Dissertation Title: The Impact of the TRIPS Agreement on Bangladesh in the Fields of Patenting Medicine, Seed and Software

PhD Thesis

PhD Candidate: Md. Mahboob Murshed

Registration No. 206, Session-2006-7

Reregistration No. 51, Session-2011-12

Supervisor: Professor Md. Maimul Ahsan Khan PhD

Department of Law, University of Dhaka

Submitted for the Degree of PhD in Law

Department of Law

University of Dhaka

2017

Dedication

To my beloved parents Ms. Rehana Hussain and Mr. Mosharaf Hussain to whom I am indebted for my birth, upbringing and all the success that I have achieved in my life.

Abstract

This thesis aims to provide a clear legislative roadmap for implementing the TRIPS Agreement in Bangladesh to protect its national interest in the medicine, seed and software industries. Besides examining the need for changes in the existing patent regime of Bangladesh, this study seeks to identify changes necessary in the laws and policies relevant to the medicine, seed and software industries, and the technology transfer from developed countries within the scope of the TRIPS Agreement.

This thesis argues that Bangladesh can successfully use the TRIPS Agreement's flexibilities in implementing its provisions through patent law to protect the medicine and software industries, establish an effective *sui generis* system to protect the seed industry, harmonizing the legal regimes relevant to these sectors through changes in the patent regime. Using this argument, the thesis identifies the modes of incorporation of flexibilities such as compulsory license, research exception and Bolar provisions, exhaustion of rights and parallel import, and exhaustion of rights and parallel exports, and the provisions for implementing Article 27 of TRIPS through Bangladesh's patent law in protecting its national interest on medicine.

Similarly, this study explores an effective *sui generis* system for implementation of Article 27.3 (b) of the TRIPS agreement to protect the seed industry of Bangladesh and to preserve farmers' rights by striking a balance with the commercial interests of multinational corporations (MNCs). The relevant legal and policy regimes of medicine and software have also been examined to identify the necessary changes for harmonizing with the TRIPS agreement. Finally, this thesis investigates the viability of software patenting for Bangladesh in the global context to protect its software industry, and to recommend the changes required in its relevant patent and legal regimes.

Based on the argument developed in this thesis, the implementation mechanism of Article 66.2 of TRIPS for the transfer of technology in the fields of medicine, seed and software is delved into and legislative and policy options for adopting TRIPS flexibilities through the patent regime and relevant legal regimes are scrutinized with reference to important communications with the TRIPS Council.

The world might undergo some seismic changes with the advent of mega-regional trade agreement like the Trans-Pacific Partnership (TPP) and the Transatlantic Trade and Investment Partnership (TTIP). Consequently, these may change the multilateral trading system and may have a potential to reduce the role of WTO as the mediator of commercial relations amongst nations. In the backdrop of these significant developments, this study highlights the flexibilities of the TRIPS to be exploited through legislative measures to protect the national interest of Bangladesh in the fields of medicine, seed and software. On the one hand, Bangladesh faces pressure from the US and EU to implement the TRIPS' provisions through its national legislation during the transitional period or before the end of it; and on the other hand, at present Bangladesh is not in a position to decide its role in the negotiation process of the regional trade agreements due to its inadequate legal and policy framework and details of these agreements have been shrouded in secrecy.

The TRIPS' multilateralism allows least-developed countries (LDCs) to have a voice (however limited) over the rules that affect their collective destiny. In contrast, critics contend that a mega-regional agreement like TPP might breed global inconsistencies in standards, provide competitive advantages for certain countries, and increase trade distortions. The role of multilateral trading system cannot be replaced by Mega-regional Agreements (MRAs). This is since there are certain vital issues such as trade facilitation which can only be negotiated at the common platform of WTO. In the same way, WTO must

negotiate sensitive issues like export subsidies in agriculture, fishing and support measures. While global trade rules must evolve, countries that are excluded will suffer because MRAs will damage their terms of trade and weaken their trade preference. This reality prompts an effective exploration of the TRIPS' flexibilities through legislative measures of Bangladesh.

Investor-state arbitration claim is a great challenge for an effective implementation of the TRIPS Agreement's flexibilities through domestic legislation for an LDC like Bangladesh. Recent trend shows companies are increasingly challenging domestic decisions pursuant to bilateral and multilateral agreements that provide protection to foreign investors and permit them to bring the investor - state dispute. In these disputes companies, may not only challenge the patentability standards they disagree with but also exceptions to patent rights i.e. flexibilities even where these exceptions are permissible under TRIPS. This study explored that Bangladesh as an LDC should take sufficient legal measures in protecting its national interest in medicine, seed and software before entering any such bilateral or multilateral agreements.

The legal and policy options explored in this thesis, for exploiting the TRIPS' flexibilities to protect Bangladesh's medicine, seed and software industries, would help to modify the country's patent regime and to harmonize the relevant legal regimes within the transitional period. Additionally, LDCs with similar socioeconomic conditions would also benefit from this study.

Acknowledgments

In the name of Allah, the Beneficent, the Merciful. I am thankful and indebted to my Supervisor Professor Dr. Maimul Ahsan Khan, who guided me to complete this scholarly work and to navigate this journey from the beginning to the end. At every stage of my research on a rare field of intellectual property law as a supervisor he helped me with his scholarly experience and vast academic expertise.

I would like to thank Dr. Shah Alam, Member Law Commission who is my teacher and who supervised me while I was the Chief Research Officer of the Law Commission of Bangladesh, from whom I learnt how to conduct legal research and many more things on legal arena.

During this long research work I got help from the faculty and staff Members of the Department of Law of the University of Dhaka in both academic and administrative matters. I convey my thanks to all of them who extended their sincere cooperation in completing this study.

My parents' inspiration always encouraged me to complete this work to whom I am indebted for my birth and upbringing. I am grateful to my elder brother, Captain Monzoor Murshed, my wife Lubna, beloved daughter Maryam and sons Rafid and Sadid for their unique contributions in my life and career.

Finally, I convey my sincere thanks to Dr. Abu Ahsan Mohammad Shamsul Arefin Siddique, the Hon. Vice Chancellor of the University of Dhaka for his dynamic leadership in creating a sound academic atmosphere congenial to conduct research work that substantially helps me accomplish the study.

Statement of Original Authorship

The work contained in this thesis has not been previously submitted to meet requirements for an award at this or any other higher education institution. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made.

Md. Mahboob Murshed
Advocate, Supreme Court of Bangladesh
& PhD candidate
Dhaka
7 May 2017

Certificate

This is to certify that the thesis titled "The Impact of the TRIPS Agreement on Bangladesh in the Fields of Patenting Medicine, Seed and Software" is the original piece of investigation and a distinct contribution to the advancement of knowledge by the candidate in the field of intellectual property law and a comprehensive and self-contained account of the candidate's research. The work is satisfactory regarding literary presentation and suitable for publication in a recognized journal or in book form with necessary modification.

I also certify that I have perused the draft and final version of the thesis and found it satisfactory for submission to the Department of Law, University of Dhaka in fulfillment of the requirements for the degree of Doctor of Philosophy in Law.

8/5/16

(Professor Dr. Md. Maimul Ahsan Khan)
Department of Law
University of Dhaka
Dhaka, Bangladesh

Professor
Department of Law
University of Dhaka

Dhaka
8 May 2016

Contents

List of Abbreviation

A2I	Access to Information
API	Active Pharmaceutical Ingredients
APSA	Asia Pacific Seed Association
ARVs	Antiretroviral
BARC	Bangladesh Agricultural Research Council
BASIS	Bangladesh Association of Software Industries and Services
BAU	Bangladesh Agricultural University
BLD	Bangladesh Legal Decisions
BPA	Bangladesh Patent Act (Draft)
CBD	Convention on Biological Diversity
CGMP	Current Good Manufacturing Practices
CIPR	Commission on Intellectual Property Law
DAE	Department of Agricultural Extension
DLR	Dhaka Law Reports
DPDT	Department of Patent Designs and Trademark
EMRs	Exclusive Marketing Rights
EPC	European Patent Cooperation
EPO	European Patent Office
EPP	Entry Point Programs
EU	European Union
EVI	Economic Vulnerability Index

FAO	Food and Agriculture Organization
FDI	Foreign Direct Investment
GI	Geographical Indications
GM	Genetically Modified
GMP	Good Manufacturing Practices
GOB	Government of Bangladesh
HCD	High Court Division
HIV	Human Immunodeficiency Virus
HRs	Human Rights
IDC	International Data Corporation
ICCPR	International Covenant on Civil and Political Rights
ICESRC	International Covenant on Economic, Social and Cultural Rights
ICT	Information and Communication Technology
ICTSD	International Centre for Trade and Sustainable Development
IP	Intellectual Property
IPRs	Intellectual Property Rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
ISF	International Seed Federation
ISTA	International Seed Testing Association
ITT	International Technology Transfer
LDC	Least Developed Country

MLR	Mainstream Law Reports
MNCs	Multi-National Companies
NARS	National Agriculture Research System
NCPGR	National Committee on Plant Genetic Resources
NDP	National Drug Policy
NKEA	National Key Economic Area
NSB	National Seed Board
NSP	National Seed Policy
OECD	Organization for Economic Cooperation and Development
OSS	Open Source Software
PD Act	Patents and Designs Act
PPA	Plant Protection Act
PVPA	Plant Variety Protection Act
RMG	Ready Made Garments
R&D	Research and Development
SAARC	South Asian Association for Regional Cooperation
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
TK	Traditional Knowledge
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TT	Technology Transfer
UDHR	Universal Declaration of Human Rights
UNHCR	United Nations High Commissioner for Human Rights

UPOV	International Convention for the Protection on New Varieties of Plant
US	United States
UNCTAD	United Nations Conference on Trade and Development
UN	United Nations
USPTO	United States Patent and Trademark Office
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Cases

Chapter 1: Introduction

1.1. Background of the study

The intellectual Property regimes of the Members of the WTO have been immensely affected and influenced by The Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (henceforth TRIPS Agreement).[1] It binds all Members of the WTO to promote effective and adequate protection of intellectual property rights (henceforth IPRs).[2] TRIPS Agreement has also opted for establishing a minimum threshold for the protection of IPRs on one hand and diminishing the barrier or hindrance to the legitimate trade and business in the field of IPRs on the other. Thus, TRIPS has aspired to have a balanced right and obligation system under its legal framework so that private rights of IPRs holders and interests of the consumers or mass people can be ensured.

