangladesh includes: Muinul Islam, *Prantio Punjibadi Rashtro O Onunnayan Proshongo* (in Bangla) (2003); Abul Kalam, *Globalisation and Bangladesh*, (Palok, 2002); Abul Kalam, 'Challenges of the Age of Globalization' (2001) XX(4) *Spotlight on Regional Affairs (Islamabad)*; Dr Md. Abdul Mannan Choudhury, 'Bishsha Banirjha O Antorjhatic Landenar Arthoniti' (in Bangla) (Rural Economics Program, Department of Economics, University of Chittagong, 1 January 1997); Munim Kumar Barai, 'Economic Liberalization and Macro Economic Stability in Bangladesh: An Overview (Paper presented at a national workshop organised by Bangladesh Institute of International and Strategic Studies (BIISS), Dhaka, 29 February–1 March 2000); Md. Shamsul Huq, 'Bangladesh and the Emerging New Global Order' (Paper presented in a seminar organised by BIISS, 1 March 2000); Hafiz G A Siddiqui, 'WTO and Economic Security: Bangladesh Perspectives' (Paper presented in the BIISS workshop, 29 February 2000); and a number of reports and occasional papers published by the Center for Policy Dialogue (CPD) from 2000–2008.

[46] Major literature relating to the trade policy and limited legal policies of multilateral trading systems from the perspective of Bangladesh includes: Dr A K Enamul Haque et al., Market Access Issues: EU–Bangladesh Trade Regime–A Case Study on Market Access–Myths and Realities, a report (Dhaka, Bangladesh, 2005); Nurul Islam, *Looking Outward: Bangladesh in the World Economy* (2004); Farhad Mazhar, *Banijja O Bangladesher Jonogon* (In Bangla) (2004); Mahafuz Ullah, *Intellectual Property Rights and Bangladesh* (2002); Nasiruddin Ahmed, *Trade Liberalisation in Bangladesh: An Investigation into Trends* (University Press Ltd., 2001); Sadequl Islam, *The Textile and Clothing Industry of Bangladesh in a Changing World Economy* (University Press Ltd., 2001); D Bhattacharya and R.A.M. Titumir, *Setting the Agenda for the Next WTO Round: Perspectives from Bangladesh on the Seattle Ministerial* (2000); World Bank reports namely 'Bangladesh Trade Liberalization: Its Pace and Impacts' (1999) and 'Bangladesh: Key Challenges for the Next Millennium' (1999); N Ahmed, 'Liberalizing Bangladesh's External Sector' (Paper presented at the International Conference on South Asia held at the University of Sydney, 12–14 September 1997); M I Hossain and M M Rahman, 'Current External Sector Performance and Emerging Issues' in R Sobhan (ed.), *Growth or Stagnation? A Review of Bangladesh's Development* (Center for Policy Dialogue, University Press Limited, 1996); M Rahman, 'The GATT Uruguay Round Multilateral Accord: Implications for Bangladesh' in James Love and Mozammel Huq (eds.), *Strategies for Development in Bangladesh* (1995); H Ahammad, 'Foreign Exchange and Trade Policy Issues in a Developing Country: The Case of Bangladesh' (Working Paper#95/1, Canberra Research School of Pacific and Asian Studies, Australian National University, 1995); M Alam, *Trade and Financial Liberalization in Bangladesh* (Desh Prakashan, 1995); N Choudhury, 'Impact of GATT Uruguay Round on Bangladesh's External Economy' (Report prepared for the World Bank, Dhaka, 1994); R A Mahmood and D K Roy, 'Non Traditional Exports from Bangladesh: Problems and Prospects' (Paper prepared for a seminar organised by Export Promotion Bureau, Dhaka, 1994); S H Rahman, 'Trade and Industrialization in Bangladesh: An Assessment' in G K Helleiner (ed.), *Trade Policy and Industrialization in Turbulent Times* (Routledge, 1994); R Sobhan, *Bangladesh: Problems of Governance* (University Press, 1994); K H Imam, 'Some Aspects of the Foreign Trade Policies of Bangladesh' in E A G Robinson (ed.), *The Economic Development of Bangladesh* (1974).

[47] Major literature that deals with issues of TRIPS and the pharmaceutical industry in Bangladesh includes: Mohammad Towhidul Islam, 'TRIPS Agreement and Public Health: Implications and Challenges for Bangladesh' (2011) 17(1) *International Trade Law and Regulation*; Public and Private Sector Approaches to Improving Pharmaceutical Quality in Bangladesh (Bangladesh Development Series, Paper No 23, March 2008), A study by the World Bank, 1 June 2009,

The first two categories of literature identified above deal with the economic dimension of TRIPS and will not be examined as this goes beyond the scope of this thesis. The literature from the third group is examined as it forms the subject matter of this thesis.

2.4.1 TRIPS Agreement and Domestic Pharmaceutical Industry

Padmashree Gehl Sampath conducted two studies[48] on the pharmaceutical industry in Bangladesh, examining the strategies of Bangladeshi pharmaceutical firms and their capacities. The first study explored whether IPRs could directly stimulate research and development (R&D) and innovation in an LDC such as Bangladesh. Padmashree Gehl Sempath found that the presence of IPRs in Bangladesh would not play a role either as a direct incentive for innovation or as an indirect incentive for technology transfer.[49] However, the study did not focus on the challenges that exist for Bangladesh in trying to make and implement a TRIPS-compliant patent law, nor the direction for capacity building of the pharmaceutical sector in a TRIPS-compliant patent regime. The second study[50] investigated the capacity for innovation and competitiveness in the local pharmaceutical sector in Bangladesh and concluded that indigenous pharmaceutical firms in Bangladesh may not be able to capitalise on the Doha extension for pharmaceutical exports unless they invest in technological progress and enhance their competitiveness.[51] Like the first study, the second study did not consider the implementation of a TRIPS-compliant patent law.

Anne St. Martin, in a thesis[52] on the Impact of TRIPS on Access to Essential Medicines in the Developing World, conducted her research in Bangladesh and identified the prospect of Bangladesh being able to provide cheap pharmaceuticals during the waiver period. However, the thesis did not examine the legislative and policy directions Bangladesh may need to take.

In that context, S. M. Anowar Uddin[53] examined the TRIPS waiver period and how access to medicine in Bangladesh may be affected. He conducted his research using secondary internet-based sources and concluded that Bangladesh as an LDC should

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<www.worldbank.org.bd/bds>; Yusuf and Alam, above n 12; S M Anowar Uddin, *TRIPS Waiver but Why the Pharmaceutical Medicines Hard to Get in Bangladesh* (Denmark, 2008) A project report submitted to Roskilde University; Sampath, above n 40; Martin, above n 15; Md. Farhad Hossain Khan, IP Administration and Enforcement System: Towards Modernisation of IP Protection in Bangladesh and A Comparative Analysis of IP Administration between Japan and Bangladesh (April 1–September 30, 2004), Tokyo Institute of Technology, Japan; Professor Tony VanDuzer, 'TRIPS and Pharmaceutical Industry in Bangladesh: Towards a National Strategy' (Paper 24 April, 2003) Centre for Policy Dialogue (CPD), Dhaka, Bangladesh, Md. Shah Amran, TRIPS, Pharmaceuticals and Bangladesh 28 March 2009 <www.bangladeshinfo.com/news/special16.php> etc.

[48] Sampath, above n 40; Gehl Sampath 'Intellectual Property in Least Developed Countries: Pharmaceutical, Agro-processing, and Textiles and RMG in Bangladesh'(2007) Study prepared for UNCTAD as a background paper for The Least Developed Countries Report, background Paper No 9, UNCTAD, Geneva, Switzerland.

[49] Sampath, above n 48.

[50] Sampath, above n 40.

[51] Ibid.

[52] Martin, above n 15.

[53] S M Anowar Uddin, *TRIPS Waiver but Why the Pharmaceutical Medicines Hard to Get in Bangladesh* (Denmark, 2008) A project report submitted to Roskilde University.

use the waiver period leading to 1 January 2016 to capacity build in the pharmaceutical sector and make allied reforms to the patent law. However, S. M. Anowar Uddin did not provide any specific direction for such legislative reforms.

In the context of the pharmaceutical industry specifically, Md. Shah Amran[54] studied the impact of TRIPS on the developing countries in general. He recommended that Bangladesh should take advantage of the waiver period but did not express what should be done during that period.[55]

Syed Farhat Anwar[56] tried to argue that there may be greater export opportunities for pharmaceuticals from Bangladesh utilising the TRIPS waiver period. In a study by the World Bank Bangladesh Office[57] on the pharmaceutical sector of Bangladesh, the quality and price of pharmaceuticals in Bangladesh was investigated. The study suggested some alternative mechanisms[58] to improve the quality of pharmaceuticals available in Bangladesh. The study concluded with some policy and institutional suggestions for the government of Bangladesh to improve the price and quality competitiveness of Bangladesh's pharmaceuticals. However, like other existing studies on Bangladesh, it did not suggest any policy direction that may be available to implement a TRIPS-compliant patent law to achieve such improvements.

Conversely, Professor Tony VanDuzer,[59] in his research, made an attempt to evaluate the challenges for the pharmaceutical industry in Bangladesh in the context of the TRIPS Agreement. Whilst he evaluated the challenges, the research failed to suggest any substantial policy direction for future law making. Further, the research is somewhat dated as it does not deal with the subsequent changes of the TRIPS Agreement in line with the Doha Declaration and does not address the important issue of how an LDC such as Bangladesh can balance access to medicine whilst promoting pharmaceutical innovation and also making a TRIPS-compliant patent law.

In the context of IPRs, Mohammad Abu Yusuf and Qamrul Alam, in their study,[60] tried to examine some policy options, such as the utilisation of compulsory licensing. The research did not analyse the existing flexibilities, the weakness of the existing patent-law provisions in Bangladesh and any direction for patent-law reforms in Bangladesh in line with the TRIPS Agreement.

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[54] Md. Shah Amran, TRIPS, Pharmaceuticals and Bangladesh, 27 March 2009, <www.bangladeshinfo.com/news/special16.php>.

[55] Ibid.

[56] Syed Farhat Anwar, 'Pharmaceutical Sector of Bangladesh: Trade Prospects with Nepal and the Impact of TRIPS' in Forrest E Cookson and A K M Shamsul Alam (eds.), *Towards Greater Sub Regional Economic Cooperation: Limitation, Obstacles and Benefits* (Chapter Six), (University Press Limited, 2002).

[57] Public and Private Sector Approaches to Improving Pharmaceutical Quality in Bangladesh, Bangladesh Development Series, Paper No. 23, A study by the World Bank, March 2008, 1 June 2009, <www.worldbank.org.bd/bds>.

[58] Alternative mechanisms such as export-led improvement, regulatory led quality improvement, competition-led quality improvement, private-sector-led improvement and knowledge-transfer-led improvement.

[59] Professor Tony VanDuzer, 'TRIPS and Pharmaceutical Industry in Bangladesh: Towards a National Strategy' (Paper 24 April, 2003) Centre for Policy Dialogue (CPD), Dhaka, Bangladesh.

[60] Yusuf and Alam, above n 12.

More recently, Mohammad Towhidul Islam[61] argued that the introduction of the TRIPS compliant patent law and pharmaceutical patents will create barriers for access to pharmaceuticals for LDCs including Bangladesh. He also suggested that the extended compliance deadline of 1 January 2016 offers Bangladesh an opportunity to copy patented pharmaceuticals for domestic consumption at affordable prices and for their export to other markets, especially LDCs. He also suggested that TRIPS flexibilities such as parallel imports and compulsory licenses will be useful to ensure access to cheaper pharmaceuticals. He concluded that the existing intellectual property laws in Bangladesh do not support these measures but did not provide any detailed suggestions for changes required to the patent law of Bangladesh apart from compulsory licenses and parallel imports.

From the review of literature the gap in the existing literature concerns the critical examination of the specific legislative and other governmental options available to Bangladesh as it moves toward the requirement to be TRIPS compliant.

Helpfully, there are a number of studies that analyse developing countries such as India, Thailand, South Africa and Brazil and those countries' experiences in introducing TRIPS compliant patent law into their pharmaceutical industries. The extent of the impact identified will be useful in guiding this research.

For example, Dr Tandi Dorji[62] examined the effects of TRIPS on pricing, affordability and access to essential medications in Bhutan and established that with the enactment of TRIPS compliant patent law in India in 2005 (which is a major supplier of generic medicine to Bhutan) and with Bhutan in the process of becoming a member of the WTO, the affordability of essential medicines was limited.[63]

Further, Amal Nagah Elbeshbishi,[64] in his study of the TRIPS Agreement and African countries argued that compulsory licences, generic drugs, parallel imports and differential pricing may be useful to protect African countries in a TRIPS compliant regime. This study followed a general approach for all African countries rather than examining the impact upon a particular country. How far these solutions can be utilised in Bangladesh will be explored, even though there may be differences in the technological capabilities of Bangladesh and some African countries.

Padmashree Gehl Sampath,[65] Lanjouw,[66] Grace,[67] Choudhuri,[68] Fink,[69] Watal,[70] Arvind[71] and Subramanian[72] have all conducted studies using the experience of

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[61] Mohammad Towhidul Islam, 'TRIPS Agreement and Public Health: Implications and Challenges for Bangladesh' (2011) 17(1) *International Trade Law and Regulation.*

[62] Dr Tandi Dorji, above n 26, 128–41.

[63] Conversely, having no pharmaceutical capacity, Bhutan may not utilise the Doha waiver for LDCs.

[64] Amal Nagah Elbeshbishi, 'TRIPS and Public Health: What Should African Countries Do? African Trade Policy Centre (ATPC)' (Work in Progress No 49, January 2007).

[65] P Gehl Sampath, Economic Aspects of Access to Medicines Post-2005: Product Patent Protection and Emerging Firm Strategies in the Indian Industry, Background Study: Commission on Intellectual Property Rights, Innovation and Public.
Health, WHO, Geneva, 2005 and P Gehl Sampath, 'India's Product Patent Protection Regime: Less or More of "Pills for the Poor"?' (2006) 9(6) *The Journal of World Intellectual Property* 694–26.

[66] Lanjouw, above n 36.

[67] C Grace, 'Update on China and India and Access to Medicines Briefing Paper' (DFID/HSRC, London November, 2005) 1–42.

India. Each tried to predict the impact a TRIPS-compliant patent regime would have on the strategies of Indian pharmaceutical firms. These studies can be used to evaluate, through comparison, the differences between Bangladesh and India in relation to knowledge, the technological and infrastructural capacity of pharmaceutical firms, the different waiver period and the different economic and local market structure to provide a point of reference from where to provide potential options for Bangladesh.

In the context of potential legislative options, A. Naomi Bass, in a study on the implications of the TRIPS Agreement for developing countries,[73] examined the effects of the implementation of patent laws in Brazil and South Africa. In studying the effects of implementation, Bass also explored the legal and socio-economic implications of the TRIPS regime on the international pharmaceutical industry and the consumers of patented medicines. In the study, she argued that compliance with the TRIPS Agreement may ultimately induce multinational companies to establish monopolies within the domestic industry to prevent domestic companies from realising any additional benefits. Her findings highlight the difficulties faced in trying to reach a consensus within the global community on a method of implementing patent-protection laws while simultaneously protecting the specific needs of developing countries. This is an important consideration given the position of Bangladesh in the context of its current ability to produce generic pharmaceuticals.

In sum, the existing literature tends to focus on the economic dimension and trade policy issues that arise as a consequence of TRIPS rather than on the specific issues of the legislative compliance. In particular there is an absence of literature examining the specific requirements of a TRIPS-compliant patent law in Bangladesh and the consequences that may flow in the context of the patenting of the pharmaceuticals. It is at this point where the research will be an original contribution to knowledge as the aims of the research are to consider the imminent problems facing Bangladesh, particularly the need to provide possible legislative policy and governmental intervention options that ensure TRIPS compliance but also protect the domestic industry and provide affordable pharmaceuticals.

2.5 Research Questions and Aims of This Study

Given the identified gap in the literature examining the specific legislative and governmental intervention issues with the TRIPS implementation, this thesis

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[68] S Choudhuri et al., *Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India* (2004).

[69] C Fink, 'How Stronger Patent Protection in India Might Affect the Behaviour of Transnational Pharmaceutical Industries' (The World Bank Working Paper No 2352, The World Bank, 2000).

[70] J Watal, 'Introducing Product Patents in the Indian Pharmaceutical Sector: Implications for Prices and Welfare' (1999) 20 *World Competition* 5–21.

[71] S Arvind, 'Putting Some Numbers on the TRIPS Pharmaceutical Debate'(1995) 10 *International Journal of Technology Management* 252–68.

[72] A Subramanian, 'Putting Some Numbers on the TRIPS Pharmaceutical Debate' (1995) 10 *International Journal of Technology Management* 252–68.

[73] A Naomi Bass, 'Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century' (2002) *George Washington International Law Review*.

represents a contribution by identifying the major areas of reform in the national patent law of Bangladesh. This leads to the research questions that are the focus of this thesis.

2.5.1 Research Question (RQ)-1

Using the experience of India and Brazil as a point of reference, what are the different options available to Bangladesh in changing its existing patent law to comply with TRIPS?

2.5.2 Research Question (RQ)-2

Using the options identified, what changes to the Bangladeshi patent law will best support the pharmaceutical industry whilst ensuring access to pharmaceuticals in Bangladesh?

No existing literature has dealt with these questions specifically, so the process of change to TRIPS compliance is yet to be fully considered.

2.6 Moving Forward

To answer research question 1 this thesis will adopt a legal doctrinal review to analyse the patent-law reforms adopted by India and Brazil to move toward TRIPS compliance. To answer research question 2, a mixed-method research approach was adopted which used surveys and interviews to examine the situation in Bangladesh. Participants commented on the current condition of the domestic pharmaceutical industry, the perceptions of different stakeholders towards TRIPS-compliant patent law, possible implications for access to pharmaceuticals and for the future of the pharmaceutical industry in Bangladesh. In the next chapter, the research methodology which underpins the exploration of the research questions is discussed in more detail.

Chapter 3: Research Methodology

3.1 Introduction

This chapter discusses the research methodology as adopted in this thesis, namely a legal doctrinal method, comparative analysis method and mixed-method to answer the two research questions identified in chapter 2. Additionally this chapter introduces the data-collection instruments and data analysis process undertaken with respect to the data that was collected.

3.2 Research Design

As a general proposition it is accepted that legal research is either doctrinal or non-doctrinal research.[74] Non-doctrinal research can be either qualitative or quantitative or a combination of both, while doctrinal research is mostly qualitative as it does not involve the statistical analysis of any collected data.[75] However, both types of research may overlap. This study had adopted a mixture of doctrinal research and non-doctrinal research methods to answer the research questions.

3.3 Research Methodology

This kind of combined research method has been previously applied. For example, in the intellectual property law field (the subject matter of this thesis is also within this field) a study on Copyright and Access to Knowledge in Eight African Countries applied the research method of combining doctrinal analysis, qualitative impact assessments and a comparative review.[76] Again, Lorenzo Cotula, in a PhD thesis on Property Rights, Negotiating Power and Foreign Investment in Africa applied doctrinal and comparative legal analysis along with a further component of field studies for data collection.[77]

In this study, the legal doctrinal analysis constitutes the core of the study, as the first research question identified in this study could be tackled through legal analysis alone. To answer research question two, a mixed-method approach is used to complement the legal analysis, and relates it to an analysis of options that may help Bangladesh to balance pharmaceutical innovation and access to pharmaceuticals. Comparative review was used to draw lessons for Bangladesh utilising the options identified from the doctrinal review of patent laws and pharmaceutical regulations in India and Brazil.

[74] M McConville and H C Wing (eds), *Research Methods for Law* (Edinburgh University Press, 2007).
[75] Ibid.
[76] Chris Armstrong et al., *Copyright and Access to Knowledge in Eight African Countries* (2010).
[77] Lorenzo Cotula, *Property Rights, Negotiating Power and Foreign Investment: An International and Comparative Law Study on Africa* (PhD Thesis, University of Edinburgh School of Law, 2009).

3.4 Doctrinal Research

Doctrinal research is defined as a systematic exposition of the rules governing a particular legal category that analyses the relationship between rules, explains areas of difficulty and, perhaps, predicts future developments.[78] In general, doctrinal research exposes what the law is on a particular issue. It is concerned with analysis of the legal doctrine and how it has been developed and applied. This type of research is also called pure theoretical research. Mostly, it deals with research questions directed at finding a specific statement of the law or a more complex and in-depth analysis of legal reasoning.

The doctrinal analysis uses interpretive methods to examine relevant sources of patent law and to construct the protection of pharmaceutical patents in India and Brazil from the perspective of both the local pharmaceutical industry and in terms of access to medicines. As the core research question involves options taken up by India and Brazil while adopting TRIPS-compliant patent law, the doctrinal analysis assesses such options, based on flexibilities available within the TRIPS Agreement.

It also explores whether options adopted by India and Brazil are compatible with TRIPS obligations or not, and how far these options are viable for an LDC such as Bangladesh.

The legal analysis relies on both primary and secondary sources (patent law, government reports, regulations, orders and judicial decisions and academic literature, respectively). As the research question cuts across different bodies of law (from the TRIPS Agreement to various branches of national law, patent law and pharmaceutical regulations), the spectrum of primary sources used is quite broad. Further, as part of a mixed-method approach, selected experts on Indian, Brazilian and global patent law were also interviewed.

The advantage of doctrinal research is that it is a systematic formulation of the law in particular contexts, and it clarifies ambiguities within rules, and places them in a logical and coherent structure and describes their relationship to other rules.[79] Doctrinal research is therefore concerned with the discovery and development of legal doctrines and dictates what the law is. The validity of doctrinal research findings is unaffected by the empirical world. Doctrinal research makes no attempt to explain, predict or even to understand human behaviour, which is considered as one of the major disadvantages of doctrinal research. In asking 'what is the law?' doctrinal research takes an internal, participant-orientated epistemological approach to its object of study and, for this reason, is sometimes described as research *in* law.[80] That is why there is a criticism that doctrinal research is not research *about* law at all.[81]

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[78] Commonwealth Tertiary Education Commission (1987); Terry Hutchinson and Nigel Duncan, 'Defining What We Do: Doctrinal Legal Research' (Australian Law Teachers Conference, 2010).
[79] H L A Hart, *The Concept of Law* (Clarendon Press, 1961).
[80] H W Arthurs, *Law and Learning: Report to the Social Sciences and Humanities Research Council of Canada by the Consultative Group on Research and Education in Law* (Information Division, Social Sciences and Humanities Research Council of Canada, 1983).
[81] Terry Hutchinson, *Researching and Writing in Law* (Law Book Co, 3rd ed., 2010) 22.

There have also been criticisms made of the doctrinal methodology; for example, that it is too theoretical, too technical, uncritical and narrow in its choice and range of subjects, and that it does not take full account of the social and economic significance of the legal process. Against these criticisms, doctrinal research provides foundations for further socio-legal research and it may be combined with other non-doctrinal research.[82]

Therefore, it is important to understand that doctrinal research is not simply a single isolated category of scholarship. Some element of doctrinal analysis will be found in all but the most radical forms of legal research. For example, although legal reform-oriented research and socio-legal research appear as separate categories, their practitioners emphasise the importance of doctrinal legal analysis within their socio-legal work.[83] This study used doctrinal analysis to understand the question 'what the patent law is' in Bangladesh, India and Brazil. However, it also analyses the historical, political and local pharmaceutical industry motivation behind the patent-law reforms in these countries. In this way the doctrinal research leads into a comparative analysis.

3.5 Comparative Analysis

Comparative legal research methods have long been used in cross-national studies to identify, analyse and explain similarities and differences across countries' legal system and practices. The benefit of this kind of comparative review is to gain a deeper understanding of other countries and their legal process so as to identify good practices and draw important lessons that may be replicated in other countries. Comparative legal research is very beneficial in a legal development process where modification, compliance, amendment and changes to the law are required.[84] It is typical for researchers who undertake this kind of research to examine the law as it is, while at the same time providing ideas and views for future legal development.[85]
This study employes a comparative review to compare and contrast the perspectives of India and Brazil in order to identify all the options used by those countries in the context of the implementation of the TRIPS Agreement so as to draw options for Bangladesh. The identification of these options then form the basis of the exploration of research question two and in so doing employ the mixed method approach.

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[82] Ibid 23.
[83] F Cownie, *Legal Academics: Culture and Identities* (Hart Publishing, 2004) 55–6.
[84] V V Palmer, 'From Lerotholi to Lando: Some Examples of Comparative Law Methodology' (2005) 53 *American Journal of Comparative Law* 261–2.
[85] For example, Jakkrit Kuanpoth, in his research study titled 'Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future', made a comparative analysis between the patent laws of India and Thailand and has drawn some lessons for developing countries in general. See, Jakkrit Kuanpoth, *Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future* (Edward Elgar Publishing Ltd., 2010). Again, Daya Shanker made an analysis of the TRIPS Agreement with reference to the analysis of some specific TRIPS flexibility categories such as compulsory licenses and parallel imports, as used in Argentina, Brazil and India, and through comparative analysis suggested possible options for developing countries. For details see, Daya Shanker, *Fault Lines in the World Trade Organization: An Analysis of the TRIPS Agreement and Developing Countries* (PhD Thesis, University of Wollongong, 2005).

3.6 Mixed-method Research

While the doctrinal legal analysis is used with respect to the first research question of this study, it is accompanied by a complementary mixed-method approach to strengthen the analysis with respect to the second research question. This component mainly draws on data gathered in Bangladesh. The purpose of this component is to complement the findings of the first research question with an understanding of the extent and ways in which these legal norms can be utilised in Bangladesh. This understanding helps address this thesis second research question in a way that better reflects the perceptions of the relevant stakeholders.

The mixed-method approach is adopted as both qualitative and quantitative data is required to answer the research questions, particularly the second research question.[86] Mixed-method research is defined as:

> a research design with philosophical assumptions as well as methods of inquiry. As a methodology, it involves philosophical assumptions that guide the direction of the collection and analysis of data and the mixture of qualitative and quantitative approaches in many phases in the research process. As a method, it focuses on collecting, analysing, and mixing both quantitative and qualitative data in a single study or series of studies. Its central premise is that the use of quantitative and qualitative approaches in combination provides a better understanding of research problems than either approach alone.[87]

Mixed-method research is an attempt to legitimate the use of multiple approaches in answering research questions, rather than restricting or constraining researchers' choices.[88]

In the context of this thesis, the use of the mixed-method approach can be justified in the following ways:

- A mixed-method approach provides strengths that offset the weaknesses of both quantitative and qualitative research if used in isolation.[89]
- Mixed-method approach research provides more comprehensive evidence for studying a research problem than either quantitative or qualitative research alone. Researchers are free to use all of the tools of data collection available rather than being restricted to the types of data collection typically associated with qualitative research or quantitative research.[90]
- A mixed-method approach helps answer questions that cannot be answered by qualitative or quantitative approaches alone.[91]
- A mixed-method approach is considered 'practical' because the researcher is free to use all methods possible to address a research problem.[92]

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[86] For details on the mixed-method approach see John W Creswell and Vicki L Plano Clark, *Designing and Conducting Mixed Methods Research* (Sage Publications, 2007); David L Driscoll et al., 'Merging Qualitative and Quantitative Data in Mixed Methods Research: How To and Why Not' (2007) 3(1) *Ecological and Environmental Anthropology* 19–28.
[87] Creswell and Plano Clark, above n 96 at 5.
[88] R Burke Johnson and Anthony J Onwuegbuzie 'Mixed Methods Research: A Research Paradigm Whose Time Has Come' (2004) 33(7) *Educational Researcher* 14–26.
[89] Creswell and Plano Clark, above n 96.
[90] Ibid 9.
[91] Ibid.
[92] Ibid 10.

- Finally, the mixed-method approach provides stronger evidence for a conclusion through convergence and verification of the findings.

3.7 Description of Data-collection Instruments

The data used in this thesis was collected through surveys and conducting interviews. The surveys collected both qualitative and quantitative data whilst the interviews collected qualitative data only.

It is acknowledged that both the survey and interview methods of data collection have their own strengths and weaknesses.[93] For example, a survey method is not flexible in the context of the questions provided, whereas the interview process is flexible and can go in different directions.[94] Further, in case of survey research there is the possibility of non-response bias and response-order bias (where respondents pick a response that comes easily to mind rather than the most accurate) and response-set bias (where respondents do not consider each question and rather just answer all the questions with same response; for example, they answer disagree or no to all questions).[95]

There is also the possibility of a low response rate, reduced quality data and the knowledge produced might be too abstract and general for direct application to the study.[96] These weaknesses are not evident when using interviews for data collection as they are useful for in-depth examination.

However, there is the danger that interview findings might be unique to the people included in the research study, they can be time consuming and interview data may be difficult to statistically test hypotheses and theories.[97] This is not the case for a survey, as not only can a survey can be less time consuming but is useful for canvassing the views of a larger number of people and is subject to statistical analysis.

Therefore, the basis for employing a mixed-method approach adopting the processes of surveys and interviews to collect data is to expand the scope or breadth of the research and to offset any of the weaknesses of either approach that are found in the survey or interview alone.[98]

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[93] For details on strengths and weaknesses of surveys and interview and different other research methods see Chapter 14, *Mixed Research: Mixed Method and Mixed Model Research*, 11 September 2009, <http://www.southalabama.edu/coe/bset/johnson/dr_johnson/lectures/lec14.htm>.
[94] Ibid.
[95] Ibid.
[96] Ibid.
[97] Ibid.
[98] R Blake, 'Integrating Quantitative and Qualitative Methods in Family Research' (1989) 7 *Families Systems and Health* 411–27; V J Caracelli and J C Greene, 'Data Analysis Strategies for Mixed-Method Evaluation Designs' (1993) 15(2) *Educational Evaluation and Policy Analysis* 195–207; J Greene, V Caracelli, and W Graham, 'Toward a Conceptual Framework for Mixed-Methods Evaluation Designs' (1989) 11 *Educational Evaluation and Policy Analysis* 255–74; G Rossmanand and B Wilson, 'Numbers and Words Revisited: Being "Shamelessly Eclectic"' (1991) 9(5) *Evaluation Review* 627–43.

In the context of this research, gaining both qualitative and quantitative data enabled the examination of the views of all stakeholders regarding the introduction of pharmaceutical patents so as to understand the differing positions of stakeholders with a view to providing policy options for the smoother implementation of a TRIPS-compliant patent law.

The survey instrument attached in appendix three was designed in order to gain an understanding of the perceptions of different stakeholders regarding TRIPS-compliant patent law and pharmaceutical patent protection. It was also useful to collect qualitative data about the pharmaceutical companies so as to understand the strategies and innovation capacities of the firms. Obtaining qualitative and quantitative data was also used to in answer the research questions by pinpointing major concerns and motivations for the transition from a pre-TRIPS to a TRIPS-compliant patent regime.

Obtaining qualitative and quantitative data via interviews was also helpful in understanding the institutional details of the pharmaceutical industry, the Directorate of Drug Administration (DDA), the patent office, research and educational institutions and public-health groups. Interviews, in particular, were very valuable in understanding the required policy directions needed for the reform of patent law from the participants' perspective, showing how they weigh costs and benefits for themselves, and the extent to which they trusted in the change to a TRIPS-compliant pharmaceutical patent system.

This researcher used closed-ended questions, where the range of responses is highly restricted, usually by agree–disagree or numerical response scales (e.g. 1 = strongly agree; 5 = strongly disagree).[99] Closed-ended techniques are designed to obtain information from each respondent that is as comparable as possible.[100] One means of doing so is to present each participant with a standard 'stimulus' in the form of a question with a restricted set of answers.[101] The researcher also provided some specific questions relating to the research questions of this study by using as little structure as possible so that the perspectives and concerns of the participants could come into view.[102]

The survey instrument and interview question schedule are attached in appendix three and four respectively, together with a copy of the information sheet and consent form to demonstrate how the mixed-method approach to obtain both qualitative and quantitative data was used in this study. The instruments and questions used in this study were approved by the Central Queensland University Human Research Ethics Committee (CQUHREC).[103]

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[99] See J M Converse and S Presser, *Survey Questions: Handcrafting the Standardized Questionnaire* (Sage, 1986).

[100] Research Procedures, 12 September 2009, <http://www.llc.rpi.edu/web/ResearchMethodsForCommunicationScience/ch18.pdf>.

[101] William M K Trochim, Social Research Methods, 13 September 2009, <www.socialresearchmethods.net/kb/questype.php>.

[102] Aletha C Huston, 'Mixed Methods in Studies of Social Experiments for Parents in Poverty: Commentary' (January 2001), Prepared for Conference on Discovering Successful Pathways in Children's Development: Mixed Methods in the Study of Childhood and Family Life, Santa Monica, CA.

[103] See Letter of Ethical Clearance in the appendix one.

3.7.1 The Survey

The data collection process with respect to the survey began in October 2009 and was carried out until June 2010. During this time, pharmaceutical companies were approached by way of a phone call, email and personal visit to the office. During this time it was not possible to contact all the selected participants. That is why another field visit was made from September 2010–January 2011. Survey findings, as discussed in this study, are based on the direct field work in Bangladesh.

In addition to the questionnaire survey, the interview was used to collect related data from the major organisations in Bangladesh associated with the change process of TRIPS and the pharmaceutical industry such as the Bangladesh Association of Pharmaceutical Industry (BAPI), the DDA, the Department of Patents, Designs and Trade Marks, pharmacy and intellectual property academic staff and researchers, NGOs working for public-health services and executives of some leading pharmaceutical companies. Interview findings are discussed and accommodated, where required.

3.7.2 Interview

In the interview, the researcher followed the structure outlined below in order to gain important findings so as to answer the research questions for this study including:

(a) questions on opportunities and challenges for the local pharmaceutical industry due to the Doha waiver for pharmaceutical patents and on the overall impact of the TRIPS Agreement.
(b) what the specific options available to Bangladesh were in order for the country to meet post-TRIPS challenges after the introduction of pharmaceutical patents and what steps had been taken by the industry itself and by the government of Bangladesh in terms of capacity building.
(c) questions regarding the role of specific regulatory bodies and the participants' areas of involvement to find out more detail regarding on-going preparations and possible options for Bangladesh to balance pharmaceutical innovation and access to medicines and
(d) how far the experience of other countries in general, and the experiences of India and Brazil, in particular, would be useful for Bangladesh in order to comply with TRIPS and for the introduction of pharmaceutical patents.

However, the researcher maintained a flexible structure as much as possible so as to allow the participants to feel comfortable and to share their views regarding their respective field of expertise and involvement. Considering the time limit, before the interview the researcher pre-selected some questions that were most relevant to the specific participant and relevant to the identified research questions (the information sheet and model interview questions, as used in this study, are provided in the appendix four).

3.8 Procedure and Methods of Data Collection

This thesis applied 'purposeful sampling' to ensure the quality and richness of data collection so as to draw out findings for the identified research questions. Purposive sampling is a form of non-probability sampling[104] with the sample being 'hand-picked' for the research. Due to the long professional involvement of this researcher with the relevant field and country perspectives, the researcher selected participants who had had some exposure to pharmaceutical patents, the pharmaceutical industry and patent-law discourse.

The advantage of purposive sampling is that it allows the researcher to concentrate on particular people or events that the researcher has good grounds to believe will be critical for the research.[105] Instead of going for the typical instances, a cross-section or a balanced choice, the researcher will be able to concentrate on instances that display a wide variety of responses and it may even be possible to focus on extreme cases to illuminate the research question at hand. In this sense it might not only be economical, but might also be informative in a way that conventional probability sampling cannot be.[106] With a non-probability sampling method the researcher feels that it is not feasible to include a sufficiently large number of examples in the study. The aim of the study is to explore the quality of the data and not the quantity.[107] Another justification for using non-probability purposive sampling is that it stems from the idea that the research process is one of 'discovery' rather than of the testing of hypotheses. It is a strategy that is both 'emergent and sequential'.[108] Almost like a detective, the researcher follows a trail of clues, which leads the researcher in a particular direction until the questions have been answered and things can be explained.[109] The procedure of the selection of the survey and interview participants is further discussed in detail in this chapter.

3.8.1 Selection of Survey Participants

To select survey participants and make a distinction between different categories within the pharmaceutical industry, the researcher used the data collected from the BAPI, the DDA of Bangladesh and used internationally well recognised IMS health data on the pharmaceutical industry in Bangladesh. In addition to this, to determine the category of pharmaceutical company as local or multinational and big, medium or small among the local pharmaceutical industries, there are a number of questions in the survey such as the nature of the company, the number of generics launched and exported and major export destinations (see survey instrument, Section A in the appendix). Considering the data collected from the BAPI, DDA and IMS, if a

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[104] D F Polit and B P Hungler, *Nursing Research–Principles and Methods* (Lippincott Williams & Wilkins, 6th ed, 1999) 284.
[105] F C Dane, *Research Methods* (Brooks/Cole, 1990) 284.
[106] M Descombe, *The Good Research Guide: For Small-Scale Social Research Projects* (Open University Press, 1998) 232.
[107] D Nachmias, *Research Methods in the Social Sciences* (St. Martin's Press, 1996) 122.
[108] Y S Lincoln and E G Guba, *Naturalistic Inquiry* (Sage Publications, 1985).
[109] C Robson, *Real World Research: A Resource for Social Scientists & Practitioner Researchers* (Blackwell, 1993) 182.

company launched more than 50 generics and exported to and/or received certification for export from the highly regulated markets in Europe or the USA or Australia, then they were considered as a large local pharmaceutical industry. In the same way, if a company had launched less than 50 generics but more than 25 generics and was exporting to a minimally regulated market in Asia or Africa, then it was considered as medium, whereas a company that had less than 25 generics and that relied only on the local market was considered as a small local producer. This was further supplemented by a secondary source of data, such as through the study of UNCTAD and the World Bank on the pharmaceutical industry of Bangladesh. After the data-collection procedure, the firms were also checked again to ensure whether they were big, medium or small.

Considering the nature and categories of pharmaceutical companies in Bangladesh and the possible low response rate that can occur with any kind of survey, all the big pharmaceutical companies in Bangladesh (five in total), all the medium companies (ten in total) and ten small-sized pharmaceutical companies and all multinationals operating in Bangladesh were approached to take part in the survey.

It is remarkable that five big and ten medium pharmaceutical firms, along with two top multinationals, as approached for this survey, controlled eighty per cent of the local market and almost one hundred per cent of pharmaceutical exports from Bangladesh.[110] Among them, the top ten control sixty per cent of the local market.[111] Small pharmaceutical companies have no export markets and they simply serve the local market and engage in the production of low-priced essential medicines. However, to understand the perceptions of small local pharmaceutical industries, ten of them were also approached to take part in the survey. Therefore, this study applied purposeful sampling to ensure that the collection of data would best represent the industry perceptions required for the identified research questions. The sampling approach undertaken was required in order to access participants who represented the majority of pharmaceutical producers and exporters in Bangladesh, and who would hopefully have the most important data that would answer the study questions at hand.

3.8.2 Profile of Survey Participants

As noted above, the researcher approached five large, ten medium and ten small pharmaceutical companies and a further six multinational pharmaceuticals were also contacted for survey. The profile and coding of participants is given in Table 3.1.

[110] This is confirmed by the statistics of the DDA, Bangladesh (2009), Export Promotion Bureau of Bangladesh (2009) and IMS Health data (2008–2008). For details, also see Public and Private Sector Approaches to Improving Pharmaceutical Quality in Bangladesh, above n 65 and Sampath, above n 40.

[111] Ulrike Pokorski da Cunha, *Study on the Viability of High Quality Drugs Manufacturing in Bangladesh* (A Study Commissioned by the Federal Ministry for Economic Cooperation and Development, GTZ, 2007).

Table 3.1: Survey participant profiles

Code	Category of Pharmaceutical Industry	Number of Participants' (selected)	Feedback Received From	Product Range
BG001-005	Large	5	5	More than 50
ME001-009	Medium	10	9	Less than 50 but more than 25
SM001-005	Small	10	5	Less than 25
MN001-003	Multinational	6	3	More than 50

Based on collected survey data (Section A of survey instruments), the characteristics of the survey participants are also given in Table 3.2, which reflects the standard, the nature of, the inventiveness and the R&D approaches of the pharmaceutical industries that were surveyed for this study.

Table 3.2: Survey participant characteristics

Code	Quality/ Standard	Nature	Patent/ Invention	Scope of R&D
BG001-005	World-Class Standard	Generic with little R&D	No product patent or invention	Low priority to R&D investments for basic research and concentrate on reverse engineering
ME001-009	Maintain International Standard	Generic	No product patent or invention	Marginal R&D
SM001-005	Lower Standard	Generic	No product patent or invention	No R&D
MN001-003	World-Class Standard	Basic Research and generic	Agreed to having some patents and inventions (but did not disclose details)	Considerable R&D

3.8.3 Selection of Interview Participants

Considering the objectives of this research and the selected research questions, the researcher identified some areas that needed to be explored to better understand the change process for making a TRIPS-compliant patent law in Bangladesh.

First, to understand the challenges ahead for the pharmaceutical industry, executives from the Bangladesh Association of Pharmaceutical Companies were interviewed. To complement that data executives of some pharmaceutical companies were interviewed to better understand their strategies and possible options in a post-TRIPS regime. There, the researcher selected participants from the Bangladesh Association of Pharmaceutical Industries (BAPI), based on their official designation, whereas executives of pharmaceutical companies were interviewed when the researcher came to know about their involvement and expertise with pharmaceutical industry policy making.

Second, to understand the required preparation and capacity building of government regulatory bodies, the researcher interviewed officials at the Department of Patents, Designs and Trade Marks (DPDT) and the DDA. These participants were selected based on their official designation and involvement with the government capacity building project.

Third, the researcher contacted some experts on Indian and Brazilian patent law and global patent law to gain an understanding of the experience of India and Brazil during the transition to a TRIPS regime and the options used by them during that process, so that some lessons could perhaps be drawn for Bangladesh. These experts were selected based on their research articles in reputed international journals and because of their involvement in relevant research and their academic positions in the field of investigation.

Fourth, to understand the capabilities of the pharmaceutical industry in Bangladesh in terms of them being able to carry out basic research, innovation and possible collaboration between industry and research institutions to cope with the TRIPS challenges, academics and researchers in the field of pharmacy and related fields were also interviewed at the leading universities in Bangladesh.

Fifth, intellectual property academics and researchers were interviewed in the leading universities in Bangladesh so as to understand the weaknesses in the existing patent laws and the possible reform options to create the right balance between innovation and access to medicines.

3.8.4 Interview Procedure

The researcher first approached the selected participants for interview by way of a telephone call, email and by visiting their respective offices, where required, and the purpose and scope of the interview was then explained to them in brief. Most of them agreed to participate in the interviews. Some of them agreed to be interviewed on the same day. All the government offices provided a schedule for interviews within a week. However, in the case of the multinationals, it took around one month to get a

schedule for an interview. Experts on Indian, Brazilian and global patent law provided their feedback by email.

The principal method used in any interview research is the use of open-ended interview questions in which interviewees are asked general questions allowing for latitude in responses.[112] Open-ended interviews are based on the assumption that the respondent should be given maximum opportunity to set the agenda of the topic.[113]

3.8.5 Profile of Interview Participants

The participants for the interviews can be divided into three groups.

First were participants from the pharmaceutical industry, from both BAPI and from individual firms (see Table 3.3).

Table 3.3: Pharmaceutical industry

Code	Background	Remarks/Criteria for Selection.
CEB001-002 (Large) CEM 001-002 (Medium) CES 001(Small) CEMN 001-002 (Multinational)	CEO/Management Pharmaceutical Industry	Selected on designation and during survey it was revealed that they were involved with national policy making.
BAPI 001-003	Top Executives of the BAPI	Based on official designation.

Second, officials of two public-health non-governmental organisations (NGOs) and regulatory bodies were interviewed, after considering their official designation in related fields and therefore they could perhaps explain the official position, present status and future directions for the TRIPS-compliant patent regime in Bangladesh (see Table 3.4).

Table 3.4: Public-health NGOs and regulatory bodies

Code	Background	Remarks/Criteria for Selection.
PHN001-002	Public-health NGOs	Based on official designation and related activities.
PO001-003	DPDT (Registrar and Examiners)	Based on their official designation.
DDA001-003	Directorate of Drug Administration (Director and Examiners)	Based on their official designation.

[112] See for detail, William M K Trochim, *Research Methods: The Concise Knowledge Base* (Cornell University, 1st ed., 2005).
[113] Emily Hansen and Clarissa Hughes, Interviews in Qualitative Research, 11 September 2009, <http://www.phcred.utas.edu.au/InterviewingWS2009.pdf>.

Third, academics and patent-law experts were selected for interview based on their academic articles, research reports and present involvement in the area of investigation (see Table 3.5).

Table 3.5: Academics and patent-law experts

Code	Background	Remarks/Criteria of selection.
IP001-005	IP Academic and Researcher in Bangladesh	Based on their expertise and official position.
PHA001-005	Pharmacy Academic and Researcher in Bangladesh	Based on their expertise and official position.
IND001-003(India)	Experts on Indian Patent Law	Based on their academic articles and present involvement.
BZ 001-003(Brazil)	Experts on Brazilian Patent Law	Based on their academic articles and present involvement.
GE001-003(Global)	Experts on Global Patent Law	Based on their academic articles and present involvement.

3.9 Data Analysis

Both the qualitative and quantitative data as obtained during field studies was analysed using data-analysis software, categorised under different themes and then integrated together to draw findings together for this study. The data-analysis process is discussed below.

3.9.1 Quantitative Data Analysis

The quantitative data collected from survey questionnaires was compiled and organised, and responses from different participants on the same questions were entered into a Microsoft Excel spread sheet. Descriptive statistical analysis was carried out on the close-ended questions, where frequency counts (number and %) were calculated. Based on the responses from different survey participants on a particular question (either strongly agree, agree, unsure, disagree or strongly disagree) the results were organised in different rows and the nature of the different pharmaceutical companies, the responses in each category, the total number of responses in each category and,, finally, the frequency of responses were organised in different columns. In this way, the response to each question was as closely related to the research questions that were generated into rows and columns. These responses were labelled according to the survey questionnaire so as to make links with the interview findings at a later stage.

The survey also used some open-ended questions such as ‘what challenges do you think a TRIPS-compliant patent regime will have on the pharmaceutical sector in Bangladesh?’[114] and ‘what are the options available to Bangladesh to ensure access to

[114] Survey question 14.

medicines while making TRIPS-compliant patent law?'[115] The responses to these open-ended questions helped in the understanding of further options used by the different pharmaceutical industries in reply to the close-ended questions and their perspectives and strategies regarding TRIPS-compliant patent law and possible options to be used after the introduction of pharmaceutical patent protection in Bangladesh. Thus, the analysis of questionnaire data was used for descriptive purposes to complement the qualitative analysis in order to gain a better understanding of the different themes and draw findings for future policy direction based on the identified research questions of this study. This made it possible to compare and integrate the two sets of data side by side.

3.9.2 Qualitative Data Analysis

The qualitative data obtained in this study from interviews was coded to highlight ideas, categories and/or themes that facilitated linking participants' replies and the research questions' posed.[116] The aim of coding was to assemble or reconstruct the data in a meaningful or comprehensible fashion, as Charmaz observes:

> Codes serve to summarize, synthesize, and sort many observations made of the data....coding becomes the fundamental means of developing the analysis....researchers use codes to pull together and categorize a series of otherwise discrete events, statements, and observations which they identify in the data. At first the data may appear to be a mass of confusing, unrelated, accounts. But by studying and coding (often I code the same materials several times just after collecting them), the researcher begins to create order.[117]

After coding, sorting**,** compiling and arranging themes in line with the research questions, to draw out the main finding, computer-aided data-analysis software, QSR Nvivo 9 was used.[118] The use of this software enable the data analysis to be linked with the research questions. The effectiveness of using data-analysis software is supported by Miles and Hauberman as they argue that 'the researcher who does not use software beyond a word processor will be hampered in comparison with those who do'.[119]

The use of Nvivo for this study provided a number of advantages, such as dealing with a huge amount of data with ease, systematic data management and handling, retaining context where coding and sections of information link back to the original source, enabling ready reference to data, allowing different relationships to be explored without damaging the integrity of original data, improved rigour through the detail of analysis and enhanced credibility of data.

In this study, a convergence model was chosen as a variant under triangulation design, where quantitative and qualitative data were collected and analysed

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[115] Survey question 22.

[116] T N Basit, 'Manual or Electronic? The Role of Coding in Qualitative Data Analysis' (2003) 45(2) *Educational Research* 143–54.

[117] Kathy Charmaz, 'The grounded theory method: An explication and interpretation' in Robert M. Emerson (ed.), *Contemporary Field Research: A Collection of Readings* (Little Brown, 1983) 112–4.

[118] M L Jones, 'Using Software to Analyse Qualitative Data' (2007) 1(1) *Malaysian Journal of Qualitative Research* 64–6 and N G Blismas and A R J Dainty, 'Computer-Aided Qualitative Data Analysis: Panacea or Paradox?' (2003) 31(6) *Building Research and Information* 455–63.

[119] Michael Huberman and Matthew B Miles (eds.), *The Qualitative Researcher's Companion* (Sage, 2002) 110–12.

separately and then the results were converged during the interpretation stage. Triangulation is made to better understand the problem and to maintain the quality and rigour of the findings based on the collected data.[120] The merging of data enabled the researcher to answer the research questions with a more detailed reasoning and to draw important lessons, while using the options available, to reform the patent law to comply with TRIPS in Bangladesh.

3.9.3 Validity and Reliability Procedures

To ensure validity and reliability of the collected data, proponents of mixed-method research advocate the use of certain procedures. Creswell suggests several procedures that researchers should follow to ensure that their research is consistent, valid and reliable:[121]

- Checking transcripts for mistakes.
- Ensuring that the coding of data is consistent.
- Cross-checking codes and comparing results by different researchers.
- Communicating the progress in each step of data collection and analysis with members of the research team through regular meetings and sharing analysis.

The first two procedures were followed by the researcher, whilst the third and fourth were achieved through discussion with the research supervisor.

Validity in qualitative research is based on determining whether the findings are accurate from the point of view of the researcher, participant or the readers of an account.[122] The researcher used all the practicable steps to ensure the credibility and validity of the data so as to ensure that correct and non-biased information was collected from the pharmaceutical companies: the data given by them was cross-checked with their submission of data, information and reports to the government offices such as the patent office, the DDA, board of investment, export promotions' bureau and via the occasional submission relating to government policy changes for the pharmaceutical industry. Academic articles, studies and reports prepared by the pharmaceutical industries and their associations were also examined to compare the information given by them. Again, to ensure the credibility of the information given by the government offices, several government submissions to the WTO, WIPO, reports by the law Commission of Bangladesh and other consultative documents were also collected and compared.

Further the participants verified any notes collected during the interview and in some cases rectified some minor errors.

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[120] Creswell and Plano Clark, above n 96, 136–8.
[121] John W Creswell, *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches* (Sage, 2009) 190–92.
[122] C.Marshall and G B Rossman, *Designing Qualitative Research* (Sage, 3rd ed., 1999) 143–5.

3.10 Conclusion

This chapter has explained the research methodology adopted along with details of the data-collection instruments and data-analysis procedures. In summary a doctrinal review was used to understand the policy options used by India and Brazil while introducing TRIPS-compliant patent law and was based on a comparative review of the options used by them so that preliminary lessons could be drawn for Bangladesh. Whereas mixed-method methodology was used to understand the situation of the pharmaceutical industry in Bangladesh and the possible options to be used to reform the existing patent law of Bangladesh when complying with TRIPS so as to create a balance between pharmaceutical innovation and access to medicines. Both approaches assist in distinct ways to answer the research questions. The next chapter will explore the experiences of India and Brazil.

Chapter 4: The Experience of India and Brazil

4.1 Introduction

This chapter will analyse the policy options used by Brazil and India in their transition to a TRIPS-compliant patent law and the introduction of the pharmaceutical patents. This comparative review can then be used to propose options that could also be utilised by Bangladesh. Therefore, this chapter will explicitly address research question one of this study.

4.2 Journey towards TRIPS and the Pharmaceutical Patent Regime

The debate over the consequences of patenting essential products such as medicines is not new and has taken place globally.[123] Countries have therefore developed divergent approaches: some countries[124] choosing to exempt medicines from all or parts of the patent law, whilst other (such as Canada and Australia) patent regimes are moderated by mechanisms to control prices, or to facilitate local production under compulsory licenses.[125] In countries such as India, Thailand and Brazil other legal means were found to allow competitors to circumvent the negative effects of patents by allowing the patenting of processes but not of products.[126] The reaction of WTO member countries has depended much on the nature of their pharmaceutical industry. So in countries such as India and Brazil, where their pharmaceutical industry is important both economically and socially but their IPR regime was not TRIPS-compliant, they were confronted with the issue of how to manage the continued viability of the local pharmaceutical industry whilst still providing access to affordable medicines and implementing TRIPS.

While implementing a TRIPS-compliant patent law, countries such as India and Brazil were confronted with two major concerns. The first being the future of the local pharmaceutical industry, the second being access to affordable pharmaceuticals. India and Brazil have already implemented a TRIPS-compliant patent law and introduced patent protection for both pharmaceutical products and processes. Those countries' experiences of utilising TRIPS flexibilities and other

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[123] See Mohammad Monirul Azam and Morshed Mahmud Khan, 'TRIPS Agreement and Protection of National Interest: Contention between Developed and Developing Countries' (2000) V *The Chittagong University Journal of Law* 1–34.

[124] Countries such as Italy, Switzerland, Brazil and India prohibited pharmaceutical patent protection for a considerable period of time to encourage 'learning by imitation' and promote the local pharmaceutical industry. See for detail 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), 31(10) *The World Economy* 1367–82.

[125] In an affidavit filed in support of the Treatment Action Campaign, Professor Collen Flood of the University of Toronto explained how patent law in Canada had evolved since 1923 with the 'expressly stated goal of making food and medicine affordable to the public' (at [4]). To facilitate this, various legal devices, including compulsory licensing and administrative mechanisms (a Patented Medicines Prices Review Board) were established. However, in common with developing countries, Canada has been pressured to strengthen intellectual property protection. Conversely, in Australia, the government negotiates with industry as a monopolist purchaser and is thus able to provide drugs to the community at greatly reduced prices under a 'Pharmaceutical Benefits Scheme'.

[126] See for detail Li, above n 124.

possible policy mechanisms have important lessons for the LDCs such as Bangladesh as they move towards TRIPS-compliant patent laws by July 2013 and pharmaceutical patents from 1 January 2016.

The TRIPS Agreement provides flexibility for members to determine their own approach regarding the relationship between the country's intellectual property regime and access to medicines in a number of ways. It permits WTO members to (i) define the nature of invention and to regulate the criteria of patentability within the broad framework of TRIPS Agreement rules; (ii) to establish exceptions to patent rights; (iii) to grant government use and compulsory licenses; (iv) to provide recourse to a range of options with respect to the protection of data submitted for regulatory purposes; (v) to enable member countries to determine their own policies with respect to exhaustion of rights; (iv) to allow parallel importation of medicines; and (vi) to limit protection of undisclosed test data in a number of ways, including by direction to 'unfair commercial use'.[127]

4.3 The Experience of Brazil

Brazil has unequivocally claimed its position in the global pharmaceutical market, with 2008 sales estimated at US$ 12.7 billion.[128] About twenty per cent of the 370 established pharmaceutical companies in Brazil are foreign, mainly European or from the United States, and it is estimated that they control about seventy per cent of the pharmaceutical market in Brazil.[129] Brazil has a population of over 180 million, so is not only an important pharmaceutical market with low development costs and qualified professionals but is also an important centre for R&D with clinical trial facilities.[130] Whilst the pharmaceutical industry is dominated by multinational corporations, issues surrounding access to medicines have come to the fore; affordability being one of the main problems in Brazilian healthcare.[131] Given this tension, Brazil, within its intellectual property regime, attempted to create a balance between pharmaceutical innovation and access to medicines.

In 1883, Brazil was one of the sixteen countries in the world that signed the Paris Convention.[132] This pre-TRIPS convention allowed countries to utilise the patent system as an instrument of economic and technological development. Under that convention, each country could establish its own intellectual property regime in a way that would favour national policies. The Brazilian industrial property legislation granted patent protection for pharmaceutical processes and products until 1945. In

[127] Article 39.3 of the TRIPS Agreement requires member countries to establish protection for submitted test data. However, this requirement is in fact narrowly drawn, and countries maintain substantial flexibility in terms of implementation. The public interest in limiting protection for data is to promote competition and to ensure that data protection does not become the means to block the timely entrance of generic competitors to off-patent drugs, because generic competitors drive down price, thereby promoting greater accessibility of medicines. See Correa, above 44.

[128] A Business Wire Pharmaceutical Market Report titled Research and Markets: Pharmaceutical Pricing and Reimbursement in Brazil: Population and Demand for Pharmaceuticals is Forecast to Increase in the Next 12 Years (January, 2010).

[129] Kermani Faiz, *Brazil-Not a Market for Faint Hearted* (October, 2005), on file with author.

[130] Ibid.

[131] Ibid.

[132] Oliveira et al., *Brazilian Intellectual Property Legislation* (2005).

fact Brazil was the fourth country in the world and the first in Latin America to protect the rights of inventors.[133]

The 1945 legislation was modified to exclude the protection of inventions related to foodstuffs, medicines, materials and substances obtained by chemical means or processes.[134] In 1969, a change in the Brazilian Industrial Property Code completely eliminated patenting in the pharmaceutical sector.[135] However, when Brazil became a member of the WTO[136] it was required to implement a TRIPS-compliant patent regime, which included patent protection for both pharmaceutical products and processes. Brazil institutionalised the TRIPS Agreement by a Presidential Decree in December 1994,[137] and its TRIPS-compliant regime came into effect on 14 May 1996, thereby bringing both pharmaceutical product and process protection.[138]

Brazil began granting patents in the pharmaceutical sector in May 1997.[139] Given this early implementation, Brazil was criticised by public-health groups for implementing a TRIPS-compliant law in Brazil[140] which failed to fully utilise the flexibilities and safeguards in the TRIPS Agreement and to ensure access to medicines.[141] Given this criticism, the Brazilian government took steps to facilitate access to drugs by introducing a number of amendments to the patent law including a strong compulsory licensing regime.[142] In response to these provisions, multinational pharmaceutical companies and developed countries, more particularly the United States of America (USA), objected[143] and a WTO dispute was initiated by the USA against Brazil.[144] Daya Shanker precisely noted the main points of contention between USA and Brazil as local working requirement in the Brazilian industrial property law, parallel importing in the same law and Brazil's request for consultation for the alleged violation of WTO provisions in the patent law of USA that patents which are developed with the help of public funding need to be worked in the USA.[145]

The complaint of USA was that Article 68 of Brazil's Industrial Property Law had imposed a requirement that a patent be subject to compulsory licensing if not worked in the territory of Brazil, or not used to manufacture the product in Brazil or if the patented process was not used in Brazil.[146] The view of the USA was that these

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[133] Ibid.
[134] Decree/Law#7.903/45, Consolidated Industrial Property Code.
[135] Decree/Law#1.005/69, New Industrial Property Code.
[136] Brazil has been a member of the WTO since 1 January 1995.
[137] Presidential Decree#1.335/94.
[138] Law#9.279/96, New Industrial Property Law.
[139] Ibid.
[140] Law#9.279/96.
[141] M A Oliveira et al., 'Has the Implementation of the TRIPS Agreement in Latin America and the Caribbean Produced Industrial Property Legislation That Favours Public Health Policy?' (2004) 82(11) *The Bulletin of the World Health Organization*.
[142] Kermani Faiz, above n 129.
[143] Oliveira et al., above n 132.
[144] On 8 January 2001, the USA requested a WTO Dispute-Settlement Panel to resolve its differences with Brazil over its 1996 Industrial Property Law.
[145] Daya Shanker, Fault lines in the World Trade Organization: An analysis of the TRIPS agreement and developing countries, PhD thesis, Department of Economics, University of Wollongong, 2005. http://ro.uow.edu.au/theses/497, p. 33.
[146] Article 68(1) of Brazilian Industrial Property Law provides that, the following also occasion a compulsory license: I. non-exploitation of the object of the patent within the Brazilian territory for

provisions were in conflict with Articles 27.1[147] and 28.1[148] of the TRIPS Agreement. The Brazilian law also provided that if a patent owner chose to exploit the patent through importation, others could either import the patented product or obtain the product from the patented process.

In reply to the complaint Brazil contended that Articles 204[149] and 209[150] of the patent code of USA[151] had similar provisions, and consequently, Brazil would raise a dispute against USA over these provisions.[152] In the end, the complaint was withdrawn due to pressure from public-health organisations and human-rights groups both from within and outside of the USA.[153] Daya Shanker has commented that "the weakness of its position was known to the USA but the main purpose of initiating the dispute appear to be to communicate potential US displeasure and possible action against weak and poor countries of the Third World so that they would not incorporate such provisions in their patent Acts and should such provisions have already been incorporated in their patent Acts that they would not use them".[154] The success of the US action was evident from the fact that South Africa, Kenya and many other African countries refrained from using local working provisions to

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failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the patented process, except cases where this is not economically feasible, when importation shall be permitted.

[147] Article 27.1 of the TRIPS Agreement provides that 'patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. … patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced'.

[148] Article 28.1 of the TRIPS Agreement deals with the exclusive rights of the patent owner to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling or importing of the patented product.

[149] The relevant provision is 35 U.S.C. 204- Preference for United States Industry, which provides that **'**Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or non-profit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States'.

[150] The relevant provision is 35 U.S.C. 209- Licensing Federally Owned Inventions, which provides that '… in the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced'. It further adds that 'A Federal agency shall normally grant a license … to use or sell any federally owned invention in the United States only to a licensee who agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States'.

[151] The United States Patents, Law, as consolidated in 2007, see for detail, 3 August 2010, <http://www.wipo.int/clea/en/text_pdf.jsp?lang=EN&id=5399>.

[152] The United States Patents, Law, as consolidated in 2007, among other things, provides that when any patent is obtained, as a result of research funded by the US government and agencies, the patent should be worked in the United States and cannot be licensed for production elsewhere.
See for detail the United States Patents, above n 166.

[153] The possibility of providing easier compulsory licensing in case of national emergencies is recognized under TRIPS. As mentioned earlier, Brazil has, however, gone much further and adopted a decree establishing rules concerning the granting of compulsory licenses in cases of national emergency and public interest.

[154] Daya Shanker, Fault lines in the World Trade Organization: An analysis of the TRIPS agreement and developing countries, PhD thesis, Department of Economics, University of Wollongong, 2005. http://ro.uow.edu.au/theses/497, p. 111.

manufacture anti-AIDS pharmaceuticals even when substantial part of their populations was suffering from AIDS.[155]

However, Brazil has managed to win price reductions from big pharmaceutical companies by threatening to break patents by the issue of a compulsory license. For example, in 2007 Brazil decided to issue a compulsory license for the HIV drug *Storcrin* (the brand name for *Efavirenz*), after failure to secure a considerable discount from the patent owner. The then Brazilian President signed a compulsory licence on the grounds of public interest[156] for *Efavirenz*, which permitted the purchase of the patented pharmaceutical from generic suppliers.[157] Thus Brazil successfully utilised the compulsory license flexibility of TRIPS to protect public health. In addition to compulsory license provisions, Brazilian law also utilised, within its TRIPS-compliant regime, other TRIPS flexibilities such as parallel importing,[158] experimental use, early working or Bolar exceptions[159] and a strict novelty requirement.[160]

Using the parallel-import flexibility, Brazil permitted pharmaceuticals to be brought from outside the country if the pharmaceutical had previously been commercialised by the patent holder or the authorised third party in another country at a lower price than the price offered in Brazil.[161]

Brazillian Industrial property law also included a provision on experimental flexibility, which allowed the use of the invention without compensation for the patent holder.[162] The Bolar exception, as it applies in Brazil, allows a company to complete all of the procedures and tests that are necessary to register a generic product before the original patent expires.[163] Bolar flexibility allows the immediate marketing of a generic pharmaceutical after the patent has expired, thus promoting

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[155] See, Daya Shanker, India, the Pharmaceutical Industry and the validity of TRIPS (May 2002) 5(3) The Journal of World Intellectual Property, 331 and also see, Amir Attaran and Gillespie Lee, Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa? (2001) 286(15) Journal of American medical Association, pp.1886-1892.

[156] The definition of what falls into the public interest is of great interest. Public interest includes public health, nutrition, the protection of the environment and elements of primordial importance for technological, social or economic development. The possibility of providing compulsory licensing in each of these cases implies that the fulfilment of the most basic needs would be covered for the public.

[157] The Ministerial Ordinance No. 866 dated 24 April 2007 declared that 'there exists the possibility of compulsory licensing of patents in the public interest', as provided for in national laws, and decided 'to declare public interest in relation to *Efavirenz* for the purposes of the granting of compulsory licensing for public non-commercial use, in order to guarantee the practicability of the National STD and AIDS Programme, ensuring the continuity of universal and free access to all medicines necessary for the treatment of people living with HIV and AIDS'.

[158] Article 43(IV) of the Brazilian Industrial Property Law (Law#9.279/96).

[159] This was introduced in Brazil by Law#10.196/2001 as an amendment to Article 43 and 229 of Law#9.279/96.

[160] Article 229 C of the Law#9.279/96.

[161] In September 2003, Decree # 4.830/03 allowed for the importation of the object also from countries where the product is not patented. Therefore, Brazil has the right to import products from any country, including those still using the transition period for pharmaceuticals, such as Bangladesh.

[162] Article 43(II) of the Brazilian Industrial Property Law (Law#9.279/96).

[163] Industrial Property Amendment Law#10.196/2001 modified Articles 43 and 229 of Law#9.279/96. Article 43, which describes the limits of rights conferred to the patent holder (Exception to Rights Conferred), was amended to include the Bolar exception (early working) to allow local generic producers to complete all of the procedures and tests that are necessary to register a generic product before the original patent expires.

competition with the patent holder.[164] Another notable feature of the Brazilian Industrial Property Law is the innovative use of the novelty flexibility.

In terms of the novelty flexibility, Article 229C of the Brazilian Industrial Property Law, 1996 was used to establish the National Health Surveillance Agency (ANVISA). The Agency must be consulted before the granting of a pharmaceutical patent (both products and processes) and the Agency will determine whether the novelty requirement is truly satisfied, so that by making small changes there is not a patented product that prevents generic producers from producing the patented pharmaceutical.[165] Furthermore, in December 2010 the Brazilian Senate approved the text of a new competition Act, which has been pending in the Brazilian Parliament since 2005, when it was proposed by the Government.[166] It is expected this law may also help Brazil to prevent excessive pricing and abuse of dominant position by the pharmaceutical industry.[167] However, this law yet to be tested in the pharmaceutical sector. [168]

By using the flexibilities inherent in the TRIPS Agreement, Brazil was able to balance the need for pharmaceutical innovation with the public-health concern of access to medicines. India had a a similar vision, but took a different path towards TRIPS compliance.

4.4 The Experience of India

After more than one hundred years of British rule, India became an independent nation in 1947 and India adopted the Patents and Design Act of 1911 (a British piece of legislation).[169] Jawaharlal Nehru, India's first Prime Minister, was concerned about the influence and control of foreign companies over the Indian economy.[170] This concern was validated in two subsequent committee reports.

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[164] This can ultimately lower the price of medicines. The WTO Panel in the *EC–Canada* case validated the Bolar exception as compatible with Article 30 of the TRIPS Agreement. See for detail, *Canada–EU*, see Christopher Garrison, *Exception to Patent Rights in Developing Countries* (Issue Paper 17, UNCTAD–ICTSD Project on IPR and Sustainable Development, 2006), 15 December 2009, <http://www.unctad.org/en/docs/iteipc200612_en.pdf>.

[165] Oliveira Bermudez and Egleubia Oliveira, 'Expanding Access to Essential Medicines in Brazil: Recent Regulation and Public Policies' in Jorge A Z Bermudez and Maria Auxiliadora Oliveira (eds.), *Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for Public Health* (2004) 129.

[166] See, The Brazilian Senate Approves the Text of the New Competition Act, available at http://kluwercompetitionlawblog.com/2011/02/07/the-brazilian-senate-approves-the-text-of-the-new-competition-act (15 December 2011).

[167] See, Loraine Hawkins, WHO/HAI Project on Medicine Prices and Availability Review Series on Pharmaceutical Pricing Policies and Interventions, Working Paper 4: Competition Policy (May 2011).

[168] Ibid.

[169] Stephen Barnes, Note, *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa* (2002–2003) 91 *Kentucky Law Journal 911*, 924.

[170] David K Tomar, 'A Look into the WTO Pharmaceutical Patent Dispute between the United States and India' (1999) 17 *Wisconsin International Law Journal* 579–82.

The 1948 Tek Chand Committee, and in 1957 the Ayyangar Committee, both concluded that foreign interests were exploiting Indian patent protection to monopolise various markets, including the pharmaceutical market.[171] At the time of both reports, India was dependent on foreign sources for pharmaceuticals. Its dependence was on the import of the bulk chemicals and the completed medicines. The great majority, some ninety per cent of the Indian pharmaceutical market was controlled by foreign companies.[172] Indian pharmaceutical prices at that time were among the highest in the world.[173] Initially, India sought to solve this problem by instituting high tariffs and price controls on pharmaceuticals.[174] India then amended its patent laws to encourage imitation and local pharmaceutical production. The change came with the passage of the Patents Act of 1970, which eliminated product patents for pharmaceuticals and only allowed a process patent, which gave protection for a maximum period of seven years.[175]

India thus encouraged the mass production of low-cost pharmaceuticals at the expense of innovation. Prime Minister Indira Ghandi, in her statement to the World Health Organisation Assembly in 1982 argued that, 'the idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death'.[176] Given this focus, Indian pharmaceutical companies principally engaged themselves in the production of generic versions of name-brand pharmaceuticals by reverse engineering those pharmaceuticals, and by applying modified production processes they successfully avoided conflict with the original patent or having infringing claims made against them.[177] By 'free riding' on others' inventions, Indian companies avoided R&D costs. By focusing on existing pharmaceuticals, Indian pharmaceutical companies were able to offer generic alternatives at a fraction of the patented name-brand pharmaceutical costs and thus India entered both the local and global pharmaceutical market quickly.[178]

The Indian generic industry now 'holds fourth position in terms of volume and thirteenth in terms of the global value of production'.[179] It also enjoys a twenty per cent share of the global generic market.[180] Currently, domestic companies control eighty per cent of the domestic market, whereas in 1970, Indian companies only had a twenty per cent share.[181] Only two multinational corporations, Glaxo Smithkline (GSK) and Pfizer, figure in the top-ten pharmaceutical companies in India.[182] Only four multinational corporations find their place among the top twenty pharmaceutical

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[171] Ibid.
[172] Ibid.
[173] Ibid.
[174] Ibid.
[175] The Patents Act, No. 39 of 1970; India Code (1970).
[176] Indira Gandhi's message to the World Health Assembly at Geneva in 1982.
[177] Susan Finston, 'Essay, India: A Cautionary Tale on the Critical Importance of Intellectual Property Protection' (2002) 12 *Fordham Intellectual Property, Media and Entertainment Law Journal* 887–8.
[178] Ibid.
[179] Planning Commission of India, *Report of the Working Group on Drugs and Pharmaceuticals for the Eleventh Five Year Plan* (Planning Commission, 2006) 21.
[180] Ibid.
[181] Padmashree Gehl Sampath, *Economic Aspects of Access to Medicine After 2005* (2005, UNU Merit), 15 December 2009, <http://www.who.int/intellectualproperty/studies/PadmashreeSampathFinal.pdf>, 22.
[182] Rasmus Alex Wendt, *TRIPS in India* (PhD Thesis, Roskilde University, December, 2007) 160–78.

companies in India.[183] The exports of pharmaceuticals by the Indian pharmaceutical industry are around USD $5.3 billion.[184] Indian pharmaceutical companies also play an important role globally in providing life-saving drugs at affordable prices. For instance, seventy per cent of the antiretroviral (ARV) drugs procured to treat HIV/AIDS under the Global Fund to Fight HIV/AIDS, TB and Malaria (GFATM) come from Indian companies and seventy per cent of the United Nations' Children's Fund (UNICEF), International Development Association (IDA) and Clinton Foundation procurement is also from Indian companies.[185]

The policy to exclude product patents for pharmaceuticals allowed the Indian pharmaceutical industry to grow rapidly. However, by joining the WTO, India agreed to adopt the requirements of the TRIPS Agreement. This necessarily required India to implement patent protection for pharmaceutical products and processes. After a three-stage amendment process in 1999, 2002 and 2005, India finally entered into a TRIPS-compliant patent regime from 1 January 2005, taking advantage of the entire transition period.[186]

The impact of stronger intellectual patent rights was felt by larger Indian drug firms and damaged smaller local firms' ability to meet the rising costs of production and the payment of royalties for patented pharmaceuticals.[187] The Indian TRIPS-compliant patent law was criticised by the public-health groups as being 'likely to bring about a legal regime that is less favourable from the point of view of access to drugs for the people of this country'.[188] It is also argued that the new patent law in India generally provides stronger protection to patent holders, which implies that the balance of interests between inventors and the general public is being shifted in favour of the inventor.[189] However, India tried to preserve public health by incorporating TRIPS flexibilities such as by incorporating stricter patent standards, pre-grant and post-grant opposition procedures, compulsory licenses and government use, prior-use exceptions, early working or Bolar exceptions, research and experimental-use exceptions, parallel imports and by limiting data protection. India also tried to set high thresholds with respect to the novelty of patent applications so that multinational corporations could not extend the life of a patent by making small changes known as 'ever-greening'.[190] In this respect, in 2006 the Swiss-based pharmaceutical company, Novartis AG, challenged the constitutional validity of Section 3(d) of the Indian Patent Act, which tried to exclude inventions that were not a 'significant enhancement of the known efficacy' of the pharmaceutical. Novartis AG challenged the law on the grounds that the provision provided absolute power to

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[183] Sudip Chaudhuri, *The Indian Pharmaceutical Industry: Post TRIPS* (2009).
[184] Reji K Joseph, 'India's Trade in Drugs and Pharmaceuticals: Emerging Trends, Opportunities and Challenges' (Discussion Paper No 159, Research Information System for Developing Countries, 2009).
[185] Ellen t' Hoen, *The Global Politics of Pharmaceutical Monopoly Power* (AMB Publishers, 2009).
[186] Janice Mueller, The Tiger Awakens: The Tumultuous Transformation of India's patent System and The Rise of Indian Pharmaceutical Innovation (2007) 68(49) University of Pittsburgh Law Review 491-641.
[187] Ibid 9.
[188] Philippe Cullet, Patents Bill, TRIPS and Right to Health, available at http://ielrc.org/content/a0108.pdf, accessed on October 22, 2010.
[189] Ibid.
[190] Section 2(m) and Section 3 (a) (d) (e) (p) of the Indian Patents (Amendment) Act, 2005.

the controller of the patent and denied the rights existing under Article 27[191] of the TRIPS Agreement obliging WTO member states to provide patent protection to all fields of technology without discrimination.[192] The Indian High Court of Madras held that Section 3(d) was not in violation of the Constitution of India and denied to rule on its incompatibility with the TRIPS Agreement.[193]

Government use is another effective means to curb abuse of patents and a government, or its authorised agent, can then use the patents without the authorisation of the patent holder. The Indian Patent Act of 2005 provides for three types of government use. First, a patent is granted in India with a condition that the government can import the medicines for the distribution of pharmaceuticals in public-sector hospitals or any other hospitals to be notified in the *Gazette*.[194] Second, the government or authorised persons can use a patent against a royalty payment.[195] Third, the government can acquire a patent after paying compensation. The government can exercise these powers at any time.[196] The patented article as produced under government use flexibility can only be sold for non-commercial use.[197] However, the Act provides room for challenging the government decision to use or acquire the invention in the High Courts.[198] This means that the patentee could delay such government use, as under the legislation the government has to prove its need before the court.[199]

The Indian Patent Law Amendment of 1999 provides for the early working or Bolar exception provision to ensure quick entry of generics into the market for competition and hence reduce the price of medicines in India.[200] The 1999 amendment also included a provision on parallel-importation by incorporating Section 107(A) (b) into the Patent Act. Under this Section, parallel importation is permitted if the 'importation of patented products by any person from a person who was duly authorised by the patentee to sell or distribute the product'.[201] However, this requires authorisation from the patentee. The result being that a product cannot be imported where the product is produced under a compulsory licence. This was resolved by a 2005 amendment to enable India to import pharmaceuticals even if they were drugs produced under compulsory licence.[202]

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[191] Article 27[1] of TRIPS states that: '(...) patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application (...) patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced'.
[192] *Novartis A.G.Vs. Union of India and Others*, High Court of Madras (W.P. Nos. 24759 and 24760 of 2006).
[193] Ibid.
[194] Section 47 of the Patents (Amendment) Act, 2005 (India).
[195] Sections 99 and 100 of the Patents (Amendment) Act, 2005 (India).
[196] Section 100 of the Patents (Amendment) Act, 2005 (India).
[197] Section 100(6) of the Patents (Amendment) Act, 2005 (India).
[198] Ibid.
[199] Ibid.
[200] Section 107(A) of the Patents (Amendment) Act, 1999 (India).
[201] Section 107(A) (b) of the Patents (Amendment) Act, 1999 (India).
[202] Section 107(a) of the Patents (Amendment) Act 2005 (India).

Indian patent law also contains a provision on research and experimental use that allows for the use of patented products for R&D purposes.[203] Another feature of the Indian law is the provision under prior-use exceptions, or the grandfather clause, that allows generic producers to continue the production and marketing of the generic product if they invested in it before the introduction of the product patent in India.[204] This means that if a generic producer can show that it has invested significantly in the production and marketing of a particular product before 1 January 2005 it could continue in the same way after the introduction of the product patent as well. However, if any prior use is approved, then the company is required to pay the patent holder a reasonable royalty.[205]

India, in contrast to Brazil, maintains a price-control mechanism to ensure access to affordable medicines.[206] India also utilises traditional medicinal knowledge in the country to ensure access to affordable medicines and has also embarked in documenting traditional knowledge to prevent the misappropriation of that knowledge by the multinational corporations.[207] Multinational corporations also put pressure on India for the introduction of test-data protection, which is submitted to get marketing approval, and thereby these corporations have attempted to extend their monopoly pricing beyond the patent term. However, India has refused to introduce that protection and, even considering the history of Article 39 of the TRIPS Agreement, claim that protection need not be in the form of data exclusivity.[208] In 2002, the Indian government also enacted the Competition Act 2002 that can be utilised to prevent abuses of patents, abuses of dominant market positions and excessive pricing.[209]

This analysis highlights that India and Brazil used different options in their transition to a TRIPS-compliant patent law framework using the flexibilities present in the

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[203] Section 47 of the Patents Act, 1970 (retained as it is in the TRIPS-compliant Indian atent law of 1999).

[204] Section 11 A (7) of the Patents (Amendment) Act, 2005 (India).

[205] Ibid.

[206] See for detail K M Gopakumar, 'Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime' (2010) 3(2) *The Law and Development Review*.

[207] VK Gupta, Traditional Knowledge Documentation and Defensive Protection: An Example from India, available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_tk_mct_11/wipo_tk_mct_11_ref_t_5_1.pdf (12 December 2011).

[208] Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Oxford University Press, 2001).

[209] However, until now no successful attempt has been made for the use of competition law in the pharmaceutical sector. Having a national competition law, India may well embrace the South African experience to apply competition law in order to prevent excessive pricing, if that kind of situation occurs in India. In brief, one of the most cited South African example is the pharmaceutical companies, GSK and Boehringer, patent owners of ARV (HIV/AIDS) drugs, set unjustifiably high prices for these drugs in South African markets. AZT (300 mg) sold at US$ 0.92 as compared to the WHO generic price of US$ 0.25. Compulsory licensing negotiation under their Patent Act proved futile as the companies demanded twenty-five per cent royalties on sales as compared to the international rate of 4–5 per cent. The Competition Commission took action under Section 8 of the SA Competition Act, which prohibits 'a dominant firm to charge an excessive price to the detriment of the consumers', ordering the issuance of licenses to market generic versions of the patented ARV drugs in return for the payment of a reasonable royalty to be decided by the Competition Tribunal. See, Anand Grover, 'Anti-Competitive Practices in Patent Licensing Arrangements and the Scope of Competition Law/Policy in Dealing with Them' (AMTC, National Workshop on Patent and Public Health, Ministry of Health, India, 11 April 2005).

TRIPS Agreement. These flexibilities are also available to Bangladesh as it moves towards TRIPS compliance. The issue for Bangladesh is which flexibilities to adopt, and when during the transition process the chosen flexibilities should be utilised. The different policy options taken by India and Brazil can be represented diagrammatically, as in Table 4.1 below.

Table 4.1: Policy options used by Brazil and India

Stages	Legislative Position	India	Brazil	Remarks
Pre-TRIPS	1. Process patent only. 2. No patent protection for pharmaceuticals. 3. Limited duration protection.	To encourage the generic production of drugs and to develop imitating capacity India prohibited product patents and allowed only process patents for pharmaceuticals.. Process patent for only seven years.	Brazil eliminated both process and product patents for pharmaceuticals.	Thus during their pre-TRIPS regime, India followed the process patent only, whereas Brazil eliminated patent protection for pharmaceuticals altogether.
Transition period (until 1 January 2005 for developing countries and until 1 January 2016 for LDCs)	Utilisation of full transition period.	India utilised the full transition period.	Brazil introduced pharmaceutical patents before expiration of the transition period. Brazil introduced a TRIPS-compliant patent law with pharmaceutical products and process patents from May 1997.	So Brazil introduced TRIPS-compliant law before transitional periods, whereas India waited until the expiration of the whole period.
TRIPS Compliant	1. Compulsory license and government use. 2. Parallel imports. 3.Early working or Bolar exception and Research & Experimental use. 4. Price control. 5. Utilisation of traditional medicinal knowledge. 6. Pre-Grant and post-grant opposition. 7. Prior-use exception. 8. Limit test data protection. 9. Absolute novelty and high level of disclosure 10. Competition law.	India has included all these legislative options in its national patent law.	Brazil has included all these provisions in its national patent law: especially compulsory licensing. But use of traditional medicine not significant and test data protection is not limited like India.	A combination of the Brazilian and Indian approach may be useful to balance innovation and public health. Consider, in addition, price control and competition law.

The requirement to move towards TRIPS has created apprehension within Bangladesh where the fear is that the price of pharmaceuticals in the local market will increase and local pharmaceutical companies may not survive due to the high cost of royalties for the patented medicines and the need to compete with multinational corporations.[210] In this regard the experience of Brazil and India in their utilisation of the TRIPS flexibilities and other alternative measures to balance innovation and access to pharmaceuticals should be considered by Bangladesh.

The present patent regime in Bangladesh has no effective provisions to be able to utilise the TRIPS flexibilities as India and Brazil have done. Importantly to utilise the flexibilities consideration will need to be had for amending the Patents and Designs Act of 1911 of Bangladesh. The remainder of the thesis will consider against the experience of India and Brazil the potential options for Bangladesh.

4.5 Conclusion

The analysis in this chapter highlights that Bangladesh can look to the experience of India and Brazil in how to utilise the TRIPS flexibilities to ensure access to pharmaceuticals and to gain an understanding of how local pharmaceutical companies can survive the change to a post-TRIPS compliance regime. However, before proposing possible changes to the existing patent law of Bangladesh the present position of the pharmaceutical industry in Bangladesh and the status of its patent law and other related regulations will be examined. The next chapter will provide this overview.

[210] Yusuf and Alam, above n 12.

Chapter 5: Pharmaceutical Patent and Pharmaceutical Industry in Bangladesh: In Search of Policy Directions for a Post-TRIPS Regime

5.1 Introduction

In general, developing countries and LDCs are apprehensive[211] of strong patent protection considering that patent protection may be harmful to the nascent stage of their pharmaceutical industries and may have a negative impact upon access to pharmaceuticals for their citizens. Bangladesh is able to produce generic versions of patented medications until 1 January 2016 as per Doha waiver for LDCs. Therefore, Bangladesh may need to be ready for the introduction of pharmaceutical patent from 1 January 2016 and may need to introduce required legal and institutional reforms prior to 2016. One of the major concerns for Bangladesh is to preserve its local pharmaceutical industry and ensure access to pharmaceuticals for its citizens. This chapter will evaluate existing legislative and institutional frameworks in Bangladesh to explore possible policy direction for post-TRIPs regime, as Bangladesh moves towards the requirement of being compliant with the TRIPS Agreement by 2016.

5.2 The Position of Bangladesh: The Importance of Its Pharmaceutical Industry

The pharmaceutical industry of Bangladesh began in the 1950s when a few multinationals and local entrepreneurs set up manufacturing facilities in what was then East Pakistan. Now 245 companies are listed with the DDA in Bangladesh as producing medicines in Bangladesh.[212] Now the pharmaceutical industry is the second largest taxpayer and meets ninety-seven per cent of local pharmaceutical requirements.[213] The pharmaceutical industry is represented by all three sectors: private enterprises, the state-owned Essential Drug Company Limited and *Ganashastha Kendra* (GK) as a representative of civil society.[214]

According to the June 2009 Business Monitor International Report, in 2008 Bangladesh had a domestic pharmaceutical market worth US$ 858 million.

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[211] See generally, Shiva, above n 23and Edwin Mansfield, 'Patents and Innovation: An Empirical Study' (1986) 32(2) *Management Science* 173–81.

[212] See: Directorate of Drug Administration in Bangladesh, 13 June 2010, <http://www.ddabd.org/allopathic.htm>.

[213] The remaining three per cent consists of imported hi-tech products such as insulin, other hormonal products, anti-cancer products andblood components/derivatives infusions. See: Dr Sayedul Islam, *Bangladesh Zooms in Pharma as Priority Sector* (27 July 2006), 18 June 2010, <http://www.pharmabiz.com/redfr.asp?fn=/brief/about.asp&title=About%20Pharmabiz>.

[214] See Ulrike Pokorski da Cunha, 'Study on the Viability of High Quality Drugs Manufacturing in Bangladesh, Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ)' (2007), 12 September 2009, <http://www.gtz.de/de/dokumente/en-high-quality-drugs-bangladesh-2007.pdf>.

According to IMS Health Data research, the market size of Bangladesh, with nearly 250 pharmaceutical companies, had grown by 16.83 per cent in 2009.[215]

Table 5.1: Nature of pharmaceutical companies in Bangladesh

Nature/Type of Company	Number	Quality Control Practice
World-Class large scale	5	Maintain international standard
Multinationals	6	Maintain international standard
Export-oriented Medium Scale	15	High standard in quality control
Local-market-oriented Medium Scale	40	Satisfactory standard in quality
Small Scale	70	Substandard quality
Licensed-oriented Pharmaceutical Company	117	Incomplete production unit

Source: Based on information collected from the DDA, the Bangladesh Association of Pharmaceutical Companies and the Export Promotion Bureau of Bangladesh and the Board of Investment Bangladesh, 2010.

It is remarkable that now the pharmaceutical market in Bangladesh is mostly dominated by local players. Out of the top-ten players, nine are local and only one is MNC (Sanofi-Aventis).[216] The top-ten companies represent sixty-four per cent and the top twenty companies' represent eighty-two per cent of the total market.[217] Among the local pharmaceutical industries, Square Pharmaceuticals is the largest firm in the market, which is followed closely by Incepta, Beximco, ACME and Eskayef (IMS, 2008).[218] Other firms in the top-ten lists include ACI, Opsonin, Renata, Aristopharma and Drug International.[219] The market is extremely concentrated: the top-ten firms cater to about seventy per cent of the market and only two companies, Beximco and Square, hold twenty-five per cent of the entire market.

However, the growth and sales of multinational pharmaceutical companies remained steady during 2009. Sanofi-Aventis (market share of 2.97 per cent) ranked top among the multinational pharmaceutical companies, followed by GlaxoSmithKline (2.24 per cent) and Novartis-Sandoz (1.65 per cent).

In addition to meeting local needs, Bangladesh exports a wide range of pharmaceutical products (therapeutic class and dosage forms) to 72 countries[220] in Asia, Africa and Europe and in 2006–2007 total exports were US$ 28.12 million with a growth rate of some forty-seven per cent.[221] Bangladesh also exports specialised products such as HFA (Hydro-Fluoro-Alkaline) inhalers, suppositories,

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[215] Pharma Record Double-Digit Growth, *Bangladesh Weekly Market Review* (Dhaka) 20 February 2010, 16 July 2010, <http://www.aims-bangladesh.com/admin/publication/558%20weekly%20feb%2022-2010.pdf>.

[216] This is supported by the IMS Health Data 2008–2009 and an interview with the Association of Pharmaceutical Companies in Bangladesh (BAPI 001-003).

[217] Interview Data-BAPI 001, CEB001 and IMS Health Data, 2008–2009.

[218] IMS Health Data, 2008.

[219] IMS Health Data, above n 272.

[220] Directorate of Drug Administration, Bangladesh 10 June 2010, <http://www.ddabd.org/exporting_country.htm>.

[221] 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>.

hormones, steroids, oncology and immunosuppressant products, nasal sprays, injectables and IV (intra-venous) infusions.[222] 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/AIDS[223] and anti-Bird-Flu drugs. Some of the most stringent regulatory authorities in the world have approved Bangladeshi pharmaceutical companies for export.[224]

Among the 49 countries classified as an LDC,[225] Bangladesh is the only country that has the pharmaceutical manufacturing capability to be (nearly) self-sufficient in pharmaceuticals.[226] Bangladesh's pharmaceutical industry now caters for ninety-seven per cent of the country's pharmaceutical needs and is worth about US$ 868 million.[227] These figures represents Bangladesh's ability to still produce generic versions of patented medications so as to service the pharmaceutical needs of other poorer countries with no or low manufacturing capacities.[228] It is because of these economic and health reasons that it is important to explore how Bangladesh can implement a TRIPS-compliant patent regime while preserving its local pharmaceutical industry and ensure access to pharmaceuticals for its citizens. In this regard, the legislative and institutional framework will have a major role to play.

5.3 Legislative and Institutional Framework: Pharmaceutical Patents and the Pharmaceutical Regulation

The implementation of the TRIPS Agreement, particularly in the context of Bangladesh as an LDC,[229] will require a reorganisation and restructuring of the country's intellectual property regime. A pressing concern is the need to consider Bangladesh's legislative and policy framework as it relates to the recognition and enforcement of pharmaceutical patents.

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[222] Ibid.
[223] Ibid.
[224] Such as the Gulf Central Committee for Drug Registration, the TGA of Australia, the Medicines and Healthcare products Regulatory Agency (MHRA) for the United Kingdom and the USFDA. These bodies have already issued GMP clearance to many local pharmaceutical companies in Bangladesh.
[225] Of those 49 countries 32 are WTO members.
[226] Yusuf and Alam, above n 12, 21–23.
[227] Azam and Richardson, above n 13.
[228] Martin, above n 15.
[229] There are no WTO definitions for 'Developed', 'Developing' or 'Least Developed' countries. The WTO recognizes as LDCs those countries which have been designated as such by the United Nations. According to the United Nations, LDCs are countries which exhibit the lowest indicators of socioeconomic development, with the lowest HDI ratings of all countries in the world. A country is classified as an LDC if it meets three criteria based on low income (three-year average GNI per capita of less than US $750, which must exceed $900 to leave the list), human resource weaknesses (based on indicators of nutrition, health, education and adult literacy) and economic vulnerability (based on instability of agricultural production, instability of exports of goods and services, economic importance of non-traditional activities, merchandise export concentration, handicap of economic smallness and the percentage of the population displaced by natural disasters). However, countries can 'graduate' out of the LDC classification when indicators exceed these criteria. See for detail: Criteria for LDCs, 13 July 2010, <http://www.un.org/special-rep/ohrlls/ldc/ldc%20criteria.htm>.

Although Bangladesh's intellectual property laws have been referred to as out-dated and enforcement of the laws as being weak,[230] Bangladesh has never been on the United States Trade Representatives 'Special 301 Watch List'.[231] Bangladesh inherited its patent law from the then British government whilst in power in India. Bangladesh still continues with essentially the same law; only a few minor amendments have been made since the enactment of the legislation. The present legislative regime comprises the Drugs Act 1940, the Patents and Designs Act 1911 and the Patent and Design Rules 1933. In 2003, amendments were made to the Patents and Designs Act 1911 to establish the Department of Patents, Designs and Trade Marks. The Department of Patents, Designs and Trade Marks is controlled by the Ministry of Industries and has jurisdiction to issue patents and designs.[232] The current law in Bangladesh with respect to patents is largely the same as it was in India before India moved to meet the requirements of TRIPS in 2005.[233]

In common with other countries, Bangladesh follows a process for the granting of patents and has criteria for 'something' to be able to be patented: that criteria being novelty, inventive step and industrial application.[234] When an application is made by the first and true inventor or their assignee/legal representative, an examination of the specification commences. An examination of the specification can trigger either one of three outcomes: (i) there are no issue with the specification and the invention is patent-worthy, (ii) the specification does not reflect any new invention therefore is rejected, or (iii) the specification is accepted subject to modification or amendment. There are provisions for appeal to the Registrar and further to the High Court Division of the Supreme Court. Any amendments or modifications may be made to the original patent under an application for patents of addition.[235] If such an application is successful without objection, or if an objection is found to be not justified, the Department of Patents, Designs and Trade Marks (hereinafter referred as DPDT or Department) will issue a certificate of patent registration. Once granted, a patent is valid for sixteen years from the date of application.[236]

There have been disputes among scholars in Bangladesh about the patentability of pharmaceutical products and processes under the Patents and Designs Act 1911.[237] Some consider that the patenting of pharmaceutical processes but not of

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[230] Mohammad Monirul Azam, 'Journey towards WTO Legal System and the Experience of Bangladesh: The Context of Intellectual Property' (Paper accepted for presentation at the Society of International Economic Law's 2010 Conference, IELPO, University of Barcelona, 2010).

[231] This List identifies countries that deny what the United States Trade representative considers adequate and effective protection for intellectual property rights. For details see: Special 301 Report, 2009, 10 July 2010, <http://www.ustr.gov/about-us/press-office/reports-and-publications/2009/2009-special-301-report>.

[232] Sampath, above n 40.

[233] Ibid.

[234] Mohammad Monirul Azam, *Intellectual Property, WTO and Bangladesh* (New Warsi Book Corporation, 2008) 270.

[235] Patents and Designs Act 1911(Bangladesh) s 15A.

[236] Patents and Designs Act 1911(Bangladesh) s 14.

[237] Section 2(10) of the Patents and Designs Act 1911 provides that the term 'manufacture' includes any art, process or manner of producing, preparing or making an article and also any article prepared or produced by manufacture. See also, Md. Mahboob Murshed, Trips Agreement and Patenting of Pharmaceutical Products', *The Daily Star* (Dhaka) 03 August 2006, <http://www.thedailystar.net/law/2006/08/03/index.htm>.

pharmaceutical products should be adopted in Bangladesh.[238] Whilst other scholars argue that in the absence of a clear legislative provision or any court ruling on the distinction between processes and products, that both pharmaceutical products and processes are patentable under the Patents and Designs Act 1911.[239] To some extent this is a purely academic debate, as in 2008 DPDT suspended the patenting of pharmaceuticals in Bangladesh until 1 January 2016 in accordance with the Doha Declaration.[240] The notification by DPDT provides that applications relating to patents for medicines and agricultural chemicals will be preserved in a 'mail box' to be considered after January 2016.

Prior to the suspension, the available information indicates that from 1998–2007 there was a significant increase in both patent applications and patents granted in Bangladesh. Interestingly ninety per cent of those patents were owned by multinational corporations.[241] In 2007, DPDT registered 269 foreign patent applications of which fifty per cent related to multinational pharmaceutical formulas.[242] But after the suspension of pharmaceutical patent in 2008 number of patent applications decreased sharply with a slight increase in 2009. Table 5.2 depicts the numbers and types of patents granted in Bangladesh from 1995–2009.

Table 5.2: Patent applications and granted patents in Bangladesh (1995–2009)

	Patent Applied For			**Patent Accepted**		
Year	**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.

The reasons behind the lower number of patent applications from local (i.e. Bangladeshi) researchers and research institutions in Bangladesh are 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

[238] Ulrike Pokorski da Cunha, above n 214.
[239] Mahboob Murshed, above n 237.
[240] Jashim Uddin Khan, 'New Patent Rights of Drug Suspended', *The Daily Star* (Dhaka), 14 March 2008, 28 September 2009, <http://www.thedailystar.net/story.php?nid=27621>.
[241] 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>.
[242] Ibid.

awareness about the benefits of patents among the researchers, research institutions and industry.[243] In terms of capacity to affect any change, DPDT 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.

In addition to the role of DPDT and Patents and Designs Act 1911, the legislative and institutional framework with respect to pharmaceuticals also requires consideration of the works of the Directorate of Drug Administration (DDA) and the Drugs Act 1940.

The Drugs Act 1940 is an Act that regulates the import, export, manufacture, distribution and sale of pharmaceuticals in Bangladesh. The Act was originally enacted by the government of India in 1940, was then adopted by the Pakistan Government in 1957 and subsequently adopted in Bangladesh in 1974. The Drugs Act 1940 permits the importation of certain classes of pharmaceuticals only under the licenses or permits issued by the relevant authority appointed by government.[244]

All classes of pharmaceuticals imported into the country are required to comply with the prescribed standards and are to be labelled and packed in the prescribed manner.[245] Licenses are also required for the manufacture and for the sale or distribution of pharmaceuticals in Bangladesh.[246] Further control over manufacturing and sales is exercised by periodic inspection of licensed premises.[247] Surveillance of the standard of pharmaceuticals is maintained by taking samples from pharmaceuticals, manufactured or offered for sale for testing in the Central Drugs Laboratory.[248] The Act also establishes a Drugs Technical Advisory Board and a Drugs Consultative Committee. The Drugs Technical Advisory Board advises the government on technical matters arising out of the enforcement and administration of the Act, while the Drugs Consultative Committee was established to advise the government and the Board to ensure the proper application and functioning of the Act throughout the country. Both the Drug Advisory Board and Drug Consultative Committee work as complementary to the regular role of the DDA, which is the only responsible regulatory body in Bangladesh for licensing the production of medicines, controlling on-going production, and if necessary, the withdrawal of licenses.

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[243] Mohammad Monirul Azam, Interview with Officials of Patent Office in Dhaka, 22–24 September 2010 (interview data–PO001–PO003).

[244] Drugs Act 1940 (Bangladesh) Chapter III.

[245] Section 8(1) of the Drugs Act 1940 provides that the expression 'standard quality' when applied to a drug means that the drug complies with the standard set out in the Schedule of the Act. Again, Section 10 of the Act prohibits the import of certain drugs such as (a) any drug which is not of standard quality, drugs, (b) any misbranded drug, and (c) any drug for the import of which a licence is prescribed, otherwise than under, and in accordance with, such licence etc.

[246] Drugs Act 1940 (Bangladesh) Chapter IV.

[247] Drugs Act 1940 (Bangladesh) ss 21–22.

[248] Section 35 of the Drugs Act 1940 provides that, 'no patent or proprietary medicine or pharmaceutical specialty or any other medicine, whether allopathic, unani, and Ayurvedic (some form of traditional medicines), homoeopathic or biochemic, for the time being not recognised by the accepted pharmacopoeias. shall be offered for sale to the public or advertise for such sale, unless two samples thereof shall have been sent to the Director Central Drug Laboratory, and the later shall have determined that the medicine or specialty is suitable or proper for use by the public.'