It is emphatically stated in the preamble of the TRIPs that Members of the WTO recognize "the special needs of the least-developed country Members in respect of exploiting maximum flexibility in the domestic implementation of laws and regulations in order to enable them in creating a sound and viable technological base;"[3]. Besides providing a minimum standard of protection for IPRs as enshrined in the TRIPS, the Members are at liberty to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.[4]

Being a Member of the WTO and as a least developed country (LDC) Bangladesh is under obligation to implement the provisions of the TRIPs and at the same time she is capable of

[1] WTO Agreement: Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 4 (1999), 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994) [hereinafter Marrakesh Agreement or WTO Agreement].
[2] the WTO Agreement (Marrakesh Agreement), paragraph 2 of Article II.
[3] TRIPS Agreement (1994), Preamble.
[4] The TRIPS Agreement (1994), paragraph 1 of Article 1.

enjoying the special flexibilities of the TRIPS earmarked for LDCs and developing countries. Bangladesh is now under an obligation to revisit its archaic Patents and Designs Act, enacted in 1911- more than hundred years back by the British colonial regime to harmonize it with the provisions of the TRIPS. At present, Bangladesh is enjoying an exemption from implementing the TRIPS provisions except the provisions of the Articles 3, 4 and 5.[5] However, this exemption will cease on the date of cessation of the LDC status.[6]

Bangladesh may graduate from LDC in 2024 since it has already fulfilled one of the three criteria, i.e. economic vulnerability index (EVI).[7] Thus for ensuring patent for pharmaceutical products under TRIPS, Bangladesh may not be able to enjoy the waiver until 2033 and that may cease by 2024 on its graduation from LDC. While implementing TRIPS through legal provisions Bangladesh should be aware of this fact as well. On the other hand, Bangladesh must implement TRIPS provisions apart from patenting pharmaceutical products before July 2021.[8]

Medicine, seed and software have been given special status in different national policies like the National Drug Policy 2005, National Industrial Policy, 2010, National Agriculture Policy, 2013, National Seed Policy, 1993, ICT Policy, 2015, Export Policy 2015-2018, Import Order 2012-2015 and 7th Five Year Plan. These three sectors are the emerging prospective industries and key sectors in the development of Bangladesh.[9] Therefore, at the time of revisiting the existing patent regime in the light of the TRIPS agreement, Bangladesh should put due emphasis on protecting its national interest in these sectors.

---

[5] As per paragraph 1 of Article 66 of the TRIPS, the TRIPS Council decided to extend the extension until July 2021 vide its decision no. IP/C/64 and with respect to pharmaceutical products the exemption is extended till January 2033 vide the TRIPS Council decision no. IP/C/73.

[6] ibid, TRIPS Council's decisions.

[7] *Bangladesh to remain LDC until 2024: UN review*, http://bdnews24.com/economy/2015/11/26/bangladesh-to-remain-ldc-until-2024-un-review , 2015, (accessed 8 February 2016).

[8] TRIPS Council decision no. IP/C/64.

[9] The preamble of the Export Policy 2015-18 of Bangladesh.

Putting medicines and lifesaving drugs under the patents regime by the TRIPS may result in genuine concerns for the LDC's or middle income countries since the price of such items may go out of reach. It is a great challenge for a country like Bangladesh to be compliant with TRIPS while protecting national interests in a delicate sector like pharmaceutical industry, which at the same time has a huge public health implication.

The agro based countries in world particularly Brazil and Sub Saharan Countries are facing tremendous problems with genetically modified seeds and patented seeds of MNCs like Ciba Gaige, Monsanto etc. In Bangladesh, Agriculture is gradually becoming dependent on genetically modified seeds and branded seeds of MNCs. Its traditional seeds and knowledge of agriculture are national assets and this need to be protected from being stolen/taken away by MNCs or other entities or countries.

If Bangladesh provides protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof,[10] the MNCs will considerably increase the price of GM seeds. Consequently, our agriculture may substantially be controlled by the MNCs. But one of the said protections is necessary to protect the traditional seeds and knowledge of agriculture of Bangladesh and it should adopt any of the said measures to protect its plant varieties by 2021. To overcome this dilemma Bangladesh must strike a balance between controlling MNCs from making skyrocketing profit and ensuring transfer of technology in its Seed Industry. Simultaneously, it should protect its traditional seeds and knowledge of agriculture, by protecting its plant varieties through any of the three methods provided in TRIPS.

The software industry of Bangladesh is rapidly growing and earning a considerable amount of foreign currency by exporting software. The Copyright Act, 2001 of Bangladesh is

[10] See paragraph 3 (b) of Article 27 of the TRIPS Agreement.

providing protection to the software. TRIPS does not specifically provide or prohibit software patenting. In the international jurisdictions, the US provides for software patenting and the EU and Japan have restricted software patenting. India has also provided software patenting under certain conditions. But, Pakistan does not provide for software patenting. Experts' opinions are divided for and against granting software patent. In this backdrop Bangladesh is to decide whether it should continue to provide software patent in the present form or in the modified form or exclude software patenting considering overall situations prevailing in its software industry and convenience of technology transfer in the Industry.

Bangladesh should revisit relevant laws on medicine, seed and software apart from a substantial review of the Patents and Designs Act, 1911 and Patents and Designs Rules, 1933 to be TRIPS compliant, to protect medicine, seed and software industries by incorporating flexibilities enshrined in the TRIPS.

1.1 Contribution and Significance of the Dissertation

This thesis contributes by gap analysis in the existing patent regime of Bangladesh the way out to protect its medicine, seed and software industries as well as facilitating technology transfer therein in the context of implementation of the TRIPS' provisions by introducing a new patent regime and an effective *sui generis* system to protect plant varieties and efficient utilization of the TRIPS' flexibilities through legislative and policy measures by Bangladesh as well as LDCs with similar socio economic and legal background.

The focus of the study is on the effective and efficient maneuvering of the TRIPS flexibilities in complying TRIPS' provisions in the patent regime as well as relevant laws to protect the medicine, seed and software industries of Bangladesh. At the same time, it also intends to ensure technology transfer from the developed countries to these sectors.

Bangladesh as an LDC played a vital role in negotiating the extension of the transitional period for implementing TRIPS provisions with the TRIPS Council and succeeded to extend the transitional period to July 2021.[11] The successful implementation of TRIPS Provisions through the legislations of Bangladesh would be a role model for other LDCs.

Medicine, seed and software are thrust and emerging sectors in Bangladesh. This study reveals the challenges and the way forward in protecting the national interest in these sectors through effective incorporation of the TRIPS flexibilities in the patent regime of Bangladesh and necessary revision of relevant laws to create a harmonious legal regime for implementing the TRIPS' provisions in Bangladesh.

How far the TRIPS' flexibilities like compulsory license, research exception and BOLAR provision, exhaustion of rights and parallel import can be used in protecting medicine, seed and the software industries of Bangladesh by taking lessons from the experience of neighboring India, Singapore and Malaysia has been highlighted in the study. This would play a significant role in designing an effective IP regime for Bangladesh.

Developed country Members are in compulsion to "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 create a sound and viable technological base."[12] The exploration in the dissertation of the effectiveness of this provision of TRIPS and the provisions of Article 67 of TRIPS for technical cooperation in technology transfer to the least developed countries with particular attention to the medicine, seed and software industries of Bangladesh would be highly useful for developing a sound and viable patent regime and an ancillary legal regime for Bangladesh as well as LDCs with similar socio economic and infrastructural background.

[11] But for pharmaceutical products the transition period under Article 65 of the TRIPS is till January 1, 2033 and Bangladesh played a vital role in this extension as well.
[12] The TRIPS Agreement (1994), paragraph 2 of Article 66.