Unfortunately regulatory authorities in developing countries are often described as weak and inefficient, sometimes even corrupt.[249] During the interview, participants remarked these descriptions are applicable to the DDA in Bangladesh as well.[250] 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 and is responsible for the registration of pharmaceuticals as well as for inspection of premises, and for licensing of medicines for the Bangladesh market and for exporting overseas. The DDA also issues licenses for the 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.

In this way, the DDA in Bangladesh works in a similar way to that of the Australian Therapeutic Goods Administration (TGA) as it has the specific role of maintaining the quality, safety and efficacy of pharmaceuticals produced and imported in Bangladesh.[251] This role is different to the broad scope given to the United States' Federal Drug Administration (FDA).[252]

In order to monitor and to have 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.[253] However when survey participants were asked the question, "Do you think that The Directorate of Drug Administration of Bangladesh controls the quality of medicines produced in Bangladesh?" there were differences in the views of participants. Conversely, during the surveys, most of the local pharmaceutical companies either strongly agree (forty-five per cent) or agree (thirty-two per cent) that the DDA maintains the quality of medicines produced in Bangladesh. Yet multinational pharmaceutical companies operating in Bangladesh disagreed about the role of the DDA in maintaining the quality of medicines. Table 5.3 reflects the view of participants with respect to the question posed.

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[249] See for detail The Viability of Local Pharmaceutical Production in Tanzania (2007), 21 April 2010, <http://www2.gtz.de/dokumente/bib/07-0300.pdf>.

[250] Interview with Pharmaceutical Academics and Researcher (PHA 002-003) and Pharmaceutical Industry (CEM 002, CES 001).

[251] The TGA, which is a unit of the Australian government's Department of Health and Ageing, empowered by the Therapeutic Goods Act of 1989,[251] is responsible for ensuring the quality, safety and efficacy of medicines and of ensuring 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 in administering the provisions of the legislation.

[252] In the United States the FDA (or USFDA) is the body responsible 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 (EREDs), veterinary products and cosmetics. It is an agency of the United States Department of Health and Human Services, which regulates almost every facet of prescription pharmaceuticals, including testing, manufacturing, labelling, advertising, marketing, efficacy and safety.

[253] Bangladesh Pharmaceutical Market, Q 2, 2010 (Espicom Business Intelligence, 2010).

Table 5.3: The Directorate of Drug Administration (DDA) of Bangladesh control the quality of medicines produced in Bangladesh

Scale/Responses	Nature of Pharmaceutical Industry					%
	Large	Medium	Small	Multinational	Total	
Strongly Agree	3	3	4	0	10	45
Agree	1	5	1	0	7	32
Unsure	0	0	0	0	0	0
Disagree	1	1	0	3	5	23
Strongly Disagree	0	0	0	0	0	0

Chi Square is: 0.421768 with Degrees of freedom (df) 6 and Chi square tabulated value 12.59159*.

*See appendix for descriptive statistics.

During an interview, one participant reflected on the role of the DDA in the following way:

> … if we say that DDA is not maintaining and monitoring quality of medicine in Bangladesh that will have negative impact on our exports whereas if we say it is working properly that is also not the reflection of true scenario as they don't have sufficient institutional and technical facilities to monitor huge number of pharmaceutical companies operating in Bangladesh therefore most of consumers in the local market rely on the reputation of the company to determine good quality or less quality of a particular medicine.[254]

This reflected the true picture of DDA as the number of pharmaceutical company increased rapidly whereas the number of staffs and facilities in the DDA still more or less in the same position as it was back in 1972 after the independence of Bangladesh. Therefore it is really difficult for DDA to monitor quality of medicines produced in more than 200 pharmaceutical companies in Bangladesh with limited resources.

Apart from the weak role played by the DDA one participant during interview also criticised the Drugs Act of 1940 as grossly inadequate for the control of prices of pharmaceutical raw materials and processed pharmaceuticals.[255] The Drugs Act largely fails to prevent the appearance of substandard and spurious pharmaceuticals on the market, unethical promotion and the proliferation of harmful and useless pharmaceuticals.[256] To avert these weaknesses, in 1982, the government of Bangladesh formulated a National Drug Policy (NDP) and enacted the Drugs Control Ordinance of 1982 that widened the power of the DDA in addition to the operation of the Drugs Act 1940.

[254] Interview Data-(CEB 002).
[255] Interview data-(PHA 001).
[256] Zafarullah Chowdhury, *The Politics of Essential Drugs: The Makings of a Successful Health Strategy: Lessons from Bangladesh* (Zed Books Ltd., 1995) 49.

The ultimate objective of the NDP was to ensure that procurement, local production, quality control, distribution and utilisation of all drugs came under unified legislative and administrative control.[257] The NDP was to be the uniform policy for both the private and public sector, and for both the traditional and the modern medical systems.[258] It was intended to be an integral part of national health policy to promote access to affordable medicine and health care for all. The major recommendations were as follows:

- There should be a basic list of 150 essential drugs and a supplementary list of 100 specialised drugs to be prescribed by specialists and consultants.
- The 45 most essential drugs among the list of 150 drugs that are used by the government health-care centres at rural level were to be manufactured and/or sold under their generic names only.
- A National Formulary incorporating all formulations of essential and supplementary drugs should be prepared and published not later than 1983. This was one of the most important initiatives to promote the use of generic drugs, as during that time most of the physicians used to rely on the drug-promotion literature supplied by the pharmaceutical companies to prescribe medicines and most of the time patients needed to buy costly brand medicines despite the availability of cheaper generic versions in the local market.[259]
- Product patents in respect of pharmaceutical substances should not be allowed. Process patents could be allowed for a limited period if only the basic substance was manufactured within the country. However, this was never formally adopted in the national Patent Law of Bangladesh until 2008. In 2008, due to the pressure from local pharmaceutical companies and public-health NGOs, a notification in the *Official Gazette* from the Department of Patents, Designs and Trade Marks prohibited pharmaceutical patents until 1 January 2016, utilising the Doha waiver for pharmaceutical patents for LDCs.
- To ensure good manufacturing practice (GMP), each manufacturing company should employ qualified pharmacists. No manufacturer would be allowed to produce drugs without adequate quality control practice. However, the small national drug manufacturers might be allowed to on a collective basis.
- A properly staffed and equipped National Drug Control Laboratory with proper facilities should be set up as early as possible and not later than 1985.
- The government was to control the prices of finished drugs as well as raw materials, packaging materials and intermediates. The maximum retail price (MRP) of finished drugs would be fixed on the basis of cost of production and reasonable profit. The DDA was to be responsible for the control of pricing and its enforcement.
- Multinational companies would not be allowed to manufacture simple products such as common analgesics, vitamins, antacids etc. These were to be manufactured exclusively by local pharmaceutical firms.
- The Drugs Act of 1940 should be revised and replaced by new drug legislation with provision for a system of drug registration, control of prices

[257] Ibid 59.
[258] Ibid.
[259] Ibid 117–9.

of finished products and raw materials and the control of the manufacture and sale of drugs.

To fulfil the objectives of NDP 1982, The Drugs Control Ordinance 1982 was enacted, which regulates the manufacture, import, distribution and sale of pharmaceuticals in Bangladesh and that promoted the local pharmaceutical industry and discouraged imports of medicines.[260] Under this Ordinance,

(i) no medicine of any kind can be manufactured for sale or be imported, distributed or sold unless it is registered with the licensing authority;
(ii) no drug or pharmaceutical raw material can be imported into the country except with the prior approval of the licensing authority;
(iii) the licensing authority cannot register a medicine unless such registration is recommended by the Drug Control Committee;
(iv) the licensing authority may cancel the registration of any medicine if such cancellation is recommended by the Drug Control Committee on finding that such a medicine is not safe, efficacious or useful;
(v) the licensing authority is also empowered to temporarily suspend the registration of any medicine if it is satisfied that such a medicine is substandard;
(vi) the government may, by notification in the *Official Gazette*, fix the maximum price at which any medicine may be sold and at which any pharmaceutical raw material may be imported or sold;
(vii) no person is allowed to manufacture any pharmaceuticals except under the personal supervision of a pharmacist registered in Register 'A' of the Pharmacy Council of Bangladesh;
(viii) no person, being a retailer, is allowed to sell any pharmaceutical without the personal supervision of a pharmacist registered in any Register of the Pharmacy Council of Bangladesh; and
(ix) the government may, by notification in the *Official Gazette*, establish Drug Courts as and when it considers necessary.[261]

The NDP 1982 and Drug Control Ordinance 1982 derived substantial benefits for Bangladesh: especially, it increased local production of essential drugs from thirty to ninety per cent. Local companies gained a substantial market share that can now meet ninety-seven per cent of local needs, which has also reduced the prices of medicines substantially in the local market.[262] It also reduced the dependence on imports and prioritisation of useful products helped Bangladesh to save approximately US$ 600 million.[263] The quality of the products improved and the proportion of pharmaceuticals found to be substandard fell from thirty-six per cent to nine per cent.[264] In a study by the DDA in 1992, ten years after the introduction of the NDP and Drug Control Ordinance in 1982, revealed that the retail prices of most of the drugs produced locally showed a downward trend between 1982 to 1992, or at

[260] Interview with public-health NGOs-PHN001.
[261] Drug Control Ordinance 1982 (Bangladesh) s 23.
[262] See for detail: Chowdhury, above n 256, and Public and Private Sector Approaches to Improving Pharmaceutical Quality in Bangladesh, n 57.
[263] Ibid.
[264] Ibid.

worst they were static.[265] During that time the minimum price decrease was 23.1 per cent while the maximum decrease was 96.8 per cent.[266] However, among the 30 most important drugs reviewed in the study, the prices of a small number of drugs including aspirin, paracetamol, ampicillin, amoxicillin, cloxacillin, antacids and chloroquine went up.[267] Therefore, the NDP and Drug Control Ordinance in 1982 were successful in meeting partial objectives aimed at reducing prices of medicines and promoting the local production of essential medicines and the local pharmaceutical industry.

While evaluating the role of the NDP and Drug Ordinance of 1982, a foreign health expert who advised on the Bangladeshi policy remarked that 'it was pro-people and anti-poverty, an attempt to give people access to essential drugs. The policy had flaws but it was strong and it was enforced and mobilised throughout the country. The government took on the big drug companies and won.'[268] It is also worth noting here that the Association of Pharmaceutical Industries in Bangladesh initially opposed the adoption of the NDP and its elated ordinance in 1982, but later it itself appreciated the policy, which is rightly reflected by Zafarullah Chowdhury, the primary personality behind the NDP in 1982 as:

> … the pharmaceutical association of Bangladesh which had fought tooth and nail against the NDP since 1982 suddenly printed a full page newspaper advertisement in several dailies declaring that '...the ordinance [the Drug Control Ordinance, 1982] represents a philosophy whose scope extends beyond the need of today into the realms of the future ... it has been applied, tested and has to its credit today many examples of beneficial aspects'... in the advertisement association showed by means of graphs the substantial drop in imports but dramatic growth in local production.[269]

However, the introduction of pharmaceutical patents under the TRIPS Agreement will require the the NDP and Drug Control Ordinance to be updated to fulfil the the obligation of the country to become TRIPS compliant whilst also meeting the local need to preserve the pharmaceutical industry and achieve public-health goals. Notably, combination pharmaceuticals are not considered therapeutically useful and are therefore not allowed in Bangladesh.[270] This was a useful simplification when the Ordinance was drafted; however, nowadays it is obsolete and hampers the manufacturing of useful (often patented) combination therapies.[271]

To wipe out the limitations of the NDP and Drug Control Ordinance of 1982, the NDP 2005 was formulated by the government of Bangladesh to take advantage of the opportunities available to Bangladesh during the transition period leading to the implementation of TRIPS. In particular, and relevantly, the policy was formulated with following objectives:

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[265] Changes in nominal retail prices of 30 important drugs in Bangladesh, Bangladesh Drug Administration (1992).
[266] Ibid.
[267] The first four of these drugs are manufactured from locally produced raw materials. Local pharmaceutical companies consider this was due to the introduction of fifteen per cent Value Added Tax (VAT) on the locally produced raw and packaging materials.
[268] Quoted in: Make Vital Medicine Available for People-Bangladesh, OXFAM, 25 July 2010, <http://www.oxfam.org.uk/resources/policy/health/downloads/bangladesh.pdf>.
[269] Chowdhury above n 249, 89.
[270] Ibid.
[271] Ibid.

- To make it more applicable, effective and adaptive to the remarkable technological advancements that have been made in the medicine world
- To guide the drug sector of the country to perform better in the competitive world market
- To make the country a producer and exporter of good quality drugs in the world
- To ensure that the common people have easy access to useful, effective, safe and good quality essential and other drugs at affordable prices
- To strengthen the DDA by raising its status to that of a Directorate General of Drug Administration with a corresponding increase in its manpower and infrastructure facilities to make it more effective as a Drug Regulatory Authority (DRA)
- To update, from time to time, the criteria of registration for import of all systems of medicines in line with the quality guidelines followed in developed countries to ensure safety, efficacy and usefulness of such medicines
- To provide, on a priority basis, required services and facilities to local drug-manufacturing industries of all the recognised systems of drugs so that self-sufficiency is attained in the manufacture of both drugs and pharmaceutical raw materials
- To encourage all local and foreign companies to manufacture good quality essential drugs in adequate quantities in the country
- To continue the current system of controlling prices of the commonly used essential drugs as listed and updated from time to time by the government
- To encourage foreign companies to invest, manufacture and sell drugs in Bangladesh with the corresponding assurance of the transfer of new technology and technical knowledge in the country
- To ensure that no discrimination is made between the local and multinational companies, which have manufacturing plants in Bangladesh, while applying the principles of this policy
- To encourage both local and multinational manufacturers to establish full-fledged R&D facilities in the country.[272]

Each of these matters desperately needs the attention of the government of Bangladesh to ensure that the interests of the pharmaceutical producers are balanced against the need to ensure access to pharmaceuticals for the local population in a post-2016 TRIPS-compliant regulatory environment. But after the making of this policy in 2005 there has been little or no progress towards capacity building in the pharmaceutical industry to deal with post-TRIPS challenges. The low level of institutional capacity and the weakness of the existing institutional framework to deal with post-TRIPS challenges was reflected by participants in the surveys and the interviews.

[272] National Drug Policy 2005 (Bangladesh), 14 July 2010, <http://www.ddabd.org/policy_2004.htm>.

5.3. In Search of Policy Direction for Post-TRIPS Regime

Bangladesh will need to initiate legislative and institutional reforms to preserve its local pharmaceutical industry and ensure access to pharmaceuticals by its citizens. But the preparation is not adequate as there is no progress regarding patent law reforms or institutional reforms at the DPDT or DDA. During the survey, in reply to a query regarding the preparation of Bangladesh for the introduction of TRIPS compliant patent regime, most participants disagreed with the statement that Bangladesh had made sufficient preparation for the post-TRIPS regime. Table 5.4 presents the views of participants responding to the statement.

Table 5.4 Bangladesh has made sufficient preparations for the introduction of TRIPS Compliant patent law

Scale/Responses	Nature of Pharmaceutical Industry					%
	Large	Medium	Small	Multinational	Total	
Strongly Agree	0	0	0	0	0	0
Agree	0	1	1	0	2	9
Unsure	0	0	1	0	1	5
Disagree	4	6	2	1	13	59
Strongly Disagree	1	2	1	2	6	27

Chi Square is: 0.894023 with Degrees of freedom (df) 9 and Chi square tabulated value 16.91898*.
*See appendix for descriptive statistics.

The lack of preparation of Bangladesh to deal with post the TRIPS regime will have disastrous effects for the small and medium size local pharmaceutical companies. In reply to a statement, "Small and Medium size pharmaceutical companies will face difficulties in a TRIPS compliant patent regime", most survey participants either strongly agreed (seventy three per cent) or agreed (twenty seven per cent) that small and medium size pharmaceutical companies will face difficulties in a TRIPS compliant patent regime. The survey data is presented in Table 5.5.

Table 5.5: Small and Medium size pharmaceutical companies will face difficulties in a TRIPS compliant patent regime

Scale /Responses	Nature of Pharmaceutical Industry					%
	Large	Medium	Small	Multinational	Total	
Strongly Agree	4	5	5	2	16	73
Agree	1	4	0	1	6	27
Unsure	0	0	0	0	0	0
Disagree	0	0	0	0	0	0
Strongly Disagree	0	0	0	0	0	0

Chi Square is: 0.999345with df 4 and Chi square tabulated value 7.814728*.
*See appendix for descriptive statistics.

Apart from the difficulties to be faced by the small and medium size enterprises there will be more challenges for Bangladesh to adjust to in the process of adopting a TRIPS compliant patent law. During interviews in reply to the question, "What do you think will be the major challenges for pharmaceutical companies in Bangladesh post-2016?", participants argued that local pharmaceutical companies in Bangladesh **c**annot produce generic medicines of the patented pharmaceuticals and that will have serious impacts on the supply and pricing of medicines in the local market.[273] One participant argued that the sentiment was not true all cases, only medicines that are patented in Bangladesh cannot be used. The practice is that multinationals do not take patents for all medicines in all countries.[274]

In fact Bangladesh is not yet considered as a lucrative market by the multinational pharmaceutical companies. Even after the introduction of pharmaceutical patent after 1 January 1 2016 the DPDT will consider patent applications that are deposited in the mailbox. During an interview one participant referred to the Indian patent law provision by which 'any company that has already invested and produced pharmaceuticals may be exempted, if later on any patent is granted on the same product'.[275] Some other participants also considered this as a very viable option for Bangladesh in a post-TRIPS regime.[276] Officials of the relevant regulatory bodies stated that Bangladesh was considering this and other options to protect investment in the pharmaceutical sector.[277] Some participants in the interview considered that after the introduction of pharmaceutical patents the export market for the pharmaceutical industry in Bangladesh is to be limited only for non-patented or

[273] Interview data-(CEB001–002 CEM 001–002, CES 001, BAPI 001–003, IP001, PHA001–005 PHN001–002 PO001, DDA001, IND001, BZ 003).
[274] Interview data-(CEMN 002).
[275] Interview data- (IPA002).
[276] Interview data-(IND 002, BZ 001and GE 001–002).
[277] Interview data- (PO001 and DDA001).

patent-expired pharmaceuticals.[278] It may also become problematic to determine which patented products they can use and which they cannot as there is no or very weak IP and regulatory affairs department among the pharmaceutical companies in Bangladesh. This sentiment was supported by a participant during interview saying that, ' it will become a big hurdle as there is no online database of the patent office of Bangladesh regarding patented pharmaceuticals and existing regulatory staff in the pharmaceutical companies lack proper understanding of these issues'.[279] Therefore, it will become extremely necessary to introduce major restructure of internal regulatory affairs in the pharmaceutical companies in Bangladesh to understand post-TRIPS patent law requirements.

One participant also mentioned that after the introduction of pharmaceutical patents local pharmaceutical companies may need to negotiate with patent owner for license and rate of royalties for some pharmaceuticals in demand in Bangladesh.[280] In the existing patent law there is no clarification regarding this. Therefore, if the royalty rate is not fixed by the amended patent law of Bangladesh that will be detrimental for the local pharmaceutical industry. Another major challenge of a post-TRIPS regime for the pharmaceutical industry in Bangladesh will be the increase of price for the Active Pharmaceutical Ingredients (API) and hence will reduce the profit margin as 'Bangladesh still dependent on India and China for most of the API'.[281] Therefore, to cope with the challenges of the introduction of pharmaceutical patents while implementing the TRIPS Agreement, Bangladesh may need to reform national patent law and regulatory bodies in a way that will help local pharmaceutical companies. During an interview one participant remarked that

> intelligent use of flexibilities to reform the national patent law of Bangladesh is a must to preserve local pharmaceutical industry otherwise Government of Bangladesh will help the destruction of local industry and employment in the sector at the cost of strict patents and profits for some MNCs [multinational corporations] and big players in the pharmaceutical market.[282]

MNCs have better research and sufficient financial resources to be able to exploit a pharmaceutical patent to a greater extent than local pharmaceutical companies. In fact lack of R&D among local pharmaceutical companies will be a great problem after the introduction of pharmaceutical patents.

From the surveys responses most of the pharmaceutical companies in Bangladesh agreed that local pharmaceutical companies do not have enough investment in R&D to make new medicines. Large, medium and small pharmaceutical companies in Bangladesh all agreed that none of them had any new inventions and no patents.[283] Some large-scale companies simply mentioned that they had just started basic research after considering their preparation for the post-TRIPS product patent regime.[284] Some medium size and small companies mentioned that they were considering utilising traditional knowledge to make country specific traditional

[278] Interview Data-(CEB001–002, CEM 001–002, CES 001, CEMN 001–002, BAPI 001–003, PHA001–005).
[279] Interview data-(IP 002).
[280] Interview data-(BAPI 001).
[281] Interview data-(BAPI 002).
[282] Interview data (SM 002).
[283] Survey data-BG001-005, ME001-009 and AM001-005.
[284] Survey data-BG001-002.

medicine as an alternative opportunity in a post-TRIPS regime.[285] In contrast, multinationals operating in Bangladesh agreed that they had new inventions and patented pharmaceuticals elsewhere and that some were patented in Bangladesh as well, prior to 2008. However, they were not interested in disclosing any details or the possible impacts of those patented pharmaceuticals in Bangladesh.[286]

Table 5.6 below reflects that sixty-eight per cent of the participants in the survey strongly agreed that Bangladesh has no capacity to produce new medicines and eighteen per cent also agreed with this statement, whereas fourteen per cent disagreed with this statement.

Table 5.6: Bangladesh has no capacity to produce new medicines

Scale/ Responses	Nature of Pharmaceutical Industry					%
	Large	Medium	Small	Multinational	Total	
Strongly Agree	4	5	4	2	15	68
Agree	0	3	1	0	4	18
Unsure	0	0	0	0	0	0
Disagree	1	1	0	1	3	14
Strongly Disagree	0	0	0	0	0	0

Chi Square is: 0.997745 with df 6 and Chi square tabulated value 12.59159*.
*See appendix for descriptive statistics.

During the interview, one CEO of a multinational stated that they did not have any innovative capacity in the local manufacturing unit although they had many patents, which were mostly based on their R&D in developed countries.[287] In contrast, pharmaceutical researchers in Bangladesh considered that it was possible to improve the innovative capacity in Bangladesh, but most of the local pharmaceutical companies tended to think about quick cash profits rather than long-term investment in R&D.[288] Therefore, they added that the government should come forward to provide the necessary funds to do some basic research in the pharmaceutical sector.[289]

At present, the ability to apply for new pharmaceutical patents is also not possible in Bangladesh, as patent protection for pharmaceuticals is not allowed until 1 January 2016. This in itself creates a barrier for the local pharmaceutical industry in

[285] Survey data-(ME01-04 and SM-01 and 05).
[286] Survey data-MN001-003.
[287] Interview data-CEM001.
[288] Interview data-PHA001-002.
[289] Ibid.

Bangladesh and will become a huge impediment in a post-TRIPS environment. There is an evident tension between the current capacity of the industry (pre-TRIPS position) and its potential to develop and change. Samson H. Choudhary, the CEO of Square Pharmaceuticals, commented in 2009 that the NDP, while encouraging local industry, also took away the opportunity for technological advancements and developments in the industry.[290] That is why pharmaceutical companies in Bangladesh need to invest in R&D. In reply to the statement, "Pharmaceutical companies in Bangladesh need to invest in R&D" sixty-three per cent of the participants strongly agreed and thirty two per cent agreed that they need to invest in R&D while five per cent disagreed. The survey data is presented in Table 5.7.

Table 5.7 Pharmaceutical companies in Bangladesh need to invest in R&D

Scale /Responses	**Nature of Pharmaceutical Industry**					**%**
	Large	**Medium**	**Small**	**Multinational**	**Total**	
Strongly Agree	4	5	2	3	14	63
Agree	1	4	2	0	7	32
Unsure	0	0	0	0	0	0
Disagree	0	0	1	0	1	5
Strongly Disagree	0	0	0	0	0	0

Chi Square is: 0.965283 with df 6 and Chi square tabulated value 12.59159*.
*See appendix for descriptive statistics.

During the interviews participants remarked that the cost for basic research in the field of pharmaceutical R&D is beyond their reach; the cost of equipment and the investment necessary for the manufacturing plants being impediments.[291]

Unfortunately there appears to be a lack of imperative to increase and encourage investment in R&D. There are no government initiatives in place to support or promote R&D. The failure to support and promote R&D is a major barrier for the post-TRIPS survival of the pharmaceutical industry in Bangladesh. In response to the statement that, "a renewed waiver for pharmaceutical patents for the LDCs after 2015 is necessary", participants either strongly agreed(fifty nine per cent) or agreed (twenty seven per cent) that a renewed waiver is necessary for LDCs like Bangladesh beyond 2015, Five per cent of participants disagreed and nine per cent strongly disagreed with this statement. The view of the participants is reflected in Table 5.8.

[290] As he stated during the Bangladesh Pharmaceutical Expo, 22 January 2009.
[291] Interview data (ME 003 and SM 001).

Table 5.8: A renewed waiver for pharmaceutical patents for the LDCs after 2015 is necessary

Scale /Responses	Nature of Pharmaceutical Industry					%
	Large	Medium	Small	Multinational	Total	
Strongly Agree	4	5	4	0	13	59
Agree	1	4	1	0	6	27
Unsure	0	0	0	0	0	0
Disagree	0	0	0	1	1	5
Strongly Disagree	0	0	0	2	2	9

Chi Square is: 0.105891 with df 9 and Chi square tabulated value 16.91898*.
*See appendix for descriptive statistics.

Some participants during interviews remarked that a renewed waiver may not be useful for Bangladesh as multinationals may not be interested in the transfer of technology and new investment in the pharmaceutical sector unless there is patent protection for pharmaceuticals in Bangladesh.[292] During an interview one participant also argued that a renewed waiver for pharmaceutical patents will be of no use unless the Government utilises it for the development of a required legislative and institutional framework.[293] In reply to the survey question, "What are the options available for Bangladesh to ensure access to medicines while making TRIPS-compliant patent law?",[294] participants provided different viewpoints including:

- the utilisation of TRIPS flexibilities;[295]
- compulsory licenses for export[296] considering export opportunity for them in the countries having low or no manufacturing capacity[297]
- That the patent law of Bangladesh should adopt parallel imports and the Bolar exception as these would be beneficial to reduce the price of medicines.[298]

On the other hand, during an interview in reply to the question, "What are the required changes to the patent law of Bangladesh to ensure access to medicines and pharmaceutical innovation in a post-TRIPS regime?", public health activists and intellectual property academics in Bangladesh specifically mentioned that Bangladesh may need to adopt all the possible TRIPS flexibilities in its patent law so

[292] Interview data (CEMN 001-002).
[293] Interview data (IP 002).
[294] Survey Question 22.
[295] Survey data (BG001, 005 and ME005, 009).
[296] Survey data (BG002 and ME001–003, 007–008).
[297] But some participants remarked that compulsory license for patented pharmaceuticals should be confined to only on those that are very important and especially on the prevalent diseases in Bangladesh -survey Data (BG004 and ME004–005).
[298] Survey data (SM 001-005).

as to ensure adequate tools for ensuring access to pharmaceuticals and preserve its local pharmaceutical industry.[299] Another participant during the interview specifically suggested that Bangladesh should include in the amended patent law a high threshold for patentability, compulsory licensing, pre-grant and post-grant opposition and parallel imports.[300] One participant argued that the, 'existing patent law of Bangladesh contains a provision on compulsory licensing which is very complex and dysfunctional. This provision needs to be simplified and should have a provision to grant a compulsory license within a reasonable time which should not be more than two months".[301] But simply amending the existing law will not be effective unless there is efficient staff and sufficient resources at the DPDT and DDA.

One participant during their interview remarked that the legal framework is not enough Bangladesh needs to consider institutional reforms as well. Otherwise patent law reform will become futile if the Patent Department does not have the expertise to apply the law properly and the Drug Administration does not have adequate skills and resources to deal with pharmaceutical patents.[302]

One expert on patent law remarked that Bangladesh should adopt a similar approach to India and Brazil but that Bangladesh need to be cautious about its low level of technological and infrastructural development.[303] Another expert added that Bangladesh may consider adopting process patents for pharmaceuticals and should encourage joint venture and public-private partnerships in the pharmaceutical sector considering its limited financial and technical resources.[304] Another participant during the interview remarked that considering technological limitations and financial resources the Government of Bangladesh should also consider government intervention through price control, patent prizes and a strong competition law authority.[305] Some participants expressed the view that the Government of Bangladesh should make the price control mechanism stronger in the post-TRIPS regime.[306]

Thus, there are divergent opinions among the participants in the survey and interviews regarding the policy options for Bangladesh to deal with post-TRIPS challenges. There is uncertainty and tension between stakeholders (pharmaceutical companies, government officials, public-health experts and intellectual property and pharmaceutical technology academics) with respect to the two questions.[307] The first

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[299] Interview data (PH001-002 and IP 001-002).
[300] Interview data-(GE 001).
[301] Interview data-(IP001).
[302] Interview Data (IP 003).
[303] Interview data (IND 001).
[304] Interview data (BZ001).
[305] Interview data (GE 002).
[306] Interview data-(CES001, IP 002 and IND 003).
[307] Nazmul Hasan (Chief Executive Officer, Beximco and Secretary, Bangladesh Association of Pharmaceutical Industries) *Export Opportunities in Pharmaceuticals from 2005* (on file with author). He considers that, 'Pharmaceuticals' manufacturing opportunities in Bangladesh are brighter than ever because of the country's LDC status until 2016, this is a win–win situation for both Bangladesh and foreign pharmaceutical or investment companies because investors/companies will get high returns on their investment and this will create high paid jobs in Bangladesh.' He further added that, 'the cost of medicines has increased in China and India since they entered the WTO. Bangladesh has a unique opportunity to pare the costs of manufacturing medicines due to the low-cost high-qualified manpower and its LDC status'.

being a question of what options will best suit Bangladesh while developing the TRIPS compliant pharmaceutical patent regime to serve its local industry and meet the societal demands of access to medicines. The second being a question of what kind of technical and institutional capacity building is necessary for Bangladesh to cope with the challenges of a post-TRIPS patent regime.

5.5 Conclusion

This chapter highlighted that all the relevant stakeholders agreed that changes to the existing legal and regulatory framework is necessary to deal with post-TRIPS challenges. The future of the pharmaceutical industry in Bangladesh lies at the centre of what legislative and policy intervention options are taken by the Bangladeshi Government to implement a TRIPS-compliant patent law.

However, the ability of the LDCs like Bangladesh to utilise the flexibilities of the TRIPS Agreement is being slowly eroded away through various bilateral and regional negotiations with developed countries. High-income and industrialised countries, more particularly the USA and EU, put pressure on the developing and LDCs for the introduction of commitments beyond those specified by TRIPS and more extensive protection than TRIPS, which are called TRIPS-plus.[308] TRIPS-plus provisions are introduced through bilateral agreements, such as free trade agreements (FTAs) and investment treaties.[309] During the period 2001-2010, 72 FTAs with intellectual property clauses have been announced to the WTO.[310] Of specific concern are the FTAs between developed countries and markets, most notably the US and the EU with low and middle income countries because extensive patent provision in the FTAs restrict utilisation of TRIPS flexibilities and hence present barriers to access to essential pharmaceuticals.[311] More recently serious concerns have been raised regarding The Trans-Pacific Partnership Agreement (TPP)[312] and Anti-Counterfeiting Trade Agreement (ACTA)[313]

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[308] Intellectual Property Rights and Access to Medicines, Prepared for the High-Income Countries Dialogue of the Global Commission on HIV and the Law, Oakland (CA), United States of America (17 September 2011), available at http://www.hivlawcommission.org/index.php/hicrd-dialogue-documentation?task=document.viewdoc&id=48, accessed on 6th August, 2012.

[309] Peter Drahos, BITS and BIPS: Bilateralism in Intellectual Property.4(6) *Journal of World Intellectual Property (*200) 791–808; see also, Mohammed El Said, The Road from TRIPS-Minus to TRIPS to TRIPS-Plus: Implications of IPRs for the Arab World, 8(1) *Journal of World Intellectual Property* (2005) 53–66.

[310] Ibid.

[311] According to one study that estimated the total economic impact of the TRIPS-plus provisions in the US-Colombia FTA, by 2020, Colombia would need to spend an additional USD 919 million dollars for medicines, or alternatively reduce medicine consumption by 40%. See for details, Gamba M. Intellectual Property in the FTA: Impacts on Pharmaceutical Spending and Access to Medicines in Colombia (Mission Salud-Fundacion Ifarma, Bogota, Columbia, 2006), available at http://www.ifarma.org/web/wp-content/uploads/2009/02/tlc_colombia_ingles1.pdf, accessed on 3 August 2012 and also see, Susan K Sell, TRIPS-Plus Free Trade Agreements and Access to Medicines, 28 *Liverpool Law Review* (2007) 41-75.

[312] The Trans-Pacific Partnership Agreement (TPP) originally based on an agreement originally concluded in 2005 between Brunei, Chile, New Zealand and Singapore, and now negotiated also between Australia, Malaysia, Peru, the US, and Vietnam has been harshly criticized that provisions on IPR protection have been negotiated largely under pressure from the US government and they have raised serious concerns about the public health. See for details, Susan K Sell, TRIPS Was Never

due to the inclusion of TRIPS plus patent provisions which may have serious impacts on public health. LDCs like Bangladesh should be aware of the various TRIPS-plus provisions that can have a negative impact the use of the TRIPS Agreement flexibilities and subsequently on access to affordable medicines. Below are some of the most common TRIPS-plus provisions related to public health and access to medicines:[314]

- *Waiving the LDC exception*— LDCs that are members of the WTO are entitled to a transition period until January 1, 2016 to fully implement patent protection for pharmaceuticals—and until July 2013 to undertake other obligations of the TRIPS Agreement.
- Defining "innovation" for the purposes of determining patent protection to include minor "me-too" molecular variations.
- Restricting patent oppositions.
- Extending patent terms beyond 20 years for delayed marketing approval.
- Limiting parallel imports of patented drugs.
- Restricting grounds for compulsory licensing.
- Imposing "data exclusivity" rules.
- Linking patent systems to drug regulatory systems.

These TRIPS-plus provisions if adopted by any developing and LDCs that will outweigh the benefits of the TRIPS flexibilities for the country concerned and will have severe consequences for the access to medicines.[315] Therefore, the Government of Bangladesh should try to resist any bilateral pressures to include "TRIPS-plus" obligations and may need to be aware of and try to mitigate TRIPS-plus obligations in various bilateral and regional free trade or investment agreements. It would be crucial for Bangladesh to utilise the experience of India and Brazil to develop IPR policies that preserve the full complement of TRIPS flexibilities. In this regard, the comment of Rochelle Cooper Dreyfuss is worth noting, "these practices [practices of India, brazil and other developing countries] achieve recognition as they are defended in international courts and put on the agendas of international

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Enough: Vertical Forum Shifting, FTAS, ACTA and TPP, 18 *Journal of Intellectual Property Law* (2011) 447-478.

[313] The Anti-Counterfeiting Trade Agreement (ACTA) aims to establish a new international legal framework for IPR enforcement and to create its own governing body outside the WTO Council on TRIPS. So far officially released drafts, as well as the text that is described as "final" indicate that ACTA focuses strongly on copyright infringement on the Internet, includes anti-counterfeit measures, but also TRIPS-plus measures related to patent rights. At the ACTA signing ceremony in October 2011 in Tokyo, Australia, Canada, Japan, Morocco, New Zealand, Singapore, South Korea and the US signed the treaty. The EU, Mexico, and Switzerland have confirmed their preparations to sign ACTA, which is open for signatures until 31 March 2013.

[314] See for details, Gaelle P. Krikorian and Dorota M. Szymkowiak, Intellectual Property Rights in the Making: The Evolution of Intellectual Property Provisions in US Free Trade Agreements and Access to Medicine, 10 (5) *The Journal of World Intellectual Property* (2007) 388–418 and also see, Good Practice Guide: Improving Access to Medicines by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement (UNDP, 2010), available at http://apps.who.int/medicinedocs/documents/s17762en/s17762en.pdf, accessed on 5 August 2012.

[315] Trading Away Health-How the U.S's Intellectual property Demands for the Trans-Pacific partnership Agreement Threaten Access to Medicines (MSF Access campaign, Issue brief, July 2012).

organisations".[316] Therefore, domestic actors may interpret the law in a particular way that allows them to offer a new approach that others may choose to emulate.[317] The next chapter will explore possible legislative and governmental intervention options for Bangladesh utilizing the experiences of India and Brazil.

[316] Dreyfuss, Rochelle Cooper, The Role of India, China, Brazil and Other Emerging Economies in Establishing Access Norms and Intellectual Property and Intellectual Property Law Making (IICJ Working paper 2009).

[317] See for details, Susan K Sell, TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA and TPP, 18 *Journal of Intellectual Property Law* (2011) 447-478.

Chapter 6: Legislative and other Government Options for Bangladesh

6.1 Introduction

This chapter will explore possible legislative options available to Bangladesh as it moves towards TRIPS compliance. The TRIPS Agreement provides flexibility for WTO members to determine their approach to patent protection. As has been examined both India and Brazil utilised these options in different ways to change their national patent regime to one that was TRIPS compliant.[318] There were some difficulties experienced by Brazil and India with respect to the legislative measures they enacted.[319] However, the legislative provisions were found to be within the scope of the flexibilities of the TRIPS Agreement. Bangladesh as an LDC faces similar national health emergencies but also has the potential to become a substantial (global) producer of generic medicines. The need to balance these competing interests (pharmaceutical innovation and access to pharmaceuticals) highlights that there may be good grounds for Bangladesh to use the Indian and Brazilian experience as a way in which to guide Bangladesh's legislative transition to a TRIPS-compliant patent regime.

6.2 Legislative Options for Bangladesh

Using the Indian and Brazilian experience, a number of legislative options should be considered by Bangladesh in order to introduce TRIPS-compliant patent laws that will help to preserve its local pharmaceutical industry and promote innovation and access to medicines. For the purposes of this chapter the legislative options include (i) having a high threshold for patentability and exclusion from patentability provisions, (ii) having a high level of patent disclosure, (iii) providing exceptions to

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[318] For example, Brazil implemented a system of compulsory licensing. See Brazil, n 45. Conversely, India's experience is very different. India entered the WTO in 1995 and went through a long process of amendment to have a TRIPS-compliant patent regime which was effective from 1 January 2005. The impact of stronger intellectual patent rights created problems for the larger Indian drug firms and greatly damaged smaller local firms' abilities to meet the rising costs of royalties and remuneration of experienced and efficient pharmacists and other technical people. Cullet, n 50. Indian Patent Act of 2005.

[319] For example, the DSB of the WTO set a panel, as requested by the United States, to go into the complaint about the patent laws of Brazil in 2001, which the USA said illegally required the local working of patents and enabled compulsory licensing of the patent or the authorization of imports of the patented product (parallel imports) without the authorization of the patent holder. However, due to huge public pressure and campaigns by public-health groups, both parties negotiated it outside the DSB. Conversely, Indian patent law was challenged even in the Indian Court by a multinational pharmaceutical company, Novartis, claiming that it was inconsistent with some of the provisions of the TRIPS Agreement. See for detail Rajshree Chandra, 'The Role of National Laws in Reconciling Constitutional Right to Health with TRIPS Obligations: An Examination of the Glivec Patent Case in India' in Thomas Pogge, Mathew Rimmer and Kim Rubenstein (eds.), *Incentives for Global Public Health-Patent Law and Access to Essential Medicines* (2010). Another major concern is the confiscation of generic Indian medicines used to treat illnesses such as AIDS and hypertension in several European countries, regarding which India and Brazil complained to the WTO saying that the EU had wrongfully confiscated generic medicines. See for detail 13 August 2010, <http://www.businessweek.com/news/2010-05-12/india-brazil-complain-at-wto-over-eu-drug-seizures-update3-.html>.

product patent rights such as early working, parallel imports, and research and experimental-use exceptions, (iv) limiting the breadth of patent claims, (v) a strong compulsory licensing mechanism, (vi) prior-use exceptions, (vii) pre-grant and post-grant opposition, and (viii) making the duration of patent protection subject to exceptions. Each of these options will be examined in turn.

6.2.1 High Threshold and Exclusion Clause

The TRIPS Agreement considers novelty, meaning that the invention is not already part of the existing invention and represents an inventive step.[320] It is a common practice of patent owners within the pharmaceutical sector to seek to extend the effective duration of the patent by obtaining a second later patent on a new mode of delivery of a patented drug (for example capsules instead of tablets) or some other small change in a patented product. Setting high standards for novelty and inventive steps would help to ensure that a patent on a product was not, in effect, extended by a subsequent patent on a trivial improvement.[321] However, the TRIPS Agreement does not prescribe the content of these requirements and national approaches do differ.

The existing patent law of Bangladesh, the Patents and Designs Act 1911 (the Act) contains no legislative provision as to the patentability of a pharmaceutical product and no provisions detailing excluded categories of inventions. By defining thresholds for novelty so as to impose a significant requirement for novelty, Bangladesh could ensure that trivial improvements in technology could not gain the protection given by existing patents. India adopted such an approach when it amended its Patent Act in 2005.[322] The Indian Patent Act now restricts the scope for the granting of patents based on frivolous claims.[323] The Indian Patent Act 2005 clarifies that an "inventive step" means a feature of an invention that 'involves technical advances as compared to the existing knowledge or having economic significance or both'.[324] It also provides a definition for 'pharmaceutical substance' as being 'a new entity involving one or more inventive steps'.[325] Further, the Act provides that 'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy' is not patentable.[326]

Further, in an attempt to meet the need to ensure access to medicine, Section 3(b) of the Indian Patent Act 2005 excludes from patentability, 'an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health

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[320] See TRIPS Agreement, Article 27 (providing that subject to the provisions of paras. 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application and subject to para. 4 of art. 65, para. 8 of art. 70 and para. 3 of this article patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced).

[321] See Rajnish Kumar Rai. 'Patentable Subject Matter Requirements: An Evaluation of Proposed Exclusions to India's Patent Law in Light of India's Obligations under the TRIPS Agreement and Options for India (2008) 8 *Chicago-Kent Journal of Intellectual Property* 41–84 (12 November 2010) <http://jip.kentlaw.edu/art/volume%208/8%20Chi-Kent%20J%20Intell%20Prop%2041.pdf>.

[322] Ibid.

[323] Ibid.

[324] Section 2(ja) of the Patents(Amendment) Act, 2005 (India).

[325] Section 2(ta) of the Patents (Amendment) Act, 2005 (India).

[326] Section 3(d) of the Patents(Amendment) Act, 2005(India).

or to the environment', Section 3(p) of the 2005 Act also excludes patenting of 'an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components'. This provision of the Indian Act is an attempt to avoid bio-piracy and ensures that traditional knowledge handed down to the indigenous community or that has been developed is incapable of being captured by patents, and, as such, one interview participant commented that Section 3 of the Indian Patents Act is a powerful instrument to prevent frivolous patents and the abuse of traditional knowledge and resources in India.[327]

Given the absence of patentability and exclusion clauses in the existing patent law of Bangladesh, such legislative provisions should be considered by Bangladesh as it moves towards TRIPS compliance. Such legislative provisions are justified on the basis that limiting the availability of patents should promote competition in the local market and is accepted as complying with the TRIPS agreement.[328] However, in the Draft Patents and Designs Act 2010 of Bangladesh (the Draft)[329] there is a provision on patentable inventions[330] and exclusion from patentability.[331] But these provisions also fail to utilise the high threshold option like India as there is no provision for pharmaceutical substances and no exclusion clause on mere improvement or abuse of traditional knowledge. The Draft attempts to extend the ambit of prior art under the definition of novelty as:

> … prior art in the case of an invention shall be taken to comprise-(a) all matter, whether a product, a process, information about either, or anything else, made available to the public anywhere in the world, by written or oral description, by use or in any other way, at any time prior to the filing or, as the case may be, the priority date, of the application for patent claiming the invention.[332]

Again similar to the Indian legislation this provision may not be effective without a specific exclusion clause like India has. Therefore, it would be better to revise these draft provisions in the light of the Indian Patent Act of 2005. To this end, local pharmaceutical companies in Bangladesh consider this provision is very important for generic producers and consumers, as this will create options for more competition in the local market.[333] From the opposite perspective multinationals consider that setting high thresholds for patentability exclude local inventions from patentability. [334] The middle ground would suggest that a provision similar to that of the Indian provision would balance the need to maintain and support innovation with

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[327] Interview data (IND 001).
[328] Mohammad Monirul Azam, above n 7, 23–46.
[329] A draft patent law was prepared by the Law Commission of Bangladesh in 2001 in consultation with WIPO. It was not considered until 2007, as in the meantime, transitional periods for the introduction of TRIPS-compliant intellectual property law including patent law was extended for the LDCs until July 2013 and the obligation to introduce pharmaceutical patents was extended until 1 January 2016 for the LDCs. This Draft was reviewed lightly in 2007 and now it is under consideration by the Ministry of Law and Parliamentary Affairs of Bangladesh as the Draft Patents and Designs Act, 2010. Unless this Draft is approved by the Parliament of Bangladesh, the existing Patents and Designs Act, 1911 will remain in force.
[330] Section 3 of the Draft Patents and Designs Act, 2010 (Bangladesh).
[331] Section 4 of the Draft Patents and Designs Act, 2010 (Bangladesh).
[332] Section 5(2) a of the Draft Patents and Designs Act, 2010 (Bangladesh).
[333] Interview data (CEB001, CEM002 and CES001).
[334] Interview data -(CEMN001).

the need to access to pharmaceuticals. There is a similar finding to a second option of high level of patent disclosure.

6.2.2 High Level of Patent Disclosure

Article 29 of the TRIPS Agreement requires that an applicant for a patent discloses the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art so that may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date. Section 4(2) of Bangladesh's ACT simply provides that 'a complete specification must particularly describe and ascertain the nature of the invention and the manner in which the same is to be performed'.[335] Bangladesh should take better advantage of the potential held in Article 29 of the TRIPS Agreement and require that the best known mode for carrying out the invention be disclosed and that the disclosure enables the execution of all embodiments of the invention.

During an interview one participant argued that a weakness of the existing provisions in Bangladesh was that patent applications in Bangladesh were mostly ambiguous and it was difficult to ascertain a precise description of the invention. This ultimately frustrates the objective of granting the patent in exchange for sufficiently disclosing the invention to contribute for technical learning and teaching.[336] Another participant argued the ultimate benefit of disclosure is to help further development of the particular invention and competition in the market after the expiry of the patent term when competitors can enter the market with more viable option. [337] Both India and Brazil adopted a requirement for significant disclosure.Section II, Article 24 of the Brazilian Industrial Property Law, provides that the specifications shall clearly and sufficiently describe the object, so as to permit its reproduction by a technician versed in the subject, and shall indicate, when applicable, the best way of doing it.[338] On the other hand, section 10(4) of the Indian Patent Law 1970 provides that

Every complete specification shall-

a. fully and particularly describe the invention and its operation or use and the method by which it is to be performed;
b. disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection;[339]

Therefore, Bangladesh should adopt similar a requirement so as to facilitate innovation and the development of competing products. It is worth noting that Section 11 of the Draft law of Bangladesh included a provision as follows:

...(4) Every complete specification:

(a) Shall fully and particularly describe the invention and the method by which it is to be performed.

[335] Section 4 of the Patents and Designs Act, 1911 of Bangladesh.
[336] Interview data-PHA 002.
[337] Interview Data-IP 005.
[338] Section II, Article 24 of the Industrial Property Law of 1996, Brazil.
[339] Section 10(4) of the Patents Act 1970 (India).

(b) Shall disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection.[340]

If this provision is finally adopted it would help the DPDT of Bangladesh to refuse the granting of patents if the inventions were not sufficiently disclosed and will also help for technical teaching and learning on the latest development in the pharmaceutical sector. However, one interview participant argued that, 'in the absence of qualified and experienced examiners, this provision would have little effect'.[341] In addition to high-level disclosure, limiting the scope of patent claims may also be useful for Bangladesh.

6.2.3 Narrow the Scope of Patent Claims

Generally speaking, the broader the claims that an inventor can make under a patent law, the wider the monopoly the inventor can obtain.[342] Broad claims reduce the scope for competing products in the market, whereas narrow claims create greater opportunities for innovation and competition as opposed to broader monopoly.[343] National laws vary in the nature and breadth of claims permitted. In relation to pharmaceutical products, claims can be restricted to the chemical structure or composition of a new product. The TRIPS Agreement is silent on the form of and limits on allowable claims, and so arguably Bangladesh should be free to adopt adopt a patent law that requires that pharmaceutical patent claims be limited to the precise chemical composition of the product.

Currently section 4(3) of the Bangladesh's Act provides that a specification, whether provisional or complete, must commence with the title, and in the case of a complete specification, must end with a distinct statement of the invention claimed.[344] Based upon this provision, the law is not able to facilitate a narrowing of the coverage of a pharmaceutical patent, but rather encourages applications for broad patents.[345] By way of comparison the Brazilian legislation provides that the claims shall be substantiated in the specifications, characterising the particulars of the application, and clearly and precisely defining the subject matter that is the object of the protection.[346] During the interview one participant argued that most of the pharmaceutical patents granted in Bangladesh prior to suspension of pharmaceutical patents in 2008 were based on broad claims which could in the future restrict the making of generic pharmaceuticals.[347] Therefore, Bangladesh should adopt a provision like Brazil that narrows the ability to claim a pharmaceutical patent so as to restrict patenting on broad claims. This kind of provision will limit the broad claims on any pharmaceutical invention and encourage further development and innovation on any patented product. Additional exceptions are necessary so as to facilitate

[340] Section 11 of the Draft Patents and Designs Act, 2010, Bangladesh.
[341] Interview data-(IP 003).
[342] Chris Dent, 'An Exploration of the Principles, Precepts and Purposes that Provide Structure to the Patent System' (2008) 4 *Intellectual Property Quarterly* 456–77.
[343] Mohamed Lahouel and Keith E Maskus, *Competition Policy and Intellectual Property Rights in Developing Countries: Interests in Unilateral Initiatives and a WTO Agreement* (The WTO/World Bank Conference on Developing Countries in a Millennium Round, 20–21 September 1999).
[344] Section 4(3) of the Patents and Designs Act, 1911 (Bangladesh).
[345] Daniel R Cahoy, An Incrementalist Approach to Patent Reform Policy (2006) 9 *Journal of Legislation and Public Policy* 589–60.
[346] Article 25 of the Brazilian Industrial Property Law.
[347] Interview data-(IP 004).

generic competition and cheaper products for consumers. Such exceptions include early working, research and experimental use exception and parallel imports.

6.2.4 Provide Exceptions to Product Patent Rights

Article 30 of the TRIPS Agreement permits member countries to 'provide limited exceptions to the exclusive rights conferred by a patent'. This Article does not list the specific acts for which exceptions can be provided. What it says is that such exceptions should satisfy certain conditions that it does not 'unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'.[348] The TRIPS Agreement does not contain any explanation of the terms, 'limited exceptions', 'unreasonably conflict', 'legitimate interests' and hence the use of this provision depends on the interpretation of these conditions.[349] There are two exceptions used by India and Brazil in their legislative framework, those exceptions being (i) early working (Bolar exceptions) and research and experimental use, and (ii) parallel importing.

6.2.4.1 Early Working (or "Bolar Exceptions") and Research and Experimental Use

The early working exemption is commonly referred to as the "Bolar" provision or exception, as it derives from the US case of *Roche Products Inc v Bolar Pharmaceutical Co.*[350] The case concerned the manufacturing of generic pharmaceuticals. Bolar Pharmaceutical (Bolar) was the generic drug manufacturer and Roche Products was the pharmaceutical company that made and sold "Valium", the active ingredient of which was protected by patent. Before the patent expired, Bolar used the patented chemical in experiments to determine if its generic product was the bioequivalent to Valium in order to obtain US FDA approval for Bolar's generic version of Valium. Bolar argued that its use of the patented product was not an infringement under the experimental-use exception to the patent law and public policy favoured the availability of generic drugs immediately following a patent's expiration. Therefore, Bolar's experimental use of the patented product was justified due to the delay in conducting experiments. Roche disagreed with that proposition.

The Court of Appeal for the Federal Circuit rejected Bolar's contention, holding that the experimental-use exception did not apply because Bolar intended to sell its generic product in competition with Roche's Valium after patent expiration.[351] In other words, Bolar's experiments had a business purpose. The Court considered that any change to the patent law needed to be made by Congress.[352] Shortly after the

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[348] Article 30 the TRIPS Agreement.

[349] 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, Submitted as partial fulfilment for the course work on the 'Political and Legal Foundations of Capitalism' (IUC Torino, Italy, 18 December 2009).

[350] 733 F.2d 858 (Fed. Cir. 04/23/1984).

[351] Anshull Mithal, Patent Linkage in India: Current Scenario and Need for Deliberation (2010) 15 *Journal of Intellectual Property Rights* 187–96.

[352] See Satyajeet Mazumdar, Bolar Provisions (Patents): Position in different countries and case laws (24 December 2009). Available from: http://knol.google.com/k/satyajeet-mazumdar/bolar-provisions-patents/3cc0jmgzt3vqu/6.

case was decided, Congress passed a law permitting the use of patented products in experiments for the purpose of obtaining FDA approval.[353] As a result of this change in position, exceptions for early working gained momentum and now 'Bolar exceptions' have been enacted in most jurisdictions.[354] Importantly, the WTO Dispute Panel upheld the use of the Bolar exception as being in conformity with the requirements of the TRIPS Agreement in the Canada–EU dispute.[355]

The Doha Declaration agreed that 'the TRIPS Agreement be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles'.[356] This permits exceptions for research and experimental use of patented medicines for the promotion of technological innovation, transfer and dissemination of technology to be contained within a TRIPS-compliant patent regime. An exemption for research and experimental use is important for maintaining and developing efficient alternatives to protect public health and to encourage innovation within the industry. The opportunity to use patented products for R&D purposes will enable the indigenous firms to be ready with efficient processes and use these whenever they are permitted to do so, which increases efficiencies.

Under Section 21 the Act provides for experimental use exceptions. However, the language and process as mentioned in the existing Act is so ambiguous and complicated so as to have no positive effect. The law must be amended in a way to simplify the entry of generic pharmaceuticals into the market. The research and experimental provision is very important for generic entry. It permits generic entry

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[353] Section 271-e-1 of the Drug Price Competition and Patent Term Restoration Act (USA). It is informally known as the 'Hatch–Waxman Act' [Public Law 98-417], which established the modern system for FDA approval of generic drugs.

[354] In the United States, this exemption is also technically called the § 271(e) (1) exemption or Hatch–Waxman exemption. The US Supreme Court considered the scope of the Hatch–Waxman exemption in *Merck v Integra*. The Supreme Court held that the statute exempts from infringement *all* uses of compounds that are reasonably related to submission of information to the government under any law regulating the manufacture, use or distribution of drugs. In Canada, this exemption is known as the Bolar provision or Roche–Bolar provision, named after the case *Roche Products v. Bolar Pharmaceutical*. In the EU, equivalent exemptions are allowed under the terms of EC Directives 2001/82/EC (as amended by Directive 2004/28/EC) and 2001/83/EC (as amended by Directives 2002/98/EC, 2003/63/EC, 2004/24/EC and 2004/27/EC).

[355] See Canada—Patent Protection of Pharmaceutical Products—Complaint by the European Communities, WT/DS114/R (17 March 2000) [Canada—Patent Protection of Pharmaceutical Products]. Article 30 of the TRIPS Agreement authorizes limited exceptions to patent rights for such things as research, prior-user rights and pre-expiration testing. Often called the 'research exception,' the provision is commonly used by countries to advance science and technology by allowing researchers to use a patented invention to gain a better understanding of the technology. In addition, the provision is also used by countries to allow manufacturers of generic drugs to apply for marketing and safety approval without the patent owner's permission and before the patent protection expires. The generic producers can then market the drug. This practice, often called the 'regulatory exception' or 'Bolar' provision, has been upheld as conforming to the TRIPS Agreement. The Panel also held that manufacturing and stockpiling patented drugs prior to the exhaustion of patent protection is not a 'limited exception' which can be exempted under Article 30.

[356] Article 7 of the TRIPS Agreement states that the protection and enforcement of intellectual property rights *'should'* contribute to the mutual advantage of patent holders and the users of patented medicines, in a manner conducive to social and economic welfare and to a balance of rights and obligations. In Article 8, the TRIPS Agreement affirms that members may adopt measures to protect public health, among other overarching public policy objectives, such as nutrition and socio-economic and technological development. See Article 5(a) of the Doha Declaration on the TRIPS Agreement and Public Health, Doha (14 November 2001).

soon after the patents expire and, hence, allows consumers to benefit from competition and lower prices without delay. In the absence of it, generic companies will have to wait until the patent actually expires before starting the tests necessary to gain regulatory approval. It will take time to get such approvals and without such an exception, the patentee will effectively enjoy monopoly status even though there are no legal barriers to entry. However, the Draft law has tried to simplify the process by stating that:

> … any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person for the sole purpose merely of experiment or research including the imparting of instruction to pupils.[357]

However, the exemption, as laid down in the Draft law, may not be enough if a generic producer wants to use it for experimental purposes leading to the collection of data to be submitted to the drug-approval authority for the production of on-patent drugs.[358] In the context of the terms of the legislative provision itself, guidance can be sought from Section 107 A (a) of the Indian Patent Act, which provides that 'any act of making, constructing, using, selling or importing a patented invention solely for use reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product shall not be considered as infringement of patent rights'.[359]
The present provision in Bangladesh needs to be extended to include a similar provision like India in order to facilitate the generic entry of patented drugs as early as possible after the introduction of pharmaceutical patents in Bangladesh. In Bangladesh there are divergent opinions among the pharmaceutical industry regarding this. During the interviews members of the local pharmaceutical industry[360] strongly supported the inclusion of this provision so as to allow generic producers whereas multinationals[361] considered that this may discourage investment and technology transfer in the pharmaceutical sector.

One interview participant argued that in the absence of a research and experimental-use provision, generic producers in Bangladesh will be restricted from experimenting with patented products.[362] Arguably, the absence of a research and experimental-use provision encourages the high pricing of pharmaceuticals given the monopoly of the patent holder. As part of its transition to a TRIPS-compliant regime, the legislative option of including a research and experimental-use exemption should be considered. A further exemption that should be considered is the practice of permitting parallel imports.

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[357] Section 48(c) of the Draft Patents and Designs Act, 2010 (Bangladesh).
[358] Shamnad Basheer, 'India's Trust with TRIPS' (2005) (1) *Indian Journal of Law and Technology* 31.
[359] Section 107 A (a) of the patents (Amendment) Act, 2002 (India).
[360] Interview data-(CEB 001, CEB 002, CEM 001-002 and CES 001).
[361] Interview data-(CEMN 001-002).
[362] Interview data-(PHN 001).

6.2.4.2 Parallel Imports

Article 28 of the TRIPS Agreement provides that the patent owner has the exclusive right to prevent others not only from making, using or selling the invented product or process in the country, but also importing the product from other countries. However, this right is subject to Article 6 of the TRIPS Agreement, which deals with the principle of 'exhaustion'. The principle of exhaustion states that once a patent holder has sold a patented product, they cannot prohibit the subsequent re-sale or import of that product, since their rights in respect of that market have been exhausted by the act of selling the product.[363] Such imports of patented products without the consent of the patent holder in the importing country are known as 'parallel imports'. This is very important in the pharmaceutical industry because the same patented medicine is often sold at different prices in different countries and, hence, parallel imports permit a country to shop around for the lowest price.[364] The underlying justification of allowing parallel imports is that since the innovator has been rewarded through the first sale of the product, its patent rights have been 'exhausted' and, hence, it should have no say over the subsequent re-sale.[365] Article 6 of the TRIPS Agreement was further clarified by the Doha Declaration, which provided that each country was 'free to establish its own regime for such exhaustion without challenge'.[366]

There are three kinds of exhaustion regime for the purpose of parallel imports: national, regional and international.[367] The United States has adopted a national exhaustion principle whereby the patent owner has no control over the product once it is placed in the domestic market, however the patent holder can exercise rights outside of the United States' market regarding the price and quantity of the product.[368] In contrast, the European Union (EU) has adopted a regional exhaustion regime whereby rights are exhausted within the boundaries of EU.[369] By comparison, international exhaustion has no jurisdictional limit; the rights of the patent owner are exhausted once the product is sold. International exhaustion is consistent with the objective of Article 7 of the TRIPS Agreement.[370] The advantage of international

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[363] Access to Medicines (2005) 19(3) *WHO Drug Information*.

[364] Arghya Sengupta, 'Parallel Imports in the Pharmaceutical Sector: Must India be More Liberal' (2007) 12 *Journal of Intellectual Property Rights* 400–409.

[365] Sudip Chaudhuri, Indian Generic Companies, Affordability of Drugs and Local Production in Africa with Special Reference to Tanzania' (IKD Working Paper No 37, September 2008), 12 September 2010, <http://www.open.ac.uk/ikd/documents/working-papers/ikd-working-paper-37.pdf>.

[366] Para. 5(d) of the Doha Declaration on the TRIPS Agreement and Public Health, Doha, November, 2001, 21 April 2009, <http://www.who.int/medicines/areas/policy/tripshealth.pdf>.

[367] See Marco C E J Bronckers, 'The Exhaustion of Patent Rights under World Trade Organization Law' (1998) 32 *Journal of World Trade Law*.

[368] N Lalitha, TRIPS and Pharmaceutical Industry: Issues and Prospects, 12 December 2009, <http://www.iprsonline.org/ictsd/docs/ResourcesHealthArticleLalitha.doc>.

[369] Ibid.

[370] Article 7 is a key provision that defines the objectives of the TRIPS Agreement. It clearly establishes that the protection and enforcement of intellectual property rights do not exist in a vacuum. They are supposed to benefit society as a whole and do not aim at the mere protection of private rights and should be utilized in a way for the mutual advantage of producers and users of technological knowledge; social and economic welfare; and the balance of rights and obligations. Therefore, each provision of the TRIPS Agreement should be read in light of the objectives and principles set forth in Articles 7 and 8. Such an interpretation finds support in the Vienna Convention on the Law of Treaties (concluded in Vienna in 23 May 1969), which establishes, in Article 31, that '[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose'. See generally TRIPS**:** Council discussion on

exhaustion is that developing countries can scout for lower priced patented products anywhere in the world.

However, during an interview one participant argued that, 'international exhaustion will be of no benefit for Bangladesh rather it will increase counterfeiting and low-quality medicine in the local market'.[371] He further added that, 'in the name of cheaper medicines from other alternative sources that will open flood gates of different products and considering the present level of limted resources in the DDA of Bangladesh it would be really difficult to inspect and monitor all the possible cheaper pharmaceutical products.'[372] But another participant argued that in the absence of parallel imports a monopoly will be created and may threaten the adequate supply of and access to affordable pharmaceuticals.[373] He further added that due to fear of counterfeiting, 'you cannot shut down your door of opportunities rather taking proper steps counterfeiting can be prevented.'[374]

The Bangladesh Act does not contain any provisions dealing with the legality or otherwise of parallel imports. In contrast, Brazilian patent law also does not support international exhaustion.[375] However, the Indian Patent Act (under Section 107) allows for the taking advantage of parallel imports and permits the import of patented drugs at the lowest available price in the global market (international exhaustion). Section 107A (b) of the Indian Patent Act provides that the following act is to be considered as an exception to patent infringement, 'Importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights'.[376]

The Draft law of Bangladesh included a provision in its Section 92 as follows:[377]

Meaning of Use of Invention for Purposes of Government

(1) For the purposes of this chapter, an invention is said to be used for the purposes of government if it is made, used, exercised or vended for the purposes of the government or a government undertaking.
(2) Without prejudice to the generality of the provisions of sub-Section (1) of this Section:
(a) the importation, by or on behalf of the government, of any invention being a machine, apparatus or other article covered by a patent granted before the commencement of this Act, for the purposes merely of its own use; and
(b) the importation, by or on behalf of the government, of any invention being a medicine or drug covered by a patent granted before the commencement of this Act:
(i) for the purpose merely of its own use; or
(ii) for the purpose of distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the government or in any other dispensary, hospital or other

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access to medicines, Developing country group's paper, 12 August 2010, <http://www.wto.org/english/tratop_e/trips_e/paper_develop_w296_e.htm>.
[371] Interview data-CEMN-002.
[372] Ibid.
[373] Interview data-(PHN 002)
[374] Ibid.
[375] Subject to certain exceptions involving the non-working of a patent in Brazil or a compulsory license, Brazilian law prohibits all imports of patented products. See, International Exhaustion of Industrial Property Rights: Brazil (AIPPI Congress in Melbourne, 2001), 25 July 2009, <http://www.aippi.org/reports/q156/gr-q156-Brazil-e.htm>.
[376] Section 107 A (b) of the Patents Act, 2005 (India).
[377] Section 92 of the Draft Patents and Designs Act, 2010 (Bangladesh).

> medical institution that the government may, having regard to the public service that such other dispensary, hospital or medical institution render, specify in this behalf by notification in the Official Gazette, shall also be deemed, for the purposes of this Chapter, to be use of such invention for the purposes of Government.

This provision is ambiguous and only allows government institutions and duly authorised institutions to make use of parallel imports. There is also even the provision of notification in the *Official Gazette*. Considering the bureaucratic hurdles and delayed procedures to make a notification combined with the dysfunctional government health services, this provision will have no positive effect in terms of the availability and accessibility of cheaper generic drugs in Bangladesh. Therefore, it is suggested that provisions permitting parallel importing by anyone based on the principle of international exhaustion, similarly to India's provision, should be incorporated into Bangladesh's TRIPS-compliant legislative regime.

However, the Indian parallel-imports regime also has some defects as it may restrict the importation of cheaper drugs unless the exporter is duly authorised by law to produce, sell or distribute such drugs. Shamnad Basheer explained this problem with an example that if any patented drugs from a multinational pharmaceutical company, say 'Roche', which India cannot produce due to the introduction of a pharmaceutical patent, then these drugs can be imported from a Bangladeshi drug producer as there is no pharmaceutical patent in Bangladesh and, therefore, the drug producer in Bangladesh does not need any authorisation from 'Roche'.[378] In that case, under the existing provision in India, an Indian importer may be barred for importing from Bangladesh as there may be a question of violation of Article 28 of the TRIPS Agreement[379] as the goods produced in Bangladesh by a third party did not have the authorisation of Roche, were not distributed by the original patent holder, Roche, and therefore there has been no "exhaustion" of Roche's patent right. In this kind of situation there will be complications when trying to import drugs from cheaper sources that may also trigger unnecessary legal hurdles and litigation for violation of the TRIPS provisions. Therefore, Basheer suggested following amendment to be included as Section 107B, to the existing Patent Act of India:

107B. Exhaustion of Rights

(1) For the purposes of this Act, the rights of a patentee or anyone claiming through such patentee shall be exhausted after a patented article has been sold once anywhere in the world (including within India), by or with the authorization of such patentee.[380]

This suggestion seems to be more logical as after the first sale,[381] anywhere in the world, by the patent holder, would be considered an exhaustion of rights and, therefore, could be imported from anyone and from anywhere in the world.

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[378] Shamnad Basheer and Mrinalini Kochupillai, 'TRIPS, Patents and Parallel Imports: A Proposal for Amendment' (2009) 2 *Indian Journal of Intellectual Property Law* 63–86.

[379] Article 28(1) of the TRIPS Agreement which states in a pertinent part that 'a patent owner shall have the exclusive right to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product'.

[380] For details on the proposed amendment see Basheer and Kochupillai, above n 350 84–85.

[381] Exhaustion of rights or the doctrine of first sale is inherent to IPRs and a necessity in bringing about legal certainty in downstream markets. See for detail Thomas Cottier, 'The Exhaustion of

Therefore, using this approach, parallel-importation provisions can be designed in Bangladesh so as to meet the needs of ensuring access to medicine because patented drugs can be imported and sold at the best possible price, which is beneficial for the people of Bangladesh. Allowing the parallel import of pharmaceuticals could be considered an effective tool for forcing patent holders to sell their protected pharmaceuticals at reasonable and affordable prices.[382]

In addition to research exceptions and parallel imports, a strong position within a compulsory licensing regime is considered very important for ensuring access to affordable medicines.

6.2.5 Strong Compulsory Licensing Mechanism

Whilst the TRIPS Agreement does not use the term 'compulsory license', Article 31 of the Agreement permits 'use without authorization of the right holder' and includes both use by third parties and government use. This is for all intents and purposes considered as "compulsory licensing". The Doha Declaration clarified the WTO's position on compulsory licensing by providing that, 'each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.'[383]

Article 31 of the TRIPS Agreement dealing with compulsory licensing does not clarify the grounds under which a compulsory license can be given. However, certain conditions listed in the Article will have to be satisfied. These include (i) that authorisation of such use will have to be considered on its individual merits; (ii) that before permitting such use (except in such cases as situations of national emergencies, extreme urgency, public non-commercial use), the proposed user will have to make efforts over a reasonable period of time to get a voluntary license on reasonable commercial terms; (iii) that the legal validity of the compulsory licensing decision and the remuneration will be subject to judicial or other independent review; and (iv) that the compulsory licenses can be terminated if and when the circumstances that led to it cease to exist and are unlikely to recur. Nevertheless, there are some less controversial grounds for issuing compulsory licenses as contemplated in TRIPS itself, such as to correct anti-competitive practices, national emergencies or other situations of extreme urgency, including public-health crises and public non-commercial use, such as in providing health care to the poor.[384]

In all these circumstances, Article 31 of the TRIPS Agreement permits a member to grant compulsory licenses without first having to make efforts to obtain a license from the patent owner under reasonable commercial terms and conditions. However, even in these cases TRIPS requires the payment of 'adequate remuneration in the

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Intellectual property Rights: A Fresh Look' (2008) 39(7) *International Review of Intellectual Property and Competition Law* 755–82.

[382] See Krithpaka Boonfueng, Parallel Imports in Pharmaceuticals: Increase Access to HIV Drugs, Thailand Law Forum, 19 July 20101, <http://www.thailawforum.com/articles/hivdrugs1.html>.

[383] Article 5(b) of the Doha Declaration on the TRIPS Agreement and Public Health, Doha (14 November 2001).

[384] Graham Dutfield, Delivering Drugs to the Poor: Will the TRIPS Amendment Help? (2008) 34(2–3) *Journal of Law and Medicine* 1–18, 25 November 2010, < http://owninglife.com/AJLMDutfield.pdf>.

circumstances of each case, taking into account the economic value of the [license]'.[385]

In the Bangladesh Act there is also provision dealing with the issue of compulsory licenses. Section 22 of the Act provides that:

(1) Any person interested may present a petition to the government which shall be left at the Department of Patents, Designs and Trade Marks, together with the prescribed fee, **alleging that the demand for a patented article in Bangladesh is not being met to an adequate extent** and **on reasonable terms** and praying **for the grant of a compulsory license**, or, **in the alternative**, for the **revocation of the patent.**
(2) The government shall consider the petition, and **if the parties do not come to an arrangement between themselves** the government may, as it thinks fit **either dispose of the petition itself** or **refer it to the High Court Division for a decision.** (emphasis added)

As the emphasis shows, there are some limitations within Section 22 in the context of meeting the needs of the local pharmaceutical industry and in ensuring access to pharmaceuticals. The first limitation is that the Section only applies where a situation is one of inadequacy and unreasonable terms. These terms are not defined in the Act so that there is uncertainty as to the extent of these terms. The second limitation is that there is no expert body to deal with a compulsory license application, there is only referral to the High Court Division. The third limitation is that the provision only applies to domestic need; therefore, local generic producers in Bangladesh may not take the opportunity to export to countries having no manufacturing capacity or countries in extreme need of pharmaceuticals. The fourth limitation is that the Section does not provide any clear indication as to royalties or a ceiling on the royalties in case of a compulsory license. The absence of a clear provision on royalties may give rise to higher claims for royalties and related litigation.[386] The absence of a clear provision about royalties arguably creates a degree of uncertainty. The fifth limitation is that the Section does not prescribe any time limit for the conclusion of the proceedings. The sixth limitation is that the Section does not provide that a compulsory license can be issued on the grounds of public interest, a health emergency or for public non-commercial use.

Further, Section 23(3) of the Act states that 'No order revoking a patent shall be made…which is at variance with any treaty, convention, arrangement or engagement with any foreign country'. Such a provision may be used to prevent the issue of a compulsory license or revocation of a patent to argue that Bangladesh is breaching the TRIPS Agreement or any other bilateral free-trade and investment agreement. Thus patent-holders could take advantage of the cumbersome procedure and frustrate the efforts of interested enterprises in getting compulsory licenses. There have been

[385] See Article 33 of the TRIPS Agreement. See for detail Swarup Kumar, 'Compulsory Licensing Provision under TRIPS: A Study of Roche vs. Natco Case in India vis-à-vis the Applicability of the Principle of *Audi Alteram Partem*' (2010) 7(1) *SCRIPTed* 136–54, 12 November 2010, <http://www.law.ed.ac.uk/ahrc/script-ed/vol7-1/kumar.pdf>.
[386] See generally, F M Scherer and Jayashree Watal, Post-TRIPS Options for Access to Patented Medicines in Developing Countries' (CMH Working Paper Series, Paper No WG4:1), 20 November 2010, <http://www.whoindia.org/LinkFiles/Commision_on_Macroeconomic_and_Health_04_01.pdf>.

no compulsory licenses issued in Bangladesh for the patented drugs based on the existing provision of compulsory license prior to prohibition of pharmaceutical patents in the country in 2008.[387]

These limitations need to be removed and the Act needs to be amended to incorporate a viable compulsory licensing mechanism. In this regard, the legislative examples of India and Brazil may be useful.

Both India and Brazil have included compulsory licensing mechanisms within their legislative regimes. Such legislation has the potential to not only meet the need to ensure access to pharmaceuticals, but also to serve local generic producers to enable the export and supply of generic pharmaceuticals to other poor countries, to countries having no manufacturing capacity or those countries in urgent need of pharmaceuticals.[388]

Bangladesh should consider adopting a provision similar to the Indian provision that permits the issue of a compulsory license in the case of a national emergency, health crisis or for public non-commercial use. For example, Section 92(1) of the Indian Patent Act[389] provides that:

> (1) If the Central Government is satisfied, in respect of any patent in force, in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary that compulsory licences should be granted at any time after the sealing thereof to work the invention, it may make a declaration to the effect, by notification in the *Official Gazette*…

To then allow exportation under a compulsory license in Section 92A of the Indian Act lays down that:

> (1) Compulsory licences shall be available **for the manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity** in the pharmaceutical sector for the concerned product to address public-health problems, provided compulsory licences have been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India. (emphasis added)[390]

Bangladesh should adopt a similar provision to allow local generic producers to exploit the opportunity to export cheap generic medicines to other countries that have no manufacturing capacity or that are facing an extreme health emergency. It is also interesting to note that the Indian Patent Act includes a provision listing of the prime objectives for granting a patent for pharmaceuticals. In the event of a violation of any of these provisions, grounds for the issue of a compulsory license could be raised. In this regard, Section 83 of the Indian Patent Act[391] provides as follows:

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[387] Interview data-(PO 001-003).

[388] Cecilia Oh and Sisule Musungu, 'The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?, Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)', Study 4C, 12 October 2010, <http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf>.

[389] Section 92 (1) of the Patents Act, 1970 (India).

[390] Section 92 A of the patents (Amendment) Act, 2005 (India).

[391] Section 83 of the Patents (Amendment) Act, 2002 (India).

Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely:

(a) that patents are granted **to encourage inventions and to secure** the **Public-health Safeguards in Indian Patents Act** that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
(b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
(c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;
(d) That **patents granted do not impede protection of public health and nutrition and should act as instruments to promote public interest,** especially in sectors that are of vital importance for the socio-economic and technological development of India;
(e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;
(f) that the patent right is not abused by the patentee or person deriving title or interest on-patent from the patentee, and the patentee or a person deriving title or interest on-patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and
(g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public. (emphasis added)

By inserting the above Section the Indian government validated its present and any future actions as a measure to protect the public interest. In particular, Section 83(d) and (e) is adopted from the objectives and principles clause of the TRIPS Agreement,[392] which validates government actions based upon the socio-economic conditions of the country. Bangladesh should adopt a similar provision as a proactive measure so that it can validate future actions to protect the public interest, and other socio-economic interests and developmental goals of the country.

However, commentary on the Indian compulsory licensing regime has highlighted a limitation of the Section because there is no clear detail with respect to the requirement to pay royalties. Gopakumar has stated that, 'gaps in the law take away the effectiveness of a compulsory license regime under the Patents Act. As a result, during the last five years only one application was filed for the issuance of a compulsory license in India'.[393]

In this respect, to speed up the process of issuing compulsory licenses in the case of an emergency situation there should either be an administrative body to deal with the application or provision for the government to itself issue a compulsory license

[392] Article 7 and Article 8 of the TRIPS Agreement.
[393] Gopakumar, above n 206.

without application. In this respect, Article 72 of the Brazilian Industrial Property Law provides:

> In cases of **national emergency or of public interest, as declared in an act of the Federal Executive Power,** and provided the patent holder or his licensee does not fulfil such need, **a temporary and non-exclusive compulsory license for exploiting the patent may be granted, ex officio,** without prejudice to the rights of the respective titleholder. (emphasis added)

This provision empowers the Brazilian government to issue a compulsory license without any application being made to it if negotiations between parties fail.[394] Such a legislative option should be considered by Bangladesh as part of its TRIPS-compliant legislative regime.

The Draft law of Bangladesh tried to utilise the Indian option but this still needs some clarification,[395] as it is not clarified in the Draft provision whether exports can be made to non-WTO member countries, or to countries that do not have pharmaceutical patents or patents of a particular drug.[396] Again, the issue of compulsory licenses still needs to be determined by the court, as in India, rather than by any specific executive body, as happens in Brazil. The court procedure in Bangladesh is generally long, costly and complicated. This may discourage potential applicants applying for compulsory licenses. Therefore, it would be better for Bangladesh to follow the Brazilian approach of issuing compulsory licenses and establishing an expert body to deal with compulsory licensing issues within the shortest possible time to speed up the production of generic drugs in the case of public-health crises.

Further, the issue of reasonable remuneration is not clearly defined. Therefore, bargaining over this issue may also unnecessarily delay the procedure of issuing compulsory licenses. In this case, Bangladesh could perhaps adopt the Canadian approach of fixing royalties based on the United Nations human development index (HDI)[397] with slight modification. The same formula should be used based on the ranking of the country where the manufactured drugs under the compulsory license are to be exploited, as the Canadian model is only for exports based on the destination of the drugs (the importing country).[398] With this modification,

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[394] Brazil used this provision to threaten with compulsory licenses in order to gain substantial price reductions on several occasions, as mentioned in Chapter 4 of this study.

[395] Section 84 of the Draft Patents and Design Act, 2010 (Bangladesh).

[396] Islam, above n 69.

[397] The HDI is a comparative measure of life expectancy, literacy, education and standards of living for countries worldwide. It is a standard means of measuring well-being, especially child welfare. It is used to distinguish whether the country is a developed, a developing or an under-developed country, and also to measure the impact of economic policies on quality of life. The origins of the HDI are found in the annual Human Development Reports of the United Nations Development Programme (UNDP). It was devised by Economist *Mahabub-ul Haq* in 1990 and had the explicit purpose of shifting the focus of development economics from national-income accounting to people-cantered policies.

[398] In 2005, Canada proposed royalty guidelines for the export of medicines under the Jean Chrétien Pledge to Africa Act, which implements the WTO waiver of Article 31(f) of the TRIPS Agreement. The Canadian royalty guidelines are a sliding scale of the generic sales price. The rate depends entirely upon the location of the importing market and the rank of the importing country in the UNHDI. The formula is one, plus the number of countries on the UNHDI, minus the importing country's rank on the UNHDI, divided by the number of countries on the UNHDI, multiplied by 0.04.

Bangladesh would be able to produce drugs locally using compulsory licenses or it could use compulsory licenses for exporting by paying the minimum fixed royalties without any cumbersome bargaining, as Bangladesh still holds a very low ranking in the HDI and most of the exporting destinations of Bangladeshi pharmaceutical products are still in the lower level of the HDI.[399]

Furthermore, the Government of Bangladesh may need to modify existing provision regulating 'local working' of the patent or related provision concerning patented products or processes, which are manufactured outside of Bangladesh. Section 23 of the Patents and Designs Act 1911 provides that

> "(1) At any time not less than four years after the date of a patent granted under this Act, any person may apply to the Government for relief under this section on the ground that the patented article or process is manufactured or carried on exclusively or mainly outside Bangladesh.
> (2) The Government shall consider the application, and, if after inquiry it is satisfied-
> (a) that the allegations contained therein are correct; and
> (b) that the applicant is prepared, and is in a position, to manufacture or carry on the patented article or process in Bangladesh; and
> (c) that the patentee refuses to grant a license on reasonable terms,
> then, subject to the provisions of this section, and unless the patentee proves that the patented article or process is manufactured or carried on to an adequate extent in Bangladesh, or gives satisfactory reasons why the article or process is not so manufactured or carried on, the Government may make an order-
> (a) revoking the patent…"

The existing patent law of Bangladesh does not contain any definition of the term 'manufactured or carried on exclusively or mainly outside Bangladesh' as mentioned in the section 23 of the Act. This absence of a definition may result in varied and ambiguous interpretations. Again, section 23 of the Act requires that four years should lapse from the date of granting of a patent and only then one can make application for the revocation of patents on the ground of 'non-working in the territory of Bangladesh. Therefore, ambiguity of the existing provision and four years requirement will delay the entry of cheaper local pharmaceuticals. This will allow the MNCs to enjoy monopoly for their patented pharmaceuticals without any transfer of technology and investment for local manufacture as they will rely on the manufacturing facilities outside of Bangladesh. In this regard, Section 84 of the Indian Patent Act[400] and Article 68 of the Brazilian Industrial Property Act (1996)[401]

The rate is then applied to the generic sales price. With 177 countries currently in the UNHDI index, the royalty rate can be expressed as: Royalty rate = 0.04 * [(178)–rank importing country]/177. During the time of adoption of this royalty approach in 2004, the top rate was four per cent of the generic sales price for Norway, as it was the number one country in the HDI in 2004, and the lowest rate was 0.02 per cent for Sierra Leone, as it was lowest ranking country in the HDI in 2004.

[399] The ranking of Bangladesh in the HDI of 2010 was 129. For the HDI of other countries see 26 July 2011, <http://hdr.undp.org/en/media/HDR_2010_EN_Table1_reprint.pdf>.

[400] 84. Compulsory licenses. –
(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of a compulsory license on patent on any of the following grounds, namely –
(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied . . .

may be a model for Bangladesh which have so far successfully resisted the pressure of the USA and multinational pharmaceutical companies.[402]

The Indian Controller of Patents while disposing an application for compulsory license in *Natco Pharma Ltd. v. Bayer Corporation*[403] clarified the issue of working of the patent in the territory of India. The Controller noted that the term "worked in the territory of India" had not been defined in the Indian Patent Act, and so he needed to interpret the term with regard to "various International Conventions and Agreements in intellectual property," the 1970 Patent Act and the legislative history[404]. The Controller using Article 27(1) of TRIPS and Article 5(1)(A) of the Paris Convention supported an interpretation that failure to manufacture in India supported the grant of a compulsory license to Natco stating that:

> "[p]atents are not granted merely to enable patentees to enjoy a monopoly for importation of the patented article" and .. that "the grant of a patent right must contribute to the promotion of technological innovation and to the transfer and dissemination of technology."[405] (emphasis added)

Therefore, considering Indian experience, the Government of Bangladesh may adopt following provision on the working of the patent in the territory of Bangladesh-

> "Compulsory License for Non-Working in the territory of Bangladesh
> At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Department of Patents, Designs and Trademarks or to the duly authorised office for grant of a compulsory license on patent on any of the following grounds, namely –
> (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied . . .
> (ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms . .
> (b) that the patented invention is not available to the public at a reasonably affordable price
> (c) that the patented invention is not worked in the territory of Bangladesh.

(ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms . . (b) that the patented invention is not available to the public at a reasonably affordable price . . .
(c) that the patented invention is not worked in the territory of India.

[401] Article 68 of the Industrial Property Act, 1996 (Brazil)…
Article 68…
(1) The following also shall occasion a compulsory license:
I. non-exploitation of the object of the patent within the Brazilian
territory for failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the patented process, except cases where this is not economically feasible, when importation shall be permitted; or
II. commercialization that does not satisfy the needs of the market.

[402] See for details, Daya Shanker, India, the Pharmaceutical Industry and the validity of TRIPS 5(3) *The Journal of World Intellectual Property* (May 2002) and Daya Shanker, Brazil, Pharmaceutical industry and the WTO, 5(1) *The Journal of World Intellectual Property* (January 2002) 53–104.

[403] *Natco Pharma Ltd Vs. Bayer Corporation*, Compulsory licensing Application No. 1 of 2011 (decided by the Controller of Patents, Indian Patent office, 9th March 2012).

[404] Ibid

[405] *Natco Pharma Ltd Vs. Bayer Corporation*, C.L. No. 1/2011 (Before the Controller of Patents, Delhi, India 9th March 2012) available at http://www.cbgnetwork.org/downloads/BackgroundNexavar.pdf, accessed on 6th August, 2012.

> Explanation: This section to be applied to the extent giving due consideration to the fact that patents are not granted merely to enable patentees to enjoy a monopoly for importation of the patented article but the grant of a patent right must contribute to the promotion of technological innovation and to the transfer and dissemination of technology".

During the interviews participants[406] argued that Bangladesh should have strong compulsory licensing mechanisms. But one participant argued that a compulsory license is not viable option as it will discourage technology transfer and foreign direct investment in Bangladesh.[407] Another participant commented that simply making provision is not enough if the procedure is complicated with inordinate delays in the issuing of the compulsory license.[408] Therefore, using the experience of India and Brazil if Bangladesh can integrate in its future amended patent law a provision on compulsory licenses, whilst avoiding clumsy and complicated procedures, it will be advantageous in the context of ensuring access to pharmaceuticals in the event of any public-health emergencies in Bangladesh and will give a competitive advantage to its local pharmaceutical industry when exporting to any other country having low or no manufacturing capacity. Similarly, there should be a prior-use exception to protect local producers within the pharmaceutical industry.

6.2.6 Prior-use Exceptions

Considering the number of local generic producers in Bangladesh and the investment made in the area of producing cheap generics of patented medicines prior to the possible introduction of pharmaceutical patents in Bangladesh, the prior-use exception should be incorporated into Bangladesh's TRIPS-compliant patent law. In a study by the World Bank the Indian example of prior user rights, termed a "Grandfather clause" or automatic compulsory license and is illustrated as follows-

> Generic versions of patented medicine can continue to be manufactured in India provided that: (1) the generic manufacturer was producing and marketing the product prior to January 1, 2005; (2) the generic manufacturer made significant investment in the production and marketing for the product; and, (3) a reasonable royalty is paid to the patent holder.[409]

During the interviews participants strongly supported the position that the patent law of Bangladesh should include a provision like India on the prior user rights.[410] Conversely, one participant argued that such a provision will discourage foreign investment and transfer technology in Bangladesh.[411]

The Indian example of prior user rights has some weakness as it may be challenged by the patent holder on a number of grounds such as it was not exploited prior to 1 January 1 2005 or prior to the introduction of the pharmaceutical patent, the

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[406] Interview data –(CEB001-003, CEM 001-002, CES 001, PHN 001-002, PO 001-003, IP 001 and PHA 001-002).
[407] Interview data-(CEMN 001).
[408] Interview data-(IP 002).
[409] Public and Private Sector Approaches to Improving Pharmaceutical Quality in Bangladesh, Bangladesh Development Series, Paper No. 23, A study by the World Bank, March 2008, 1 June 2009, <www.worldbank.org.bd/bds>.
[410] Interview data–(CEB001-003, CEM 001-002, CES 001, PHN 001-002, PO 001-003, IP 001 and PHA 001-002).
[411] Interview data-(CEMN 002).

investment was not sufficient or on the ground of reasonable rate of royalties. These weaknesses may create barriers for generic production. In this case, the Brazilian provision should perhaps be replicated in Bangladesh, which has no such limitations. Such an exception is contained in Article 45 of Brazil's Industrial Property Law and provides that:

> A person who in good faith, prior to the filing or priority date of a patent application, was exploiting the object thereof in this country, shall be assured the right to continue the exploitation, without onus, in the same manner and under the same conditions as before.

Whilst the above legislative options go towards defining the matters of patentability and exceptions, consideration should also be given to the process adopted for objections to be made to patent applications.

6.2.7 Pre-grant and Post-grant Opposition

Pre-grant and post-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 patents. An opposition provision is currently contained in Section 9(1) of the Bangladesh's Act and provides that:

Any person may, on payment of the prescribed fee, at any time within **four months from the date of the advertisement of the acceptance of an application,** give notice at the Department of Patents, Designs and Trade Marks of opposition to the grant of the patent on any of the following grounds, namely:

(a) that the applicant obtained the invention from him, or from a person of whom he is the legal representative or assign; or
(b) that the invention has been claimed in any specification filed in Bangladesh which is or will be of prior date to the patent, the grant of which is opposed; or
(c) that the nature of the invention or the manner in which it is to be performed is not sufficiently or fairly described and ascertained in the specifications; or
(d) that the invention has been publicly used in any part of Bangladesh or has been made publicly known in any part of Bangladesh; or
(e) that the complete specification describes or claims an invention other than that described in the provisional specification, and that such other invention either forms the subject of an application made by the opponent for a patent, which if granted would bear a date in the interval between the date of the application and the leaving of the complete specification, or has been made available to the public by publication in any document published in Bangladesh in that interval;

but on no other ground. (emphasis added)

As emphasised, objections are limited by two conditions. The first is that the objection must be made within four months of the advertisement of the acceptance of the application and the second is that the objection can only be based on the grounds provided by Section 9(1). If defects with respect to the granted patent are revealed, or identified after the four-month period, then no objection can be raised against the patent application. In other words, the existing provision does not permit any type of post-grant opposition. 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[412] are broad enough to challenge novelty, inventive steps and the process of industrial application, the best method, claims and disclosure of origin and even the use of indigenous or local knowledge. Given this comparison it is suggested that the existing Bangladeshi Section is not sufficient and should be amended to include more extensive pre-grant heads of objection and include a process for post-grant opposition.

In taking such a legislative step it is suggested that the heads of objection should be as wide as possible so that the twin aims of ensuring access to medicine and promoting innovation within the pharmaceutical industry are not hampered. During the interviews participants considered that the Indian example of pre-grant and post-grant opposition ought to be replicated in Bangladesh.[413] One participant argued against that suggesting that the local pharmaceutical industry and public health organisations in Bangladesh lack adequate expertise and resources to effectively exploit pre-grant and post-grant opposition therefore they should prepare themselves to use this effectively.[414] Another participant also criticised that there is no accessible online information about on-going patent applications in Bangladesh and even paper copies of the DPDT's journal is not distributed regularly therefore interested parties will have difficulties in collecting the required information to oppose any patent application or granted patent.[415] Therefore, simply having this provision may not be enough unless access to information regarding patent applications and granted patents are regularly updated and available for interested parties. One participant argued that if this provision it enacted it may open flood gates with unnecessary opposition and may even frustrate the investments in the pharmaceutical sector.[416] The issue of how long a patent should last also needs consideration.

6.2.8 Duration of Patent Protection

Under Section 14 of the Bangladesh Act, patent protection is available for sixteen years. The TRIPS Agreement requires that patent protection be available for twenty years. Brazilian Industrial property law simply indicated that patent protection shall be for twenty years from the date of filing.[417] The Indian Patent law extended the duration to twenty years subject to the patent legislation and that the period starts from the date of filing of the application:

> Subject to the provisions of this Act, the term of every patent granted, after the commencement of the Patents (Amendment) Act, 2002, and the term of every patent which has not expired and has not ceased to have effect, on the date of such commencement, under this Act, shall be twenty years from the date of filing of the application for the patent.[418]

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[412] Archana Shanker and Neeti Wilson, 'The Patent Opposition System in India', 08 July 2010, <http://www.iam-magazine.com/issues/article.ashx?g=4ed76a24-e544-4547-a651-84c0542aecd1>.

[413] Interview data-(CEB001-003, CEM 001-002, CES 001, PHN 001-002, IP 001, IP 003 and PHA 001-002).

[414] Interview data-(IP 001).

[415] Interview data-(IP 002).

[416] Interview data-(CEMN-001).

[417] Industrial Property, Law No. 9.279 of 14 May 1996 (Brazil), *Section II Term of the Patent* -40. **"**An invention patent shall remain in force for a period of 20 (twenty) years, and a utility model patent for a period of 15 (fifteen) years from the date of filing."

[418] Section 53(1) the patents (Amendment) Act, 2002 (India).

Whilst the TRIPS Agreement limits the ability of Bangladesh to explicitly reduce a patent period, any legislative amendment should contain a qualification. To that extent it is suggested that in amending the Act to be TRIPS compliant the Section should provide that the, 'duration of protection is subject to exceptions as included in this Act or to be included by any future amendments'. Such an extension may provide the government with some freedom to act as times change and TRIPS compliance is assessed. It will also permit the government to act immediately in the case of a health emergency or out of some other type of public interest. During the interviews some participants considered this kind of reservation may be useful to limit patent protection, if necessary for the grounds of public interest.[419] But one participant argued that limiting patent protection will discourage investment in the pharmaceutical sector. That participant argued that twenty years is not sufficient to recover investment so that a patent should be extended for thirty years in the pharmaceutical sector.[420] Apart from the above legislative options, the government of Bangladesh should consider some additional interventions to ensure access to medicines and to promote pharmaceutical innovation in the process of moving towards a TRIPS-compliant regime.

6.3 Other Government Options

While interviewing researchers, academics and public-health NGOs in Bangladesh the message echoed by them was that simply utilising the TRIPS flexibilities to reform the national patent law may not be enough to ensure access to pharmaceuticals in Bangladesh. Especially when the country's economic development, health infrastructure, drug distribution and availability of existing drugs is in disarray.[421] There is also apprehension that MNCs and developed countries might stop Bangladesh from producing and importing cheaper generic drugs, which compete with the more expensive patented brands of pharmaceuticals.[422] However, Bangladesh is not being pressured for pharmaceutical patents yet by the MNCs and developed countries such as the USA and EU, as Bangladesh still has five years to comply with the pharmaceutical patents of the TRIPS Agreement. Further Bangladesh is not a competitive threat yet as Bangladesh is not a country that promises vast profits.[423] Some critics consider that despite having 150 million people, the average wage, life expectancy and literacy rates are among the lowest in the world and its local pharmaceutical industry is considered as being incapable of making the raw materials for new drugs so that MNCs are not interested in putting any pressure on Bangladesh.[424] In 1997, the US Embassy in Bangladesh reported that, 'Intellectual property infringement is common, but is currently of relatively limited significance for US firms'.[425]

However, this attitude may change soon, as has happened in other poor countries such as Ghana and Uganda, where multinational companies have already acted to put the pressure on regarding pharmaceutical patents. Therefore, apart from reforming

[419] Interview data-(CEB 001, CEM 002, CES 001).
[420] Interview data-(CEMN 001).
[421] Interview data-IPA 001-002, PHN001, DDA001.
[422] Make Vital Medicine Available for People: Bangladesh, OXFAM, above n 268.
[423] Ibid.
[424] Ibid.
[425] Ibid.

the patent law, Bangladesh may need to consider some other alternative governmental-intervention options to ensure access to medicines.[426] Supporting alternative measures apart from market-based instruments, Dr Zafarullah Chowdhury remarked that:

> Medicines are one commodity you can't leave to market forces. The market is simply not competent. It makes for monopolies and cartels, not competition. And every drug is, by definition, essential. If you have a malfunctioning liver and only one drug can save your life, that to you is the most essential drug in the world. Allowing the global drug market to be controlled by foreign firms (with lengthy periods of patent control) is not going to help us.[427]

Dr Chowdhury further added that 'local drug firms have no innovative technology, therefore when Bangladesh is bound to honour foreign patents on new drugs that could be our collapse'.[428] Another renowned public-health activist in Bangladesh, Farhad Mazahar, remarked that 'the impact of pharmaceutical patents on Bangladesh will be huge because most of our raw materials [for new and existing drugs] come from India and China and our companies are only pharmacies, really not pharmaceutical industry'.[429] Therefore, considering the delicate infrastructure of the public-health situation and the low level of access to medicines and lack of innovation among the local pharmaceutical industries in Bangladesh, it is suggested that Bangladesh may adopt some alternative measures using the examples of India, Brazil and some other countries, which are: (i) drug price control, (ii) national competition law, (iii) the introduction of the patent prize system, (iv) limiting data protection, (v) developing a patent pool on country specific diseases, and (vi) lobbying for the extension of the transition period for pharmaceutical patents beyond 2016.

6.3.1 Drug Price Control

Control over the cost of medicines exists in one form or the other in most countries. For example, in Australia, new drugs with no advantage over existing products are offered at the same price. Where clinical trials show superiority, incremental cost effectiveness is assessed to determine whether a product represents value for money at the price sought.[430] In the United Kingdom, the pharmaceutical price-regulation scheme (PPRS), a voluntary agreement between the United Kingdom's Department of Health and the Association of the British Pharmaceutical Industry exists so that companies negotiate profit rates from sales of drugs to the National Health Service (NHS).[431] The PPRS regulates profits to a band of seventeen to twenty-one per cent on historic capital or the initial capital used to begin the venture with a twenty-five per cent variation on either side.[432] Companies are free to set prices, provided the

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[426] Interview data-GE001-002.
[427] Quoted in: Make Vital Medicine Available for People: Bangladesh, OXFAM, above n 268.
[428] Ibid.
[429] Ibid.
[430] See generally, Jon Sussex, Koonal K Shah and Jim Butler, 'The Publicly Funded Vaccines Market in Australia, Office of Health Economics'(OHE Consulting Report 10/02, 25 October 2010 and Access to Essential Medicines, National Coordination Committee, Jan Swasthya Abhiyan, February 2007), 25 November 2010, <http://www.healthpolicy.cn/rdfx/jbywzd/gjjy2/yd/yjwx/201002/P020100227572014659949.pdf> at.
[431] See generally, Kevin A Hassett, Price Controls and the Evolution of Pharmaceutical Markets, 22 July 22 2004, <http://www.who.int/intellectualproperty/news/en/Submission-Hassett.pdf>.
[432] Ibid.

rate of return is within the band.[433] If the profits are higher, the companies have to reduce profits the next year and if the profits are lower, they can raise their prices. In France, Italy and Belgium, prices are set in relation to relative cost, prices elsewhere in the EU and the contribution made to national economy.[434]

In Bangladesh there is no drug price-control mechanism under the existing Patent Act. However, the Drug Control Ordinance 1982 provides for the fixing of prices by a committee appointed by the government.[435] The committee mostly deals with the essential medicines, as listed by the DDA in Bangladesh. Accordingly, no drugs can be circulated without such pricing controls.

This is a vital guarantee that the prices of pharmaceuticals, whether produced nationally or imported from outside, will not increase without prior government authorisation.[436] Further, it is within the government's purview to refuse the registration of any pharmaceuticals that are regarded as too expensive or unaffordable.[437]

In 1982, 150 pharmaceuticals were defined as essential pharmaceuticals[438] and any changes to prices were decided by the Drug Control Committee. However, since 1993 the number of price-controlled pharmaceuticals has reduced to 117 primary health-care pharmaceuticals.[439] The Drug Control Ordinance 1982 has empowered the government to determine the MRP of 117 essential drug-chemical substances. The MRP is broken down into trade price (75.5 per cent), wholesale commission (2.3 per cent), retail commission (12.0 per cent) and VAT (12.5 per cent) for local products.[440] The breakdown for the imported products is made into trade price (88.89 per cent) and retail commission (11.11 per cent).[441] Non-essential drugs are priced through a system of indicative prices.