The communications of developing countries, LDCs and developed country Members with the TRIPS Council for providing protection to the plant varieties under paragraph 3 (b) of Article 27 of TRIPS are crucial to understand the position of the developed, developing and LDC Members to implement the provision of TRIPS. The important communications of the Members in this regard have been explicitly analyzed in this thesis.

The short term, midterm and long term recommendations of the dissertation for bringing necessary changes in the patent regime as well as ancillary legal regime to implement TRIPS provisions using its flexibilities to protect the national interest in the medicine, seed and the software industries of Bangladesh would be highly beneficial for taking policy decisions to implement TRIPS in Bangladesh as well as LDCs with similar background.

1.2 Dissertation Objectives

This dissertation aims to provide a clear legislative roadmap for implementing the TRIPS Agreement in Bangladesh to protect its national interest in medicine, seed and software industries. Besides examining the need of necessary changes in the existing Patent regime of Bangladesh this study seeks to find required changes in the laws and policies relevant to the medicine, seed and software sectors and technology transfer to these sectors from the developed countries within the ambit of the TRIPS Agreement. In order to achieve these objectives, this thesis investigates the effective use of the TRIPS' flexibilities earmarked for LDCs and developing countries in favor of an efficient and effective reenactment/reframing of the Patent Law and rules, enacting an effective *sui generis* system for protecting plant varieties of Bangladesh with particular reference to medicine, seed and software.

1.3 Dissertation Overview and Structure

For achieving these objectives this study is intended to be the most comprehensive and definitive work on this contentious subject through a methodical literature review and

doctrinal legal research augmented by qualitative evidence from the Government of Bangladesh, international agencies and other sources.

Chapter II states the impact of TRIPS on Bangladesh in the field of patenting medicine. It analyzes the medicine patenting within the TRIPS' ambit. It explores the role of Doha Declaration on the implementation of the provisions of TRIPS on medicine patenting, extension of transition period on medicine patenting and the impact of patent on price of drugs in LDCs like Bangladesh.

This chapter scrutinizes other consequences of medicine patenting, flexibilities under TRIPS agreement and the scope for maneuvering the flexibilities by Bangladesh; legislative measures for incorporating the flexibilities; important findings that might be helpful in enacting amendments or new laws on patent and framing new rules thereon for implementing the TRIPS' provisions.

The chapter concludes with the key findings on the requirements to incorporate changes in the relevant laws and policies, to administer medicine in Bangladesh and with a summary of the impact of patenting seed in Bangladesh and the importance of seed for medicine along with the necessity of medicinal plants with strong database of seed for the improvement of medicine sector of Bangladesh.

Chapter III builds on chapter II by giving an introduction that analyzes Article 27 of the TRIPS to explain the modes of protection of plant varieties to be incorporated through national legislation and probable options for Bangladesh to implement the provision of paragraph 3 (b) of this Article. It critically examines in the same way like medicine, patentability of seed under the existing Patents and Designs Act, 1911 (PD Act) of Bangladesh as well as the TRIPS' requirements on the protection of seeds. The important issues raised before the TRIPS Council by Members during the review process of the

paragraph have been scrutinized in detail and important findings have been sorted out as lessons for Bangladesh as well as LDCs.

The third option for seed varieties' protection i.e. the combination of patent and an effective *sui generis* system as enshrined in paragraph 3 (b) of Article 27 of the TRIPS Agreement has also been carefully examined in the light of famous US case references and important findings derived from the investigation. The entire gamut of laws and policies of Bangladesh on and relevant to seed has been critically examined in the section of protection of seeds in Bangladesh and relevant changes are explored for an effective and efficient implementation of paragraph 3 (b) of Article 27 of the TRIPS Agreement prioritizing the national interest as well as the farmers' interest on plant varieties and seed industry of Bangladesh.

Protection of seed through international Conventions/Treaties/Agreement has been explored and State responsibilities of Bangladesh under important conventions and treaties like CBD and PGRFA have been located. In particular, the obligations under the Convention and Treaty to be reflected in the seed laws and policy have been determined. The question of why Bangladesh should not accede to the UPOV is examined in this section. Finally, the legislative options for Bangladesh to protect seed have been recommended with specific findings of the chapter and a brief summary of the impact of the TRIPS on software patenting in Bangladesh is given with the importance of software for medicine and seed.

Chapter IV scrutinizes the impact of TRIPS on software patenting in Bangladesh. It examines briefly the historical perspective of software patenting, software protection under prevalent IPRs system, historical development of software patenting in the US. In addition, this provides an overview of software patenting in EU and leading Asian Countries like Japan, China, South Korea and Singapore. It also briefly examined the status of software patenting in India and Pakistan, two leading SAARC countries. The chapter critically examined the

scope of software patenting under the TRIPS Agreement and derived specific findings thereon. Patentability of software under the existing legal framework of Bangladesh has been investigated with specific reference for granting patent of software. It derived important findings thereon.

The proposed draft of the Bangladesh Patent Act, 2015 has been carefully scrutinized to analyze gaps in the proposed law with particular reference to the Patent law of Malaysia and suggested incorporation of the TRIPS' flexibilities like compulsory license, parallel import, exceptional treatment of research and experiments in the proposed law. The legal regime of software and ICT has been examined in the light of the TRIPS flexibilities and famous US case references to find out specific legislative policy requirements for Bangladesh and LDCs on software patenting.

The impact of software patenting on protecting medicine and seed industry has been critically examined and specific findings have been derived there from. Human Rights compatibility with the software patenting has been analyzed in depth and specific recommendations have been drawn from the investigation. The findings of the chapter are summarized and a brief idea of the next chapter on transfer of technology is given at the end of the chapter.

Chapter V encompasses the impact of TRIPS on transfer of technology with particular reference to medicine, seed and software industries of Bangladesh. The introductory section envisaged the guiding principles of technology transfer as enshrined in Articles 7, 8 and technology transfer to the least-developed country Members in Article 66.2 of the TRIPS Agreement as the basis of the study of technology transfer (TT) to Bangladesh.

This chapter briefly analyzed the TRIPS' Provisions on TT with experts' views on the effectiveness of Article 66.2 of the TRIPS Agreement. Attention is given on the controversial issue of providing incentives by the developed country Members to the LDCs to create a

sound and viable technological base through public and private enterprises of the respective developed country Members. The meaning and modes of TT have been critically examined to find a way out for Bangladesh and LDCs for determining policy needs on TT. Necessary assessment of TT for Bangladesh is determined in this chapter on the basis of the TRIPS Council's decision and communications of Bangladesh to the Council on technology transfer. The effectiveness of the Communications of Bangladesh has been assessed on the basis of communication of Sierra Leon.

The entire gamut of laws and policies on TT in pharmaceutical industry of Bangladesh has been examined to incorporate the TRIPS Agreement's flexibilities in the proposed Patent law of Bangladesh. The legal regime and policies of technology transfer on and relevant to seed have been scrutinized to find out necessary changes required in the legal and policy regime of TT on seed to implement the TRIPS' provisions using TRIPS' flexibilities.

This chapter seeks to analyze TT of the software industry of Bangladesh. The legal and policy framework of software industry of Bangladesh have been examined carefully in the light of good practices of leading Asian Countries like South Korea, Malaysia and India. The findings of the chapter have been summarized with concluding remarks at the end.

Chapter VI is the Conclusion of the dissertation that summarizes the findings of the thesis and acknowledges the limitations of this study highlighting area of future works.

1.4 Literature Review

A doctrinal legal research has been conducted that provides a systematic exposition of the laws governing patent regime of Bangladesh on medicine, seed and software. It analyses the relationship between the laws and predicts future development. The Bangladesh Code and the website of Bangladesh laws titled Laws of Bangladesh are studied rigorously during the research, from where most of the primary research materials have been collected.

The GOB's Policies, reports, Five Year Plans and other documents have been collected from Bangladesh Gazette and national portal of GOB. International journals, books, articles, law reviews, law reports, materials from the websites of WTO, WIPO, UN, UNCTAD, WHO, FAO and other international agencies have been collected and studied carefully.

In addition, the laws, policies and reports of foreign jurisdictions have been collected and reviewed from the respective national websites of the countries and the WIPO Lexis. The relevant case laws of India, US, Canada, Japan, Germany have been cited in appropriate places. The famous legal research website 'Westlaw' has been explored to collect case laws and latest articles from the reported law journals. The literature review has been divided into four parts, i.e. medicine, seed, software and transfer of technologies to these three industries.

1.4.1 Medicine

Our Pharmaceutical Industry is a developing industry which has been booming since 1982 with the introduction of the National Drug Policy. Still, the industry is flourishing and not in a position to invent new drugs by R&D that needs a huge investment of money and highly skilled manpower in which Bangladesh is considerably lagging behind. Bangladesh, even, cannot produce active pharmaceutical ingredients (API) from the scrap and generic medicine. Pradip (2013) claimed that despite the pitfalls, the Pharmaceutical industry in Bangladesh is one of the leading priority sectors that fulfills 97% of the domestic demands of Drugs.[13] The Patents and Designs Act, 1911 of Bangladesh allows patenting of medicine from which we are arguably exempted till 1 January, 2033 under TRIPS Regime.