The rule is applicable only in the case of locally produced goods. A fixed percentage of mark-up is applied to the custom and forwarding (c&f) price of finished goods to determine the MRP of imported finished goods. This is followed irrespective of whether they are essential or non-essential products. Therefore, for pharmaceuticals that do not fall into the controlled category, the manufacturer is able to set the price of the pharmaceutical. In principle, this does not mean that an exorbitant price can be set by a manufacturer, as the price must be approved (but not controlled) by the Drug Control Committee.[442]

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[433] Ibid.
[434] See Alan Maynard and Karen Bloor, 'Dilemmas in Regulation of the Market for Pharmaceuticals' (2003) 22(3) *Health Affairs* 31–41.
[435] See Azam and Richardson, above n 133.
[436] No drug can be introduced into the market without prior approval from the Drug Control Committee and price fixation by the Drug Price Committee as per Drug Control Ordinance (1982).
[437] Drug Control Ordinance, 1982 (Bangladesh) s 11.
[438] Bangladesh, Drug Control Committee, Report No 1 (1982).
[439] Interview data (DDA002).
[440] A K Monaw-war Uddin Ahmad, Competition, Regulation and the Role of the State: The Case of Bangladesh, 10 July 2011, <http://www.asiaticsociety.org.bd/journals/Dec_2008/contents/ManwarUddinAhmed.htm>.
[441] Ibid.
[442] 'Drug Control Committee is constituted by the Ministry of Health According to Section' (1982) 4(1) *Drug Control Ordinance.*

But in practice the Committee accepts the pricing as offered by the manufacturers or importers if it is not within the list of essential medicines; no other stakeholders have a say in fixing the price.[443] Therefore, sometimes the manufacturer or importer can fix a higher price if it is not within the essential medicines list in Bangladesh and the Committee has no objection or is critical of the pricing. The list needs to be updated from time to time, as in some cases the old listed medicines may not work and patients will need expensive new medicines that are often beyond price control. One such situation is found in multi-drug resistance, where the older drugs are not working yet the patient is unable to buy the new expensive drugs. Dr Zaman Khan explained the situation in Bangladesh in this way:

> … we have recently lost four patients to multi-drug resistance disease. Eventually there will be new drugs but they will be even more expensive than the antibiotics we use now, Cefrazidine from Glaxo, for instance, at 450 taka ($8) a dose or Ceftriazone from Roche, at 500 taka ($9). Very few people can even afford the drugs we have got. We ask patients about their economic history and then we decide who can and can't afford drugs. But I would say 70 per cent of the people we see cannot afford to buy medicines. Even the cheaper versions are often beyond them.[444]

This view is supported by Dr Khurshid Talukder of the Institute of Child and Mother Health in Bangladesh:

> We just want the best possible answers to treat all diseases. Simply, we must have the drugs here when they are available in developed countries. And they have to be affordable for poorer people to buy. People are often too poor to buy the correct drugs needed to cure an illness or cannot complete the full course of medicines, which in turn leads to more resistance.[445]

His concluding view was that after the introduction of pharmaceutical patents and the TRIPS-compliant patent law, the 'people of Bangladesh could be very seriously affected. It is an alarming and dismal picture.'[446]

That is why, most of the public-health NGOs and public-health experts in Bangladesh consider that in order to make the existing price-control mechanim more effective, the government of Bangladesh should establish a permanent price-control mechanism accessible to the general public and public-health groups.[447] Any individual or public-health group should then be permitted to challenge or review the pricing of medicines on social or health grounds.[448] Another concern is that there are a number of pharmacies in the country that operate without a license to sell pharmaceuticals without the customer having a prescription and at a higher price.[449]

Therefore, the Committee should be given jurisdiction to deal with these issues and the public and interest groups should be able to access the Committee.[450] An example of such a body is the Canadian Patented Medicine Prices Review Board (PMPRB) which was set up in 1987, under the Patent Act as an independent quasi-judicial

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[443] Interview data-PHN002.
[444] Quoted in: Make Vital Medicine Available for People: Bangladesh, OXFAM, above n 268.
[445] Ibid.
[446] Ibid.
[447] Interview data-(PHN 001-002 and PHA 001-003).
[448] Ibid.
[449] Interview data-(PHA004).
[450] Interview data-(PHN 001).

tribunal to limit the prices set by manufacturers for all patented medicines, new and existing, sold in Canada, under prescription or over the counter, to ensure the pricing was not excessive.[451] As an independent quasi-judicial body, the PMPRB carries out its mandate independently of other organisations, such as Health Canada, which approves drugs for safety and efficacy; and public drug plans, which approve the listing of drugs on their respective formularies for reimbursement purposes.[452]

The PMPRB has a dual role of regulation and reporting.[453] Its regulatory role is to protect consumers and contribute to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive.[454] Whilst its reporting role is in contributing to informed decisions and policy making by reporting on pharmaceutical trends and on the R&D spending by pharmaceutical patentees.[455] This Board is unique in the sense that it was set up exclusively to monitor the prices of patented drugs. Besides, it also analyses the therapeutical contribution of the patented pharmaceuticals and documents the pharmaceutical R&D investment in Canada. A similar mechanism should be considered by Bangladesh as it moves towards a TRIPS-compliant patent regime.

However, it is interesting to note here that both the leading local pharmaceutical industries in Bangladesh and the multinationals operating in Bangladesh, except some small pharmaceutical companies, oppose the price-control mechanism.[456] One participant during their interview argued that, 'some companies are trying to seize the market with low price-low quality products which may become a real threat for public health'.[457] This was also supported by another participant claiming that price control may encourage cheap drugs and may in way encourage low quality counterfeited pharmaceuticals.[458] Whereas the CEO of one small pharmaceutical company during their interview argued that that the, 'withdrawal of price control will become a threat for access to medicines and for their survival' as well. He further added that, 'it is better to have price control to encourage local competition and ensure affordability of pharmaceuticals for the local people'.[459] The Bangladesh Association of Pharmaceutical Industries made no comment about this, as it considered this an issue of contention from both legal and political perspectives, and agreed that in their organisation there is a conflict of opinions among the members.[460]

Yet, public-health NGOs and IP academics in Bangladesh support a broadening of the role of price control and consider that any attempt to withdraw price control will

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[451] See Patented Medicine Prices Review Board (PMPRB) (25 November 2010) <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=175&mp=87>.
[452] Ibid.
[453] Ibid.
[454] Ibid.
[455] Ibid.
[456] During the survey, fifty per cent of pharmaceutical companies operating in Bangladesh strongly agreed with the withdrawal of price control and twenty-seven per cent also agreed with this (this represent all multinationals and large and medium size companies that participated in the survey). Conversely, eighteen per cent strongly disagreed and five per cent disagreed with the proposition (all of them small pharmaceutical companies).
[457] Interview data-(CEB 01).
[458] Interview data-(CEMN 001).
[459] Interview data- (CES 001).
[460] Interview data- (BAPI 001-002).

be a disaster.[461] One IP academic in Bangladesh argued that, 'reality shows that even the Government is not able to control price effectively with the present ordinance. So the non-existence of the Price Control Ordinance would definitely lead towards the real disaster in terms of access to drugs'.[462] During another interview, that participant stated that, 'in the absence of it, the price of drugs would be sky-high, which would ultimately lead towards the real obstacle in order to access to drugs'.[463]

In India there is a National Pharmaceutical Pricing Authority (NPPA) which was established under the Drugs (Prices Control) Order 1995[464] and is entrusted to fix/ revise the prices of controlled bulk drugs and formulations (bulk drugs are those for which the prices are controlled like essential medicines list in Bangladesh) and to enforce prices and availability of the medicines in India. It is also empowered with the task of recovering amounts overcharged by manufacturers for controlled drugs from consumers and also monitors the prices of decontrolled drugs in order to keep them at reasonable levels. But the drug control mechanisms in India are considered ineffective in the opinion of a taskforce popularly known as the Dr Pronab Sen Taskforce formed by the Government of India to evaluate the drug control mechanisms in India. The taskforce argued that

> no price regulatory mechanism can be effective unless there is a credible threat of price controls being imposed and enforced. However, it is also felt that the present price control system is dysfunctional and its legislative authority inappropriate.[465]

It further that price controls should be imposed not on the basis of turnover, but on the 'essentiality' of the drug and on strategic considerations regarding the impact of price control on the therapeutic class. This must be a dynamic process. The ceiling prices of controlled drugs should normally not be based on cost of production, but on readily monitor-able benchmarks.[466] Some other recommendations of the taskforce which may also be relevant for Bangladesh are as follows:[467]

- A process of active promotion of generic pharmaceuticals should be put in place, including mandatory de-branding for selected drugs.
- All public health facilities should be required to prescribe and dispense only generic drugs, except in cases where no generic alternative exists.
- In the case of proprietary drugs, particularly anti HIV/AIDS and Cancer, drugs the government should actively pursue access programmes in collaboration with drug companies with differential pricing and alternative packaging, if necessary.
- Public Sector Enterprises (PSEs) involved in the manufacture of drugs should be revived where possible and used as key strategic interventions for addressing both price and availability issues. Arrangements may need to be made to ensure their continuing viability and

[461] Interview data-(PHN 001-002, IP 001-003).
[462] Interview data-(IP 002).
[463] Interview data-(PHN001-2).
[464] The Drugs price Control order was first passed in 1970 and then revised in 1979, 1987 and 1995. See for details, Impacts of TRIPS on Pharmaceutical prices, available at http://whoindia.org/LinkFiles/Trade_Agreement_Chapter03_Trade_Agreement_Impact_of_TRIPS.pdf (6 January, 2012).
[465] Ibid.
[466] Ibid.
[467] Dr. Pronob Sen taskforce Report, Explore Options other than Price Control for Achieving the Objective of Making Available Life-saving Drugs at Reasonable Prices (2005) 'Department Chemicals and Petrochemicals (India).

- Fiscal incentives should be provided on a long-term assured basis to research and development activities in drugs.

One pharmaceutical technology researcher in Bangladesh during their interview remarked that the Government of Bangladesh should also appoint a taskforce to review its drug control mechanism suggesting it would benefit from the Indian taskforce report to restructure existing drug control mechanism.[468] However, another participant remarked that the Canadian approach is free from the problems identified by the Indian taskforce. Therefore an agency like the Canadian Authority and the empowering of the Drug control Authority with the recommendations made by the Dr Pronob Sen taskforce may help Bangladesh to develop a unique mechanism to maintain access to medicines, to assess the R&D investment in the pharmaceutical sector and to feed information back to the government on such matters as incentives like tax exemptions and other policy measures.[469] However, some researchers such as A. K. Monawar Uddin Ahmad stated that the withdrawal of price controls for many pharmaceutical products did not lead to any rise in the price level and the Maximum Retail Price (MRP) of some finished formulations actually reduced due to competitive bulk drug pricing.[470] He believes that competition law may be a potential instrument for Bangladesh.[471]

6.3.2 National Competition Law

Article 8.2 of the TRIPS Agreement permits WTO members to adopt appropriate measures to prevent the abuse of IPRs or practices that unreasonably restrain trade or adversely affect the international transfer of technology. Again, Article 40 of the TRIPS Agreement recognises the possible link between intellectual property laws and competition policy.[472] Therefore, while implementing the TRIPS requirements, members can prevent the abuse of IPRs and control anti-competitive practices either by integrating competition rules within the national IP law or by framing a separate competition law to prevent abusive monopoly practices or the abuse of a dominant position.[473] The use of competition law and policy provides developing countries with several advantages including[474] (a) countries have flexibilities under the TRIPS Agreement to use a competition framework appropriate to their socio-economic condition, (b) countries have the freedom to define what constitutes anti-competitive behaviour, (c) competition law and policy is well suited for implementation by an independent competition authority vested with extensive investigative powers, and (d) competition law and policy have already been used successfully by South Africa to reduce the price of essential medicines.

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[468] Interview data-(PHA 001).
[469] Interview data-(IP 004).
[470] Monawar Uddin Ahmad, An Assessment on the Competition Law in Bangladesh (on file with author).
[471] Ibid.
[472] Thomas Cottier and Ingo Meitinger, *The TRIPS Agreement Without a Competition Agreement*, presentation at the Trade and Competition in the WTO and Beyond (Venice, 4–5 December 1998).
[473] Sislu F Musungu et al., *Utilizing TRIPS Flexibilities for Public Health Protection Through South–South Regional Framework* (South Centre, 2004) 19–20.
[474] T Avafia, J Berger and T Hartzenberg, *The Ability of Select Sub-Saharan Africa Countries to Utilize TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines* (2006).

The government of Bangladesh should also consider enacting a national competition law to prevent the abuse of monopoly pricing during the post-TRIPS patent regime. Brazil introduced a new competition law in December 2010,[475] whereas India enacted competition law in 2002.[476] India and Brazil are yet to effectively use competition law or policy for the pharmaceutical sector, whereas South Africa has already successfully implemented and tested its competition law in the pharmaceutical sector and is appears to have a viable role to play in reducing the price of medicines.[477] Therefore, the model of South African competition law could be adapted to suit Bangladesh's unique national circumstances.

In South Africa the Medicines and Related Substances Control Amendment Act[478] created the grounds for using competition law to ensure access to medicines in case of excessive pricing and abuse of a dominant position. This Act was enacted in response to the HIV/AIDS crisis that the country had been facing and the lack of access to pharmaceuticals due to their cost. Section 15C was considered controversial by the multinational pharmaceutical companies as the section provides that:

Measures to Ensure Supply of More Affordable Medicines

15C. The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public and in particular may:

(a) Notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978) determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine that has been put onto the market by the owner of the medicine or with his or her consent.
(b) Prescribe the conditions on which any medicine that is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic but that is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and that originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported.

[475] In Brazil, there is a competition law since 1994 (Law 8884 of 1994) which was replaced by an updated Competition Act in December 2010. Article 1 of the Brazilian competition law states that the statute's objective is to "set out antitrust measures in keeping with such constitutional principles as free enterprise and open competition, the social role of property, consumer protection, and restraint of abuses of economic power."
[476] In India, Competition Act was enacted in 2002 to replace the Monopolies and Restrictive Trade Practices (MRTP) Act, 1969. It established Competition Commission of India to prevent practices having adverse effect on competition, to promote and sustain competition in markets, to protect interests of consumers and to ensure freedom of trade carried on by other participants in markets.
[477] See fro details, Carina Smith, The rationale for Competition Policy: A South African Perspective (Paper presented at the biennial ESSA Conference, 7-9 September 2005, Durban, South Africa).
[478] Act No. 90/1997 Medicines and Related Substances Control Amendment Act 1997, 16 June 2010, <http://www.info.gov.za/view/DownloadFileAction?id=70836>.

The above provision authorises the South African government to determine to what extent a specific drug patent will apply. This provision was a direct challenge to the pharmaceutical industry.[479] Such an enactment demonstrates that in becoming TRIPS compliant, a nation may avail itself of some latitude within the flexibilities allowed under the TRIPS Agreement; particularly, in pursuance of the imperative of public welfare.

The South African Competition Commission has already applied competition law successfully in the pharmaceutical sector to deal with restrictive practices and abuse of a dominant position. In the *Hazel Tau and Others vs. GlaxoSmithKline and Boehringer Ingelheim*[480] the prices set by these two companies were considered as an obstacle to access antiretroviral medicines. The Competition Commission ruled that the companies had violated the Competition Act 1998 by denying, 'a competitor access to an essential facility, excessive pricing and engaging in an exclusionary act.' The pharmaceutical companies' position was that they were merely exercising the exclusive right they were granted through their patent.[481] The Competition Commissioner stated that:

> Our investigation revealed that each of the firms has refused to license their patents to generic manufacturers in return for a reasonable royalty. We believe that this is feasible and that consumers will benefit from cheaper generic versions of the drugs concerned. We further believe that granting licenses would provide for competition between firms and their generic competitors. We will request the Tribunal to make an order authorizing any person to exploit the patents to market generic versions of the respondent's patented medicines or fixed dose combinations that require these patents, in return for the payment of a reasonable royalty.[482]

Even though the two companies denounced the complaint as unfounded, they compromised with the Commission and granted voluntary licenses to produce a generic version of their patented pharmaceuticals. Since this case, there has been significant progress in South Africa towards providing access to pharmaceuticals for anti-HIV and AIDS.[483]

Bangladesh does not have a competition law or authority, although a Competition Bill has been pending for several years.[484] The progress of the Bill has been delayed; the political will to implement a competition law is limited and there is some

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[479] A group of 39 pharmaceutical companies has dropped its lawsuit against the government of South Africa. They had taken South Africa to court over its Medicines and Related Substances Act. The main issue was Amendment 15(c) which would allow TRIPS-compliant compulsory licensing and parallel imports of medicines in South Africa. The suit was first filed on February 18, 1998. On March 6, 2001, the South African court hearing the case ruled that the Treatment Access Campaign (TAC) would be granted a friend of the court role. It also adjourned the case until April 18, bowing to threats from the PMA to file an appeal on the grounds that they needed additional time to response to the new evidence and issues raised by TAC. On April 19, 2001, the pharmaceuticals companies, under an extremely high amount of international pressure, dropped their case.

[480] South African Competition Commission, case no.2002Sep226 <www.cptech.org/ip/health/sa/cc10162003.html>.

[481] Ibid.

[482] Quoted in: Rachel Roumet, 'Access to Patented Anti-HIV/AIDS Medicine: The South African Experience' (2010) 3 *European Intellectual property Review* 137–41.

[483] Ibid.

[484] Karen Ellis, Rohit Singh, Shaikh Eskander et al., *Assessing the Economic Impact of Competition: Findings from Bangladesh* (ODI, 2010).

opposition from business groups.[485] Indeed, competition problems are potentially more serious in a country such as Bangladesh with a weaker private sector and where one or a few dominant firms can take control and abuse their dominant position.[486] Media coverage suggests that Bangladesh may suffer from significant competition problems, with substantial costs to consumers[487] and to the public-health sector of Bangladesh, more particularly.

The Government of Bangladesh should consider adopting a competition law with its imperative to be the welfare of its population. Any future Bangladeshi competition law must increase its effectiveness as a tool for reducing prices of essential medicines so that any competition commission should be empowered with the authority to issue compulsory licenses, to recommend fixed royalty rates and to expressly allow for the export of products produced under compulsory licenses in order to maintain sustainable investment.[488] During their interview one participant agreed that the use of competition law would be viable tool for Bangladesh to prevent excessive pricing and allow generic production of particular pharmaceutical products. [489] Conversely, another participant argued that the use of competition law may not be so easy given the need to face political pressure. Therefore any competition authority would need to have enough expertise and resources to guide its reasoning.[490] Another alternative government-intervention mechanism is a prize system.

6.3.3 Introduction of Patent Prize System

A prize system may be designed to encourage local pharmaceutical companies to invest in R&D for the diseases most prevalent in Bangladesh. A prize system is justified on the grounds that granting patents stimulates a monopoly rather than the R&D necessary to deal with particular problems of a resource-less country such as Bangladesh or of inventing something where there is no hope of a huge profit.[491]

Further, the patent system and the granting of other exclusive rights are criticised as contributing to high pharmaceutical prices, global health inequities, limited access to potentially life-saving medicines and medical technologies[492] and the production of pharmaceuticals that have little incremental therapeutic value.[493] In a system that

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[485] Ibid.
[486] Ibid.
[487] Ibid.
[488] T Avafia, J Berger and T Hartzenberg, *The Ability of Select Sub-Saharan African Countries to Utilise TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries* (2006).
[489] Interview data-(IP 004).
[490] Interview data-(PHN 002).
[491] Lee N Davis, *Should We Consider Alternative Incentives for Basic Research? Patents vs. Prizes* 6 (Paper presented to the DRUID Summer Conference, Elsinore/Copenhagen, 6–8 June 2002).
[492] Amy Kapczynski et al., 'Addressing Global Health Inequities: An Open Licensing Approach for University Innovations' (2005) 20 *Berkeley Technology Law Journal* 1031 and Patrice Trouiller et al., 'Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure' (2002) 359 *LANCET* 2188.
[493] Many authors have criticized the growing numbers of 'me-too' drugs on the market, products that duplicate the therapeutic value of already existing drugs. See Aidan Hollis, *An Efficient Reward System for Pharmaceutical Innovation* 6 (21 June 2010) <http://econ.ucalgary.ca/facfiles/ah/drugprizes.pdf> and Youngme Moon and Kerry Herman,

rewards patent owners pharmaceutical company will target affluent patients who can pay a price that covers the cost of research and development and marketing. Therefore pharmaceutical companies have little incentive to invest in R&D for low-return, neglected diseases or other such "non-profitable" diseases.[494] The World Health Organisation (WHO) estimates that approximately ten million lives could have been saved with access to existing medicines and vaccines.[495] The deadweight loss[496] of monopoly pricing of pharmaceuticals is anywhere between US $3 billion to US $30 billion annually for the US pharmaceutical market alone.[497] In this context, a prize system has three underlying goals: (i) to provide incentives for R&D in new, significantly better medicines; (ii) to enhance access to medicines; and (iii) to focus more resources on non-profitable diseases such as neglected diseases.[498]

The controversy between the system of patents and a system of prizes reaches as far back as the nineteenth century where commentators proposed "bonuses" be granted to inventors by the government, professional associations financed by private industries, intergovernmental agencies or by an international association funded by private industries internationally.[499] However, these suggestions did not garner much support. The Royal Academy of Science in Paris[500] had a prize system that served as a model for scientific societies in other countries during the late eighteenth and through the nineteenth century.[501] The lack of a central authority or specific policy for prize distribution made the prize system contentious and, some claimed, corrupt.[502] Academy members were at odds when trying to determine which scientists should receive general prizes and such disputes were only partly resolved by commissions in which different disciplines were represented.[503] At the same time,

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Marketing Antidepressants: Prozac and Paxil (23 June 2010) <http://harvardbusinessonline.hbsp.harvard.edu>. For an argument favourable toward 'me-too' drugs for creating competition see, Thomas H Lee, '"Me-too" Products: Friend or Foe?' (2004) 350 *New England Journal of Medicine* 211.

[494] Only ten per cent of the world's expenditure on R&D is spent on targeting ninety per cent of the disease burden, see for detail Amy Kapczynski et al., 'Addressing Global Health Inequities: An Open Licensing Approach for University Innovations' (2005) 20 *Berkeley Journal of Law and Technology* 1031.

[495] Kapczynski et al. at 1046.

[496] Deadweight loss is the loss to society when consumers do not get a product that they value more than the cost of producing it.

[497] Dean Baker and Noriko Chatani, *Promoting Good Ideas on Drugs: Are Patents the Best Way? The Relative Efficiency of Patent and Public Support for Bio-Medical Research*, 2002 <http://www.cepr.net/Promoting_Good_Ideas_on_Drugs.pdf>; Robert C Guell and Marvin Fischbaum, 'Toward Allocative Efficiency in the Prescription Drug Industry' (1995) 73 *Milbank Quarterly* 213.

[498] Marlynn Wei, 'Should Prizes Replace Patents? A Critique of the Medical Innovation Prize Act of 2005' (2007) 13(1) *Boston University Journal of Science and Technology Law* (10 June 2010) <http://www.bu.edu/law/central/jd/organizations/journals/scitech/volume131/documents/Wei_WEB.pdf>.

[499] Fritz Machlup and Edtih Penrose, 'The Patent Controversy in the Nineteenth Century' (1950) 10(1) *Journal of Economic History* 17–22.

[500] Maurice Crosland and Antonio Galvez, 'The Emergence of Research Grants within the Prize System of the French Academy of Sciences' (1989) 19 *Social Studies of Science* 71.

[501] Ibid 71–73.

[502] Ibid 76.

[503] Ibid 89.

prizes were becoming increasingly a matter solely of money, not of honour.[504] The ultimate question of whether the costs of prize systems would in practice outweigh the benefits of a prize system over a patent system remains open and one that can only be answered empirically. There are few studies that have focused on the economic effects of prizes,[505] and there is no consensus on how prize systems should be designed.[506]

Nevertheless, as an alternate position, Bangladesh could introduce a prize system which operated together with the award of pharmaceutical patents rather than preventing patents altogether. The prize system should have as its principal queries: (i) the number of patients benefited by the invention/innovation; (ii) the incremental therapeutic benefits of the innovation; (iii) the degree to which the innovation addresses the health-care needs, including global infectious diseases, orphan illnesses, and neglected diseases affecting the poor in developing countries; and (iv) the improved efficiency of manufacturing processes for drugs.[507]

During the World Health Assembly 60.30, the governments of Bolivia, Suriname and Bangladesh presented for discussion a proposal concerning the possible use of prizes[508] as a new incentive mechanism for innovation in new cancer treatments and vaccines that would separate rewards for innovation from the price of the products.[509] This proposal is based on an earlier proposal presented by the governments of Barbados and Bolivia in April 2008 during the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property.[510] The proposal argued that access to new cancer treatments and vaccines in developing countries is limited due to several factors including poor medical infrastructure, inadequate screening and the high costs of oncology equipment, services and medicines.[511] Further the high costs associated with new cancer drugs and vaccines either discourage use completely, or place enormous burdens on the health-care budgets of developing countries.[512]

However, the proposal was not for a global prize fund. Rather, the proposal focussed on the suggestion that national governments in developing countries should introduce a new system of rewarding the development of new medicines and

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[504] Zorina Khan, Premium Inventions: Patents and Prizes as Incentive Mechanisms in Britain and the United States, 1750–1930 (24 November 2010) <http://www.international.ucla.edu/economichistory/conferences/khan.pdf>.
[505] Davis, above n 430, at 10.
[506] Michael Abramowicz, 'Perfecting Patent Prizes' (2003) 56 *Vanderbilt Law Review* 183–90.
[507] William W Fisher and Talha Syed, A Prize System as a Partial Solution to the Health Crisis in the Developing World' (Discussion Paper No 5, 2009) Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics at Harvard Law School, 26 November 2010, <http://www.law.harvard.edu/programs/petrie-flom/research/pdf/syed_prize.pdf>.
[508] Proposal by Bolivia, Suriname and Bangladesh, Prizes as a Reward Mechanism for New Cancer Treatments and Vaccines in Developing Countries, 12 July 2011, <http://www.who.int/phi/Bangladesh_Bolivia_Suriname_CancerPrize.pdf>.
[509] According to the WHO, of the more than eight million persons who died from cancer in 2008, 5.7 million or seventy-one per cent lived in developing countries. Cancer is a leading cause of death worldwide. According to the WHO, the percentage of total deaths attributed to cancer is expected to decline in developed countries, but to increase in all developing country regions.
[510] Proposal by Bolivia, Suriname and Bangladesh, Prizes as a Reward Mechanism for New Cancer Treatments and Vaccines in Developing Countries, above n 447.
[511] Ibid.
[512] Ibid.

vaccines for cancer.[513] Specifically, it proposed that developing countries will de-monopolise the entire sector of medicines and vaccines for cancer, and permit free entry by generic suppliers. In return for ending the monopoly, governments of developing countries would offer to provide a domestic system of rewards for developers of new medicines and vaccines for cancer based on a fixed percentage of the national budget for cancer treatments.

It is argued that such a proposal is consistent with the TRIPS Agreement, as developing countries can eliminate the exclusive rights to use patented inventions, in cases where patent owners receive remuneration or compensation.[514] However, there has been no outcome from this proposal. On the basis that there is no international scheme, Bangladesh could try a country specific prize fund based on the most preventable diseases in Bangladesh. In the data collected from the survey none of the pharmaceutical companies surveyed showed any interest of a prize system being an option. However, pharmaceutical researchers and public health NGOs referred to the prize system as being a viable option during the interviews.[515] One interview participant argued to make this kind of basic research there may be collaboration between several pharmaceutical companies or partnership with research institutions.[516]Limiting data protection should also be a policy position considered by the Government of Bangladesh.

6.3.4 Limit Data Protection

Generally, to get marketing approval for a newly developed pharmaceutical the innovating company is required to submit any test and clinical data relating to safety and efficacy of the pharmaceutical to the national health authorities.[517] In India, the practice is that when generic companies apply for approval of any pharmaceutical, they are not required to conduct their own studies and submit independent data.[518] Rather companies can rely on the safety and efficacy data submitted by the innovator company and get marketing approval for their products.[519] However, if the law of another country provides for data exclusivity, that is the country grants exclusive rights to the innovator company to prevent subsequent applicants from using the data submitted, then companies producing generic pharmaceuticals cannot use such data until the data-exclusivity period ends. Article 39.3 of the TRIPS Agreement[520] is being interpreted by some multinational

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[513] Ibid.
[514] Articles 30, 31 and 44 of the TRIPS Agreement.
[515] Interview data-(PHA 001-002 and PHN 001-002).
[516] Interview data-(PHA 003).
[517] Carlos M Correa, 'Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements, UNCTAD-ICTSD Dialogue on Moving the Pro-development IP Agenda Forward: Preserving Public Goods in Health' (Education and Learning Bellagio, 29 November–3 December 2004), 12 September 2010, <http://www.iprsonline.org/unctadictsd/bellagio/docs/Correa_Bellagio4.pdf>.
[518] Animesh Sharma, 'Data Exclusivity with Regard to Clinical Data' (2007) 3 *The Indian Journal of Law and Technology* 82–104, 12 November 2010, <www.iphandbook.org/jforum/posts/downloadAttach/139.page>.
[519] Ibid.

[520] Article 39.3 of the TRIPS Agreement stated that Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a

companies and some developed countries, particularly by the USA, to mean that WTO member countries are required to grant data exclusivity for a specified period of time.[521] Yet in tracing the history and the text of Article 39 of the TRIPS Agreement, Watal and Correa have concluded that the protection need not be in the form of data exclusivity.[522]

Watal has pointed out that if data exclusivity were the intention then the terms "exclusive rights" would have been used as in Article 70.9 of the TRIPS Agreement.[523] Article 39.3 of the TRIPS Agreement[524] requires countries to protect data against 'unfair commercial use'.[525] Correa has argued that countries have the discretion to protect data not solely through data exclusivity, but by proscribing situations where a competitor obtains the results of testing data through fraud, a breach of confidence or other 'dishonest' practice and derives a commercial advantage.[526] Thus, protection is not necessary if regulatory authorities do not require the submission of such data for marketing approval or if the data is already public.[527] Correa argues that protection should only be required for new chemical entities[528] so that each country can have considerable freedom in defining what is "new", and may exclude the different formulations based on the same chemicals.[529]

Thus the TRIPS Agreement requires "data protection" but does not require "data exclusivity" as there is a clear distinction between these two concepts. Data exclusivity involves a monopoly right over test data for a certain period of time whereas data protection only requires authorities to keep the data confidential. In a WHO study it is quite clearly stated that

> Given the negative impact on public health and access to medicines of providing for data exclusivity, it is important that developing countries try to avoid it. If unable to avoid data exclusivity, countries should limit the duration of data exclusivity as well as its scope (e.g. only for new chemical entities, and only for undisclosed data). Countries should also consider creating exemption mechanisms by which they can exempt products from data exclusivity provisions if necessary.[530]

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considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

[521] Ibid.
[522] Watal, Jayashree, *Intellectual Property Rights in the WTO and Developing Countries (*2001) and Correa, above n 501.
[523] Ibid.
[524] Ibid.
[525] Watal, above n 506.
[526] Carlos M Correa, above n 501.
[527] Ibid.
[528] Ibid.
[529] Ibid.
[530] World Health Organization, Intellectual property Rights and Access to medicines: A South-East Asia perspective on global issues (2008).

India did not provided any test data protection. During the survey all participants[531] except one agreed that Bangladesh should not give any test data protection. Rather, participants agreed that it would be beneficial to follow the Indian approach so as to allow generic competition. One participant during survey suggested that test data protection may encourage foreign investment and technology transfer in Bangladesh.[532] One participant during interview argued that considering the low level technological development required to conduct basic research in the pharmaceutical sector and dependence on the generic medicines in Bangladesh it would be better for Bangladesh not to give test data protection at this stage.[533]

Being an LDC Bangladesh still enjoys the Doha waiver for pharmaceutical patents. Further there is no test-data protection system current in Bangladesh. Bangladesh should adhere to this position to help local generic producers. However, in saying that, Bangladesh should work towards creating a patent pool in cooperation with other countries and private organisations.

6.3.5 Patent Pool on Country Specific Diseases

A patent pool is a mechanism through which various patents held by different entities such as companies, universities and research institutions are made available to others for production or further development.[534] Basically, a patent pool is an agreement between two or more patent owners to licence one or more of their patents to one another or third parties, whether they are transferred directly by patentee to licence or through some medium, such as a joint venture, set up specifically to administer the patent pool.[535] The patent holders receive royalties for the use of the patent but not from the user directly, rather royalties are delivered from the pool management.[536] Patent pools are increasingly seen as a useful tool in tackling barriers to access to medicines in developing countries through sharing of knowledge and technologies.[537]

The rationale for creating a patent pool is that it helps to lower the price of pharmaceuticals and it enhances innovation. [538] Further, a patent pool that licences patents in several countries can ensure that generic manufacturers operate in efficient economies of scale and ensure enhanced capacity to manage legal issues as the multitude of patents, potential claims of infringement, variance of national laws, complexity of international treaties and national patent laws and complicated rules for the export of medical technologies under compulsory licences present barriers for

[531] During survey all the local (large, medium and small) pharmaceutical companies supported that Bangladesh should not give test data protection while one MNC supported test data protection and other MNCs not disclosed their position on the issue.
[532] Survey data-(MN 002).
[533] Interview data-(PHA 005).
[534] See, Robert P Merges, *Institutions For Intellectual Property Transactions: The Case for Patent Pools*, 8 September 2009, <www.law.berkeley.edu/institutes/bclt/pubs/merges>.
[535] See Steven C Carlson, 'Note, Patent Pools and the Antitrust Dilemma' (1999) 16 *Yale Journal on Regulation* 359–73.
[536] Manisha Singh Nair, *Rationality of a Patent Pool*, 12 December 2009, <http://www.ipfrontline.com/depts/article.asp?id=22735&deptid=6>.
[537] Ibid.
[538] Ibid.

the expanded use of generic medicines.[539] The patent-pool managers have the expertise and capacity to manage issues that arise on behalf of governments, donors, public-health agencies, patent owners and generic manufacturers.[540] It is also worth noting that collective management of the patent pool will help the establishment of global "best practice" norms for licensing on such issues as quality control, remuneration and open competition.[541]

Bangladesh should consider a patent-pool structure for prevalent diseases in Bangladesh. This could be done by utilising Articles 66.2[542] and 67[543] of the TRIPS Agreement to seek technical and financial cooperation from developed countries for developing a patent pool for the specific prevalent diseases in Bangladesh. The data collected from the survey revealed that none of the pharmaceutical companies expressed any interest on the patent pool. However, during the interviews some participants argued that this option may be useful for Bangladesh to gain technological and financial assistance from the developed countries on country specific diseases.[544] Further, Bangladesh should perhaps also consider lobbying for the extension of the transition period for pharmaceutical patents for LDCs.

6.3.6 Lobby for the Extension of the Transition Period for Pharmaceutical Patents

Considering the vulnerable condition of LDCs due to their socio-economic condition and weak public-health infrastructure, the introduction of pharmaceutical patents will make LDCs more marginalised in terms of coping with the prevailing situation. Therefore, Bangladesh, in cooperation with other LDCs, should consider lobbying for the further extension of the transition period for pharmaceutical patents beyond 2015. Such an extension will give Bangladesh more time to develop its infrastructure and give its local pharmaceutical industry time to deal with public-health problems in a post-TRIPS setting.

The Prime Minster of Bangladesh has argued that it is necessary for LDCs like Bangladesh to have a further extension of 15 years based upon Bangladesh's

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[539] 'Collective Management of Intellectual Property: The Use of Patent Pools to Expand Access to Essential Medical Technologies' (2007) 3(1) *KEI Research Note*, 23 January 2007, 12 November 2010, <http://www.law.berkeley.edu/files/General_Packet.pdf>.

[540] Goutam Ghosh, Patent Pool: A Technology Management Option for Developing New Therapeutics, 12 November 2010, <http://www.btc.iitkgp.ernet.in/dey/abstracts/14.pdf>.

[541] Ibid.

[542] In accordance with Article 66.2 of the TRIPS Agreement, 'Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base'. This article puts an *obligation* on developed Member countries to provide incentives to enterprises and institutions. However, the precise nature of the incentives is not established; only their end is spelled out: to enable LDC members 'to create a sound and viable technological base'.

[543] Article 67 of the TRIPS Agreement sets out developed countries' commitments on technical cooperation. This Article provides that developed country members must provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country members to facilitate TRIPS implementation. Such assistance can include assistance in drafting laws and regulations to protect IPRs as well as the establishment or reinforcement of domestic enforcement agencies.

[544] Interview Data-(IP 003, PHA 002 and PHN 002).

underdeveloped infrastructure, vulnerable health conditions and the nascent stage of the pharmaceutical industry.[545] During her deliberation to the Sixty-fourth World Health Assembly (17 May 2011), the Prime Minister of Bangladesh, Sheikh Hasina, reiterated that the flexibilities accorded within the existing IP regime, in particular the patent waiver for LDCs for pharmaceuticals, must be extended beyond 2015.[546]

In this respect Bangladesh could argue that the socio-economic situation and low level of development and health and technical infrastructure for which the transition period was granted are still prevalent in LDCs such as Bangladesh. To that extent, the graduation to a pharmaceutical patent regime will have a negative impact on Bangladesh.[547]

Therefore, unless there is considerable progress in social and economic development and a change from the low level of health infrastructure and a move away from problems with accessibility and availability of medicines, Bangladesh could argue for the continuation of the waiver for pharmaceutical patents under the principle of Special and Differential Treatment for the derogation from commitment.[548]

More recently, on behalf of the LDC group, the delegation of Bangladesh to the WTO submitted to the TRIPS Council an elements paper on the extension of the TRIPS transition period for LDCs. The paper highlighted that LDCs are facing serious economic, financial and administrative constraints in their efforts to bring their domestic legal systems into conformity with the TRIPS Agreement.[549] The request for the extension has been made without any specific length of time being requested.

Data gathered from the survey highlighted that large, medium and small local pharmaceutical company participants agreed that the Government of Bangladesh

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[545] Her Excellency Sheikh Hasina, Prime Minister of Bangladesh, Speech to the 64th Assembly of World Health Organisation (17 May 2011), 26 July 2011, <http://www.who.int/mediacentre/events/2011/wha64/sheikh_hasina_speech_20110517/en/index.html >.

[546] Ibid.

[547] To continue the transitional period until graduation to a higher level of social and economic development and hence an ideal situation for the introduction of pharmaceutical patents case by case or under a country driven approach with recourse to the WTO, Special and Differential Treatment may be sought. See for detail Thomas Cottier, 'From Progressive Liberalization to Progressive Regulation in WTO Law' (2006) 9(4) *Journal of International Economic Law* 779–21.

[548] Special and differential treatment (S&D) is a set of GATT provisions (GATT 1947, Article XVIII) that exempts developing countries from the same strict trade rules and disciplines of more industrialized countries. For example, in the Uruguay Round Agreement on Agriculture, LDCs are exempt from any reduction commitments and developing countries are given longer time periods to phase in export subsidy and tariff reductions than the more industrialized countries. Using this principle, exemption from introducing pharmaceutical patents may also be extended as long as problems of access to pharmaceuticals and a low level of social and economic development persists in the particular developing countries and LDCs. See for example, Javier Lopez Gonzalez, Maximillano mendez Parra and Anirudh Shingal, TRIPS and Special & Differential Treatment-Revisiting the Case for Derogations in Applying Patent Protection for Pharmaceuticals in Developing Countries' (Draft Working Paper No 2011-37, NCCR Trade Regulation, May 2011).

[549] Elements Paper on the Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement, WTO-IP/C/W/566, 11 November 2011.

should lobby for a further extension for pharmaceutical patents until 2025.[550] Conversely, the response provided by multinational companies participating in the survey was that any further extension of waiver for pharmaceutical patents would be of no benefit to Bangladesh as any further extension would hamper technological development and further investment in the sector.[551] During an interview one participant argued that the local pharmaceutical sector in Bangladesh did not have enough R&D to compete with the MNCs therefore a further extension would help them to engage in R&D and prepare for transition to pharmaceutical patent regime.[552] An expert in the DPDT commented that considering the technical and infrastructure limitations in the DPDT, it would be better to have a transition period until 2030 for the introduction of pharmaceutical patents.[553] Given these views it is suggested that Bangladesh should lobby for further extension.

6.10 Conclusion

This chapter identified the policy options for patent law reform in Bangladesh. More particularly this chapter has examined how Bangladesh can utilise the TRIPS flexibilities while making TRIPS compliant patent law using the comparative experience of India and Brazil. The chapter also canvassed some of the limitations of Bangladesh's current patent law. Considering the limitations of the current patent law, this chapter also explored other possible options for government intervention such as a drug price control, national competition law, a patent prize system and a patent pool system to facilitate access to pharmaceuticals. This chapter also raised the option to lobbying for the further extension of the transition periods for the introduction of pharmaceutical patents. However, a country cannot benefit from an extended transition periods or utilisation of the TRIPS Agreement flexibilities unless it has attained a certain level of technological capacity and developed a strong generic pharmaceutical industry.[554] Even a compulsory licensing mechanism will be of little use without the technological capability to produce generic pharmaceuticals and a well-developed local pharmaceutical industry.[555] Therefore, to ensure the effective functioning of policy options to deal with the post-TRIPS challenges, the Government of Bangladesh also needs to consider technical and infrastructure issues. The next chapter explores the required technical and infrastructure issues for the future development of the pharmaceutical industry in Bangladesh along with a summary of findings and some recommendations.

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[550] This position was supported by all the large, medium and small local pharmaceutical companies in Bangladesh participated in the survey.
[551] Survey data-(MN 001-003).
[552] Interview data-(PHA 003).
[553] Interview data-(PO 002).
[554] Bryan Mercurio, Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines (2006) 5(1) Northwestern Journal of International Human Rights, 1-40.

[555] Ibid.

Chapter 7: Summary of Findings, Recommendations, Further Research and Concluding Remarks

7.1 Introduction

This chapter will summarise the findings of the research and make some final comments about Bangladesh as it moves towards TRIPS compliance. The chapter will conclude with a discussion of further avenues for research.

7.2 Summary of Findings and Recommendations

This thesis has identified the options and flexibilities used by India and Brazil during the transition to a TRIPS-compliant patent regime. The options not only enabled India and Brazil to promote their local pharmaceutical industry but to also maintain access to pharmaceuticals. The research conducted for this thesis in Bangladesh revealed that despite having impressive sales and export growth, the local pharmaceutical industry in Bangladesh, particularly after the introduction of Drug Control Ordinance 1982 limited the local industry's innovative capacity for basic research and patenting of new pharmaceuticals. Further, the lack of proper monitoring by the DDA raises the question of a lack of expertise whilst the last of resources in the DPDT raises the question of capability to deal with pharmaceutical patents and a TRIPS compliant patent law.

Inevitably, Bangladesh will need to amend its current patent law and consider other government intervention options. The previous chapter examined possible options for legislative change and government intervention. This chapter will suggest that the Government of Bangladesh should consider other technical and infrastructure issues to promote pharmaceutical research and ensure access to pharmaceuticals in Bangladesh. The necessity to introduce technical and infrastructure development was commented upon by participants during the interview research. For example, one interview participant remarked:

> … apart from policy options for patent-law reform, the Government of Bangladesh may need to take technical and infrastructural steps for the effective outcome and promote pharmaceutical research and ensure access to medicines in the country. Ultimately technical capacity building in the pharmaceutical sector and greater public–private partnership for R&D can make a balance. Simply making patent law either weak or TRIPS compliant can make no difference.[556]

Whilst, another participant commented that:

> The DDA and patent office should have adequate expertise to deny any patent registration and registration of pharmaceuticals respectively if it considers little improvement and may become a threat for public health in the country. There should be greater public access to the patent office to gain information about patent applications, expired patents and granted patents in the field of pharmaceuticals.[557]

[556] Interview data-(GE001).
[557] Interview data-(PHN 002).

Again showing dissatisfaction with the existing facilities and lack of proper action on the part of the Government of Bangladesh one industry participant commented on the:

> inordinate delay for the establishment of the Active Pharmaceutical Ingredients (API) Park and no proper initiative for the establishment of a bio-equivalency lab at the DDA with all modern facilities is a sign of sheer negligence on the part of the government … we want action in practice not in words.[558]

Whereas another participant emphasised that, 'the Government may consider the introduction of product patents before 2016, withdrawal of restrictions on imports and price controls and strict quality control of medicines produced in Bangladesh as a step forward for capacity building'.[559]

Therefore, Bangladesh needs to consider issues relevant to technical and infrastructure capacity building so as to better serve the pharmaceutical industry promote innovation and ensure access to medicines while making the transition towards TRIPS-compliance. Some of the more important technical and infrastructure policy considerations are discussed in this chapter.

7.2.1 Capacity Building in the Department of Patents, Designs and Trade Marks (DPDT)

It is expected that the function of the DPDT will change after the implementation of a TRIPS-compliant patent regime. The DPDT will be responsible for ensuring that an invention is truly "new" and not similar to any previously granted patent. To perform this function the DPDT must be equipped with adequate technical resources and professional staff with experience in all relevant fields. The present workforce of the DPDT does not meet these requirements. The DPDT currently comprises one Registrar, four Deputy Registrars, nine Assistant Registrars, 25 Examiners and 73 support staff: a total number of 112 staff.[560]

Among the 112 officials, less than fifty per cent work in the field of patents. Arguably, the present number of 25 examiners will not be sufficient to ensure the timely disposal and consideration of patent applications. One interview participant commented that the existing examiners also lack proper training and technical facilities to deal with the complex applications in the field of pharmaceuticals.[561]

Relevantly, the present patent law nor the proposed Draft patent law deals with the human-resource issues of the DPDT. Fortunately however, the need to modernise the DPDT has been recognised. Currently, two projects are underway using the technical and financial assistance of WIPO).[562] As part of this capacity building

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[558] Interview data-(CEB 001).
[559] Interview data-(CEMN 002).
[560] Mohammad Monirul Azam, Interview with a Deputy Director, DPDT, Bangladesh (anonymous), Dhaka (27 September 2010).
[561] Mohammad Monirul Azam, Interview with a patent examiner (anonymous), Dhaka (27 September 2010).
[562] The projects being the Modernization and Strengthening of Patents & Designs Systems in Bangladesh and the Nationally Focused Action Plan (NFAP) for the Government of Bangladesh for Modernization of the Patent Office.

project, Bangladesh should consider building up an online database of current patents and expired patents. Such a database could be used by participants in the local pharmaceutical industry to produce generic and off-patented pharmaceuticals..

7.2.2 Online Databases and the Use of Expired Patents

It is vital to highlight the increased importance of making use of inventions that have entered the public domain. To ascertain such information, it is necessary to know and recognise which patents have entered into the public domain. A study by the WHO highlighted that due to the lack of adequate administrative and legal infrastructure in developing countries it is difficult to determine the patent status of pharmaceuticals.[563] It is recommended that an authority, be it governmental (such as the DPDT) or non-governmental, be created or be given sufficient competence to search for expired patents and then declare that such patents are freely available to interested parties for future exploitation. Such an authority should cooperate with other regional or international organisations (such as the WHO) in order to achieve the greatest possible advantage that an expired patent will bring. It is recommended that a free online database be developed for all educational and research institutions in Bangladesh. During the interview process public health NGOs, a pharmaceutical researcher and intellectual property academics argued that this kind of database will not only help technological teaching and learning but also the generic production of expired patented pharmaceutical products..[564] However, to attain optimum benefits of any online patent database, it is necessary to promote R&D.

7.2.3 Research and Development (R&D) Promotion

Unfortunately, in Bangladesh there appears to be a lack of imperative to increase and encourage investment in R&D. During their interview, one participant commented that there are no government initiatives in place to support or promote R&D.[565] Another participant commented that the failure to support and promote R&D is a major barrier for the post-TRIPS survival of the pharmaceutical industry in Bangladesh.[566] It is highly recommended that an on-going policy for R&D based on domestic raw materials and traditional plant varieties be adopted. In this regard, one participant commented that it is important to establish new scientific research centres with a view to taking part in modernising the domestic pharmaceutical industry and in creating new pharmaceuticals to be available for the public at reasonable prices.[567] To promote R&D in the local research centres and pharmaceutical industry, it is crucial to have adequate investment for R&D.

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[563] World Health Organization, Intellectual property Rights and Access to medicines: A South-East Asia perspective on global issues (2008) p.20.
[564] Interview data-(PHN 001-002, PHA 004-005 and IP 001-004).
[565] Interview data-(PHA 001).
[566] Interview data-(IP 002).
[567] Interview data-(PHA 003).

7.2.4 Investment in R&D for Invention

As Bangladesh has an opportunity to manufacture patented drugs for its local needs as well as export to other LDCs, the industry needs to invest in R&D so that it can manufacture patented drugs by reverse engineering. From the survey data collected on this issue, sixty three per cent of participants strongly agreed and thirty two per cent of participants agreed that the pharmaceutical companies in Bangladesh need to make investment in R&D. Five per cent of participants disagreed that investment in R&D was required. [568] To highlight the need for investment by Government a small size pharmaceutical company represented suggested that it is not possible for such companies to make the significant investment required for new invention and basic pharmaceutical research.[569] Such investment needs to be the focus of the Government or the industry on a wider level. In addition to investment in R&D, pharmaceutical companies need to develop standards.

7.2.5 Developing Standards for Pharmaceutical Companies

Many pharmaceutical companies in Bangladesh cannot boast of complying with Good Manufacturing Practices (GMP) status or other national or international standards. Modifications are essential to develop manufacturing plants and infrastructure so as to ensure the production of quality pharmaceuticals. During their interview, one participant argued that maintaining GMP status is extremely important to create a good reputation for the pharmaceutical products produced in Bangladesh so as to expand pharmaceutical exports.[570] Another participant argued that maintaining standards is essential not only to produce quality medicines and exports but also to compete with the MNCs.[571] Another participant remarked the DDA does not monitor the standards of the pharmaceutical companies regularly which increases the presence of low quality cheaper pharmaceuticals in the local market.[572] The DDA will need to monitor modifications and improvements strictly to seize the opportunity for export. The Government of Bangladesh should approach the WHO for assistance to bring improvements in the DDA.