If medicine patenting is not applicable or postponed until the exemption period for Bangladesh as an LDC, the industry can only use generic medicines and can produce some brand medicines by using the technique of reverse engineering. Medicine patenting would

[13] P. Royhan, Market Access Challenges and Opportunities for Bangladesh Pharmaceutical Products under TRIPS, *Journal of Intellectual Property Law & Practice*, 2013, Vol.8, No.12 p. 932.

stop the way of using the method of reverse engineering. Because when multinational medicine companies would start getting their newly invented medicines patented from Bangladesh, local pharmaceutical industry would be unable to use that medicine to produce modified brand medicine by using the method of reverse engineering. Pradip (2013) apprehended that due to TRIPS compliance on Pharmaceutical patenting, Bangladesh might lose the market access in international competition in general and mass people might also be deprived of access to medicines in particular.[14]

Similar concerns have been expressed, though in different ways, by several other researchers, WHO and WTO regarding impacts of medicine patenting on access to health or public health in Bangladesh.[15] It is suggested that Bangladesh should take the opportunity provided for the least developed countries by the Doha Ministerial Conference, 2001 i.e. not to provide medicine patenting till transition period.

Islam (2013) identified challenges for LDCs, taking Bangladesh as a case study in patenting for the pharmaceutical field. He recommended that LDCs must press for further extension beyond 2016 on one hand, and on the other hand Bangladesh should invoke the flexibilities under TRIPS.[16] In spite of his findings and recommendations in the field of patenting medicine and public health issues, there is still scope for further research by narrowing down

[14] P. Royhan, Market Access Challenges and Opportunities for Bangladesh Pharmaceutical Products under TRIPS, *Journal of Intellectual Property Law & Practice*, 2013, Vol.8, No.12 p. 932.

[15] M. M. Azam, 'Globalizing Standard of Patent Protection in WTO Law and Policy Option for LDCs: The Context of Bangladesh', *Chicago-Kent Journal of Intellectual Property*, vol. 13, no. 2, 2014, p. 402. See, Alexandra Bhattacharya, The Use of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*(2001):* 'A Review of Implementation Experience in the Developing Countries', *The Journal of World Investment & Trade*, vol. 13, no. 2, 2012, pp. 186-209, See, M. T. Islam, 'TRIPS Agreement and Public Health: Implications and Challenges for Bangladesh', *International Trade Law & Regulation*, vol. 17, no. 1, 2011, pp. 10-39.

[16] M. T. Islam, *'TRIPS Agreement of the WTO: Implications and Challenges for Bangladesh'*, Newcastle, U.K., Cambridge Scholars Publishing, 2013.

the area of research, i.e., by assessing the legal impacts of TRIPS on medicine patenting in Bangladesh.

Azam (2014) explored the challenges of globalized standardization of Patent under the WTO and recommended policies for Bangladesh to adopt as LDC. He discussed at length the flexibilities of TRIPS which Bangladesh needs to pursue. He extensively researched on globalized standard of patent and policy option for Bangladesh. However, there is scope of further research by pinpointing a research area on the issue on how Bangladesh should draft Proposed Patent Law to provide medicine patent so that Bangladesh can be TRIPS compliant and can also protect its national interests with specific reference to the draft Bangladesh Patent Act, 2015.

The study conducted by the Centre for Policy Dialogue of Bangladesh on the impact of drug patenting on Bangladesh in its policy paper titled “TRIPS and Pharmaceutical Industry in Bangladesh: Towards a National Strategy” has outlined some of the key aspects of policy options and market orientation for Bangladeshi medicine. Thus, by recognizing and endorsing the existing literature, pertinently, it is possible to assess the impacts of drug patenting in Bangladesh and find out the legal provisions which can be incorporated in the patent law to prevent the negative impact of drug patenting in Bangladesh remaining within the orbit of the TRIPS Agreement.

The scope of the study is limited to legal aspects of medicine patenting and the impact of TRIPS in Bangladesh in this regard. To keep the focus on the legal issues of medicine patenting the study has been basically confined to the TRIPS Agreement. It would not explore other international agreement like the Paris Convention for the Protection of Industrial Property, 1967 or Patent Cooperation Treaty, 1970.

However, the TRIPS Agreement itself adopted the vital provisions of the Paris Convention. This study has not explored the impact of the bilateral agreement namely the Trade and Investment Co-operation Framework Agreement (TICFA)[17] between Bangladesh and the US on patenting medicine, seed and software in Bangladesh. This study also does not explore the impact of Trans-Pacific Partnership (TPP) and the Regional Comprehensive Economic Partnership (RCEP) on patenting medicine, seed and software in Bangladesh.

1.4.2 Seed

To explore the protection of seed/ plant varieties under paragraph 3 (b) of Article 27 of the TRIPS a number of national and international laws, policies, reports, treaties, conventions, articles published in famous journals, e.g. Harvard Journal of Law and Technology, Intellectual Property Quarterly, John Marshall Review of Intellectual Property Law, Tulane Journal of Technology and Intellectual Property, Intellectual Property & Technology Law Journal etc., IP Books, websites of GOB, Bangladesh Gazette, Bangladesh Code, Laws of Bangladesh website, websites of other foreign jurisdictions have been visited extensively.

No specific study has yet been conducted on the legal implications of the implementation of paragraph 3 (b) of Article 27 of the TRIPS in an LDC like Bangladesh. Islam (2013) has explored "possible implications and challenges arising from the TRIPS establishment of IPRs in agriculture by means of PVP."[18] Islam suggested introduction of plant varieties protection (PVP) in the name of *sui generis* protection in the law of Bangladesh for protecting the rights of farmers and plant breeders. The study did not explain the convenience and inconvenience

[17] M. J. Abdin, 'TICFA: Issues, realities and possible impacts', *SSRN Electronic Journal*, 2013, www.researchgate.net/publication/259464647_TICFA_Issues_realities_and_possible_impacts, (accessed 4 April 2016).

[18] M. T. Islam, *TRIPS Agreement of the WTO: Implications and Challenges for Bangladesh*, Newcastle, U.K., Cambridge Scholars Publishing, 2013.

of the three ways of protection of PVP, i.e. by patents or by an effective sui generis system or by any combination thereof as provided in paragraph 3 (b) of the Article 27 of TRIPS.

Islam (2013) also could not explore the latest draft of the Bangladesh Patent Act, 2015 because the study was conducted earlier in terms of time. His study also did not refer the Geographical Indications of Goods (Registration and Protection) Act, 2013 (Act No.54 of 2013) of Bangladesh. The study did not explore the detailed legal regime of seed of Bangladesh and National Agriculture Policy, 2013 of Bangladesh.

This dissertation explored the aforementioned unexplored areas in depth to make recommendations in the legal regime of seed of Bangladesh and ways of implementing paragraph 3 (b) of Article 27 of the TRIPS in Bangladesh by 2021 through appropriate legislation. Islam (2013) suggested to follow Brazilian legislation as a guide for drafting Patents Act of Bangladesh. But this study refers Malaysian Law to be followed for introducing a Plant Varieties Act of Bangladesh. It is to be noted Islam (2013) did not mention about the draft Plant Varieties Act, 1998 of Bangladesh in his study which has been analyzed in the present study.

The important communications of the developing country Members, LDC Members and developed country Members with the TRIPS Council in accordance with the provision of paragraph 3 (b) of Article 27 of the TRIPS Agreement have been analyzed in depth in this study to facilitate the adaptation of the mode of protection for the plant varieties of Bangladesh.[19]

During the literature review, the Patents and Designs Act, 1911, the Patents and Designs Rules, 1933, the Seed Rules, 1998, the Seed Policy, 1993, Plant Quarantine Act, 2011 (Act no. 5 of 2011), National Institute of Biotechnology Act, 2010 (Act no. 10 of 2010),

[19] Bangladesh must provide any of the three modes of protection for its plant varieties as enshrined in the paragraph 3 (b) of Article 27 of the TRIPS Agreement by 2021.

Competition Act, 2012 (Act no. 23 of 2012), the Safe Food Act, 2013 (Act no. 43 of 2013), the Agricultural Produce (Grading and Marketing) Act, 1937 (Act No. I of 1937), the Agricultural Pests Ordinance, 1962 (East Pakistan Ordinance No. VI of 1962), the Agricultural Produce Markets Regulation Act, 1964 (East Pakistan Act No. IX of 1964) and the Geographical Indications of Goods (Registration and Protection) Act, 2013 (Act No.54 of 2013) that deal directly or indirectly with the governance of seed in Bangladesh have been critically explored. The review gives an overall idea about the necessary changes in the seed regime of Bangladesh to implement the provision of paragraph 3 (b) of Article 27 of the TRIPS through legislative process.

Specific attention has been given on the draft Bangladesh Patent Act, 2015 and draft Plant Varieties Act, 1998 through which initiative was started in Bangladesh to implement TRIPS provisions to protect plant varieties in Bangladesh preserving farmers' and breeders' interest as well as protecting traditional seeds and knowledge in agriculture of Bangladesh. In revisiting the draft Act, famous case references like Diamond vs. Charkrabarti, Asgrow Seed Company vs. Denny Winterboer and J.E.M. AG Supply v. Hi-Breed International have been cited and briefly discussed to show how courts' decisions frustrated the objectives of legislature in legislating Plant Protection Act and Plant Varieties Protection Act regarding seed saving exceptions.

The study has made a brief analysis of the advantages and disadvantages for Bangladesh to become a Member of International Conventions like CBD, Cartagena Protocol and Nagoya Protocol of CBD, PGRFA, UPOV, Budapest Treaty and SPS Agreement.

1.4.3 Software

Both deductive and inductive reasoning have been used to examine the legislative provisions and case laws on software. Data and information are collected from both primary and secondary sources. Primary source includes patent related international instruments, Statutes, Laws of Bangladesh, website of the Legislative and Parliamentary Affairs Division of the Ministry of Law, Justice and Parliamentary Affairs and State practice and Case laws of different jurisdictions. On the other hand, secondary source includes books, journals and research papers on the field of software patenting. Resources of the Bangladesh Association of Software Industries and Services (BASIS) and other relevant organizations are used in assessing the impact of software industry on different sectors of Bangladesh.

The necessary content analysis has been done on the TRIPS agreement by reviewing the available literature on this issue. Existing Patent related legal instruments and policies of Bangladesh have been analyzed with due significance. Since software protection is a vital issue in the cyber space, therefore, relevant cyber laws, e.g. Information and Communication Technology Act, 2006, Antiterrorism Act and other relevant government policies and guidelines have also been explored.

The software patenting in Bangladesh is a relatively new practice and DPDT has at least on one occasion granted software patent. For example, Bijoy Bangla Typing software was patented in 2004 as a method of producing technical effects.[20] The main challenges for Bangladesh in introducing software patenting within the TRIPS periphery have been pinpointed in the light of the US, EU, Chinese, South Korean, Singaporean, Japanese and Indian experience of software patenting. Whether copyright protection is alone sufficient for

[20] WIPO, 'Localizing Technology: The Story of Bijoy', *WIPO*, Geneva, http://www.wipo.int/ipadvantage/en/details.jsp?, (accessed 5 September 2014).

protecting software or it needs patent protection besides copyright protection is a crucial issue that has been explored in this study with specific examples from US jurisdiction.

J.H Reichman opined that Software protection under the existing IPRs system is a complex and controversial matter since it does not exactly fit within the heretofore fields of classical intellectual property law.[21] But this intellectual finding on software patenting has been reversed later where one of the scholars opined that "[t]oday, the situation is dramatically reversed. Over the past twenty-five years in the United States the efficacy of copyright protection for software has waned considerably, and the availability of patent protection for software has increased dramatically."[22] In the United States software patenting has attained such a position from where it's not logically possible to deny the need of software patenting. "[w]ith the growth of technology in the last several decades, thousands of patents now cover various aspects of the Internet, and scholars estimate that 40,000 software patents are granted each year."[23]

In order to achieve an effective legal mechanism for protecting software, Bangladesh may carefully consider the conservative view of EU and other advanced Asian Countries and the US experience where software patenting has been established as an effective mean of protecting software, both online and offline.

The entire legal regime of software besides PD Act has been scrutinized in the light of experience of the US, EU, China, Singapore, Japan and India and it has been explored in this

---

[21] J.H. Reichman, 'The Know-How Gap in the TRIPS Agreement: Why Software Fared Badly', *Hastings Communications & Entertainment Law Journal,* vol. 17, 1995, p. 763,766.

[22] L. D. Prutzman, 'United States Patent Protection for Computer Software', *International Law Practicum,* vol. 19, no. 1, 2006.

[23] C. Moss, 'The Integrated Approach: A Solution to Patent Subject Matter Eligibility Standards in the Software Context', *Journal of Intellectual Property Law,* vol. 21, no. 2, 2014, p. 341.

study as to how Bangladesh may protect its software industry in the best possible way while implementing the TRIPS provisions or within the transition period of the implementation.

1.4.4 Technology Transfer to the Medicine, Seed and Software Industries of Bangladesh

The guiding principles of technology transfer as enshrined in Articles 7, 8 and technology transfer to the least-developed country Members (LDCs) in Article 66.2 of the TRIPS Agreement are the basis of the study of technology transfer in Bangladesh. The technology transfer is confined to medicine, seed and software in this study. What are the modes of technology transfer? How far is the existing PD Act conducive to technology transfer? What are the basic laws of technology transfer and how far are these laws convenient in technology transfer to Bangladesh? What are the legal impediments in technology transfer to Bangladesh? What provisions should be incorporated in the draft Bangladesh Patent Act in order to make technology transfer to Bangladesh convenient and how Bangladesh can best exploit the TRIPS flexibilities in enacting its Patent law and other relevant laws? -all these questions are explored here.

In exploring these issues relevant laws of the national jurisdiction and other jurisdictions, case laws of national and international jurisdictions, international conventions, reports of UN and other regional and international bodies, communications of LDCs and Developed countries with the TRIPS Council, published articles in reputed journals, law reports, books, websites of GOB, WTO, WIPO, UNCTAD etc. have been examined methodically.

Article 7 declares one of the objectives of the TRIPS Agreement to be transfer and dissemination of technology that should be achieved through enforcement of intellectual property rights. Paragraph 19 of the Doha Ministerial Declaration reiterated that "[i]n undertaking [the work outlined in this paragraph], the TRIPS Council shall be guided by the

objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension."[24]

Though the Doha Ministerial Conference has reaffirmed the mandatory nature of Article 66.2, it is observed that, "the obligation of developed-country WTO Members stops at the provision of incentives. The governments of those countries may not and should not be expected to intervene in the transfer of technology, because technology in developed countries is mostly controlled by private companies. Governments may not confiscate and transfer it to LDCs."[25]

Article 66.2 does not specify the incentives that should be provided by the developed Members in order to create a sound and viable technological base for LDCs. It is rightly pointed out that, "since Article 66.2 does not specify exactly what these incentives must look like or how extensive they must be, developed countries are essentially free to answer such questions on their own."[26]

Another important aspect raised by the scholars is that Article 66.2 is not limited to the IPR-related mechanism for promoting technology transfer. Andrew Michaels viewed that, "Article 66.2 does not mention IPRs specifically, so developed countries are not limited to IPR-related mechanisms for promoting ITT."[27] This view may be exploited in favour of Bangladesh to adopt measures necessary for formulating and amending its laws and regulations with a view to promote technological development on medicine, seed and software.

---

[24] P. K. Yu, 'The Objectives and Principle of the TRIPS Agreement', *Houston Law Review*, vol. 46, no. 4, 2009, p. 979 and World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Ministerial Declaration].

[25] N. Pires de Carvalho, *The TRIPS Regime of Patent Rights*, 3rd edn., Alphen aan den Rijn, The Netherlands, Kluwer Law International, 2010.

[26] A. Michaels, 'International Technology Transfer And Trips Article 66.2: Can Global Administrative Law Help Least-developed Countries Get What They Bargained For?', *Georgetown Journal of International Law*, vol. 41, no. 1, 2009, p. 223.

[27] ibid. ITT means International Technology Transfer.

1.5 Research Questions

This thesis adopts a holistic approach towards the study of the interaction among the TRIPS, national and international legal and policy regime on medicine, seed and software including the laws on patent and international conventions and treaties on plant varieties with a view to finding out a possible way out to implement the TRIPS provisions in the best possible way using its flexibilities in the patent laws of Bangladesh to protect medicine, seed and software of Bangladesh. In doing this the thesis addresses the following two main questions:

1. How far can the provisions particularly Article 27 of TRIPS be implemented through laws on patent of Bangladesh or by an effective *sui generis* system as the case may be using the flexibilities of TRIPS to protect medicine, seed and software industries as well as technology transfer to these industries of Bangladesh? And
2. To what extent the legal regimes on medicine, seed, software and technology transfer to these industries apart from patent law of Bangladesh needed to be harmonized for implementing the TRIPS' provisions in Bangladesh through legislative measures?

In addressing these two principal questions the following sub-questions will be considered:

(a) Is medicine patenting possible under the present Patents and Designs Act, 1911 (PD Act) of Bangladesh?

(b) What are the TRIPS requirements on medicine patenting that should be incorporated in the patent laws of Bangladesh which is to be introduced before January 2033?

(c) How and when do the TRIPS' flexibilities, e.g. compulsory license, research exception and BOLAR provisions, Exhaustion of rights and parallel import can be incorporated in the patent laws of Bangladesh for protecting national interest in the medicine sector?

(d) How paragraph 3 (b) of Article 27 of TRIPS should be implemented in Bangladesh to protect its seed industry and farmers' interest?

(e) How the flexibilities of TRIPS can be used in the best possible manner to implement the TRIPS' provisions with a view to protecting the seed industry and farmers' rights through legislative measures by Bangladesh?

(f) What are the obligations imposed on Bangladesh through international convention/treaty/agreement for protecting plant varieties/ seed through legislative measures and whether Bangladesh should accede to the UPOV?

(g) How far seed related legal regime will be affected for implementing the TRIPS' provisions through legislative measures to protect the seed industry of Bangladesh?