7.2.6 Capacity Building in the Directorate of Drug Administration (DDA)

During the Rid Pharmaceutical scam in July 2009, the DDA was criticised for its failure to properly monitor the standard of pharmaceuticals in Bangladesh.[573] The DDA itself admitted that it did not have enough manpower to monitor all domestic manufacturers.[574] In order to monitor and control the production of pharmaceuticals and pharmacies all over Bangladesh the DDA should have sufficient trained and skilled staff. One participant during their interview remarked that the DDA should be very strict so as to compel local pharmaceutical companies to comply with quality

[568] See Survey data in Appendix.
[569] Interview Data-(CES 001).
[570] Interview data-(CEB 001).
[571] Interview data-(CEM 002).
[572] Interview data-(CEM 001).
[573] Bangladesh Pharmaceutical Market, above n 253.
[574] Ibid.

control aspects, as these directly affect the country's image abroad and hence may shrink the export market if not handled well.[575]

Further, one participant during their interview argued that the local pharmaceutical market is dominated by twenty leading pharmaceutical companies and most of them are now more interested in exporting in order to make quick cash profits rather than adequately supplying the local market.[576] He further added that in the future this may create a shortage of supply in the local market or there may also be artificial crises of supply.[577] Considering this, one participant suggested that the DDA, while giving drug registration and marketing approval, should include a condition that an, 'adequate supply to the local market needs to be ensured.' Without this the DDA will have the option to cancel marketing approval and may impose export restrictions on the pharmaceuticals concerned.[578]

Again, the pharmaceutical sector falls under the Ministry of Health and Family Welfare (MHFW) in Bangladesh, in other countries the Ministry of Industry and Commerce (or Ministry of Science and Technology) is responsible for this area. One option may be for the pharmaceutical sector in Bangladesh to become part of a different Ministry so as to meet the dual goals of technological development in the sector and societal demands for ensuring access to pharmaceuticals. The Government of Bangladesh should also encourage local pharmaceutical industry to develop an excipient-based industry.

7.2.7 Setting Up Excipient-based Pharmaceutical Companies

At interview a participant noted that at present, almost all excipients are imported by local companies.[579] Arguably if there can be local manufacturing of pharmaceutical excipients, the excipients will be much cheaper and the overall production cost of finished products will be substantially reduced. The setting up of the local pharmaceutical industry to produce excipients and other additives would be profitable for Bangladesh and it would remove the deficiency of pharmaceutical excipients/additives in Bangladesh that are most required for the production of finished products. Another issue for Bangladesh that needs attention is the building of modern test facilities so as to facilitate international certificates for export.

7.2.8 International Certificates for Export and Modern Test Facilities

One participant during their interview commented that to acquire export registration, it is necessary to have bio-equivalence, bio-availability tests and clinical-trial reports.[580] The costs associated with implementing such a testing and documentary system are high. One interview participant argued that this is a major drawback for

[575] Interview data-(CEB 001).
[576] Interview data-(PHA 001).
[577] Ibid.
[578] Interview data-(PHN 001).
[579] Interview data-(BAPI 002).
[580] Interview data-(CEB 002).

small- to medium-size pharmaceutical companies in Bangladesh.[581] The availability of pharmaceutical-related testing facilities is an on-going challenge that will need to be met prior to Bangladesh being able to engage effectively and competitively in a post-TRIPS environment.

Bangladesh has only two pharmaceutical testing laboratories; one is in Dhaka and the other is located in Chittagong. These two laboratories are not equipped with sufficiently modern instruments to carry out all the tests required for pharmaceutical products.[582] Put simply, only having these two laboratories is not enough to monitor and check the quality status of products of a large number of pharmaceutical companies in Bangladesh. [583] The government of Bangladesh needs to consider a program of building these facilities, not only for compliance, but to maintain any momentum garnered as Bangladesh takes the opportunities afforded to it during the transition period.

Further, as argued by an interview participant in addition to the building of facilities, the Government of Bangladesh and the Bangladesh Association of Pharmaceutical Companies will need to work together to encourage local pharmaceutical companies to seek international certifications and assist companies to understand requirement of a particular country with the help of foreign missions of Bangladesh in the respective country.[584]

In addition to those technical and infrastructure initiatives, there are some more options that could be considered to build the capacity of the regulatory agencies, research institutions and to support the local pharmaceutical industry to cope with the challenges of a TRIPS-compliant patent regime.

7.3 Towards Capacity Building

There are a number of steps that can be taken to capacity build within the regulatory agencies of the DPDT and the DDA so that Bangladesh might cope with the challenges that the post-TRIPS regime will pose. Those steps include the development of a database for recording patent applications and granted patents, the introduction of an online application system, the development of an institutional framework for facilitating the implementation of IPR in Bangladesh and the establishment of an Information Centre with support policies for small and medium enterprises. Further, given its workforce and technical resource issues in the patent area, Bangladesh should consider joining the Patent Cooperation Treaty (PCT) 1970 so as to outsource patent examinations.[585] This would enable Bangladesh to extend the

[581] Interview data-(CES 001).
[582] Such as bio-equivalency tests, bio-availability tests and the conduct of clinical trials.
[583] It should be noted that among the local pharmaceutical companies in Bangladesh very few obtained export registration and only Beximco and Square have gained registration for export to highly regulated countries like the United States of America, the United Kingdom, Austria and Australia.
[584] Interview data-BAPI 02.
[585] 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.

patent protection of local inventions all over the world and would also pave the way for foreigners to apply to Bangladesh through the international application system used under the PCT.[586] 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 work 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.

7.4 University–Industry–Government Collaboration

Despite a lack of investment in basic R&D by the government and pharmaceutical companies in Bangladesh, one positive aspect is that there is a continuous supply of fresh graduates in the relevant fields from the local universities in Bangladesh. Six public and sixteen 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 660 graduates in pharmacy, 1560 graduates in chemistry, :, 250 graduates in microbiology, 150 graduates in applied chemistry and 250 graduates in chemical engineering:.[587] The job opportunities for graduates are ever increasing so that more and more universities are offering relevant degrees.

While there are more graduates, necessary steps should be taken to ensure that those graduates are recruited, deployed, trained and retained in the pharmaceutical sector. If graduates are given proper training and the opportunities 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. This is because Bangladesh has great potential in this regard, as infrastructure and labour costs are substantially lower than those in competitive countries such as China or India.

The implementation of the TRIPS Agreement in Bangladesh is inevitable. The "how" of implementation is yet to be finalised but the thesis has presented a number of options for consideration. What is certain is that there will be a need for the regulatory agencies and the pharmaceutical industry in Bangladesh to be ready, willing and able to deal with pharmaceutical patents. At the moment there is concern that the current regulatory agencies (the DPDT and the DDA) and the local pharmaceutical industry lack such capacity. This study has highlighted some of the challenges and provided possible options for patent law reform, other government options for intervention and some suggestions for capacity building in anticipation of TRIPS compliance. However, it was not possible to address all the issues relating to TRIPS implementation and challenges presented by the pharmaceutical patent regime. While saying this, this study has made a contribution to the knowledge in

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[586] Azam, Mohammad Monirul and Kristy Richardson, 'Pharmaceutical Patent Protection and TRIPS Challenges for Bangladesh: An Appraisal of Bangladesh's Patent Office and Department of Drug Administration' (2010) 22(2) *Bond Law Review.*

[587] See for detail <www.boi.bd.com> and the report of the University Grants Commission of Bangladesh: 2005–2009.

this area and this, alongside the limitations of the study there are further options for research.

7.5 Contribution to Knowledge

This thesis makes an original contribution to knowledge in identifying policy options required for an LDC such as Bangladesh to become TRIPS compliant. It also makes a contribution by way of doctrinal analysis and a comparative review of the situation of India and Brazil in the context of TRIPS implementation. The comparative review contains important lessons not only for Bangladesh but for other developing countries and other LDCs. As India and China, two major global generic producers, have introduced TRIPS-compliant patent law, it has become important to investigate whether Bangladesh's pharmaceutical sector can gradually evolve to provide low-cost substitutes of important patented drugs to other developing countries and LDCs and contribute to the global access to cheap pharmaceuticals. This thesis identified that the pharmaceutical industry in Bangladesh has so far served the local market efficiently, reduced pharmaceutical prices substantially in the local market and ventured into export markets. But to become an efficient global generic supplier which is TRIPS compliant the country needs to initiate major technical and infrastructure change. In particular, this thesis makes an original contribution to the existing knowledge in the field of global intellectual property law as:

a) This thesis analyses the impact of TRIPS-compliant patent law from the perspective of an LDC: Bangladesh.
b) The thesis evaluates the legislative and institutional framework in Bangladesh that deals with the pharmaceutical patent and pharmaceutical industry and has identified the required infrastructural and technical issues that will need to be in place.
c) The thesis also indicates future (and continuing) further research directions to provide an on-going consideration of the policy options needed in the context of successful TRIPS implementation and access to medicines.

7.6 Limitations and Further Research

This study has only provided a preliminary response as much more empirical work is needed to document the extent to which Bangladesh may be adversely affected and the extent to which its pharmaceutical companies can transform. The links between TRIPS, legal change and the impact upon various stakeholders' needs further consideration given its complex stories and relations. This, necessarily, gives rise to a study focused not only on doctrinal legal issues but on the social and regulatory impact of those doctrinal legal issues.

It would be a misjudgement to say that the TRIPS Agreement is an exogenous imposition to be implemented by Bangladesh whilst ignoring the socio-economic conditions in Bangladesh. The TRIPS Agreement itself states 'the protection and enforcement of intellectual property rights should contribute … to the mutual advantage of producers and users of technological knowledge and in a manner

conducive to social and economic welfare, and to a balance of rights and obligations'.[588]

Therefore, any future study in this field must explore the TRIPS compliance process not only in the context of the legal norms but also whilst giving consideration to the consequences of those legal norms on the various stakeholders involved. Issues with respect to change and transition also then need to be considered. Kurt Lewin's change theory is a theoretical framework through which change to TRIPS compliance could be examined.[589] A fundamental premise of change theory is that change is not an event, but rather a process. Further, as change is a process, it can be managed and facilitated. In the context of this area of examination the next research question might be: what processes (legal, social and regulatory) need to be adopted and implemented for TRIPS compliance to produce minimal impact upon the stakeholders?

Lewin argued that the process of change comprises three stages.[590] The first stage is about preparing for the change and ideally creating a situation in which change is wanted and is characterised as the *unfreeze*.[591] The second stage is characterised as *change* and occurs as changes are made and implemented.[592] The third stage is *refreeze,* which is concerned with establishing stability once the changes have been made.[593] The use of change theory in the context of the TRIPS-implementation process can be reflected diagrammatically and is shown in Figure 7.1 below.

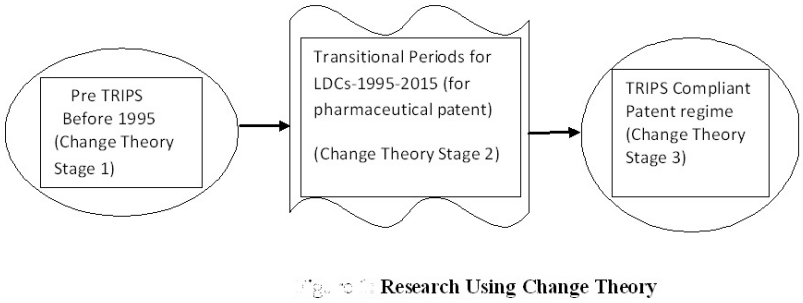

Figure 7.1: Research using change theory

[588] Article 7 of the TRIPS Agreement.
[589] Kurt Zadek Lewin, (9 September 1890–12 February 1947), a German–American psychologist, is one of the modern pioneers of social, organisational and applied psychology. Lewin is often recognised as the 'founder of social psychology'**.** He proposed change theory in his article 'Frontiers in group dynamics'. See for details, Kurt Zadek Lewin, 'Frontiers in Group Dynamics' in Lewin K (ed.), *Human Relations* (1947) 1(1) 5–41, 7 September 2009, <http://hum.sagepub.com/cgi/content/citation/1/1/5>.
[590] E H Schein, 'Kurt Lewin's Change Theory in the Field and in the Classroom: Notes Toward a Model of Managed Learning' (1995), 30 December 2009, <www.a2zpsychology.com/articles/kurt_lewin's_change_theory.htm>.
[591] Ibid.
[592] Ibid.
[593] Ibid.

Although change theory was originally presented in 1947, the theory is still relevant. Importantly, change theory has been used across disciplines and research subjects in such diverse areas as education,[594] management,[595] psychology,[596] nursing,[597] organisational change,[598] information technology and information systems.[599] The theory is yet to be applied as a theoretical research framework to law and, in particular, intellectual property law. Therefore, a future empirical socio-legal study could apply this theory in the context of the TRIPS Agreement.

In addition to this, another area of further research is the impact of the TRIPS Agreement on traditional medicines and what policy options may be taken to protect and enhance traditional medicine use in a post-TRIPS setting.[600] This limitation of this study was acknowledged in Chapter 1 together with a discussion of methodological limitations in Chapter 3.

7.7 Concluding Remarks

It is undeniable that the pharmaceutical industry has an important role to play in the future development of new pharmaceuticals and to do this the patent system must provide a mechanism through which to encourage R&D. However, a patent system must not become overprotective so as to create a barrier against access to other pharmaceuticals. Many developing countries have provisions in their national laws, for mechanisms (such as compulsory licenses and parallel imports) that mitigate against the protective market power conferred upon patent owners. The use of such safeguards may facilitate to reduce the price of pharmaceuticals and even access to generic alternatives by using a compulsory license on the grounds of public interest. It is unlikely that the use of those safeguards affect, in any significant manner, the funding of future R&D.

Many of the pharmaceuticals created for the markets of developed countries are equally important for developing countries. However, developing countries and LDCs such as Bangladesh have different pharmaceutical demands. The diseases of

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[594] Monica Edwards et al., 'Analyzing the obstacles for the academic and organizational change in universities' (3–7 September 2007) International Conference on Engineering Education-ICEE 2007, Coimbra, Portugal.

[595] Edgar H Schein, 'Kurt Lewin's Change Theory in the Field and in the Classroom; Notes Towards a Model of Managed Learning' MIT Sloan School of Management, 11 September 2009, <www.a2zpsycology.com/articles/kurt_lewin's_change_theory.htm>.

[596] Ibid.

[597] Ting-Ting Lee, *Adopting a Personal Digital Assistant System: Application of Lewin's Change Theory* (Nursing and Health Care Management and Policy, 2006).

[598] Matthew W Ford and Bertie M Greer, 'Profiling Change: An Empirical Study of Change Process Patterns' (2006) 42(4) *Journal of Applied Behavioural Science*.

[599] Harvey Bernstein et al., 'Managing Change in the Legal Firm Through the Teaching Company Scheme' (16th BILETA Annual Conference, University of Edinburgh, 9–10 April 2001).

[600] In study by WHO it is mentioned that 80% of the global populationuses traditional medicines at some point in their lives. It also mentioned protection of traditional knowledge can include ip related measures as well as non IP related mechanisms.This study also mentioned diverse objectives need to be considered for the promotion of public health goals by facilitating the use of and acess to traditional medicines. But this study not examined the impacts of TRIPS on the traditional medicines. See for details, World Health Organization, Intellectual property Rights and Access to medicines: A South-East Asia perspective on global issues (2008).

the poor attract very little R&D effort by the large pharmaceutical firms, since they are not promising income generators. R&D is driven by market considerations. R&D targeting diseases found in developing countries is marginal.

During the data collection for this thesis the researcher found that it is too easy to blame the WTO, MNCs and the TRIPS Agreement, but this will lead to a mischaracterisation of the real challenge of finding an alternative system in which pharmaceuticals neglected by the MNCs are developed and one which also puts measures in place to ensure access to pharmaceuticals. Therefore, further study is needed to explore the ways and means to encourage pharmaceutical companies in Bangladesh and in other developing countries to invest in R&D so as to develop new drugs for country specific diseases and make them available for poor people at an affordable price.

Though the patent system was devised in order to reward inventiveness, encourage technical progress and foster the dissemination of innovations, patents are used in many cases as commercial tools in order to restrict or delay legitimate competition. As generic producers of pharmaceuticals, Bangladesh will be restricted from copying patented pharmaceuticals as a consequence of becoming TRIPS compliant.

Bangladesh must in the short term decide upon a strategy of change and the implementation of a new legislative order that meets the requirements of the TRIPS Agreement with respect to patent law. In the longer term the Government of Bangladesh will need to promote R&D in its universities and research institutions and provide technical and financial assistance to support the local pharmaceutical companies to develop innovative capacities that not only capable them to make pharmaceuticals considering the country specific diseases in Bangladesh but also able to be exported.

Further, Bangladesh should also devise a strategy to encourage multinationals to invest in Bangladesh in the pharmaceutical sector under the "social business model"[601] as part of their social corporate responsibility and humanitarian goals to ensure access to affordable pharmaceuticals for newly patented drugs that are not produced by the Bangladeshi pharmaceutical companies.

[601] A social business model is a non-loss, non-dividend company designed to address a social objective. In this type of business organisation profits are used in a manner in which they may expand the company's reach and improve the product or service to a greater extent than a traditional for-profit corporation, which is the reason why the investors receive no dividends or extra payments apart from their initial investment. The most popular concept of social business was created by Nobel Peace Prize laureate Prof. Muhammad Yunus and is described in his books Creating a World Without Poverty: Social Business and the Future of Capitalism, and Building Social Business: The New Kind of Capitalism That Serves Humanity's Most Pressing Needs. The main organisations promoting and incubating social businesses are theYunus Centre in Bangladesh and the Grameen Creative Lab in Germany. See for detail Muhammad Yunus, *Creating a World Without Poverty: Social Business and the Future of Capitalism* (PublicAffairs, 2008) and, Muhammad Yunus, *Building Social Business: The New Kind of Capitalism That Serves Humanity's Most Pressing Needs* (PublicAffairs, 2010).

The outcome of this study has provided an analysis of the status of the pharmaceutical industry, the existing pharmaceutical regulations and patent law in Bangladesh. The results of this thesis are expected to guide future capacity building in Bangladesh through examination of legislative, infrastructural, technical and policy options. The outcome of this research may also be replicated in other developing countries and LDCs when addressing policy options for the shift towards TRIPS-compliant patent law.

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Appendixes

Appendix 1: Letter of Ethical Clearance

CQUniversity AUSTRALIA

Secretary, Human Research Ethics Committee
Ph: 07 4923 2603
Fax: 07 4923 2600
Email: ethics@cqu.edu.au

11 September 2009

Mr Monirul Azam
Faculty of Arts, Business, Informatics and Education
Building 33
Rockhampton Campus

Dear Mr Azam

HUMAN RESEARCH ETHICS COMMITTEE APROVAL: PROJECT H09/08-045 *TRIPS COMPLIANCE PATENT LAW AND PHARMACEUTICAL PATENT PROTECTION: OPTIONS FOR PATENT LAW REFORM IN BANGLADESH*

Thank you for submitting your application to the Human Research Ethics Committee. The committee noted that this is an interesting project and are eager to see your final report as to the outcomes of your study.

The Human Research Ethics Committee is an approved institutional ethics committee constituted in accord with guidelines formulated by the National Health and Medical Research Council (NHMRC) and governed by policies and procedures consistent with principles as contained in publications such as the joint Universities Australia and NHMRC *Australian Code for the Responsible Conduct of Research.* This is available at http://www.nhmrc.gov.au/publications/synopses/_files/r39.pdf.

On 11 September 2009, the committee acknowledged compliance with the conditions placed upon ethical approval for your research project, *Trips compliance patent law and pharmaceutical patent protection: Options for patent law reform in Bangladesh* (Project Number H09/08-045).

The period of ethics approval will be from 11 September to 30 April 2012. The approval number is H09/08-045; please quote this number in all dealings with the Committee.

The standard conditions of approval for this research project are that:

(a) you conduct the research project strictly in accordance with the proposal submitted and granted ethics approval, including any amendments required to be made to the proposal by the Human Research Ethics Committee;

(b) you advise the Human Research Ethics Committee (email ethics@cqu.edu.au) immediately if any complaints are made, or expressions of concern are raised, or any other issue in relation to the project which may warrant review of ethics approval of the project. *(A written report detailing the adverse occurrence or unforeseen event must be submitted to the Committee Chair within one working day after the event.)*

Appendix 2: Consent Form

TRIPS-compliant Patent Law and Pharmaceutical Patent Protection: Options for Patent Law Reform in Bangladesh

CONSENT FORM

I consent to participation in this research project and agree that:

1. An Information Sheet has been provided to me that I have read and understood;
2. I have had any questions I had about the project answered to my satisfaction by the Information Sheet and any further verbal explanation provided;
3. I understand that my participation or non-participation in the research project will not affect my academic standing or my employment.
4. I understand that I have the right to withdraw from the project at any time without penalty;
5. I understand the research findings will be included in the researcher's publication(s) on the project and this may include conferences and articles written for journals and other methods of dissemination stated in the Information Sheet;
6. I understand that to preserve anonymity and maintain confidentiality of participants that fictitious names may be used any publication(s) unless I have expressly granted permission as outlined below;
7. I am aware that a Plain English statement of results will be available.
8. I agree that I am providing informed consent to participate in this project.

Signature: _____ Date: _____

Name (please print): _____

Where relevant to the research project, please check the box below:

	YES	NO
1. I wish to have a Plain English statement of results posted		

to me at the address I provide below.		

Postal Address:

_____

Email Address:

_____

Appendix 3: Information Sheet and Survey Questionnaire

TRIPS-compliant Patent Law and Pharmaceutical Patent Protection: Options for Patent Law Reform in Bangladesh

INFORMATION SHEET (Survey)

Before the creation of the World Trade Organization (WTO) in 1995, individual countries were free to determine their own patents law; that position has now changed. One of the WTO agreements, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), which is binding on all members, basically aims at establishing strong minimum standards for intellectual property rights (IPRs) including patent protection for pharmaceuticals. There is debate about how to reach a balance between meeting the high costs of drug R&D and creating incentives to stimulate access to those drugs. As per the Doha Declaration least developed countries such as Bangladesh have waiver until 2016 to introduce pharmaceutical patents. This study is seeking to understand the implications of TRIPS compliance patent law on the pharmaceutical regulations and pricing of drugs in Bangladesh and to explore the avenues how Bangladesh can utilise the opportunities available under the TRIPS Agreement.

I would like you to participate in this research project. As part of this research project, you have to fill out the attached questionnaire. It is anticipated that to complete the questionnaire you will need 40–45 minutes of your time. If you do not wish to complete the process, you can withdraw at any stage, and you have the right not to answer any question. Your participation in this project will not affect the services provided by any government or community organisations, your employment or academic standing as the information collected is anonymous and you are asked not to provide any information they may identify you. These data will be stored at CQUniversity in a secured locker for a period of five years as per CQUniversity rules.

If you find any aspect of the research process distressing and require access to counselling services, this would be arranged within your local area. Counselling options are available for all research participants via Chittagong University Medical and Counselling Centre, which has a freely available service to the general public. If you want you can contact-88-031-716558-4251. Special counselling services may also be arranged, if required with the aid of Psychology Department, University of Chittagong.

You will be sent a summary of research findings at the completion of the study if you wish. Appropriate measures have been taken to ensure confidentiality and anonymity so that no individual respondent will be identified in case of any publication or result dissemination in conference or journal articles. Data will be stored securely while in use and personal information collected by the researchers will be stored securely for five years after completion of the research according to policy of CQUniversity.

If you need further questions/information regarding this project, you may contact with Mr. Mohammad Monirul Azam, CQU, on 61-07-4923-2374, email to-m.azam@cqu.edu.au. You may also contact Central Queensland University's Office of Research (Tel: 07 4923 2607; Email: research-enquiries@cqu.edu.au; Mailing address: Building 32, CQUniversity, Rockhampton QLD 4702) should there be any concerns about the nature and/or conduct of this research project.

I would like to thank you for your interest and look forward to your participation.

Sincerely yours

Mohammad Monirul Azam, PhD Researcher, CQUniversity, Australia

Section A: Background

1. What is your field of expertise?

_____

_____

_____

2. Within that field of expertise, what experience (including years of involvement) do you have with respect to the pharmaceutical industry?

_____

_____

_____

3. Within your field of expertise, what experience (including years of involvement) do you have with respect to patent law?

_____

_____

_____

4. What is the nature of your employing company/institution? (Please tick a box below)

☐ Local Generic Producer ☐ Multinational Generic Producer

☐ Research and new drug development Based Company ☐ Joint Venture

☐ Government ☐ Other(e.g., Academic)

Please specify

5. **For the last financial year, can you indicate the amount (approximate) invested by your employing company in the pharmaceutical sector?**

_____

_____

_____

6. **For the last financial year, can you indicate the amount (approximate) spent on research and development (R&D) by your company?**

_____

_____

_____

7. **How many generic drugs are manufactured by your company? (Please tick a box)**

☐ 5–10 ☐ 11–20 ☐ 21–30 ☐ 31–50 ☐ More than 50

8. How many generic drugs are exported by your company?

☐ 5–10 ☐ 11–20 ☐ 21–30 ☐ 31–50 ☐ More than 50

9. What are the major destinations of export for your company? (Please tick all boxes that may apply)

☐ Asian Countries ☐ Europe ☐ USA and Canada

☐ Australia ☐ Africa ☐ Russia ☐ Other

Please specify

_____

_____

10. How many products have been invented by your company in the last 5 years? (Please tick a box)

☐ 1–5 ☐ 6–10 ☐ More than 10 ☐ No invention so far

11. How many products are patented by your company in Bangladesh?

☐ 1–5 ☐ 6–10 ☐ More than 10 ☐ None

12. How many products are patented by your company outside of Bangladesh?

☐ 1–5 ☐ 6–10 ☐ More than 10 ☐ None

Section B: Patent Law

13. Please indicate (by circling) your agreement/disagreement with the following statements. 1 being 'Strongly Agree' 2 'Agree', 3 'Unsure', 4 'Disagree' and 5 being 'Strongly Disagree'.

	1	2	3	4	5	No Opinion /Don't Know
1. The present patent law of Bangladesh is compliant with TRIPS						
2. TRIPS waiver for LDCs is beneficial for Bangladesh						
3. A renewed waiver for pharmaceutical patent for the LDCs after 2015 is necessary						
4. Bangladesh has made sufficient preparations for the introduction of TRIPS compliant patent law						
5. Patent law can make a balance between promoting pharmaceutical innovation and access to affordable medicines						

14. What challenges do you think a TRIPS-compliant patent regime will have on the pharmaceutical sector in Bangladesh?

15. What do you think the pharmaceutical companies should do to create a balance between promoting pharmaceutical innovation and access to affordable medicines?

16. **What do you think the Government of Bangladesh should do to create a balance between promoting pharmaceutical innovation and access to affordable medicines?**

17. What do you think the international organisations (e.g. WTO, WIPO, WHO) should do to create a balance between promoting pharmaceutical innovation and access to affordable medicines?

Section C: DDA and Price Control

18. Please indicate (by circling) your agreement/disagreement with the following statements. 1 being 'Strongly Agree', 2 'Agree', 3 'Unsure', 4 'Disagree' and 5 being 'Strongly Disagree'.

	1	2	3	4	5
1. TRIPS has impacted on the rise of pharmaceutical price					
2. Compulsory licenses are adequate to protect public health and access to affordable medications					
3. Parallel imports are adequate to protect public health and access to affordable medications					
4. The government of Bangladesh should withdraw the Price Control Ordinance, 1982. 5. The Directorate of Drug Administration (DDA) in Bangladesh effectively controls the quality of medicines produced in Bangladesh					
6. The Directorate of Drug Administration (DDA) in Bangladesh effectively controls the pricing of medicines for the people of Bangladesh					
7. The Drug Control Ordinance effectively maintains the quality					

of medicines produced in Bangladesh					
8. The Drug Control Ordinance effectively maintains the price of medicines available in Bangladesh					

Section D: Pharmaceutical Industry

19. Please indicate (by circling) your agreement/disagreement with the following statements. 1 being 'Strongly Agree', 2 'Agree', 3 'Unsure', 4 'Disagree' and 5 being 'Strongly Disagree'.

	1	**2**	**3**	**4**	**5**
1. The TRIPS waiver for pharmaceutical patents provides export opportunities for Bangladesh					
2. Pharmaceutical companies in Bangladesh need to invest in R&D					
3. Small and Medium size pharmaceutical companies will face difficulties in manufacturing patented medicines in a TRIPS-compliant patent regime					
4. Bangladesh has sufficient preparation for capacity building in the pharmaceutical sector in a TRIPS-compliant patent regime					
5. Bangladesh has no capacity to produce new medicine					
6.Bangladesh should not give test data protection					

20. What are the opportunities for pharmaceutical companies in Bangladesh until 2016 transitional period? (Tick as applicable)

☐ Export to other LDCs with no manufacturing capacity ☐ Export to non-WTO members

☐Export of low cost generics of patented medicines to other countries ☐ Go for Joint Venture

☐ Other

Please specify

21. What does your employing company intend to do after 2016? (Tick as applicable)

☐ Research New Drug Development ☐ Continue with generic manufacturing

☐ Continue with generic manufacturing and research

☐ Other

Please specify

22. What are the options available to Bangladesh to ensure access to medicines while making TRIPS compliant patent law?

23. Do you wish to provide any further opinions with respect to a TRIPS-compliant patent law and any implications it may have on the pharmaceutical industry in Bangladesh?

Thanks in advance for cooperation.

(Please tear off)

Request for Statement of Results

I would like a Statement of Results for the Project titled TRIPS-compliant patent law and implications for Bangladesh–The context of Pharmaceutical Patent and Towards Better Policy Options

Please forward me the Statement of Results by:

Email:

By Post:

Return of Completed Form: If you want me to collect the completed form, then I can collect it as per your convenience or you may also send it using the given pre-paid envelope.

Appendix 4: Information Sheet and Interview Questions

TRIPS-compliant Patent Law and Pharmaceutical Patent Protection: Options for Patent Law Reform in Bangladesh

INFORMATION SHEET (interview)

Before the creation of the World Trade Organization (WTO) in 1995, individual countries were free to determine their own patents law that has now changed. One of the WTO agreements, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), which is binding on all members, basically aims at establishing strong minimum standards for intellectual property rights (IPRs) including patent protection for pharmaceuticals. The developed countries sought to provide the necessary incentives for drug innovation by way of the mandatory protection for pharmaceutical products and processes in the TRIPS Agreement. In contrast, most of the developing countries argue that enacting patent laws that comply with TRIPS may increase drug prices to the point that the drugs may become inaccessible to the vast majority of poor peoples. Thus, the debate centres around how to reach a balance between meeting the high costs of drug R&D and creating incentives to stimulate access to those drugs. As per the Doha Declaration least developed countries such as Bangladesh have waiver until 2016 to introduce pharmaceutical patents. This study will be useful to understand the implications of TRIPS compliance patent law on the pharmaceutical regulations and pricing of drugs in Bangladesh and to explore the avenues how Bangladesh can utilise the opportunities available under the TRIPS Agreement.

I would like you to participate in this research project. As part of this research project, I would like to interview you at a time and place of your choosing. It is anticipated that the interview would not take any longer than 25–30 minutes of your time. You are not obliged to answer all the questions and can terminate the interview at any stage. Your participation in this project will not affect the services provided by any government or community organisations, your employment or academic standing as the information collected is anonymous and you are asked not to provide any information that may identify you. Your answers to questions will be handwritten and you will be asked to look at the transcript to ensure that the answers recorded are accurate.

If you find any aspect of the research process distressing and require access to counselling services, this would be arranged within your local area. Counselling options are available for all research participants via Chittagong University Medical and Counselling Centre, which has a freely available service to the general public. If

you want you can contact-88-031-716558-4251. Special counselling services may also be arranged, if required with the aid of Psychology Department, University of Chittagong.

You will be sent a summary of research findings at the completion of the study if you wish. Appropriate measures have been taken to ensure confidentiality and anonymity so that no individual respondent will be identified in case of any publication or result dissemination in conference or journal articles. Data will be stored securely while in use and personal information collected by the researchers will be stored securely for five years after completion of the research according to policy of CQU.

If you need further questions/information regarding this project, you may contact with Mr. Mohammad Monirul Azam, CQU, on 61-07-4923-2374), email to-m.azam@cqu.edu.au. You may also contact CQ University Office of Research (Tel: 07 4923 2607; Email: research-enquiries@cqu.edu.au; Mailing address: Building 32, CQ University, Rockhampton QLD 4702) should there be any concerns about the nature and/or conduct of this research project.

I would like to thank you for your interest and look forward to your participation.

Sincerely yours

Mohammad Monirul Azam,

PhD researcher, CQ University, Australia

Model Interview Questions

1. Do you think that present patent law of Bangladesh is TRIPS compliant?
2. What are the general implications of TRIPS Agreement for Bangladesh?
3. Is there any impact on the public health in Bangladesh due to patenting of pharmaceuticals?
4. Do you think that TRIPS waiver for the LDCs for pharmaceutical patent will be beneficial for Bangladesh?
5. Do you think the patenting of pharmaceuticals is a problem for access to drugs?
6. Do you think that TRIPS has had great impact on the rise of pharmaceutical prices?
7. Is there any opportunity for generic drugs exports of patented medicines for the pharmaceutical companies in Bangladesh prior to 2016?
8. What do you think will be the major challenges for pharmaceutical companies in Bangladesh post-2016?
9. Do you think price control a viable tool for ensuring access to drugs? Is it compatible with TRIPS?
10. Do you think that the government should withdraw the price control ordinance?
11. In your opinion is the Directorate of Drug Administration (DDA) in Bangladesh effective to control the quality of medicines?
12. Do you think a compulsory license or parallel imports could be effective to ensure access to medicine?
13. Does your industry intend to move into research based activities or wish to stay with generics after 2016?
14. What do you think about a renewed waiver after 2015?
15. Is Bangladesh subject to all of Article 27 obligations of TRIPS?
16. Do you propose any steps to be taken for ensuring public health while complying with the TRIPS Agreement?
17. What are the steps taken by the government of Bangladesh for the capacity building in the pharmaceutical sector in the context of the TRIPS Agreement?
18. What are the steps taken by the government of Bangladesh for the capacity building in the patent office in the context of the TRIPS Agreement?
19. What are the steps taken by the government of Bangladesh for making TRIPS compliant patent law?
20. What are the necessary steps for the transformation of copycat generic industries of Bangladesh into innovative pharmaceutical industries?
21. Does Bangladesh have sufficient resources for the transformation into innovative pharmaceutical industries?
22. What is the amount of FDI in the pharmaceutical sector in last five years? Does patent protection makes any difference for FDI?
23. Does Bangladesh have sufficient resources for making new drugs?
24. Is it possible to maintain economies of scale by researching on Bangladesh specific diseases like malaria, typhoid?

25. Is there any Govt pharmaceutical research centre? Is there any patented invention by that centre?
26. Is there any substantial technology transfer from any developed countries in Bangladesh in the pharmaceutical sector?
27. Does Bangladesh have sufficient capacity/preparation to make TRIPS compliant patent law?
28. Does pharmaceutical industry in Bangladesh have sufficient preparation for a product patent regime?
29. Does pharmaceutical industry in Bangladesh can survive in a product patent regime?
30. Do you think that competition law can be an alternative to reduce price of drugs?
31. Is there any bilateral pressure to make TRIPS Plus patent law?
32. Does Bangladesh have any bilateral agreement to make TRIPS-compliant patent law prior to 2016?
33. In your opinion, how to make a right balance between the pharmaceutical innovation and access to affordable medicines?
34. What kind of financial and technical required for capacity building in the pharmaceutical sector in Bangladesh?
35. To what extent Bangladesh receive technical and financial cooperation from developed countries for the capacity building in the pharmaceutical sector?
36. To what extent Bangladesh receive technical and financial cooperation from developed countries for the capacity building in the patent regime?
37. To what extent Bangladesh receive technical and financial cooperation from WTO, WIPO and WHO for the capacity building in the pharmaceutical sector?
38. To what extent Bangladesh receive technical and financial cooperation from WTO, and WIPO for the capacity building in the patent regime?
39. What kind of changes introduced by India in its patent law to comply with TRIPS?
40. How India created a balance between the pharmaceutical innovation and access to medicines while making TRIPS-compliant patent law?
41. What kind of changes introduced by Brazil in its patent law to comply with TRIPS?
42. How Brazil created a balance between the pharmaceutical innovation and access to medicines while making TRIPS-compliant patent law?
43. What are different options used by India to comply with TRIPS to ensure access to medicines?
44. What are different options used by Brazil to comply with TRIPS to ensure access to medicines?
45. Is Indian experience applicable in Bangladesh?
46. Is Brazilian experience applicable in Bangladesh?

Appendix 5: Summary of Survey Findings

Summary of Survey Findings

Survey participant's profile

Code	Category of Pharmaceutical Industry	No. of Participants' (selected)	Feedback Received from	Quality/ Standard	Nature	Product Range	Patent / Invention	Scope of R&D
BG001–005	Large	5	5	Word Class Standard	Generic	More than 50	No product patent or invention	Low priority to R&D investments for basic research and concentrate on reverse engineering
ME001–009	Medium	10	9	Maintain International Standard	Generic	Less than 50 but more than 25	No product patent or invention	Marginal R&D
SM001–005	Small	10	5	Lower Standard	Generic	Less than 25	No product patent or invention	No R&D
MN001–003	Multinational	6	3	World Class Standard	Basic Research and generic	More than 50	Agreed to have Some patents and invention (but not disclosed details)	Considerable R&D

Table A5.1: Q1. Bangladesh has made sufficient preparations for the introduction of a TRIPS-compliant patent law

Level of Satisfaction/Dissatisfaction	Pharmaceutical Industry (Big, Medium and Small-Local Industry)					%
	Large	Medium	Small	Multinational	Total	
Strongly Agree	0	0	0	0	0	0
Agree	0	1	1	0	2	9
Unsure	0	0	1	0	1	5
Disagree	4	6	2	1	13	59
Strongly Disagree	1	2	1	2	6	27

Table A5.2: Q2. TRIPS has impacted the rise in pharmaceutical prices

Level of Satisfaction/ Dissatisfaction	Pharmaceutical Industry (Big, Medium and Small-Local Industry)					%
	Large	Medium	Small	Multinational	Total	
Strongly Agree	1	3	1	0	5	23
Agree	3	5	4	0	12	54
Unsure	1	1	0	0	2	9
Disagree	0	0	0	2	2	9
Strongly Disagree	0	0	0	1	1	5

Table A5.3: Q3.The government of Bangladesh should withdraw drug price control

Level of Satisfaction/Dissatisfaction	Pharmaceutical Industry (Big, Medium and Small-Local Industry)					%
	Large	Medium	Small	Multinational	Total	
Strongly Agree	4	4	0	3	11	50
Agree	1	5	0	0	6	27
Unsure	0	0	0	0	0	0
Disagree	0	0	4	0	4	18

Strongly Disagree	0	0	1	0	1	5

Table A5.4: Q4.Bangladesh has no capacity to produce new medicines

Level of Satisfaction/ Dissatisfaction	**Pharmaceutical Industry (Big, Medium and Small-Local Industry)**					**%**
	Large	**Medium**	**Small**	**Multinational**	**Total**	
Strongly Agree	4	5	4	2	15	68
Agree	0	3	1	0	4	18
Unsure	0	0	0	0	0	0
Disagree	1	1	0	1	3	14
Strongly Disagree	0	0	0	0	0	0

Table A5.5: Q5.Pharmaceutical companies in Bangladesh need to invest in R&D

Level of Satisfaction/ Dissatisfaction	**Pharmaceutical Industry (Big, Medium and Small-Local Industry)**					**%**
	Large	**Medium**	**Small**	**Multinational**	**Total**	
Strongly Agree	4	5	2	3	14	63
Agree	1	4	2	0	7	32
Unsure	0	0	0	0	0	0
Disagree	0	0	1	0	1	5
Strongly Disagree	0	0	0	0	0	0

Table A5.6: Q6.Doha waiver for LDCs to introduce pharmaceutical patents from 1 January 2016 provides export opportunities for Bangladesh

Level of Satisfaction/ Dissatisfaction	**Pharmaceutical Industry (Big, Medium and Small-Local Industry)**					**%**
	Large	**Medium**	**Small**	**Multinational**	**Total**	
Strongly Agree	1	3	0	0	4	18
Agree	3	5	1	0	9	41
Unsure	1	1	4	0	6	27
Disagree	0	0	0	2	2	9
Strongly Disagree	0	0	0	1	1	5

Table A5.7: Q7.The Directorate of Drug Administration (DDA) of Bangladesh maintain the quality of medicines produced in Bangladesh

Level of Satisfaction/ Dissatisfaction	Pharmaceutical Industry (Big, Medium and Small-Local Industry)					%
	Large	Medium	Small	Multinational	Total	
Strongly Agree	3	3	4	0	10	45
Agree	1	5	1	0	7	32
Unsure	0	0	0	0	0	0
Disagree	1	1	0	3	5	23
Strongly Disagree	0	0	0	0	0	0

Table A5.8: Q8.Compulsory licenses are essential to protect public health and access to affordable medications

Level of Satisfaction/ Dissatisfaction	Pharmaceutical Industry (Big, Medium and Small-Local Industry)					%
	Large	Medium	Small	Multinational	Total	
Strongly Agree	4	6	1	0	11	50
Agree	0	3	2	0	5	23
Unsure	0	0	2	0	2	9
Disagree	1	0	0	1	2	9
Strongly Disagree	0	0	0	2	2	9

Table A5.9: Q9. Parallel imports are essential to protect public health and access to affordable medications

Level of Satisfaction/ Dissatisfaction	Pharmaceutical Industry (Big, Medium and Small-Local Industry)					%
	Large	Medium	Small	Multinational	Total	
Strongly Agree	3	4	3	0	10	45
Agree	0	3	2	0	5	23
Unsure	0	0	0	0	0	0
Disagree	2	2	0	1	5	23
Strongly Disagree	0	0	0	2	2	9

Table A5.10: Q10.Small- and medium-sized pharmaceutical companies will face difficulties in a TRIPS-compliant patent regime

Level of Satisfaction/ Dissatisfaction	Pharmaceutical Industry (Big, Medium and Small-Local Industry)					%
	Large	Medium	Small	Multinational	Total	
Strongly Agree	4	5	5	2	16	73
Agree	1	4	0	1	6	27
Unsure	0	0	0	0	0	0
Disagree	0	0	0	0	0	0
Strongly Disagree	0	0	0	0	0	0

Table A5.11: Q11.A renewed waiver for pharmaceutical patents for the LDCs post-2015 is necessary

Level of Satisfaction/ Dissatisfaction	Pharmaceutical Industry (Big, Medium and Small-Local Industry)					%
	Large	Medium	Small	Multinational	Total	
Strongly Agree	4	5	4	0	13	59
Agree	1	4	1	0	6	27
Unsure	0	0	0	0	0	0
Disagree	0	0	0	1	1	5
Strongly Disagree	0	0	0	2	2	9

Table A 5.12 Descriptive Statistics

Issue/Query	Mean	SD	Maximum	Minimum
Q1.**Bangladesh has made sufficient preparations for the introduction of TRIPS Compliant patent law**	4.045	0.844	5	2
Q2. **TRIPS has impacted on the rise of pharmaceutical price**	2.238	1.044	5	1
Q3. **The Government of Bangladesh should withdraw the drug price control**	2.000	1.309	5	1
Q4. **Bangladesh has no capacity to produce new medicine**	1.565	1.037	4	1
Q5. **Pharmaceutical companies in Bangladesh need to invest in R&D**	1.455	0.739	4	1
Q6. **Doha waiver for LDCs to introduce pharmaceutical patents from January 1, 2016 provides export opportunities for Bangladesh**	2.409	1.054	5	1

Q7. **The Directorate of Drug Administration (DDA) of Bangladesh maintain quality of medicines produced in Bangladesh**	2.000	1.195	4	1
Q8. **Compulsory licenses are essential to protect public health and access to affordable medications**	2.045	1.362	5	1
Q9. **Parallel Imports are essential to protect public health and access to affordable medications**	2.273	1.486	5	1
Q10. **Small and Medium size pharmaceutical companies will face difficulties in a TRIPS compliant patent regime**	1.273	0.456	2	1
Q11. **A renewed waiver for pharmaceutical patents for the LDCs after 2015 is necessary**	1.773	1.270	5	1

Table A 5.13 Chi-Square

Issue/Query	Chi-square	Chi-square Tabulated value	Degrees of Freedom(df)
Q1	0.894023	16.91898	9
Q2	0.109603	21.02607	12
Q3	0.106071	16.91898	9
Q4	0.997745	12.59159	6
Q5	0.965283	12.59159	6
Q6	0.014531	21.02607	12
Q7	0.421768	12.59159	6
Q8	0.035448	21.02607	12
Q9	0.346599	16.91898	9
Q10	0.999345	7.814728	4
Q11	0.105891	16.91898	9

Survey Question 10: How many products have been invented by your company in the last 5 years? Survey Question 11: How many products have been patented by your company so far?

- **Large, Medium and small pharmaceutical companies-** all of them have no new invention and no patent so far (BG001–005, ME001–009 and AM001–005). Some large scale companies simply mentioned they just started basic research considering preparation for post-TRIPS product patent regime (BG001–002). Some medium size and small companies mentioned they are considering for utilising traditional knowledge to make country specific traditional medicine as an alternative opportunity in a post-TRIPS regime (ME01–04 and SM 01, 05)
- **Multinational-**all agreed they have new invention and patented pharmaceutical in elsewhere and some are patented in Bangladesh as well prior to 2008. But not interested to disclose details and possible impacts of those patented pharmaceuticals in Bangladesh (MN001–003).

Survey Question 14: What challenges do you think a TRIPS-compliant patent regime will have on the pharmaceutical sector in Bangladesh?

- Raw materials of patented products will not be available. Hence, new therapies of world market will come very late in Bangladesh. **(BG001, 002 and 005, ME 001, 002, 004, 005 and 009, SM001 and 005); (all Multinationals disapproved this assumption during interview with top executives).**
- There will be more partnerships in local market with MNCs and patent holders. **(mentioned by all big pharmaceuticals-BG001–005 and ME 001, 003, 006, 007–008, MN001 and 003 whereas MN 002 and SM 001, 002 and 005 mentioned there may not be any opportunity like that considering low technological capacity and R&D among the local industries in Bangladesh).**
- Small companies will find it difficult to get reputed partners. **(All agreed); (all small companies specially mentioned this as great threat to their survival).**
- **Investment would be a challenge for small companies for development of R &D (BG001–002, ME 001, MN001 and SM 001–005).**
- Regulatory wing of individual companies will be required to be strengthened. **(all Big and Medium pharmaceutical companies considered this as top priority during interview) (Multinationals has already maintained very strong regulatory wing) (Small companies have no separate regulatory wing)**
- Overall price of medicine may increase. **(Agreed by local companies and disapproved by multinationals-see Table 1.2)**
- Significant time will have to be dedicated to settle patent issues. **(mentioned by two big pharmaceutical company-BG001 and BG 003)**
- Drugs Administration will require more expertise and infrastructure to take care of patent issues. **(mentioned by all -big, medium, small and multinationals)**.

Survey Question 15: What do you think the pharmaceutical companies should do to create a balance between promoting pharmaceutical innovation and access to affordable medicines?

- Pharmaceutical companies should manufacture and supply ‘price controlled medications’ in addition to new molecules. Presently it is not mandatory to manufacture ‘price controlled’ molecules. (BG001–002, ME001–009)
- Rather than allowing originators to come to market, local companies may try to get license so that originators’ products can be manufactured at low cost and be supplied to public at reasonable price. (BG001–003, ME001–002)
- Pharmaceutical companies should request government to lobby for differential treatment at the WTO so that rather than treating all the LDCs similarly, WTO may go case-by-case for LDCs and exempt specific products for specific countries even after 2015. For example, some AIDS affected countries may be waived for ARVs even after 2015. (BG001, 005 and ME 001–003, 008–009)

- Multinationals are giving huge pharmaceutical donation and price reduction for the developing and LDCs. (MN001–003)
- To set reasonable price for the pharmaceuticals produced by them and should not take patent (SM001–005).

Survey Question 17: What do you think the international organisations (e.g. WTO, WIPO, WHO) should do to create a balance between promoting pharmaceutical innovation and access to affordable medicines?

- Rather than treating all the LDCs similarly, WTO may go case-by-case for LDCs and exempt specific products for specific countries even after 2015. For example, some AIDS affected countries may be waived for ARVs even after 2015. (mentioned by BG 001–004 and ME 001–005 and 008–009)
- To assist the developing and LDCs for the capacity building in the patent office and DDA (BG001–005, ME001–009 and MN001–003)
- Assist the developing and LDCs for the full utilisation of TRIPS flexibilities (BG001–005, MN001–009)
- Extension of waiver until 2030 (SM001–005)

Survey Question 22: What are the options available for Bangladesh to ensure access to medicines while making TRIPS-compliant patent law?