(h) Does TRIPS require software patenting?

(i) Is software patenting required along with copyright protection to ensure better protection of software?

(j) Is software patentable under the existing patent law of Bangladesh?

(k) Should Bangladesh provide software patenting in the light of the US, EU and Asian experiences on software patenting to protect its software industry?

(l) How and when will the patent law of Bangladesh l be craved[?] to be amended or newly introduced in protecting the software industry of Bangladesh?

(m) What other relevant laws and policies need to be changed besides patent law to ensure the protection of software industry of Bangladesh?

(n) What are the modes of technology transfer and how far is Article 66.2 of TRIPS suitable for technology transfer to the LDCs?

(o) What changes are needed to incorporate the TRIPS' flexibilities on technology transfer in the Patent law to be newly introduced in 2021 and 2032 for protecting software and medicine, respectively?

(p) What provisions are needed to incorporate the TRIPS' flexibilities on technology transfer in an effective *sui generis* system for protecting plant varieties/seed?

(q) What changes should be brought to harmonize the legal and policy regime on medicine, seed and software with the patent law to implement the TRIPS' provisions for transfer of technology in these sectors?

In answering these questions this thesis identifies and analyses several relevant national and international laws, policies, case reference on patent as well as other relevant subjects, relevant international reports, convention, treaties and agreement, Articles 27, 66.2, 7, 8 and 67 with the preamble of TRIPS. In addition, other relevant Articles of TRIPS have been critically examined in reference to scholarly articles, Members' communications to the TRIPS Council and report of the TRIPS Council and commentary books on the interpretation of TRIPS.

The TRIPS' flexibilities like compulsory license, research exception and BOLAR provisions, exhaustion of rights and parallel import have been analysed in reference to the application of these provisions by countries like India, Malaysia and Singapore and scholarly articles, books and case reference from regional and international jurisdictions have also been scrutinized to formulate a sound policy option for Bangladesh and LDCs on incorporating these provisions through appropriate legislative measures in order to implement the TRIPS' provisions.

How the seed industry is important for medicine and the software industry is significant for both medicine and seed industries as well as technology transfer to these three sectors are scrutinized to establish an interconnectivity of between these three sectors underscoring the need to conduct an in-depth investigation of these areas for achieving a sound patent regime or an effective *sui generis* system as the case may be for Bangladesh as well as LDCs.

To get answers on the questions on changes in the relevant legal regime on medicine, seed and software besides the patent law and prospective *sui generis* system, the relevant laws, policies, rules, order have been critically examined with reference to the relevant laws and policies of other important jurisdictions like the US, EU, Malaysia, China, Japan, Singapore, India and Pakistan.

1.6 Methodology

A doctrinal legal research has been conducted based on relevant laws of Bangladesh, laws and case laws of some foreign jurisdictions collected from both primary and secondary sources. This research analyses the relevant laws of Bangladesh to apply findings of this work to the solution of implementing the TRIPS Agreement in Bangladesh through legislation. Impact analysis is carried out basically from the legislative and policy perspective in this study. In order to assess the impact of the TRIPS Agreement on patenting medicine, seed, software and technology transfer therein the existing Patents and Designs Act, 1911 and the Patents and Designs Rules, 1933 have been treated as the patent regime of Bangladesh.

Besides analysing the existing patent regime, the research also carefully explores the relevant laws and policies on medicine, seed and software of Bangladesh and that of selected important Members of the WTO. The relevant laws and policies from US, EU, leading Asian Countries like China, Japan, South Korea, Singapore, Malaysia and India and Pakistan have been taken into consideration in this study to get a global perspective on the legislative implementation of the TRIPS' provisions and effective utilization of the TRIPS' flexibilities in this process.

To assess the impact of the TRIPS Agreement on Bangladesh in patenting medicine, seed and software and transfer of technology therein, this study emphasizes on the TRIPS' provisions with particular attention to Article 27 (patentable subject matter), Article 28 (rights conferred

by a patent), Article 29 (conditions for patent application), Article 30 (exceptions to right conferred) and Article 31 (other use without authorization of the right holder) of the TRIPS Agreement and the provisions of the PD Act and PD Rules that might interplay with these provisions.

In Chapter II specific attention is given on the Indian Supreme Court's famous judgment which disposed of three appeals by one judgment on April 1, 2013. The appellants, Novartis AG, Natco Pharma Ltd. And M/S Cancer Patients Aid Association filed three separate appeals against Union of India and others.[28] In these appeals the Supreme Court of India upheld the threshold of patentability of drug/pharmaceutical substance. Bangladesh and India inherited their legal system from the British regime. Therefore, both the countries have remarkable similarities in their laws and ways of judicial interpretation of laws.

Not a single case law is found on the Patents and Designs Act, 1911 in the famous law reports of Bangladesh like Dhaka Law Reports (DLR), Bangladesh Legal Decisions (BLD) or Mainstream Law Reports (MLR). No case record on patent dispute was found at the record room of the District Judge's Court, Dhaka after due search. Finding no patent cases in the national jurisdiction, this study sought relevant case laws from Indian and other jurisdictions. In interpreting TRIPS' provisions the study relied on the interpretation of the TRIPS Agreement made in the scholarly articles, books and the Novartis case of India.

Some of the important WTO Members' communications with the TRIPS Council on implementing the provisions of paragraph 3 (b) of Article 27 of the TRIPS and review process of the provisions have been critically examined to get necessary policy directives in framing an effective *sui generis* system for Bangladesh and LDCs.

[28] Novartis Ag Vs Union Of India & Others, [2013], Civil Appellate Jurisdiction, Supreme Court Of India, Nos. 2706-2716, [2013], sc. 10 http://supremecourtofindia.nic.in/outtoday/patent.pdf, (accessed 17 March 2016).

1.7 Scope of the Study

For the purposes of this study the Impact of the TRIPS Agreement implies the legal impact, i.e. impact on the Patent regime of Bangladesh. More specifically the legal impact assessment will be limited to the legal provisions of the patent law and relevant laws on medicine, seed and the software industries of Bangladesh as well as transfer of technology therein. The entire study evolves by keeping Article 27 of the TRIPS Agreement at the centre. The TRIPS' preamble and the provisions of the Articles 7, 8, 28-31 and 65-67 have been cited and examined at relevant places.

Special consideration is given to the TRIPS' flexibilities earmarked for the LDCs and developing countries. However, this study is confined in exploring the effective and efficient exploitation of these flexibilities in incorporating the TRIPS' provisions in the patent regime of Bangladesh to protect our medicine, seed and software industries and transfer of technologies therein from the developed Member States. Among the flexibilities, compulsory license, parallel import and BOLAR provisions are highlighted in this study.

In assessing the legal impact of implementation of the TRIPS' provisions through patent law on medicine, software and through an effective *sui generis* system on seed as well as revealing necessary changes required in the relevant laws for a harmonious legal regime with TRIPS, this study is restricted to the laws, rules, orders and policies of Bangladesh that deal with medicine, seed and software.

To evaluate the legal impact on patenting medicine, seed and software and exploring an effective *sui generis* system for the protection of plant varieties i.e. seed, the study seeks best practices in the US, EU, India, Malaysia, China, Japan, South Korea and Malaysia. Most of the case references are cited from US, EU and Indian Jurisdictions.

The world might undergo some seismic changes with the advent of mega-regional trade agreement like the Trans-Pacific Partnership (TPP) and the Transatlantic Trade and

Investment Partnership (TTIP). Consequently, these may change the multilateral trading system and may have a potential to reduce the role of WTO as the mediator of commercial relations amongst nations. In this backdrop this study highlights the flexibilities of the TRIPS to be exploited through legislative measures to protect national interest of Bangladesh in the fields of medicine, seed and software.

On the one hand Bangladesh is under pressure from the US and EU to implement the TRIPS' provisions through its national legislation within the transitional period or before the end of it; and on the other hand, at present Bangladesh is not in a position to decide on its role in the negotiation process of the mega regionals due to its inadequate legal and policy framework and details of these agreements have been 'shrouded in secrecy'.[29]

Investor-state arbitration claim is a great challenge for effective implementation of the TRIPS Agreement's flexibilities through domestic legislation for an LDC like Bangladesh. Recent trends show that companies are increasingly challenging domestic decisions pursuant to bilateral and multilateral agreements that provide protection to foreign investors and permit them to bring an end to the investor - state dispute. In these disputes companies, may not only challenge the patentability standards they disagree with, but also exceptions to patent rights (flexibilities), even where these exceptions are permissible under TRIPS.[30]

Bangladesh as an LDC should take sufficient legal measures in protecting its national interest in medicine, seed and software before entering any such bilateral or multilateral agreement. Since this is a recent trend and Bangladesh is in the transitional stage to implement TRIPS, the MNCs are yet to file any such dispute against Bangladesh. Therefore, this study has not explored this issue.

[29] R. Patel, 'A Public Health Imperative: The Need for Meaningful Change in the Trans-Pacific Partnership's Intellectual Property Chapter', *Minnesota Journal of Law, Science & Technology*, vol. 16, no. 1, 2015, p. 477.

[30] C. M. Ho, 'Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions', *Berkeley Technology Law Journal,* vol. 30, no. 1, 2015, p. 213.

The draft Bangladesh Patent Act, 2015 has been treated as the latest draft on the legislative effort of the Government of Bangladesh (GOB) after Bangladesh become a party to the TRIPS Agreement by signing and ratifying the Marrakesh Agreement, i.e. the WTO Agreement. The recommendations are focused on and limited to the PD Act and the draft Bangladesh Patent Act, 2015. The changes of the relevant laws are suggested on the existing and enforced legal regime of medicine, seed and software of Bangladesh in the light of international best practices.

1.8 Limitations of the Study

One of the major limitations of the study is that Bangladesh has yet to develop any case law on the PD Act. After extensive search, no patent case was found in the District Court of Dhaka and no reported case was found on patent in both the Divisions of the Supreme Court of Bangladesh. The study relied on the case laws of Indian, US and EU jurisdictions in dealing with specific issues of medicine, seed and software.

Since Bangladesh is in transition in implementing the provisions of the TRIPS and this transition particularly in implementing Article 27 of TRIPS, extends for seed and software till June 2021 and for medicine till January 2033, the policy documents and legislative efforts of the GOB do not put much emphasis on implementing TRIPS, i.e. Article 27 in these three sectors.

GOB has yet to introduce any National Intellectual Property Policy for Bangladesh. An assessment of national intellectual property system for developing a national intellectual property policy for Bangladesh[31] has been conducted recently by the WIPO and the University of Dhaka which also did not provide any clear guideline for implementing the

[31] B. H. Khondker and S. Nowshin, *Developing National Intellectual Property Policy for Bangladesh: An Assessment of National Intellectual Property System (Draft)*, [pdf] , World Intellectual Property Organization, 2013, http://dpdt.portal.gov.bd/sites/default/files/files/dpdt.portal.gov.bd/policies/0b84dc51_4a40_4333_ab01_66b4be436e26/IP%20Policy.KS.pdf , (accessed 25 February 2016).

TRIPS provisions through the Patent Laws of Bangladesh. Particularly the draft report is silent regarding patenting medicine and software and introduction of a *sui generis* system or other method for protecting the seed industry of Bangladesh.

WIPO sponsored another project on innovation and intellectual property policy and strategy for Bangladesh with the prime objective of formulating a policy to develop a well-balanced IP system and to promote innovation and creativity in Bangladesh in line with the TRIPS' obligations and for the benefit of sustainable socio-economic development of the country.[32] Though this study made some observations on transfer of technology, it did not make any attempt to shed any light on implementing the TRIPS' provisions through legislative measure by Bangladesh, particularly implementing Article 27 of TRIPS through patent law or by an effective *sui generis* system for protecting medicine, software and seed industry.

The study faces serious challenge in revealing importance of patent protection of software besides copyright protection to protect the software industry of Bangladesh. How far TRIPS imposes obligation on its Members to provide software protection is a controversial issue and it is difficult to come to any straight forward conclusion like that TRIPS does not make it obligatory for Members to provide software patenting because patenting is not necessary to protect software besides copyright protection, or software patenting might be detrimental to the national interest to protect our software industry or this will affect the human rights to getting benefit from innovation of new software.

Since our medicine industry is yet to manufacture API from scratch or incapable of producing generic medicine, the native pharmaceutical companies are not much concerned about the impact of medicine patenting on the industry. Due to this unawareness, this study finds a little

[32], M. K. Uddin, *Draft Report on Innovation and Intellectual Property Policy and Strategy for Bangladesh*, [pdf], World Intellectual Property Organization, 2012, http://dpdt.portal.gov.bd/sites/default/files/files/dpdt.portal.gov.bd/policies/04745374_f547_4d92_ba38_1299e50d98b1/IP%20Policy.MKU.pdf, (accessed 29 February 2016).

policy advocacy on the public-private level for adopting necessary legislative measures to derive benefit from the TRIPS' flexibilities on medicine patenting. This vacuum or shortcoming is also a great challenge for finding adequate data and information in this regard. Though seed is a thrust sector in the agriculture of Bangladesh, this study finds almost no public initiative to assess the legal impact of implementing the TRIPS' provisions regarding plant varieties or seed. The study finds a few private initiatives in protecting the plant varieties of Bangladesh. This, thus becomes a very crucial challenge for the researcher to find out the ground reality in Bangladesh on MNCs influence on the seed industry of Bangladesh and shortcomings of legislative and policy vacuum in this regard.

Technology transfer to medicine, seed and software industries of Bangladesh is a critical issue. However, insignificant public-private initiative is found on removing the policy barriers of transfer of technology to these sectors from the perspective of Bangladesh. This vacuum makes the study very challenging in finding appropriate information on the issues relating to the legal and policy reforms on implementing the TRIPS' provisions regarding transfer of technology to the medicine, seed and the software industries of Bangladesh.

Chapter 2: The Impact of the TRIPS Agreement on Bangladesh in the Field of Patenting Medicine

2.1 Introduction

The Agreement on Trade-Related Aspects of Intellectual Property Rights, 1995 (henceforth the TRIPS Agreement) binds all Members of the WTO to the task of protection and promotion of intellectual property rights (henceforth IPRs).[33] The TRIPS Agreement has also opted for establishing a minimum threshold for the protection of IPRs on one hand and diminishing the barriers or hindrances to the legitimate trade and business in the field of IPRs on the other. Thus, TRIPS has aspired to have a balanced rights and obligations system under its legal framework so that private rights of IPRs holders and interests of the consumers or mass people can be ensured. Putting medicines and lifesaving drugs under the patents regime by the TRIPS may result in genuine concern for the LDC's or middle income countries since the price of such items may go out of reach.

Since, Bangladesh is a Member state of the WTO, it automatically falls under the TRIPS agreement. As Bangladesh is a Least Developed Country (LDC), it is enjoying the exemption from the TRIPS' obligation until 1 January, 2033 or until the country ceases to be an LDC.[34]

In the domestic sphere, Bangladesh has an age-old patent related law on the one hand, and in the context of TRIPS, it needs to be a TRIPS compliant country on the other. It is a great challenge for a country like Bangladesh to be compliant to TRIPS at the same time protecting national interests in a delicate sector like pharmaceutical industry which has a huge public health implications. Given this, overview, review and extensive research must be carried out

[33] the WTO Agreement, Article 11.2.

34 WTO, 'Responding to least developed countries' special needs in intellectual property' WTO, Geneva, Author, https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm, (accessed 6 June 2015).

in the current legal regime and feasible policy option for countries like Bangladesh must also be explored.

In Bangladesh, patents are granted under The Patents and Designs Act, 1911 which was enacted during the colonial rule. The way Act has defined invention. However, it does not apparently put a bar to patent pharmaceutical inventions in Bangladesh. Additionally, section 2 (10) of the same section defines "manufacture" includes any art, process or manner or producing, preparing or making an article, and also any article prepared or produced by manufacture. Thus, a reading of the invention and manufacture clauses together would affirmatively confirm that new manufacture may include pharmaceutical inventions.

However, Bangladesh as an LDC is currently enjoying a transition period (not obliged to give pharmaceutical product patent) as originally envisaged by the Doha Ministerial Declaration, 2001 and which is now further extended by the TRIPS Council until January 1, 2033. Being a least developed country Bangladesh should reap full advantage of the extension of not granting pharmaceutical product patents. Issuance of medicine patent might also hamper the production of medicine by the local pharmaceutical companies, who most often use the API to produce medicines invented by the multinational companies which are not patented in Bangladesh.

In 2006, it became a news for the first time that foreign pharmaceutical companies obtained as many as 40 patents on their drug formulas which was seriously objected to by Bangladesh Association of Pharmaceutical Industries.[35] Thus, grounds of raising such objection is a matter of great significance and would be given due attention in this study. The TRIPS Agreement has some built-in flexibilities in patenting pharmaceutical products. Being a WTO

[35] M. M. Murshed, 'TRIPS Agreement and Patenting of Pharmaceutical Products', *The Daily Star*, 19 August 2006, http://archive.thedailystar.net/law/2006/08/03/index.htm , (accessed 8 August 2016).

Member and an LDC, how Bangladesh would be able to reap best possible benefits from such flexibilities is an important issue which would be addressed properly in this study. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short-term objective of allowing people to use existing inventions and creations. How this balance works in patenting pharmaceutical products would be also adequately explored in the study.

It is an important issue to understand the obligations of the Member States under TRIPS on pharmaceutical patenting and thus, the study would explore this issue with due significance. Research exception and BOLAR provision, Parallel imports and compulsory license are some important flexibilities under TRIPS to strike balance between people's right to medicine and inventors' right to exploit their invention. These technical provisions would be explained and how Bangladesh may use these tools effectively in the use of existing medicines and the creation of new medicines would be recommended at the end of this study.