- Utilising TRIPS flexibilities (BG001–005 and ME001–009)
- Compulsory license for export (BG001–003 and ME001–004, 007–009)
- Compulsory license for patented pharmaceuticals on those that are very important and especially on the prevalent diseases in Bangladesh (BG001–005 and ME001–009)
- Extension of waiver until 2030 (small pharmaceutical companies 001–005)(all big and medium also mentioned this as an option but they mentioned until 2025)
- Multinationals consider Bangladesh should seek help for infrastructure development and assistance for the reform of patent law, capacity building of the patent office and DDA which are more important in the long run rather than requesting for waiver and allowing compulsory license. (multinationsl-001–003)-these are also mentioned by some big pharmaceuticals in addition to compulsory license and requests for the extension of waiver-BG001, BG003, BG005

Appendix 6: Summary of Interview Findings

Profile of Interview Participants

Code	Background	Remarks
CEB001–002 (Big) CEM 001–002 (Medium) CES 001(small) CEMN 001–002 (multinational)	CEO/Management Pharmaceutical Industry	
BAPI 001–003	Top Executives of BAPI	
IP001–005	IP Academic and Researcher	
PHA001–005	Pharmacy Academic and Researcher	
PHN001–002	Public-health NGOs	
PO001–003	Officials of Department of Patents, Designs and Trade Marks Office (Registrar and Examiners)	
DDA001–003	Officials of Directorate of Drug Administration(Director and Examiners)	
IND001–003(India)	Experts on Indian Patent Law	
BZ 001–003(Brazil)	Experts on Brazilian Patent Law	
GE001–003(Global)	Experts on Global Patent Law	

What do you think will be the major challenges for pharmaceutical companies in Bangladesh post-2016?

- Cannot produce generic medicines of the patented pharmaceuticals (CEB001–002 CEM 001–002, CES 001(small), BAPI 001–003, IP001, PHA001–005 PHN001–002 PO001, DDA001, IND001, BZ 003). But top executives of one multinational remark that it is not true all the cases, only medicines that are patented in Bangladesh cannot be used. The practice is that multinationals do not take patent for all medicines in all countries **(CEMN 002**). Again one IP academic clarified the issue further by saying that 'only after January 1, 2016 patent office of Bangladesh will consider patent applications that are deposited in the mailbox and as per examination of it, if any patent granted only then that cannot be used by the pharmaceutical company in Bangladesh' **(IPA01**). Another IP academic referred to the one provision of India by which 'any company that has already invested and produced pharmaceuticals may be exempted, if later on any patent is granted on the same product' (IPA002). This is considered as a very viable option for Bangladesh in a post-TRIPS regime **(IND 002, BZ 001and GE 001–002).** Officials of Regulatory bodies stated that Bangladesh is considering this and

other options to protect investment in the pharmaceutical sector **(PO001 and DDA001).**

- Will have huge difficulty for survival and also closure of most of the small size pharmaceutical companies (CEB001–002, CEM 001–002, CES 001, PO003 and DDA002).
- Will have to invest for R &D (CEB001–002, CEM 001–002, CES 001, CEMN 001–002, BAPI 001-003, IP001–005, PHA001–005, PHN001–002, DDA001–003, IND001–003, BZ 001–003 and GE001–003).
- Investment would be a challenge for small companies for development of R &D **(**CEB001, CES 001 and CEMN 001).
- Export market is to be limited only for non-patented or patent expire pharmaceuticals (CEB001–002, CEM 001–002, CES 001, CEMN 001–002, BAPI 001–003, PHA001–005). However some large pharmaceutical companies are optimistic that government will amend patent law to allow compulsory license for export market (BG001–002). But some medium size pharmaceutical companies (CEM001–002) and IP academic (IPA 001–002) said it is extremely difficult considering complex nature of TRIPS provision and political pressure.
- Will have huge difficulty to determine which patented products they can use and which they cannot **(CEB001–002, CEM 001–002, CES 001, CEMN 001–002, BAPI 001–003, IP001–005)**. IP and Pharmacy academics consider it will become a big hurdle as there is no online database of the patent office of Bangladesh regarding patented pharmaceuticals and existing regulatory staffs in the pharmaceutical companies lack proper understanding of these issues (**IP002–003 and PHA003–005)**.
- May need major restructure of internal regulatory affairs to understand post-TRIPS patent law requirements **(CEB001–002, CEM 001–002, CES 001, CEMN 001–002, BAPI 001–003, IP001–005 and PHA001–005)**.
- May need to negotiate with patent owner for license and rate of royalties for some pharmaceuticals having demand in Bangladesh (CEB001–002, CEM 001–002, CES 001, CEMN 001-002, BAPI 001–003, IP001–005 and PHA001–005).
- Price of API will increase and hence will reduce the profit margin **(CEB001–002, CEM 001–002, CES 001, CEMN 001–002, BAPI 001–003 and PHA001–005).** 'Bangladesh still dependent on India and China for most of the API'-**BAPI 001.**
- 'Government of Bangladesh has already initiated a project for the establishment of API Park to facilitate production of API locally and reduce import dependence'-**DDA003.**

Does Bangladesh have sufficient preparation to make TRIPS-compliant patent law?

- No, all agreed including government officials **(CEB001–002, CEM 001–002, CES 001, CEMN 001–002, BAPI 001–003, IP001–005, PHA001–005, PHN001–002, and DDA001–003).**

What are the steps taken by the Government of Bangladesh for making TRIPS-compliant patent law?

- A draft patent law is under scrutiny by the Law Commission of Bangladesh (IPO001–003, DDA001 and IPA001).
- A project is underway with the assistance from WIPO and EU for the automation in the patent office and improving patent application, examination and information about granted patent (IPO001–002).
- 'Keeping in mind the TRIPS Agreement, we are updating some laws. At the same time, we are also continuing the infrastructure development through a 15.2 million Euro - project funded by WIPO and EU'-IPO002.
- Infrastructure development in the Directorate of Drug Administration to deal with the issues of drug development and patented medicines (DDA001).

Do you think a compulsory license or parallel imports could be effective to ensure access to medicine?

- Very important in case of urgent need of cheap medicines to produce them locally under compulsory license or using parallel imports provision to import from other countries having cheap price (CE001, CEM002, CES001, IPA003 and DDA002).
- 'These may not ensure access to medicines rather may have less interest among the innovative drug producer to launch new and more effective pharmaceuticals in Bangladesh' -CEMN001 and it is also said by CEMN002 and PHA004.
- 'Unless pharmaceutical companies in Bangladesh can attain very high technical capability compulsory license provision may not be effective therefore more concentration to be given to improve technical capacity and R&D in the local pharmaceutical industry' --PHA 001 and it is also supported by PHA 004.
- Public-health NGOs consider these are very important but yet to be incorporated in the patent law of Bangladesh (PHN001–002).

Does pharmaceutical industry in Bangladesh have sufficient preparation for a product patent regime?

- No (CEB001–002, CEM 001–002, CES 001, CEMN 001–002, BAPI 001–003). Multinational operating Bangladesh however confirmed that they are ready for product patent regime (CEMN001–002).
- But IP academic consider that 'multinationals may engage in selling products manufactured in elsewhere rather than manufacturing in Bangladesh'-(IPA001–002).
- Another IP academic and Pharmacy academic consider simply import by the multinationals rather than producing in Bangladesh will give no benefits for Bangladesh of a post-TRIPS regime as 'local scientists may not have opportunity to acquire new technical skills and there may not be further investment in the sector'-IP 003-also supported by PHA 001.

What are the steps taken by the Government of Bangladesh for the capacity building in the pharmaceutical sector in the context of the TRIPS agreement?

- Most of the pharmaceutical companies have dissatisfaction about lack of proper steps from the part of the government (CEB001-002, CEM 001-002, CES 001 and BAPI 001-003).
- In particular, as one official of BAPI mentioned 'inordinate delay for the establishment of the API Park and no initiative for the establishment of bio-equivalency lab at the DDA with all modern facilities is the sign of sheer negligence from the part of the Government' (BAPI 002). He further added 'we want action in practice not in words'-BAPI02.
- Multinationals made no points about Government actions rather they emphasised 'Government may consider introduction of product patent before 2016, withdrawal of restrictions on import and price control and strict quality control of medicines produced in Bangladesh as step forward for capacity building' -CEMN 002.

In your opinion is the Directorate of Drug Administration (DDA) in Bangladesh effective to control the quality of medicines?

- Interestingly large and small pharmaceutical company and one multinational as well remark that DDA effectively control the quality of medicines **(**(CEB001-002, CES 001 and CEMN 001).
- But one medium size and another multinational consider DDA need to be more active to ensure quality of medicines (CEM 01 and CEMN 02).
- BAPI official said 'it is satisfied with the work of DDA within limited resources'- (BAPI 001).

Do you think that the government should withdraw the price control ordinance?

- Except small pharmaceutical company other companies operating in Bangladesh including multinationals consider that 'Government of Bangladesh should withdraw price control to ensure quality of medicines and better competitive environment'-(CEB001)-which is supported by CEB002, CEM 001-002 and CEMN 001-002).
- 'Now some companies are trying to seize the market with the low price low quality products which may become real threat for public health'- (CEB 01 and CEMN 001).
- Small companies consider 'withdrawal of price control will become a threat for access to medicines and for their survival' as well. Therefore 'it is better to have to encourage local companies and ensure affordability of pharmaceuticals for the local peoples'- (CES 001).
- BAPI made no comments about this as considering this as an issue of contention both from legal and political perspectives and agreed that in their organisation there is conflict of opinions among the members (BAPI 001-002).
- 'Certainly not. Because reality shows that even the Government is not able to control price effectively with the present ordinance. So the non-existence of

Price Control Ordinance would definitely leads towards the real disaster in terms of access to drugs' - (IPO002).

- 'No. In the absence of it, price of drugs would be sky-high, which would ultimately lead towards the real obstacle in order to access to drugs'- (DDA002).

Do you think price control a viable tool for ensuring access to drugs? Is it compatible with TRIPS?

- Not viable to ensure access to medicines (CEB001, CEM001 AND CEMN001). Large and medium pharmaceutical companies although requests for withdrawal of price control, not interested to comment about compatibility with TRIPS. But multinationals consider it is not compatible with TRIPS (CEMN001).
- 'Very important and compatible with TRIPS considering the experience of India and some other countries' (IPO001 and DDA001).
- Small pharmaceutical company also endorses support for this as TRIPS compatible and consider this as one of the important safeguard for access to affordable medicines (CES001).

What are different options used by India to comply with TRIPS to ensure access to medicines?

- India traditionally used process patent for the pharmaceuticals along with price control mechanism to reduce the price of medicines since 1970 Patent Act (IND001-003).
- While introducing product patent in 2005, 'India mostly focused on the high threshold for patentability, pre-grant and post-grant opposition and compulsory license'- (IND001).
- 'Although compulsory license is a viable tool for access to medicines, I doubt about use of it considering political pressure. India rather may use the technique to deny granting of patent on the basis of patentability requirements and pre and post-grant opposition as we see in the Novartis case'-(IND002).
- India is now considering 'to use competition law to prevent abuse of dominant position in the pharmaceutical market and thereby to avoid possible conflict with other countries regarding TRIPS compatibility'-IND003.

What are different options used by Brazil to comply with TRIPS to ensure access to medicines?

- Brazil accommodated all the TRIPS flexibilities to ensure access to medicines (BZ001 and BZ002).
- 'Use of compulsory license as a bargaining tool to reduce the price of pharmaceuticals and if there is no price reduction, then granting it for local production considered as very viable tool for the access to affordable pharmaceuticals which may also be used by other developing countries'- BZ002.
- Brazil established a separate body to monitor the safety and efficacy of medicines which is also very crucial for access to medicines (BZ003).

In your opinion, how to make a right balance between the pharmaceutical innovation and access to affordable medicines?

- It is not possible to make balance using patent law therefore only allowing process patent and waiver of pharmaceuticals from product patent may ensure the balance (CEB002, CEM001-002 and CES001).
- Proper utilisation of TRIPS flexibilities using the experience of India, Brazil, China, South Africa, Thailand and other countries(IPO002 and DDA002).
- We may think about some alternatives to make the balance such as patent pool and patent prize on the country specific diseases (IPA002).
- 'Ultimately technical capacity building in the pharmaceutical sector and greater public-private partnership for R&D can make a balance. Simply making patent law either weak or TRIPS compliant can make no difference'-GE001.
- DDA and patent office should have adequate expertise to deny any patent registration and registration of pharmaceuticals respectively if it consider little improvement and may become threat for public health in the country (PHN001 and PHN002). 'There should be greater public access to the patent office to gain information about patent application, expired patents and granted patents in the field of pharmaceuticals'-PHN002.

What are the required changes to the patent law of Bangladesh to ensure access to medicines and pharmaceutical innovation in a post-TRIPS regime?

- Bangladesh should include all the TRIPS flexibilities in the amended patent law especially defining high threshold for patentability requirements, compulsory license, pre-grant and post-grant opposition and parallel imports (IPA001, GE001, IND002 and BZ001).
- It should make price control mechanism stronger (CES001, IPO002, GE002 and IND003).
- 'Existing patent law of Bangladesh contain a provision on compulsory license which is very complex and dysfunctional. This provision need to be simplified and should have a provision to grant compulsory license within reasonable time which may not be more than two months'-IPA001.

Appendix 7: Status of Patents in Bangladesh (1972–2009)

	Patent Applied			**Patent Accepted**		
Year	**Local**	**Foreign**	**Total**	**Local**	**Foreign**	**Total**
1972	51	158	209	9	3	12
1973	76	277	353	6	30	36
1974	**74**	**171**	**245**	**10**	**265**	**275**
1975	**35**	**110**	**145**	**25**	**312**	**337**
1976	35	119	154	10	119	129
1977	33	86	119	11	93	104
1978	36	113	149	13	1o8	121
1979	31	100	131	20	83	103
1980	34	102	136	19	92	111
1981	39	133	172	17	85	102
1982	40	104	144	13	105	118
1983	40	123	163	11	115	126
1984	62	108	170	17	94	111
1985	40	96	136	13	105	118
1986	16	77	93	26	81	107
1987	**23**	**98**	**121**	**10**	**79**	**89**
1988	**24**	**109**	**133**	**8**	**67**	**75**
1989	**32**	**76**	**108**	**3**	**88**	**91**
1990	**32**	**76**	**108**	**8**	**86**	**94**
1991	**36**	**77**	**113**	**10**	**68**	**78**
1992	**72**	**89**	**161**	**6**	**55**	**61**
1993	**36**	**71**	**107**	**10**	**66**	**76**
1994	**39**	**99**	**138**	**29**	**69**	**98**
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
Total	1640	5956	7596	548	4399	4947

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

Appendix 8: Relevant Provisions of the TRIPS Agreement

Article 1

Nature and Scope of Obligations

1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

Article 6

Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Article 7

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8

Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

SECTION 5: PATENTS

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[5] Subject to paragraph 4 of Article 65, paragraph 8 of

Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
3. Members may also exclude from patentability:
   (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
   (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 29

Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
2. Members may require an applicant for a patent to provide information concerning the applicant’s corresponding foreign applications and grants.

Article 30

Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a member allows for other use[7] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;
(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable.

In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
(d) such use shall be non-exclusive;
(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
(f) any such use shall be authorized predominantly for the supply of the domestic market of the member authorizing such use;
(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that member;
(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that member;

Article 33

Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.

Article 34

Process Patents: Burden of Proof

1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

Article 66

LDC Members

1. In view of the special needs and requirements of LDC members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by an LDC member, accord extensions of this period.
2. Developed country members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to LDC members in order to enable them to create a sound and viable technological base.

Appendix 9: Journal Article-1(IP Forum Journal, March 2011)

Access to Medicines and Pharmaceutical Patent Protection under the TRIPs Agreement: A Review of Literature on the Challenges for Least Developed Countries

Mohammad Monirul Azam and Associate Professor Kristy Richardson*

Introduction

The creation of the World Trade Organisation (WTO) was agreed to by 125 countries (including Bangladesh) on 15 April 1994 at a conference in Marrakesh, Morocco[1] and came into effect on 1 January 1995. The WTO replaced the looser arrangements for the conduct of international trade originally embodied in the General Agreement on Tariffs and Trade of 1947 (GATT).[2] The WTO serves as the governing body of the post-war international trading system and provides a constitution to regulate trade between members.[3]

The establishment of the WTO has been an important exercise in a number of ways. First, it represents an entirely new chapter in the jurisprudence of post-world war international organisation through the establishment of a multilateral trading system which provides a binding dispute settlement mechanism for its members.[4] Secondly, the WTO has taken responsibility for the onerous task of evolving a binding law of international trade amongst the member countries.[5] Thirdly, the WTO has in many ways displaced the internal sovereignty of the member countries.[6]

The displacement of internal sovereignty is an issue hotly debated between disciplines. On the one hand, economists argue that economic benefits will accumulate to those WTO members who implement their WTO obligations into their domestic economic policies and regulatory structures.[7] On the other hand, lawyers are enthusiastic to deal with rights and obligations as they are set out in the WTO agreements with a view to determining whether the actions of one member nullifies or impairs the benefits of other members.[8] Whether it is a matter of economic benefit or legal obligation, every member is required to adjust its domestic laws in conformity with WTO agreements.[9] Consequently, because of its status as a founding member, the legal system of Bangladesh has been subject to (and continues to require) reorganisation to satisfy the requirements of the WTO.[10]

This article presents an examination of the literature examining pharmaceutical protection, the TRIPs agreement and least developed countries with a particular focus on Bangladesh.

The TRIPs Agreement

Among the WTO agreements, the Trade Related Aspects of Intellectual Property Rights (TRIPs) agreement has been described by Peter Drahos and John Braithwaite as "probably the most important international intellectual property agreement that was signed in the 20th century".[11] The implementation of the TRIPs agreement will require a reorganisation and restructuring of Bangladesh's intellectual property regime. Given the extent of the reorganisation and the restructuring required, a group of least-developed countries (LDCs)[12] (of which Bangladesh is one) were granted an initial transition period until 31 December 2005[13] to become TRIPs compliant. The group had cited socioeconomic, administrative and financial constraints and the need to create a viable technological base as reasons duly motivating the request. The transition period was later extended to July 2013,[14] however even this extension did not seem long enough given recognition of the extent of the restructuring required. The Doha Declaration on the TRIPs Agreement and Public Health was adopted by the WTO Ministerial Conference in Doha on 14 November 2001 and further extended the transition period for LDCs to introduce pharmaceutical patent protection to 1 January 2016.[15]

It was developed nations such as the United States of America, the European Union and Japan that first put the TRIPs agreement on the WTO's agenda.[16] The TRIPs agreement, which is binding on all member countries of WTO, aims to establish minimum standards for intellectual property rights (IPRs). For the first time in a global context, TRIPs seeks to establish a global minimum standard for IPR protection, thereby representing a departure from previous international IPR treaties and agreements[17] as: (i) TRIPs requires the implementation of specific types of IPR protection;[18] (ii) TRIPs also specifies the substantive content required of a national (compliant) IPR legislative regime; and (iii) TRIPs brings national IPR legislation under the coverage of the WTO's dispute settlement procedures.[19] The impetus for placing IPRs on the agenda by these developed countries lay in the argument that the adoption

of TRIPs would create an incentive for global innovation, the development of new technologies and would encourage greater domestic and foreign investment in research into new drugs and tropical diseases.[20] The benefit of foreign investment and technology transfer would necessarily be of significant benefit to developing countries and LDCs.[21]

The contrary argument mounted by developing countries was that Western-style IP regulations are unsuited for developing countries and LDCs particularly in the context of those countries' industrial and economic development.[22] The argument mounted was that that the patent protection required to be implemented under the TRIPs agreement might not only be harmful to industrial and economic development but also to the well-being of citizens,[23] with patent protection for pharmaceuticals necessarily increasing prices whilst at the same time reducing the availability of cheap/generic pharmaceuticals.[24] Another stakeholder, pharmaceutical companies, argue that in the absence of patent protection for pharmaceuticals there may not be any investment and hence no research or innovation for new drugs.[25] The debate therefore revolves around how to reach a balance between meeting the high costs of pharmaceutical research and development and creating incentives to stimulate (and maintain) access to those pharmaceuticals in developing and LDCs.

Pharmaceutical Patents and LDCs

A patent is a legal document granted under the legal framework of a particular country giving an inventor the exclusive right to make, use, and sell an invention for a specified period of time.[26] Simply stated, a patent is "an exclusive right granted for an invention, which is a product or a process that provides a new way of doing something or offers a new technical solution to a problem".[27] The procedure for granting patents, the extent of the exclusive rights and necessary requirements that need to be addressed by the patentee vary widely between countries according to national laws and international agreements. Typically, however, a patentable invention must be new, there must be an inventive step, and it should be industrially applicable.[28] A patent system by registration provides incentives to exploit the invention by encouraging the inventor to disclose the invention once made as others are prevented from copying the invention without the authorisation of the patent owner. The system thereby facilitates the ability of other inventors to improve upon earlier patents once disclosed.[29]

However, the system of patent registration can be criticised for conferring a negative right upon a patent owner as the registration allows the patent owner to exclude competitors from using or exploiting the invention; even if the competitor subsequently develops the same invention independently. Michael Heller and Rebecca Sue Eisenberg[30] articulate that intellectual property rights may become so fragmented that, effectively, no one can take advantage of them as to do so would require an agreement between the owners of all of the fragments.

Although pharmaceutical patents facilitate some "designing around", the preservation of exclusivity rights for a certain period of time necessarily prevents generic alternatives from entering the market within the time protected by the registered patent. Consequently, the patent owner is able to maintain a high price for the pharmaceutical.[31] This can have significant impact on the availability and affordability of pharmaceuticals, particularly for poorer countries and their citizens.[32] For this reason, a number of countries like India and Brazil excluded the patenting of pharmaceuticals in their (pre-TRIPs) patent law regime.[33] Similarly, Bangladesh and other LDCs that are signatories to the TRIPs agreement derive benefit from their existing (pre-TRIPs) patent system which relies on the freedom to determine national patent laws which exclude pharmaceutical patents.[34]

The exclusion of product patents from intellectual property regimes has not been uncommon,[35] the rationale being that the non-granting of product patent protection for pharmaceuticals would allow local pharmaceutical companies to imitate and produce patented medicines by using new processes.[36] For 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.[37] In Germany, product patents were explicitly excluded under the law of 25 May 1877 but were then introduced from 4 September 1967.[38] In Switzerland, product patents for pharmaceuticals were explicitly prohibited by the constitution and were only introduced in 1977.[39] In Italy, pharmaceutical patents were prohibited until 1978.[40] 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.[41] During the period in which product patents were excluded these countries were able to gain self-sufficiency by investing in research and development (R&D)[42] enabling the transformation of their pharmaceutical industries into innovative and research-based industries by using the imitated technology.[43]

However, as a result of the requirements of the TRIPs agreement the freedom to rely on imitated technology until such time as pharmaceutical production is at a similar stage of development is no longer an option for the LDCs that a signatories to the agreement.[44] To incorporate the IPRs required by TRIPs, LDCs like Bangladesh will have to strike a balance between the competing interests of a variety of stakeholders, including domestic generic medicine producers, the domestic research and development community and foreign multinational pharmaceutical companies.

A supporter of a TRIPs-compliant patent regime for pharmaceuticals in LDCs like Bangladesh, Ashfaque ur Rahman argues that a TRIPs compliant regime will lead to an increase in the flow of technology transfer and foreign direct investment in Bangladesh (and other LDCs) and will result in the development of new drugs more suited to the needs of Bangladesh.[45] Moreover, he argues that there will be the availability of wider range of better quality patented medicines which will improve the welfare of the general population.[46] Further, a TRIPs compliant patent regime may also help the capacity building of the local pharmaceutical industry and it will encourage technology transfer to local pharmaceutical companies, which will help them to transform from "copycats" to innovative companies.[47]

Relevantly, pharmaceutical companies disagree that there is any negative correlation between TRIPs and public health.[48] Rather, they claim that the protection of intellectual property rights is essential for future innovation and for the discovery and protection of new drugs.[49] However, governments, public health organisations, civil society and some researchers consider that TRIPs has, and will continue to have, a negative impact on access to drugs because the TRIPs agreement fosters a monopoly position of product patent protection which increases drug prices, limits competition, affects local manufacturing capacity, makes reverse engineering impossible and provides no incentives for R&D for neglected diseases.[50] That is why there is concern among national and international civil societies and public health groups about the negative impact that the TRIPs-compliant patent law is expected to have on the pharmaceutical industries in the developing world, and in turn, on the production and affordability of essential medicine.[51]

Review of Existing Literature

The academic literature in the area of the WTO and the multinational trading system is generally focused on the economic dimension of the TRIPs agreement with little emphasis being placed on trade policy and legal measures. The literature that deals with trade policy and potential legal options is generally limited to considering investment laws, the textile and clothing sector or matters related to import and export policy. The literature can be divided into three categories:

(a) Literature limited to the economic dimension.[52]

(b) Literature directed at trade policy and limited legal policy measures such as investment, import and export matters, textile and clothing and intellectual property.[53]

(c) Literature that deals with socio-legal issues associated with the TRIPs agreement and the pharmaceutical industry.[54]

The literature which belongs to third group is of relevance to the present analysis and will be examined.

Padmashree Gehl Sampath,[55] Anne St. Martin,[56] Md. Farhad Hossain Khan,[57] S. M. Anowar Uddin[58] and the World Bank study[59] simply examine the pharmaceutical industry, the waiver period and the issue of patent administration without examining the challenges that arguably exist for the making of TRIPs-compliant patent law in Bangladesh. For example, Padmashree Gehl Sampath conducted two studies[60] on the pharmaceutical industry in Bangladesh examining the strategies of Bangladeshi pharmaceutical firms and their capacities. The first study explored whether IPRs could directly stimulate R&D and innovation in an LDC like Bangladesh. The study concluded by finding that the presence of IPRs in Bangladesh would not play a role either as a direct incentive for innovation or as an indirect incentive for technology transfer.[61] One limitation of the study was that it did not focus on the challenges that exist for Bangladesh in trying to make and implement a TRIPs compliant patent law nor the directions for capacity building of the pharmaceutical sector in a TRIPs compliant patent regime.

On the other hand, the second study[62] investigated the innovative capacity and competitiveness of the local pharmaceutical sector in Bangladesh and concluded that indigenous pharmaceutical firms in Bangladesh may not be able to capitalise on the Doha extension for pharmaceutical exports unless they invest in technological progress and enhance competitiveness.[63] However, like the first study, the second study also failed to consider the policy directions for making TRIPs-compliant patent law and future policy direction to face the pre-2016 and post-2016 challenges.

Anne St. Martin in a thesis[64] on the Impact of TRIPs on Access to Essential Medicines in the Developing World conducted some field studies in Bangladesh and identified the prospect of Bangladesh being able to provide cheap medication during the waiver period. However, again, the thesis did not canvass the policy directions open to Bangladesh or how Bangladesh could utilise the opportunities available to do during the waiver period. Further, the thesis did not canvas how Bangladesh may face the challenges that will arise post-2016.

Further research was conducted by S. M. Anowar Uddin examining the TRIPs waiver period and access to medicine in Bangladesh. He based his research on internet-based secondary sources and concluded that Bangladesh, as an LDC and entitled to waiver period, should use the period leading to 1 January 2016 to build capacity in the pharmaceutical sector and make allied reforms of patent law. Whilst making this suggestion, S. M. Anowar Uddin did not provide any specific directions for policy.

In the context of the pharmaceutical industry, Md. Shah Amran[65] attempted to study the impact of TRIPs on the pharmaceutical industry in Bangladesh. However, he only discussed impact of the TRIPs agreement on the developing countries in general. There was little focus on the implications of a TRIPs-compliant patent regime for Bangladesh or future policy directions. He did claim that TRIPs would have negative impacts on the domestic pharmaceutical sector as he suggested that the price of essential drugs would increase and the continuation of the traditional medicare system would be at stake. Based upon his research he recommended that Bangladesh should take advantage of waiver period but did not express what should be done during that period.[66]

In this regard, Syed Farhat Anwar[67] tried to show that there might be greater export opportunities for pharmaceuticals from Bangladesh utilising the TRIPs waiver period. Unfortunately, however, he did not critically examine the policy options available under the Doha Declaration on the TRIPS Agreement and Public Health or how far Bangladesh could balance its competing interests utilising the TRIPs flexibilities. On the other hand, in a study by the World Bank Bangladesh Office[68] on the pharmaceutical sector of Bangladesh, the quality and price of pharmaceuticals in Bangladesh was investigated. The study suggested some alternative mechanisms[69] to improve the quality of drugs available in Bangladesh. The study concluded with some policy and institutional suggestions for the Government of Bangladesh to improve the price and quality competitiveness of Bangladesh's pharmaceuticals. However, like other existing studies on Bangladesh, it also did not suggest any policy directions that may be available to implement a TRIPs compliant patent law to achieve such improvements.

Conversely, Professor Tony VanDuzer[70] in his research made an attempt to evaluate the challenges for the pharmaceutical industry in Bangladesh in the context of the TRIPs agreement. Whilst he evaluated the challenges, the research failed to suggest any substantial policy directions for future law making. Further, the research is somewhat dated as it does not deal with the subsequent changes of TRIPs agreement in line with the Doha Declaration and did not address the important issue of how an LDC like Bangladesh can balance access to medicine whilst promoting pharmaceutical innovation and also making a TRIPs compliant patent law.

In the context of IPRs, Mohammad Abu Yusuf and Qamrul Alam[71] tried to examine some policy options, such as utilisation of compulsory licensing. The research, however, lacked a clear analysis of existing flexibilities, weakness of existing patent law provisions in Bangladesh and directions for patent law reforms in Bangladesh in line with the TRIPs agreement. There is therefore a gap in the literature examining the specific legal options for Bangladesh.

There are only a few other studies examining the position of some of the Asian[72] and African[73] LDCs. There are a number of studies with respect to analysing developing countries like India, Thailand, South Africa and Brazil and those countries' experiences in introducing TRIPs compliant patent

law the impact the introduction had on their pharmaceutical industries.

For example, Dr Tandi Dorji in an article on TRIPs and Bhutan (which is a south Asian LDC and yet to become a member of WTO),[74] examined the effects of TRIPs on pricing, affordability and access to essential medications in Bhutan. In this article, he claimed that with the enactment of TRIPs compliant patent law in India in 2005 (which is a major supplier of generic medicine to Bhutan) and with Bhutan becoming a member of the WTO (membership negotiation under way), the affordability of essential medicines became severely limited.[75] Further, Amal Nagah Elbeshbishi[76] in his study of the TRIPs agreement and African countries presented a background of the international pharmaceutical market and the situation in Africa, the TRIPs agreement and patents on drugs. His study also covered what African countries should do and presented some intellectual property solutions to protect African countries such as compulsory licenses, generic drugs, parallel imports and differential pricing. This study followed a general approach for all African countries rather than making specific impact study on a particular country.

The International Intellectual Property Institute in its 2000 Report[77] examined the role of patents in relation to the access to pharmaceuticals and the HIV/AIDS crisis in sub-Saharan Africa (where out of 54 countries, 34 countries are LDCs). The report sought to determine the extent to which patents for pharmaceuticals posed an impediment to the access of HIV/AIDS drugs in sub-Saharan Africa. It concluded that, apart from the patenting of pharmaceuticals, the issue of access to affordable drugs involves numerous and complex issues, including health care infrastructure, international pricing mechanisms, financing, debt and tariffs.

To that end, Padmashree Gehl Sampath,[78] Lanjouw,[79] Grace,[80] Choudhuri,[81] Fink,[82] Watal,[83] Arvind[84] and Subramanian[85] have all conducted studies on the situation in India in which they tried to predict the impact of a TRIPs-compliant patent regime on the strategies of Indian pharmaceutical firms. Although these studies attempted to evaluate the effects of a TRIPs-compliant patent regime on the pharmaceutical industry in India, the studies may not be entirely relevant to the situation in Bangladesh considering the difference between the two countries in relation to knowledge, the technological and infrastructural capacity of pharmaceutical firms, the different waiver period afforded under the TRIPs agreement and the economic and local market structure of India.

In the context of other limitations on potential policy options, A. Naomi Bass, in a study on the implications of the TRIPs agreement for developing countries,[86] examined the effects of the implementation of patent laws in Brazil and South Africa. In studying the effects, Bass also explored the legal and socio-economic implications of the TRIPs regime on the international pharmaceutical industry and the consumers of patented medicines. In the study, she argued that compliance with the TRIPs agreement may ultimately induce multinational companies to establish monopolies within the industry and prevent domestic companies from realising any additional benefits.[87] Her findings highlighted the difficulties faced in trying to reach a consensus within the global community on a method of implementing patent protection laws while simultaneously protecting the specific needs of developing countries.

In sum, the existing literature focuses on the economic dimension and trade policy issues in general of TRIPs rather than on the specific issues of the impact of TRIPs on a LDC. Particularly, there is an absence of literature examining the specific requirements of a TRIPs-compliant patent law in the LDCs like Bangladesh and the consequences that may flow in the context of patenting of pharmaceuticals. It is at this point where future research will be an original contribution to knowledge: particularly, the problem of providing possible solutions that will strike a balance between the promotion of pharmaceutical innovation and provision of affordable medicines.

Conclusion

The literature examined shows that there are essentially three streams on in the context of examining the TRIPs agreement, pharmaceutical patents and least developed countries: (i) literature limited to the economic dimension; (ii) literature directed at trade policy and limited legal policy measures such as investment, import and export matters, textile and clothing and intellectual property; and (iii) literature that deals with the socio-legal issues associated with the TRIPs agreement and the pharmaceutical industry. An examination of the literature in the third group, the socio-legal issues associated with the TRIPs agreement and the pharmaceutical industry highlighted that there was a gap in the available

literature dealing with the specific issue of what legislative options may exist for a country in implementing a TRIPs compliant intellectual property regime. It will be in this gap where future research may contribute not only to the literature with respect to the TRIPs agreement but also how Bangladesh and other LDCs may move towards a TRIPs-compliant intellectual property regime by 1 January 2016 whilst also ensuring access to medicine for its population.

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1 See for details, http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm, accessed on 11 August 2010.

2 GATT was an attempt by 23 developed and developing countries to make a decisive break with previous policies concerning international trade.

3 Although as an organisation GATT is replaced by WTO, the WTO Agreement also includes the text of GATT. Therefore, GATT continues to exist as a substantive agreement, but the WTO Agreement also includes a set of additional agreements that build on and extend GATT principles to new areas. See: Bernard Hoekman and Michel Kosteki, *The Political Economy of the World Trading System* (1995).

4 See John H. Jackson, *The Jurisprudence of GATT and the WTO* (2000).

5 Member countries have undertaken to be bound by the commitments made by them under various agreements which are part and parcel of the WTO legal regime such as principles of national treatment, Most Favored Nations clause is introduced by way of which there cannot be any discrimination between national and foreign goods and services; members have to introduce patent protection for pharmaceuticals under the WTO TRIPs agreement.

6 This has been the most important argument of the opponents of the WTO as the decision making on the important issues of national interest has come within the WTO framework. See K. C Reddy (Editor), *WTO and Implications for South Asia* (2006) 1.

7 Conconi and Carlo Perroni, 'Self-Enforcing International Agreements and Domestic Policy Credibility' (July 2003). CSGR Working Paper No. 114/03; Giovanni Maggi and Andres Rodriguez-Clare, 'The Value of Trade Agreements in the Presence of Political Pressures' (1998), 106(3) *Journal of Political Economy* 574-601; Robert W Staiger and Guido Tabellini 'Do GATT Rules Help Governments Make Domestic Commitments?' XL2 *Economics and Politics* (1999) 109-44; Robert W. Staiger, The World Trade Organization, (An Entry for the New Palgrave Dictionary of Economics), (2nd Edition November 3, 2006).

8 Dennis Browne, 'Dispute Settlement in the WTO: How Friendly is it for the LDCs?' (January 2005) Paper 45, Centre for Policy Dialogue (CPD) 1.

9 Membership of the WTO is conditional on the full acceptance – without reservation – of almost all WTO agreements; See *General Agreement on Tariffs and Trade – Multilateral Trade Negotiations (The Uruguay Round): Final Act Embodying the results of the Uruguay Round of Trade Negotiations* (15 December 1993), (1994) 33 I.L.M. 1 [referred as WTO Agreements]. See Michael J. Trebilcock and Robert Howse, *The Regulation of International Trade*, (1999, 2nd ed).

10 Mohammad Monirul Azam, 'Establishment of the WTO and Challenges for the Legal System of Bangladesh' (2006) 3 *Macquarie Journal of Business Law* 23.

11 Peter Drahos and John Braithwaite, 'Intellectual Property, Corporate Strategy, Globalisation: TRIPs in Context' (2002) 20 *Wisconsin International Law Journal* 451.

12 There are no WTO definitions of 'Developed', 'Developing' or 'Least Developed' countries. The WTO recognises as least-developed countries (LDCs) those countries which have been designated as such by the United Nations. There are currently 49 least-developed countries on the UN list, 32 of which have become WTO members. According to the United Nations, least-developed countries (LDCs) are countries which exhibit the lowest indicators of socioeconomic development, with the lowest Human Development Index ratings of all countries in the world. A country is classified as an LDC if it meets three criteria based on low income (three-year average GNI per capita of less than US$750, which must exceed US$900 to leave the list), human resources weakness (based on indicators of nutrition, health, education and adult literacy) and economic vulnerability (based on instability of agricultural production, instability of exports of goods and services, economic importance of non-traditional activities, merchandise export concentration, handicap of economic smallness, and the percentage of population displaced by natural disasters). However, countries "graduate" out of the LDC classification when indicators exceed these criteria. See for details, http://www.un.org/esa/policy/devplan/profile/criteria.html.

13 Article 65 of the TRIPs agreement gave developed countries ten years (until 2005) to become TRIPs compliant.

14 The initial transition period for LDCs ended on 31 December 2005. Later by a decision of TRIPs Council on Tuesday 29 November, 2005 LDC members as a group were granted extension of the transitional period for 7.5 years to apply the provisions of the TRIPs agreement – that is, "until 1 July 2013, or until such a date on which they cease to be a least-developed country member, whichever date is earlier". The TRIPs Council took the decision on the request by the LDCs as a group, pursuant to Article 66.1 of the TRIPs agreement, for a 15-year extension of transition period to apply the provisions of the agreement. The decision was negotiated between the LDCs and some key developed countries during informal consultations and was adopted by the formal TRIPs Council meeting on 29 November, 2005. However, during the consultations, several developed country members, particularly the Unites States of America, were insisting that each LDC should request an extension on an individual basis and extension will be granted on a case-by-case basis.

15 As per the decision of the TRIPs Council to implement paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, LDCs shall be free to disregard the TRIPs disciplines on patents and undisclosed information with respect to pharmaceutical products until 2016. See the Decision of the Council for TRIPs on the Extension of the Transition Period under Article 66.1 of the TRIPs Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, IP/C/25 of 27 June 2002.

16 Sylvia Ostry, 'Intellectual Property Protection in the WTO: Issues in the Millennium Round' *Fraser Institute conference Santiago, Chile* (April 19, 1999) 3 and John Madely, 'Hungry for Trade' (2000) 96-97.

17 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* (2008).

18 The exceptions are utility models and plant breeders' rights, although TRIPs members are obliged to provide some kind of effective plant variety protection.

19 J. J. Simons, 'Cooperation and Coercion: The Protection of Intellectual Property in Developing Countries' (1999) 11(1) *Bond Law Review* 1.

20 Mansfield claimed that 65% of pharmaceutical and 30% 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 Corporation: A Report on Industrial Technology under Changing Public Policy* (1959), Harvard University.

21 However, the evidence linking IPRs to FDI and technology transfer is mixed. Stronger IPR protection has been found to encourage FDI and technology transfer in certain industries, most notably chemicals and pharmaceuticals. As with trade, IPRs may play less of a role in high-tech industries due to the difficulty in imitating these industries' products, while in low-tech industries other factors such as market size, cheap labour, political stability may be more important in determining FDI flows than IPRs; 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 U.S. 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.

22 See Vandana Shiva, *Protect or Plunder* (2001).

23 Martin Khor, 'Rethinking Intellectual Property Rights and TRIPs' in *Global Intellectual Property Rights-Knowledge, Access and Development*, Peter Drahos and Ruth Mayne (eds.), Palgrave Macmillan, 2002, USA pp.201-213.

24 Ma El Farag Balat and M. H. Loutifi, 'The TRIPs Agreement and Developing Countries: A Legal Analysis of the Impacts of the New IPRs Law on the Pharmaceutical Industry in *Egypt, 2 Web JCLI*, 2004, p.3.

25 In a study, Silberston categorised three groups of industries for when patents are essential, very important, or less important, based on both survey responses and objective analyses (patent and R&D intensity). He concluded that "the first category consists of one industry only, pharmaceuticals." See for details, C. T. Taylor and Z. A. Silberston, *The Economic Impact of the Patent System* (1973) and Z. A. Silberston, *The Economic Importance of Patents* (1987). Again, Edwin Mansfield surveyed the R&D directors of 100 US corporations on what fraction of the inventions they introduced between 1981 and 1983 would not have been developed without patent protection. For pharmaceuticals, the value was 60%, while the average across all industries was 14%. See Edwin Mansfield 'Patents and Innovation: An Empirical Study' (1986), 32 *Management Science* 175.

26 The historical origin of patent is as follows – In 500 BC, in the Greek city of Sybaris (located in what is now southern Italy), "encouragement was held out to all who should discover any new refinement in luxury, the profits arising from which were secured to the inventor by patent for the space of a year". (Charles Anthon, *A Classical Dictionary: Containing an account of the Principal Proper Names Mentioned in Ancient Authors, and Intended to Elucidate all the Important Points connected with the Geography, History, Biography, Mythology, and Fine Arts of the Greeks and Romans together with an account of Coins, Weights, and Measures, with Tabular Values of the Same*, Harper & Bros, 1841, p.1273). Patents in the modern sense originated in 1474, when the Republic of Venice enacted a decree by which new and inventive devices, once they had been put into practice, had to be communicated to the Republic in order to obtain the right to prevent others from using them (Helmut Schippel: 'Die Anfänge des Erfinderschutzes in Venedig, in: Uta Lindgren (Hrsg.): Europäische Technik im Mittelalter.' 800 bis 1400. *Tradition and Innovation*, 4. Aufl., Berlin 2001, S.539-550, "Wolfgang-Pfaller. de: Patentgesetz von Venedig" (in German / Italian). http://www.wolfgang-pfaller.de/venedig.htm). England followed with the Statute of Monopolies in 1623 under King James I, which declared that patents could only be granted for "projects of new invention". During the reign of Queen Anne (1702-1714), the lawyers of the English Court developed the requirement that a written description of the invention must be submitted. In the United States, during the so-called colonial period and Articles of Confederation years (1778-1789), several states adopted patent systems of their own. The first Congress adopted a *Patent Act* in 1790, and the first patent was issued under this Act on 31 July 1790 (to Samuel Hopkins of Vermont for a potash production technique). See for details, Craig Allen Nard, 'American Patent Law: With European and TRIPS Comparative Perspectives, Materailas' prepared for WIPO-Turin LLM program Intellectual Property Law, 18-22 September, 2006.

27 See World Intellectual Property Organization (WIPO) information book on patents/inventions, available at www.wipo.int/about-ip/en/patents.html, accessed on 5 September 2009.

28 Without defining what is meant by a patent, the World Trade Organization (WTO) *Agreement on Trade-Related Aspects of Intellectual Property Rights (General Agreements on Tariffs and Trade – Multilateral Trade Negotiations (The Uruguay Round): Agreement on Trade-Related Aspects of Intellectual Property Rights* (1994) recognises in Article 27.1 that, subject to certain limited exceptions, "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". US law, for example, recognises that "[a]ny new and useful process, machine, manufacture, or composition of matter, or any new or useful improvement thereof may be patented" (Patent Act § 101), Section 1(1) UK *Patents Act* 1977 and Art. 52 of the European Patent Convention (EPC) also mentioned new, inventive step and capable of industrial placation as the conditions for granting patent (see Paul Torremans, Holyoak and Torremans, *Intellectual Property Law*, 5th Edition, Oxford University Press, New York, USA, 2008), Bangladesh also follow the conditions of UK for granting patent although its present patent law not specifically mentioned the criteria. However in the draft Patent law, 2001 of Bangladesh included the same criteria as UK law (s.3 of the Draft patent law, 2001).

29 Howard T. Markey (chief judge of the United States Court of Customs and Patent Appeals and later of the Court of Appeals for the Federal Circuit), *Special Problems in Patent Cases*, 66 F.R.D. 529, 1975.

30 M.A, Heller and R.S. Eisenberg, 'Can Patents Deter Innovation? The Anti-commons in Biomedical Research' (1998) 280 *Science* 698-701.

31 Banta, D.H 'Worldwide interest in global access to drugs' (2001) 285 (22) *The Journal of the American Medical Association* 2844-2846.

32 L Ferreira 'Access to affordable HIV/AIDS drugs: the human rights obligations of multinational pharmaceutical corporations' (2002) 71(3) *Fordham Law Review* 1133-1179.

33 India excluded the product patent over pharmaceuticals in its Patent Law of 1970 to allow local pharmaceutical companies to imitate and to increase competition between generic producers. In 1957 The Ayyangar Committee highlighted that foreign multinational held the majority of pharmaceutical patents (80-90%) and maintain monopoly over the pharmaceutical market in India and hence recommended the abolition product patent regime in pharmaceuticals and chemicals. See Aditi Agarwala and Akhil Prasad, 'Patent versus Patients: reflections on blatant patent regime'(2009), 2(2) *International Journal of Liability and Scientific Enquiry*, 149.

34 Peter Drahos, 'Developing Countries and International Intellectual Property Standard Setting' (London 2002) CIPRS Study Paper 8, UK, at 9.

35 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.

36 Edwin Cameron and Jonathan Berger, 'Patents and Public Health: Principle, Politics and Paradox' (December 2004) 1(4) SCRIPT-ed 532.

37 Ibid.

38 Ibid.

39 Ibid.

40 Ibid.

41 M. Boldrin and D. K. Levine, *Against Intellectual Monopoly* (2008) 212-242.

42 Sanjaya Lall, 'Indicators of the Relative Importance of IPRs in Developing Countries' (June 2003) UNCTAD-ICTSD Project on IPRs and Sustainable Development.

43 J. O. Lanjouw, 'The introduction of pharmaceutical product patents in India: Heartless Exploitation of the poor and Sufferings?' (1998), NBER Working Paper no-6366.

44 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.

45 Ashfaque ur Rahman, managing director of Novartis (Bangladesh) Limited (Switzerland-based pharmaceutical company in Bangladesh), said, "Bangladesh will be benefited in terms strength of the sector if patent registration continues. Other countries will evaluate the situation that Bangladesh has a strong base of patent regime and its products carry specific standards." Patenting of any pharmaceutical process is a must to maintain product standards, Rahman added, see for details, *The Daily Star*, Dhaka online edition, March 14, 2008, available at www.thedailystar.net, accessed on March 15, 2009.

46 Ibid.

47 Ibid.

48 Industry Perspectives in :The Future of TRIPs: Impact of the Doha Public Health Declaration, Conference Report, Organised by ICC-The World Business Organisation and American Intellectual Property Law Association, Paris, ICC International Headquarters, Sep 13, 2002, p.9, available at http://www.iccwbo.org/home/intellectual_property/ICC-AIPLA-Report.pdf, accessed on Sep 11, 2009.

49 Correa Carlos, Integrating Public Health Concerns into Patent Legislations in Developing Countries, South Centre, Chemin du Champ d'Anier 17, 1211, Geneva, Switzerland, 2000.

50 But research-based pharmaceutical companies argue that the TRIPs and patents are not an issue. They claim that competition in the pharmaceutical industry is highly effective in reducing prices. They say that there are no patents on over 90% of the drugs on the WHO's Essential Drugs List, which are off-patent, and therefore, can be copied cheaply; see for details, Amir Attaran, 'How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?' *Health Affairs* , Vol. 23, No.3, p.155. For the debate over TRIPs and development issues, see generally, Jonathan Hepburn, 'A TRIPs agenda for development: Meeting food, health and biodiversity needs', A Report of the Conference organised by The Netherlands Ministry of Foreign Affairs and The Quaker United Nations Office (QUNO) Geneva, 2001.

51 Committee on Economic, Social and Cultural Rights, Comment no. 14; K. M. Gopakumar, 'TRIPs Implementation and Public Health Safeguards' in: *South Asian Year Book of Trade and Development*, B.S. Chimni , Mustafizur Rahman and Linu Mathew Philip (eds.), Academic Foundation, New Delhi, 2005, p.233.

52 Major literature relating to economic dimension of multilateral trading system from the perspectives of Bangladesh includes – Muinul Islam, *Prantio Punjibadi Rashtro O Onunnayan Prothongo* (in Bangla) (2003); Abul Kalam, *Globalisation and Bangladesh, Dhaka,* (2002); Abul Kalam, 'Challenges of the Age of Globalisation' in *Spotlight on Regional Affairs (Islamabad)* (May, 2001) vol. XX, no 4; Dr Md Abdul Mannan Choudhury, 'Bishsha Banirjha O Antorjhatic Landenar Arthoniti' (in Bangla) (Rural Economics Program, Department of Economics, University of Chittagong, 1 January 1997); Munim Kumar Barai, 'Economic Liberalisation and Macro Economic stability in Bangladesh: An Overview, (paper presented at a national workshop organised by Bangladesh Institute of International and Strategic Studies (BIISS), Dhaka, 29 February-1 March 2000; Md Shamsul Huq, 'Bangladesh and the Emerging New Global Order' (paper presented in a seminar organised by BIISS, 1 March 2000; Hafiz G A Siddiqui, 'WTO and Economic Security: Bangladesh Perspectives' (paper presented in the BIISS workshop, 29 February 2000; a number of reports and occasional papers published by Center for Policy Dialogue (CPD) from 2000-2008.

53 Major literature relating to trade policy and limited legal policy of multilateral trading system from the perspectives of Bangladesh includes: Dr A.K. Enamul Haque and et al, 'Market Access Issues: EU-Bangladesh Trade Regime – A Case Study on Market Access – Myths and Realities, a report', 2005, Dhaka, Bangladesh; Nurul Islam, *Looking Outward: Bangladesh in the World Economy* (2004); Farhad Mazhar, *Banijja O Bangladesher Jonogon* (In Bangla) (2004); Mahafuz Ullah, *Intellectual Property Rights and Bangladesh* (2002); Nasiruddin Ahmed, *Trade Liberalisation in Bangladesh – An Investigation into Trends* (2001); Sadequl Islam, *The Textile and Clothing Industry of Bangladesh in a Changing World Economy* (2001); D Bhattacharya and R A M Titumir, *Setting the Agenda for the Next WTO Round: Perspectives from Bangladesh on the Seattle Ministerial* (2000); World Bank reports namely 'Bangladesh Trade Liberalization: Its Pace and Impacts' (1999) and 'Bangladesh: Key Challenges for the Next Millennium' (1999); N Ahmed, 'Liberalising Bangladesh External Sector' (paper presented at the International Conference on South Asia held at the University of Sydney, 12-14 September 1997); M I Hossain and M Rahman, M, 'Current External Sector Performance and Emerging Issues' in R Sobhan (ed.), *Growth or Stagnation? A Review of Bangladesh's Development* (1996); M Rahman, 'The GATT URUGUAY ROUND Multilateral Accord: Implications for Bangladesh' in James Love and Mozammel Huq (eds.), *Strategies for Development in Bangladesh* (1995); H Ahammad, 'Foreign Exchange and Trade Policy Issues in a Developing Country: The Case of Bangladesh' (Working Paper 95/1, Canberra Research School of Pacific and Asian Studies, Australian National University, 1995; M Alam, *Trade and Financial Liberalization in Bangladesh* (1995); N Choudhury, 'Impact of GATT Uruguay Round on Bangladesh's External Economy' (report prepared for the World Bank, Dhaka, 1994); R A Mahmood and D K Roy, 'Non Traditional Exports from Bangladesh: Problems and Prospects' (paper prepared for a seminar organized by Export Promotion Bureau, Dhaka, 1994); S H Rahman, 'Trade and Industrialisation in Bangladesh: An Assessment' in G K Helleiner (ed.), *Trade Policy and Industrialization in Turbulent Times* (1994); R Sobhan, *Bangladesh: Problems of Governance* (1994); K H Imam, 'Some Aspects of the Foreign Trade Policies of Bangladesh' in E A G Robinson (ed.), *The Economic Development of Bangladesh* (1974).

54 Major literature deals with issues of TRIPs and pharmaceutical industry in Bangladesh includes – 'Public and Private Sector Approaches to Improving Pharmaceutical Quality in Bangladesh (March 2008) Bangladesh Development Series, Paper No.23', A study by World Bank, available at www.worldbank.org.bd/bds, accessed on June 1, 2009; Mohammad Abu Yusuf and Qamrul Alam, WTO TRIPs Agreement – 'Current state of Pharmaceutical Industry and Policy Options for Bangladesh' (January, 2008) 1(1) International Business Research; S. M. Anowar Uddin, 'TRIPs Waiver but why the Pharmaceutical Medicines hard to get in Bangladesh' (Denmark, 2008) A project report submitted to Roskilde University; 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,the Netherlands; 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,; Md. Farhad Hossain Khan, 'IP Administration and Enforcement System :Towards Modernisation of IP Protection in Bangladesh and A Comparative Analysis of IP Administration between Japan and Bangladesh' (April 1-September 30, 2004), Tokyo Institute of Technology, Japan; Professor Tony VanDuzer, TRIPs and Pharmaceutical Industry in Bangladesh: Towards a National Strategy, (Paper 24, April, 2003) Centre for Policy Dialogue(CPD), Dhaka, Bangladesh, Md. Shah Amran, TRIPs, Pharmaceuticals and Bangladesh, available at www.bangladeshinfo.com/news/special16.php, accessed on 28 March 2009.

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61 Padmashree Gehl Sampath, 'Intellectual Property in Least Developed Countries: pharmaceutical, agro-processing, and textiles and RMG in Bangladesh' (2007), a background paper for The Least Developed Countries Report, background paper no-9, UNCTAD.

62 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.

63 Ibid.

64 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.

65 Md. Shah Amran, TRIPs, Pharmaceuticals and Bangladesh, available at www.bangladeshinfo.com/news/special16.php, accessed on 27 March 2009.

66 Ibid.

67 Syed Farhat Anwar, 'Pharmaceutical Sector of Bangladesh: Trade Prospects with Nepal and the Impact of TRIPs' in *Towards Greater Sub Regional Economic Cooperation: Limitation, Obstacles and Benefits*, Forrest E Cookson, A. K. M. Shamsul Alam (eds.), University Press Limited, Dhaka, 2002.

68 Public and Private Sector Approaches to Improving Pharmaceutical Quality in Bangladesh, Bangladesh Development Series, Paper No.23, a study by World Bank, March 2008, available at www.worldbank.org.bd/bds, accessed on 1 June 2009.

69 Alternative mechanisms such as export-led improvement, regulatory-led quality improvement, competition-led quality improvement, private sector-led improvement and knowledge transfer-led improvement.

70 Tony VanDuzer, 'TRIPs and Pharmaceutical Industry in Bangladesh: Towards a National Strategy', Paper 24, April, 2003, Centre for Policy Dialogue(CPD), Dhaka, Bangladesh.

71 Mohammad Abu Yusuf and Qamrul Alam, 'WTO TRIPs Agreement – Current State of Pharmaceutical Industry and Policy Options for Bangladesh', International Business Research, Vol. 1, No. 1, January, 2008.

72 The LDCs in the Asia-Pacific region are: Afghanistan, Bangladesh, Bhutan, Cambodia, Kiribati, Lao People's Democratic Republic, Maldives, Myanmar, Nepal, Samoa, Solomon Islands, Timor-Lesté, Tuvalu, and Vanuatu.

73 The African LDCs are: Angola, Benin, Burkina Faso, Burundi, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, The Gambia, Guinea, Guinea-Bissau, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Niger, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Somalia, Sudan, Tanzania, Togo, Uganda and Zambia.

74 Dr Tandi Dorji, 'Effect of TRIPs on Pricing, Affordability and Access to Essential Medicines in Bhutan', *Journal of Bhutan Studies*, Volume 16, Summer 2007, Bhutan, pp.128-141.

75 On the other hand, having no pharmaceutical capacity Bhutan may not utilise the Doha waiver for LDCs.

76 Amal Nagah Elbeshbishi, 'TRIPs and Public Health -What Should African Countries Do?', African Trade Policy Centre (ATPC), Work in Progress No. 49, Jan, 2007.

77 Patent protection and access to HIV/AIDS pharmaceuticals in Sub-Saharan Africa, a report prepared for the World Intellectual Property Organisation (WIPO), 2000.

78 P. Gehl Sampath, 'Economic Aspects of Access to Medicines Post-2005: Product Patent Protection and Emerging Firm Strategies in the Indian Industry', Background Study: Commission on Intellectual Property Rights, Innovation and Public Health, WHO, Geneva, 2005 and P. Gehl Sampath, 'India's Product Patent Protection Regime: Less or More of "Pills for the Poor"?' (2006) 9(6) *The Journal of World Intellectual Property*, pp.694–726.

79 J.O. Lanjouw, 'The Introduction of Product Patents in India: Heartless Exploitation of the Poor and Suffering?' (1998) Yale University, and NBER Working Paper No. 6366.

80 C. Grace, 'Update on China and India and Access to Medicines Briefing Paper' (DFID/HSRC, London November, 2005), 1–42.

81 S. Choudhuri, P. Goldberg et al, 'Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India (2004).

82 C. Fink, 'How Stronger Patent Protection in India Might Affect the Behaviour or Transnational Pharmaceutical Industries' (2000) The World Bank Working Paper No. 2352, The World Bank.

83 J. Watal, 'Introducing Product Patents in the Indian Pharmaceutical Sector: Implications for Prices and Welfare'(1999) 20 World Competition 5–21.

84 S. Arvind, 'Putting Some Numbers on the TRIPs Pharmaceutical Debate'(1995) 10 *International Journal of Technology Management*, 252–68.

85 A. Subramanian, 'Putting Some Number on the TRIPS Pharmaceutical Debate' (1995) 10 *International Journal of Technology Management*, 252–68.

86 A. Naomi Bass, 'Implications of the TRIPs Agreement for developing countries: Pharmaceutical patent laws in Brazil and South Africa in the 21st Century' (2002) *George Washington International Law Review*.

87 Ibid.

Appendix 10: Journal Article-2 (LAWASIA Journal Vol. 2010)

TRIPS COMPLIANT PATENT LAW AND THE PHARMACEUTICAL INDUSTRY IN BANGLADESH: CHALLENGES AND OPPORTUNITIES

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1. INTRODUCTION

Before the creation of the World Trade Organisation (WTO),[1] individual countries were free to determine their own intellectual property law regime, including the framework relating to the recognition and protection of patents. This environment has now changed. One of the WTO agreements, the *Agreement on Trade Related Aspects of Intellectual Property Rights* (TRIPS) aims at establishing minimum standards for intellectual property rights (IPRs) including patent protection for pharmaceuticals. Developing and Least Developed Countries (LDCs) are apprehensive[2] of strong patent protection as such patent protection may be harmful to the nascent stage of their pharmaceutical industries and may have negative medicine-access consequences for their populations.[3] To address such concerns, the Doha Declaration was adopted by the WTO Ministerial Conference on 14 November 2001. The Doha Declaration extended the transition period for LDCs to introduce pharmaceutical patent protection to 1 January 2016. Therefore, being an LDC Bangladesh is able to produce generic versions of patented medications until 1 January 2016.

This article will explore the challenges and opportunities for Bangladesh, with a focus on the pharmaceutical industry, as Bangladesh moves towards the requirement of being compliant with the TRIPS Agreement by 2016. This article highlights that much rests with the Government of Bangladesh to decide upon a policy direction during the transition period so that Bangladesh is appropriately positioned for 1 January 2016. Consequently, the article suggests that Bangladesh not seek to be TRIPS compliant prior to the expiration of the transition period. Rather Bangladesh should utilise both the period of time available and the flexibilities available under the TRIPS Agreement to ensure that the opportunities identified by the article are captured so that strategies can be put in place to minimise the challenges identified.

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[1] The setting up of the WTO (World Trade Organisation) was agreed to by 125 countries on 15 April 1994 at a conference in Marrakesh, Morocco. The creation of the WTO was to replace looser arrangements for the conduct of international trade originally embodied in the General Agreement on Tariffs and Trade of 1947 (GATT): <http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm>.

[2] See generally, Vandana Shiva, *Protect or Plunder* (2001) and Edwin Mansfield, 'Patents and Innovation: An Empirical Study' (1986) 32(2) *Management Science* 181.

[3] 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 as they will be prevented by the patent holder: 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 Journal of Current International Legal Issues* 3.

2. THE POSITION OF BANGLADESH – PATENT PROTECTION AND PHARMACEUTICAL REGULATION

The WTO serves as the governing body of the post-war international trading system and provides a constitution to regulate trade between members.[4] Among the WTO Agreements, the TRIPS agreement has been described by Peter Drahos and John Braithwaite as, 'probably the most important international intellectual property agreement that was signed in the 20th century'.[5] This is because the implementation of the TRIPS agreement, particularly in the context of Bangladesh as an LDC,[6] will require a reorganisation and restructuring of the country's intellectual property regime. A pressing concern is the need to consider Bangladesh's legislative and policy framework as it relates to the recognition and enforcement of pharmaceutical patents.

Although Bangladesh's intellectual property laws are often considered outdated and enforcement as being weak,[7] Bangladesh has never been on the United States trade representatives 'Special 301 Watch List'.[8] Bangladesh inherited its patent law from the then British Government whilst in power in India. Bangladesh still continues with essentially the same law; only a few minor amendments have been made since enactment of the legislation. The present legislative regime comprises the *Drugs Act 1940*, the *Patents and Designs Act 1911* and the *Patent and Design Rules 1933*. In 2003 amendments were made to the *Patents and Designs Act 1911* to establish the Department of Patents, Designs and Trade Marks. The Department of Patents, Designs and Trade Marks is controlled by the Ministry of Industries and has jurisdiction to issue patents and designs.[9] The current law in Bangladesh with respect

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[4] See Peter Drahos, 'Global Property Rights in Information: The Story of TRIPS at the GATT' (1995) 13(1) *Prometheus* 6-19.

[5] Peter Drahos and John Braithwaite, 'Intellectual Property, Corporate Strategy, Globalisation: TRIPs in Context' (2002) 20 *Wisconsin International Law Journal* 451-455.

[6] There are no WTO definitions of 'Developed', 'Developing' or 'Least Developed' countries. The WTO recognises as Least Developed Countries those countries which have been designated as such by the United Nations. According to the United Nations, Least Developed Countries are countries which exhibit the lowest indicators of socioeconomic development, with the lowest Human Development Index ratings of all countries in the world. A country is classified as a Least Developed Country if it meets three criteria based on low income (three-year average GNI per capita of less than US $750, which must exceed $900 to leave the list), human resources weakness (based on indicators of nutrition, health, education and adult literacy) and economic vulnerability (based on instability of agricultural production, instability of exports of goods and services, economic importance of non-traditional activities, merchandise export concentration, handicap of economic smallness, and the percentage of population displaced by natural disasters). However countries can 'graduate' out of the LDC classification when indicators exceed these criteria. See for details, Criteria for LDCs, <http://www.un.org/special-rep/ohrlls/ldc/ldc%20criteria.htm>.

[7] Mohammad Monirul Azam, 'Journey towards WTO Legal System and the experience of Bangladesh: the Context of Intellectual Property' (Paper accepted for presentation at the Society of International Economic Law's 2010 Conference, Barcelona, 2010).

[8] This List identifies countries that deny what the United States Trade representative considers adequate and effective protection for intellectual property rights. For details see: Special 301 Report, 2009, <http://www.ustr.gov/about-us/press-office/reports-and-publications/2009/2009-special-301-report>.

[9] Padmashree Gehl Sampath, 'Innovation and Competitive Capacity in Bangladesh's Pharmaceutical Sector' (Working Paper No #2007-031, United Nations University-Maastricht Economic and Social Research and Training Centre, 2007).

to patents is largely the same as it was in India, when India moved to meet the requirements of TRIPS in 2005.[10]

In common with other countries, Bangladesh follows a process for the granting of a patent and has criteria for 'something' to be able to be patented: novelty, inventive step and industrial application.[11] When an application is made by the first and true inventor or their assignee/legal representative, an examination of the specification commences. An examination of the specification can trigger either one of three outcomes: (i) the specification is correct and the invention is patent-worthy, (ii) the specification does not reflect any new invention therefore is rejected or (iii) the specification is accepted subject to modification or amendment. There are provisions for appeal to the Registrar and further to the High Court Division of the Supreme Court. Any amendments or modifications may be made to the original patent under an application for patents of addition.[12] If an application is successful without objection, or if an objection is found not to be justified, the Department of Patents, Designs and Trade Marks will issue a certificate of patent registration. Once granted, a patent is valid for 16 years from the date of application.[13]

There have been disputes among scholars in Bangladesh about the patentability of pharmaceutical products under the *Patents and Designs Act 1911*.[14] Some consider that a policy of patenting pharmaceutical processes but not of pharmaceutical products should be adopted in Bangladesh.[15] Whilst other scholars argue that in the absence of a clear legislative provision or any court ruling on the distinction between processes and products that both pharmaceutical products and processes are patentable under the *Patents and Designs Act 1911*.[16] To some extent this is a purely academic debate as in 2008 the Department of Patents, Designs and Trade Marks suspended the patenting of pharmaceuticals in Bangladesh until 1 January 2016 in accordance with the Doha Declaration.[17] The Department's notification provides that applications relating to patents for medicines and agricultural chemicals will be preserved in a 'mail box' to be considered after January 2016.

Prior to the suspension of processing applications, the available information indicates that, on average, the Department of Patents, Designs and Trade Marks issued 300

[10] Ibid.
[11] Mohammad Monirul Azam, *Intellectual Property, WTO and Bangladesh* (2008) 270.
[12] *Patents and Designs Act 1911*(Bangladesh) s 15A.
[13] *Patents and Designs Act 1911*(Bangladesh) s 14.
[14] Section 2(10) of the *Patents and Designs Act 1911* (Bangladesh) provides that the term 'manufacture' includes any art, process or manner of producing, preparing or making an article, and also any article prepared or produced by manufacture. Md. Mahboob Murshed, 'Trips Agreement and patenting of pharmaceutical products', *The Daily Star* (Dhaka), 3 August 2006 <http://www.thedailystar.net/law/2006/08/03/index.htm> .
[15] Ulrike Pokorski da Cunha, *Study on the Viability of High Quality Drugs Manufacturing in Bangladesh* (2007), a study commissioned by Federal Ministry for Economic Cooperation and Development, GTZ, Germany.
[16] Md. Mahboob Murshed, 'Trips Agreement and patenting of pharmaceutical products', *The Daily Star* (Dhaka), 3 August 2006 <http://www.thedailystar.net/law/2006/08/03/index.htm> .
[17] Jashim Uddin Khan, 'New Patent rights of Drug suspended', *The Daily Star* (Dhaka), 14 March 2008 <http://www.thedailystar.net/story.php?nid=27621>.

patents for formula and products a year and that 90 per cent of those patents were owned by multinational corporations.[18] In 2007, the Department registered 225 foreign patent applications of which 50 per cent related to multinational pharmaceutical formulas.[19] Table 1 depicts in tabular form the number and type of patents granted in Bangladesh. It is suggested that nearly 50 per cent of the patents refer to pharmaceutical patents.[20]

Table 1: Patents Granted in Bangladesh from 2001-2008

Year	Applications Filed			Applications Accepted		
	Local	Foreign	Total	Local	Foreign	Total
2001	56	239	295	21	185	206
2002	43	246	289	24	233	257
2003	58	260	318	16	206	222
2004	48	268	316	28	202	230
2005	50	294	344	21	161	182
2006	23	287	310	16	146	162
2007	10	225	325	27	269	296
2008	60	278	338	01	36	37

Source: Department of Patents, Designs and Trade Marks of Bangladesh and Directorate of Drug Administration (DDA) of Bangladesh.

In addition to the *Patents and Designs Act 1911* the legislative framework with respect to pharmaceuticals also requires a consideration of the *Drugs Act 1940*. The *Drugs Act 1940* is an Act that regulates the import, export, manufacture, distribution, and sale of pharmaceuticals in Bangladesh. The Act was originally enacted by the Government of India in 1940, was then adopted by the Pakistan Government in 1957 and subsequently adopted in Bangladesh in 1974. The *Drugs Act 1940* permits the

[18] Nazmul Hasan, 'General Secretary, Bangladesh Association of Pharmaceuticals Industries General Secretary', *The Daily Star* (Dhaka), 14 March 2008 <http://www.thedailystar.net/story.php?nid=27621> .

[19] Ibid.

[20] See Jashim Uddin Khan, 'New Patent rights of Drug suspended', *The Daily Star* (Dhaka), 14 March 2008 <http://www.thedailystar.net/story.php?nid=27621> and 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, 2008) <http://www.afriblog.com/blog.asp?code=Yacou&no_msg=8705>.

import of certain classes of pharmaceuticals only under the licenses or permits issued by the relevant authority appointed by Government.[21]

All classes of pharmaceuticals imported into the country are required to comply with the prescribed standards and are to be labelled and packed in the prescribed manner.[22] Licenses are also required for the manufacture and for the sale or distribution of pharmaceuticals in Bangladesh.[23] Further control over manufacturing and sales is exercised by periodic inspection of licensed premises.[24] Surveillance of the standard of pharmaceuticals is maintained by taking samples from pharmaceuticals manufactured or offered for sale for testing in the Central Drugs Laboratory.[25] The Act also establishes a Drugs Technical Advisory Board and a Drugs Consultative Committee. The Drugs Technical Advisory Board advises the government on technical matters arising out of the enforcement and administration of the Act. The Drugs Consultative Committee was established to advise the Government and the Board and to ensure the proper application and functioning of the Act throughout the country. In addition to the *Drugs Act 1940,* the operation of pharmaceutical industry and quality of medicines in the local market in Bangladesh is also controlled by the *Drugs Control Ordinance 1982.*

The *Drugs Control Ordinance 1982* regulates the manufacture, import, distribution, and sale of pharmaceuticals in Bangladesh. Under the Ordinance, (i) no medicine of any kind can be manufactured for sale or be imported, distributed or sold unless it is registered with the licensing authority; (ii) no drug or pharmaceutical raw material can be imported into the country except with the prior approval of the licensing authority; (iii) the licensing authority cannot register a medicine unless such registration is recommended by the Drug Control Committee; (iv) the licensing authority may cancel the registration of any medicine if such cancellation is recommended by the Drug Control Committee on finding that such a medicine is not safe, efficacious or useful; (v) the licensing authority is also empowered to temporarily suspend the registration of any medicine if it is satisfied that such a medicine is substandard; (vi) the government may, by notification in the official gazette, fix the maximum price at which any medicine may be sold and at which any pharmaceutical raw material may be imported or sold; (vii) no person is allowed to manufacture any pharmaceuticals except under the personal supervision of a pharmacist registered in Register 'A' of the Pharmacy Council of Bangladesh; (viii) no person, being a retailer, is allowed to sell

[21] *Drugs Act 1940* (Bangladesh) ch III.

[22] *Drugs Act 1940* (Bangladesh) s 8(1) provides that the expression 'standard quality' when applied to a drug means that the drug complies with the standard set out in the Schedule of the Act. Again s 10 of the Act prohibits the import of certain drugs such as (a) any drug which is not of standard quality, drugs, (b) any misbranded drug and (c) any drug for the import of which a licence is prescribed, otherwise than under, and in accordance with, such licence etc.

[23] *Drugs Act 1940* (Bangladesh) ch IV.

[24] *Drugs Act 1940* (Bangladesh) ss 21-22.

[25] *Drugs Act 1940* (Bangladesh) s 35 provides that, 'no patent or proprietary medicine or pharmaceutical specialty or any other medicine, whether allopathic, unani, and Ayurvedic (some form of traditional medicines), homoeopathic or biochemic, for the time being not recognised by the accepted pharmacopoeias. shall be offered for sale to the public or advertise for such sale, unless two samples thereof shall have been sent to the Director Central Drug Laboratory, and the later shall have determined that the medicine or specialty is suitable or proper for use by the public.'

any pharmaceutical without the personal supervision of a pharmacist registered in any Register of the Pharmacy Council of Bangladesh; and (ix) the government may, by notification in the official Gazette, establish Drug Courts as and when it considers necessary.[26] Notably, combination pharmaceuticals are not considered therapeutically useful and are therefore not allowed in Bangladesh.[27] This was a useful simplification when the Ordinance was drafted; however, nowadays it is obsolete and hampers the manufacturing of useful (often patented) combination therapies.[28] Apart from this limitation, the *Drug Control Ordinance 1982* also has other limitations so the Government of Bangladesh formulated a National Drug Policy in 2005.

The National Drug Policy 2005 was formulated by the Government of Bangladesh to take advantage of the opportunities available to Bangladesh under the transition period leading to the implementation of TRIPS. In particular, and relevantly, the Policy was formulated with the following objectives:

(i) to make it more applicable, effective and adaptive to the remarkable technological advancements that have been made in the medicine world;

(ii) to guide the Drug Sector of the country to perform better in the competitive world market;

(iii) to make the country a producer and exporter of good quality drugs in the world;

(iv) to ensure that the common people have easy access to useful, effective, safe and good quality essential and other drugs at affordable prices;

(v) to strengthen the Directorate of Drug Administration by raising its status to that of a Directorate General of Drug Administration with corresponding increase in its manpower and infra-structure facilities to make it more effective as a Drug Regulatory Authority (DRA);

(vi) to update, from time to time, the criteria of registration for import of all systems of medicines in line with the quality guidelines followed in developed countries to ensure safety, efficacy and usefulness of such medicines;

(vii) to provide, on a priority basis, required services and facilities to local drug manufacturing industries of all the recognized systems of drugs so that self-sufficiency is attained in the manufacture of both drugs and pharmaceutical raw materials;

[26] *Drug Control Ordinance 1982* (Bangladesh) s 23.
[27] See, 'Public and Private Sector Approaches to Improving Pharmaceutical Quality in Bangladesh' (Bangladesh Development Series Paper No #23, The World Bank, 2008) <www.worldbank.org.bd/bds>.
[28] Ibid.

(viii) to encourage all local and foreign companies to manufacture good quality essential drugs in adequate quantities in the country;

(ix) to continue the current system of controlling prices of the commonly used essential drugs as listed and updated from time to time by the Government;

(x) to encourage foreign companies to invest, manufacture and sell drugs in Bangladesh with corresponding assurance of transfer of new technology and technical knowledge in the country;

(xi) to ensure that no discrimination is made between the local and multinational companies, which have manufacturing plants in Bangladesh while applying the principles of this policy; and

(xii) to encourage both local and multinational manufacturers to establish fully fledged Research and Development (R & D) facilities in the country.[29]

Each of these matters desperately needs the attention of the Government of Bangladesh to ensure that the interests of pharmaceuticals producers are balanced against the need to ensure access to pharmaceuticals for the local population in a post-2016 TRIPS compliant regulatory environment. The urgent need to consider the implementation of such policy measures in anticipation of 2016 is highlighted by the importance of the pharmaceutical industry to Bangladesh.

3. THE POSITION OF BANGLADESH – THE IMPORTANCE OF ITS PHARMACEUTICAL INDUSTRY

The pharmaceutical industry of Bangladesh began in the 1950s when a few multinationals and local entrepreneurs set up manufacturing facilities in what was then East Pakistan. Now 245 companies are listed with the Directorate of Drug Administration in Bangladesh to produce medicines in Bangladesh.[30] The industry currently is the second largest taxpayer and meets 97 per cent of local pharmaceutical requirements.[31] The pharmaceutical industry is represented by all three sectors: private enterprises, the state-owned Essential Drug Company Limited and *'Ganashastha Kendra'* (GK) as a representative of the civil society.[32]

According to the June 2009 Business Monitor International Report, in 2008 Bangladesh had a domestic pharmaceutical market worth US$ 858 million.

[29] National Drug Policy 2005 (Bangladesh).

[30] See the website of the Directorate of Drug Administration of Bangladesh at <http://www.ddabd.org/allopathic.htm> .

[31] The remaining 3 per cent consists of imported hi-tech products like insulin, other hormonal products, anti-cancer products, blood components/derivatives infusions. See, Sayedul Islam, *Bangladesh Zooms in Pharma as Priority Sector* (27 July 2006) <http://www.pharmabiz.com/redfr.asp?fn=/brief/about.asp&title=About%20Pharmabiz>.

[32] See Ulrike Pokorski da Cunha, *Study on the Viability of High Quality Drugs Manufacturing in Bangladesh* (2007) Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) <http://www.gtz.de/de/dokumente/en-high-quality-drugs-bangladesh-2007.pdf>.

According to IMS Health Data research the market size of Bangladesh, with nearly 250 pharmaceutical companies, had grown by 16.83 per cent in 2009.[33] Remarkably, the pharmaceutical market in Bangladesh is mostly dominated by local enterprises.

In addition to meeting local needs, Bangladesh exports a wide range of pharmaceutical products (therapeutic class and dosage forms) to 72 countries[34] in Asia, Africa and Europe and in 2006-2007 total exports were US$28.12 million with a growth rate of some 47 per cent.[35] Bangladesh also exports specialised products like Hydro-Fluoro-Alkaline inhalers, suppositories, hormones, steroids, oncology and immunosuppressant products, nasal sprays, injectibles and intra-venous infusions.[36] 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/AIDS[37] and anti-Bird-Flu drugs. Some of the most stringent regulatory authorities in the world have approved Bangladeshi pharmaceutical companies for export.[38]

Among the 49 countries classified as an LDC[39] Bangladesh is the only country which has the pharmaceutical manufacturing capability to be (nearly) self-sufficient in pharmaceuticals.[40] Bangladesh's pharmaceutical industry now caters to 97 per cent of the country's pharmaceutical needs and is worth about US$858 million.[41] These figures represent Bangladesh's ability to still produce generic versions of patented medications so as to service the pharmaceutical needs of other poorer countries with no or low manufacturing capacity.[42] It is because of these economic and health reasons that it is important to explore how Bangladesh can exploit the opportunities available to it during the TRIPS transition period whilst also considering how it can implement a TRIPS compliant patent regime. The implementation issue is of significance as the regime post-2016 needs to balance the (economic) interests of pharmaceuticals producers with the (social) need to ensure access to pharmaceuticals for the local population.

Despite having impressive growth of sales in the local market and export of pharmaceuticals from Bangladesh over the years, there is uncertainty and tension

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[33] '*Pharma record double-digit growth*', Bangladesh Weekly Market Review (Dhaka), 20 February, 2010 <http://www.aims-bangladesh.com/admin/publication/558%20weekly%20feb%2022-2010.pdf>.
[34] Directorate of Drug Administration of Bangladesh <http://www.ddabd.org/exporting_country.htm> .
[35] Nazmul Hasan, *Bangladesh-An Emerging Country for Generics* <http://www.jacobfleming.com/buxus/docs/downloads/case-study-smgenerics-nazmul-hassan-finalapproed.pdf>.
[36] Ibid.
[37] Ibid.
[38] Such as the Gulf Central Committee for Drug Registration, the Therapeutic Goods Administration of Australia, the Medicines and Healthcare products Regulatory Agency (MHRA) for the United Kingdom and United States' Food and Drug Administration. These bodies have already issued Good Manufacturing Practice (GMP) clearance to many local pharmaceutical companies in Bangladesh.
[39] Of those 49 countries 32 are WTO members.
[40] Mohammad Abu Yusuf and Qamrul Alam, 'WTO TRIPS Agreement-Current state of Pharmaceutical Industry and Policy Options for Bangladesh' (2008) 1(1) *International Business Research* 22-3.
[41] Sayedul Islam, above n 31.
[42] Anne St. Martin, *The Impact of Trade Related aspects of Intellectual Property Rights (TRIPS) on Access to Essential Medicines in the Developing World*, (Research Project Report, Worcester Polytechnic Institute, 2006) 2.

between stakeholders (pharmaceutical companies, Government officials, public health experts and intellectual property and pharmaceutical technology academics) with respect to two questions. [43] The first being a question of what opportunities are available for Bangladesh given that Bangladesh is allowed to produce generic forms of patented pharmaceuticals until 1 January 2016. The second being a question of what challenges exist for Bangladesh to make the transition to post TRIPS pharmaceutical patent regime from 1 January 2016.

4. OPPORTUNITIES AND CHALLENGES FOR THE PHARMACEUTICAL INDUSTRY IN BANGLADESH

Given the extension for TRIPS compliance granted to LDCs, Bangladesh is free to continue to permit the importation of generic pharmaceuticals and is free to produce and sell generic pharmaceuticals in its domestic market. [44] Given this present ability there would seem to be no impetus to bring forward a compliance with TRIPS. However, in saying that, generic products produced and manufactured by Bangladesh cannot be exported to other national markets where patent protection exists and the Bangladesh-based company does not have patent permission with respect to the pharmaceutical product. Consequently, during the transition period export markets are limited to those markets in which patent protection is not provided. Notwithstanding, there are ways by which to generate export opportunities so as to facilitate local production and development of Bangladesh's pharmaceutical sector. Arguably, the opportunities need to be developed and exploited during the remaining transition period as the opportunities may be curtailed or unavailable in a TRIPS compliant environment. Much depends upon the policy direction taken by the Government. In some areas the Government has taken action to support local participation in joint ventures with foreign companies and toll manufacturing for foreign companies. There is also further room for the Government to manoeuvre within the area of compulsory licensing.

In the context of joint ventures as an opportunity for Bangladesh during the transition period large foreign pharmaceutical companies from highly regulated markets are actively looking for joint venture projects in developing and LDCs. Several contracts have reportedly been signed between Bangladesh and some Indian and Chinese pharmaceutical companies. Bangladesh has the ability to manufacture active pharmaceutical ingredients for foreign companies for export. To that extent, the Government of Bangladesh has already taken the initiative using the National Drug

[43] Nazmul Hasan, Chief Executive Officer of Beximco and Secretary of the Bangladesh Association of Pharmaceutical Industries, *Export Opportunities in Pharmaceuticals from 2005,* text document on file with Monirul Azam. He considers that, 'Pharmaceuticals manufacturing opportunities in Bangladesh are brighter than ever because of the country's Least Developed Country (LDC) status until 2016, this is a win-win situation for both Bangladesh and foreign pharmaceutical or investment companies because investors/companies will get high return on their investment and this will create high paid jobs in Bangladesh.' He further added that, 'the cost of medicines has increased in China and India since they entered the WTO. Bangladesh has a unique opportunity to pare the costs of manufacturing medicines due to the low-cost high-qualified manpower and its LDC status.'

[44] Countries like India and China are no longer allowed to produce generic forms of patented drugs having become TRIPS compliant.

Policy 2005 to set up an active pharmaceutical ingredients park to facilitate the production of raw materials and finished products. Similarly, toll manufacturing for foreign companies is an opportunity which should be exploited during the transition period.

Toll manufacturing is a contract to manufacture a finished or semi-finished product for a client company. It is also referred to toll processing, tolling, toll conversion, contract manufacturing or custom manufacturing and can be defined as performing a service for a fee (toll). Toll manufacturing saves the client company capital investment as the toll manufacturer already has the plant and equipment necessary to make the product.[45] Toll manufacturing can take advantage of financial and tax incentives available in various markets.[46] Toll manufacturing presents an option[47] for Bangladesh as Bangladesh has a very strong manufacturing base in pharmaceutical products and its manufacturing costs are less expensive than other countries.[48] The further exploitation of the compulsory licensing regime is another alternative that should be pursued by the Government.

Compulsory licences are available to permit the manufacturing and export of patented products to any country having insufficient or little manufacturing capacity in the pharmaceutical sector without the need to comply with patent conditions.[49] The purpose of a compulsory licence is to address any public health problems that may be present in a particular country. Considering Bangladesh's pharmaceutical and manufacturing expertise Bangladesh could be ideally placed to increase its capacity to produce pharmaceuticals under compulsory licenses for the benefit of other countries without the need to be TRIPS compliant. Whilst these represent opportunities for Bangladesh during the transition period where generic pharmaceuticals can be produced and manufactured there are concomitant challenges that exist. The challenges include the risk of producing substandard products, the complexities of export registration, the lack of existing testing labs, the lack of local investment in research and development and pricing anomalies. These challenges need to be overcome in the long-term and require the Government to put strategies to be put in place. Again, given these challenges there is little for Bangladesh to gain from moving to a TRIPS compliant regime before 1 January 2016.

In particular, the Directorate of Drug Administration will play an important role in the management, investigation and enforcement of pharmaceutical standards. Much capacity building needs to take place within the Directorate for it to be fully resourced

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[45] *What is Toll Manufacturing?* <http://www.fhsons.com/toll.htm> .

[46] See Nazmul Hasan, 'Future Prospects of Pharmaceutical Industry in Bangladesh' (Speech delivered in Bangladesh, 12 October 2009). Presentation on file with Monirul Azam.

[47] In 2004, the market for contract manufacturing of prescription drugs alone was about US$ 26 billion, and expected to grow to US$ 44 billion by 2009. Data Monitor, (2005) <http://www.datamonitor.com/store/Browse/?Ntt=Pharmaceutical+Industry+of+Bangladesh+&Ntk=title>.

[48] Some bigger pharmaceutical companies in Bangladesh such as Square and Beximco have already started toll manufacturing.

[49] Syed Farhat Anwar, 'Pharmaceutical Sector of Bangladesh: Trade Prospects with Nepal and the Impact of TRIPS' in Forrest E Cookson and AKM Shamsul Alam (eds), *Towards Greater Sub Regional Economic Cooperation: Limitation, Obstacles and Benefits*, (2002), ch 6.

(human resources and technical resources) to meet this challenge. Along with the challenge of meeting accepted standards there needs to be a Government strategy to ensure that the necessary facilities exist in Bangladesh to obtain export registration.

To obtain export registration, many countries require bio-equivalence, bio-availability tests and clinical trial reports. Most Bangladeshi companies however do not have the facilities to undertake such testing. The costs of associated with implementing such a testing and documentary system are expensive. This is a major drawback for small to medium size pharmaceutical companies in Bangladesh.[50] The availability of pharmaceutical related testing facilities is an ongoing challenge which will need to be met prior to Bangladesh being able to engage in a post-TRIPS environment.

Bangladesh has only two pharmaceutical testing laboratories; one is in Dhaka and the other is located in Chittagong. These two laboratories are not equipped with sufficiently modern instruments to carry out all the tests required for pharmaceutical products.[51] Put simply, only having these two laboratories is not enough to monitor and check the quality status of products of large number of pharmaceutical companies in Bangladesh. The Government of Bangladesh needs to consider a program of building the facilities needed not only for compliance but to maintain any momentum garnered as Bangladesh takes the opportunities afforded to it during the transition period. This then highlights the need for an embedded R&D program. At this stage for Bangladesh the lack of investment in R&D represents a challenge for the future.

It is suggested that local pharmaceutical companies in Bangladesh do not invest enough in R&D to create and produce new medicines. Consequently, the ability to apply for new pharmaceutical patents is unavailable. This in itself creates a barrier for the local pharmaceutical industry in Bangladesh and will become an impediment in a post-TRIPS environment. There is an evident tension between the current capacity of the industry (pre-TRIPS position) and its potential to develop and change. Samson H Choudhary, the CEO of Square Pharmaceuticals, commented in 2009 that the National Drug Policy as pursued in Bangladesh while encouraging local industry, also took away the opportunity for technological advancements and developments in the industry.[52]

Unfortunately there appears to be a lack of imperative to increase and encourage investment in R&D. There are no Government initiatives in place to support or promote R&D. The failure to support and promote R&D is a major barrier for the post-TRIPS survival of the pharmaceutical industry in Bangladesh. A further challenge is pharmaceuticals coming into Bangladesh from other developing

[50] Although some leading local pharmaceutical companies like Beximco and Square have gained registration for export to highly regulated countries like the United States of America, the United Kingdom, Austria and Australia.
[51] Such as bio-equivalency tests, bio-availability tests and the conduct of clinical trials.
[52] Samson H Choudhary, (Speech delivered at the Bangladesh Pharmaceutical Expo, Bangladesh, 22 January 2009).

countries.[53] A failure to prevent entry of other pharmaceuticals into the Bangladeshi market may jeopardise the survival of the local pharmaceutical industry. This is particularly the case where substandard pharmaceuticals are sold at a cheaper price than local pharmaceuticals. Price anomalies within the marketplace are a challenge which requires Government intervention and strong policy stance to be taken.

Whilst there are no pharmaceutical pricing control mechanisms under the *Patents and Designs Act 1911* the *Drug Control Ordinance 1982* permits the fixing of pharmaceutical prices by Government committee.[54] At this point in time, all essential medicines listed by the Directorate of Drug Authority in Bangladesh are subject to fixed pricing.[55] This is a vital guarantee that the prices of pharmaceuticals, whether produced nationally or imported from outside, will not increase without prior Government authorisation.[56] Furthermore, it is within the Government's purview to refuse the registration of any pharmaceuticals that are regarded as too expensive or unaffordable.[57]

In 1982, 150 pharmaceuticals were defined as essential pharmaceuticals[58] and any changes to prices were decided by the Drug Control Committee. Since 1993 however, the number of price-controlled pharmaceuticals has reduced to 117 primary health care pharmaceuticals. For pharmaceuticals that do not fall into this controlled category the manufacturer is able to set the price of the pharmaceutical. This does not mean that an exorbitant price can be set by a manufacturer as the price must be approved (but not controlled) by the Drug Control Committee.[59]

However, the reality in Bangladesh is that companies are selling the same generic pharmaceutical (same dosage and strength) at different prices.[60] These anomalies in price hampers the local pharmaceutical market as the manufacturers of (higher) quality medicines find it difficult to market against the lower priced competitors. If the pricing anomaly situation persists without regulation by Government authorities it becomes difficult for those pharmaceutical companies affected to make economies of scale and support innovation and development. A pricing control system is consistent with the TRIPS Agreement[61] which allows members to adopt measures necessary to protect public health and nutrition. Bangladesh needs to redesign its pharmaceutical pricing system to prevent anomalies of pricing in the local market as a support

[53] There are different reports as it is not an easy amount to quantify but it is estimated that the value of substandard pharmaceuticals entering into the Bangladeshi market is about US$100-200 million annually.
[54] *Drug Control Ordinance 1982* (Bangladesh) s 11.
[55] Fixed pricing is determined on the recommendation of the Drug Price Committee as established by the Ministry of Health: *Drug Control Ordinance 1982* (Bangladesh) ss 11 and 25.
[56] No drug can be introduced in the market without prior approval from Drug Control Committee and a price fixed by the Drug Price Committee.
[57] *Drug Control Ordinance 1982* (Bangladesh) s 11.
[58] Bangladesh, *Drug Control Committee,* Report No 1 (1982).
[59] Drug Control Committee is constituted by the Ministry of Health according to section 4(1) of the *Drug Control Ordinance 1982* (Bangladesh).
[60] The price of all available medicines in Bangladesh is published by the Directorate of Drug Administration of Bangladesh.
[61] TRIPS Agreement (WTO), art 8(1). <http://www.wto.org/english/docs_e/legal_e/legal_e.htm>.

mechanism to help and support the local industry. The challenges and opportunities highlighted all require action on the part of the Bangladeshi Government and Government intervention lies at the centre of what the Government should be doing in anticipation of 1 January 2016. One question that remains in terms of the challenges and opportunities identified is whether Bangladesh should take steps to become TRIPS Compliant before 2016 or use the transition period to its fullest extent.

5. TRIPS COMPLIANCE BEFORE 2016?

There are likely to be few benefits but significant risks and costs borne by Bangladesh if it puts into effect a TRIPS compliant patent protection regime for pharmaceutical products in advance of the 2016 deadline. Put simply, neither the local pharmaceutical industry nor the Government is ready. Whilst, licensing agreements could be negotiated with proprietary pharmaceutical manufacturers to permit continued importation of ingredients and local production of finished products the cost to the industry and, ultimately, to the consumers of Bangladesh would be high. Further, considering the level of R&D in Bangladesh the introduction of pharmaceutical patenting may disadvantage Bangladeshi companies in the short term. All in all there seems to be no apparent advantage to voluntarily becoming TRIPS compliant prior to 2016. It is argued that the best approach is for Bangladesh to consider its policy direction and then decide upon a strategy and implementation process which takes advantage of the opportunities afforded with not being TRIPS compliant whilst at the same time moving incrementally to restructure and reorganize the industry and the legislative framework surrounding pharmaceutical patent protection and enforcement. In other words Bangladesh should utilise the full duration of the remaining time within transition period.[62]

6. CONCLUSION

After the expiry of the transition period in 2016 there will be no escaping the requirement for Bangladesh to have a TRIPS compliant intellectual property law framework. The situation for Bangladesh will change considerably from the present. In order to comply with its TRIPS obligations, Bangladesh must provide full patent protection for pharmaceutical products. Inevitably, this will mean that generic pharmaceutical producers will have to seek the permission of patent owners to continue to produce their products which may affect access to medicines for the local population. More specifically, licences will have to be obtained by Bangladeshi firms from patent owners to import patented therapeutic ingredients and to permit the manufacture and sale of the resulting finished products. The full weight of these changes may be mitigated if Bangladesh utilises the full extent of the transition period to capitalise on the opportunities that are present. Prior to implementing full patent

[62] This approach was taken by India. During the transition period the Government and the industry took proactive steps to invest in R&D for the pharmaceutical industry and capacity building in Government authorities. See, Neeraj Dixit, 'A Study of the Role of Government of India in Helping Indian Pharma Industry Cope up with the Challenges of Product Patent Regime' (2008) 13 *European Journal of Economics, Finance And Administrative Sciences* 47 and Tony VanDuzer, 'TRIPS and Pharmaceutical Industry in Bangladesh: Towards a National Strategy' (Paper 24, Centre for Policy Dialogue (CPD) Dhaka, Bangladesh, 2003).

protection measures the prospects for the growth of the Bangladesh industry depends upon opportunities for locally produced pharmaceuticals to be exported and utilised by foreign companies. Complementary policies relating to R&D, investment and other areas will be required. Much will rest with the Government. Government policy must reconcile the interests of the domestic industry with the larger social interests of ensuring affordable access to medicines and meeting the requirements of WTO membership.

Appendix 11: Journal Article-3 (Bond Law Review, Vol. 22, issue 2, 2010)

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 from1 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

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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*

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

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[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

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 option[15] 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 Health[16] 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

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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-June2008) 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] Paragrap 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 countries[19] 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/AIDS[22] 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]

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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.

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 complete[28] or provisional[29] 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.

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[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

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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>.

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]

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[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)

	Patent Applied			Patent Accepted		
Year	**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.

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 Administration[39] and the Pharmaceutical Inspection Convention[40] which are aims at maintaining quality and efficacy of medicines worldwide.

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[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), th 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.

DRAs 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 1989[42] 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

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[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.

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

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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

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[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.

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 been 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.

Appendix 12: Conference Abstract-1 (Pacific Rim Innovation Conference, University of Melbourne, 21–22 January, 2010)

Title: Effectiveness of the Patent System in Bangladesh in the context of the TRIPS Agreement: In Search of Balance between Pharmaceutical Innovation and Public Interest

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Abstract:

Before the creation of the World Trade Organization (WTO) in 1995, individual countries were free to determine their own patent laws. This position has now changed. One of the WTO agreements, the Trade Related Aspects of Intellectual Property Rights Agreement 1994 (TRIPS Agreement), which is binding on all Members, aims at establishing strong minimum standards for intellectual property rights (IPRs). Such minimum standards include the implementation of patent protection for pharmaceuticals. The developed member countries of the WTO negotiated the mandatory protection for pharmaceutical products and processes in the TRIPS Agreement on the basis that such mandatory protection will provide the necessary incentives for continued drug innovation. On the other hand, the developing and least developed member countries of the WTO argued, and continue to argue, that enacting patent laws that comply with TRIPS may increase the price of pharmaceuticals to the point that pharmaceuticals may become inaccessible to their populations.

In this regard, Doha Ministerial Conference in November of 2001 adopted a declaration addressing this problem and it calls attention to the flexibilities provided by the TRIPS Agreement to ensure public interest and to fight diseases such as HIV/AIDS, tuberculosis and malaria. So it is important to utilise the flexibilities while making TRIPS compliant national patent law. A poorly conceived patent system that fails to make a right balance between the promotion of pharmaceutical research and public interest for access to affordable pharmaceuticals is likely to result in dreary performance and undermine confidence of investor, researcher and the public.

An efficient IPRs system can promote foreign direct investment, foster innovation, revolutionize industries, improve product quality, reduce consumer prices, expand educational opportunities, increase the demand for skilled labour and hence promote economic development and can serve greater public interest as well.

Bangladesh like other developing countries began re-examining its approaches to IPRs just after the introduction of TRIPS agreement under the World Trade Organisation in 1995. This paper will discuss the steps that Bangladesh should take to develop an effective patent system in the context of TRIPS Agreement balancing pharmaceutical innovation and public interest.

Appendix 13: Conference Abstract-2 (Society of International Economic Law)

The Second Biennial Global Conference of the Society of International Economic Law (SIEL), 2010

Title: Journey towards WTO Legal System and the experience of Bangladesh: The Context of Intellectual Property

Mohammad Monirul Azam
CQ University, Australia

[It is an original work and is part of an work in progress]

Abstract:

The founding of the World Trade Organization (WTO) was agreed to by 125 countries including Bangladesh on 15 April 1994 at a conference in Marrakesh which concluded the strenuous Uruguay Round of General Agreement on Tariff and Trade (GATT) negotiations after more than seven years of hard bargaining. However the accession to the WTO raises some potential legal challenges and to take the full advantage of the world trading system, implementation of the WTO agreements is a must. Although presently Bangladesh has around 1200 laws, which are more than even many developed countries, most of them are century old and lack effective enforcement mechanisms. Therefore, present legal system of Bangladesh will have to be reorganized at every level to satisfy the requirements of the WTO. To meet this purpose, legal, administrative, and judicial resources must be put into place to act as efficient and integrated whole for the effective implementation of the WTO agreements and to minimize the conflicts with other WTO members.

Among the WTO agreements, the Trade Related aspect of the Intellectual Property Rights (TRIPS) agreement has been described as 'probably the most important international intellectual property agreement that was signed in the 20 th century'. The implementation of the TRIPS agreement will require an enormous reorganization and restructuring of intellectual property regime in the Least Developed Countries (LDCs) like Bangladesh. While implementing the TRIPS agreement and other WTO agreements, Bangladesh is facing huge challenges including technical, financial, bureaucratic, lack of expertise in the relevant field and so on. This study will try to explore the experience of Bangladesh's journey towards making WTO Compliant national law in the field of intellectual property. This study will contribute to the growing literature of WTO Law by explaining the experience of Bangladesh while implementing the WTO agreements in general and TRIPS agreement in particular, which in turn will be beneficial for making required law reforms in the context of the WTO agreements in other least developed countries as well.

Appendix 14: Conference Abstract-3

3rd International City Break Conferences, 16-19 October 2009, Athens, Greece.

TRIPS Compliance Patent Law and Implications for the Pharmaceutical Regulation and Pricing of Drugs in the LDCs with special reference to Bangladesh

Mohammad Monirul Azam

CQ University, Australia.

Abstract:

Before the creation of the World Trade Organization (WTO) in 1995, individual countries were free to determine their own patents laws. But the policy environment has now changed. One of the WTO agreements, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), binding on all members of WTO, basically aims at establishing strong minimum standards for intellectual property rights (IPRs) including patent protection for pharmaceuticals. The developed countries, in seeking to provide the necessary incentives for drug innovation, and therefore, successfully negotiated the mandatory protection for pharmaceutical products and processes in the TRIPS Agreement. On the other hand, most of the developing countries' argument is that TRIPS compliance patent law may have adverse impacts on the pricing of drugs and hence may be inaccessible to the vast majority of poor peoples in the developing and least developed countries. Thus, the debate centres around how to reach a balance between meeting the high costs of drug research and development and creating incentives to stimulate access to those drugs in developing and least developed countries. At the outset of this debate, this study will try to analyse the implications of TRIPS Compliance Patent Law in the context of the pharmaceutical sector using Bangladesh as an example and will provide future policy directions for introducing patent law reforms in Bangladesh considering the ongoing challenges and opportunities, which may in turn be useful while patent law making in other least developed countries as well.