How the Doha declaration affects the provisions of TRIPS in respect of patenting pharmaceutical products and what waivers are adopted in that declaration are very important aspects of Doha Development and would be discussed in this chapter. In considering the existing situation, what measures Bangladesh should adopt to amend or re-enact its Patent law after transition period or during the transition period would also be explored in this study. Finally, this study reveals what the guideline should be for enacting the new Patent law and immediate amendment of the existing Patent Act if any, in order to best exploit the TRIPS' flexibilities and declaration of Doha for protecting national interest in medicine/ pharmaceuticals.

2.2 Relevant Provisions of TRIPS and Medicine Patenting

The issues of patents are guided by the article 27 of the TRIPS Agreement that states the patentable subject matters with exceptions where a State party may refuse to grant a patent. Subject to the exceptions provided in that Article patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve inventive steps and are capable of industrial application.[36]

The TRIPS has allowed the Member states to refuse the grant of patent in certain cases 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.[37] The 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 protection for 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."[38]

Under the provisions of TRIPS, the Member states need to provide medicine patenting, if those products are inventions, involve inventive steps and have industrial application.

[36] For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively. -Article 27 of the TRIPS Agreement.

[37] the TRIPS Agreement, Article 27.2.

[38] the TRIPS Agreement, Article 27.3.

Furthermore, TRIPS also postulates that no discrimination can be made to the subjects of patents regarding fields of technology and the place of inventions.

Article 27 postulates that patent protection should be awarded without any discrimination in the fields of inventions and place of origin. Thus, Members are under obligation to provide the patent without any discrimination of inventions and their place of origin. This provision has established the principle of non-discrimination on a) between product patents and process patents, b) between the industries where invention applies.

On the other hand, article 7 and 8 of TRIPS delineate the objectives and principles whereby the Member states may establish the balanced approach and at the same time adopt the policy measures to ensure public health and protect public interests. Moreover, other relevant provisions on Patenting under TRIPS regime have led to the conclusion that varying scope of interpretations and implementation is possible by the Member states.[39]

2.3 Doha Declaration and its impact on medicine patenting

Ministerial Conference of Member States, the highest body of the WTO adopted the Doha Declaration, 2001, that has great implications for public health. The genuine concerns of LDCs regarding medicine patenting and access to drugs at affordable costs which may be hampered due to patents regime of MNCs around the world has been considered as the catalysts in Doha Declaration. Member States affirmed that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. They further underscored that LDC's ability to use the flexibilities under TRIPS, including compulsory licensing and parallel importing. Significantly, the Declaration endorsed the public goods interpretive way of TRIPS and at the same time affirmed the liberty of Member states to

[39] Article-6, Articles 30 and 31 of TRIPS Agreement, 1995.

determine the grounds for compulsory licensing along with right to determine what constitute national emergency and extreme urgency of a particular nation.[40]

2.4 Extension of Transition Period and Medicine Patenting

Bangladesh, as an LDC is currently enjoying the transitional arrangements provided by the TRIPS Agreement regarding enforcement of the TRIPS provisions through the patent law. For medicine patenting, the transition period has been extended twice for all LDC Members in response to a specific request by the LDC Group. In the decision of 29 November 2005, the TRIPS Council extended the period until 1 July 2013, and on 11 June 2013 it extended the transition period until 1 July 2021 or until the country ceased to be LDC.[41]

However, there was a dispute that whether such extension period is the same way applicable to Pharmaceutical Industry since there is a separate transitional period for it until January 01, 2016. Despite the dispute it is the majority view that the decision of June, 11, 2013 includes the patent as a subject matter, thus, LDC's should be exempted to 1 July 2021 from Pharmaceutical Patenting along with other sectors.[42] All the confusions have been removed by the TRIPS council decision on extending further the transitional period for pharmaceutical products and exempting the LDCs from the obligations under article 70.8 and 70.9 of TRIPS until 1 January 2033 or until the country ceased to be LDC.[43]

---

[40]See, Paragraph 5, Doha Declaration, 2001.

[41] WTO, 'Responding to least developed countries' special needs in intellectual property' WTO, Geneva, Author, https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm, (accessed 6 June 2015).

42 C. Saez, *What Does WTO Extension For LDCs To Enforce IP Mean For Pharmaceuticals?*, [html] , Intellectual Property Watch, 2013, http://www.ip-watch.org/2013/08/02/what-does-wto-extension-for-ldcs-to-enforce-ip-mean-for-pharmaceuticals/ , (accessed 15 June 2015).

43 WTO, 'Responding to least developed countries' special needs in intellectual property' WTO, Geneva, Author, https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm, (accessed 6 June 2015).

2.5 The Impact of Patent on Price of Drugs in LDCs like Bangladesh

In 2006, when DPDT of Bangladesh granted patent to as many as 40 pharmaceutical products of MNCs, the debate and concerns over medicine patenting and public health implications got new dimensions from Bangladesh's perspective. The impact of such patenting in the context of Bangladesh is a critical issue. It is apprehended that the challenges of patenting drugs are multifarious; some of the crucial consequences are as follows:

a) "The reverse engineering method applied to pharmaceutical products of MNCs by the local pharmaceutical companies would be obstructed;
b) Marketing and exporting of the pharmaceutical products manufactured by using reverse engineering would be challenged by the multinational companies which may seriously affect the local pharmaceutical companies;
c) The price of the pharmaceutical products in local and international markets may be 15-20 times higher than the present price;
d) TRIPS Council's waiver on exclusive marketing right of new pharmaceutical products by its manufacturer may highly be affected; and
e) Inability of LDCs and Developing Country Member States to reap the benefit of the waiver of the TRIPS Council regarding flexibility on granting patent on pharmaceutical products."[44]

In Bangladesh, people generally use generic medicines for diseases like cancer, HIV, malaria, tuberculosis, blood pressure and so on. Bangladesh imports a considerable amount of these medicines from India. Recently, India amended its patent law in order to make its generic medicine patentable. Now India grants patents for its pharmaceutical products. Thus, India

[44] M. M. Murshed, 'TRIPS Agreement and Patenting of Pharmaceutical Products', *The Daily Star*, 19 August 2006, http://archive.thedailystar.net/law/2006/08/03/index.htm , (accessed 8 August 2016).

enters the era of product patents for new medicines instead of process patents. Earlier different process could be adopted to make a pharmaceutical product, which had a process, patented. But from the amendment of 2005 it would be an infringement if someone adopts a different process to make a patented pharmaceutical product in India.

The essential medicine for HIV treatment is antiretrovirals (ARVs). Before the amendment, the Indian pharmaceutical companies were at liberty to produce ARVs. But from January 1, 2005 one must get a license from the patentee before producing any patented pharmaceutical product. The amendment gets retrospective effect from 1995. Thus, the Pharmaceuticals companies, which obtained a patent on a pharmaceutical product on or after 1995 from any country other than India, can enforce the right in India. Such legal provisions will make Indian generic medicine costlier than the recent past.

A recent report[45] reveals that in Bangladesh there are 3674 registered cases of HIV infection while the estimated number of people living with HIV is around 9500 who are getting medication of ARVs. The trend of HIV infection in Bangladesh is steadily upward. Therefore, Bangladesh may also be affected by the incorporation of medicine patent in Indian Law.

James Love opined that many differences in prices may be explained by the inefficiencies in the distribution systems. This is true for products that are on or off patent. For example, the December 31, 1998 report in the Wall Street Journal, which indicated that the US pharmacies routinely impose enormous markup on retail prices of generic products. Another example can

[45] UNAIDS, *Global AIDS Response Progress Report (GARPR): Annual Progress Report Bangladesh*, 2015, http://www.unaids.org/sites/default/files/country/documents/BGD_narrative_report_2015.pdf, (accessed 17 March 2016).

be given, Atenolol, a drug for high blood pressure, was sold by the generic manufacturer for $.62, and retailed by the pharmacy at $14.68, a 2,368 percent increase.[46]

"Some countries regulate pharmacy margin, that may also cause distortions. In Bangladesh low cost generic suppliers complain that pharmaceuticals are reluctant to sell the least expensive products, because the retail markups are relatively smaller. There are also many unacceptable incentives at the point of prescription. In some countries, such as South Africa, doctors also dispense products, and earn substantial income from prescribing expensive brand name products. And, of course, there are countless stories all over the world of manufacturer kickbacks and gifts to doctors who prescribe products."[47] The doctors in Bangladesh are also accused of such allegations.

High price of medicine is certainly a barrier to the easy accessibility of the essential drugs. A study reveals the fact that "only 15 of the 306 products on the WHO's Model List of Essential Drugs or less than 5% are protected by patents."[48] Rozek and Berkowitz studied the prices and found that protecting IPRs does not result in an increase of real or nominal prices of existing products. They also found that strengthening IPRs had no significant impact on the prices of any drugs including those products introduced after IPRs had been strengthened in countries with price regulation. It should also be remembered that the economic study made by the Latin American think-tank FIEL on Argentina - a country that did not allow patents for pharmaceutical products - revealed that the prices paid for 'generics' (medicines

[46] UNAIDS, *Global AIDS Response Progress Report (GARPR): Annual Progress Report Bangladesh*, 2015, http://www.unaids.org/sites/default/files/country/documents/BGD_narrative_report_2015.pdf, (accessed 17 March 2016).

[47] J. Love, 'Presented at the WHO/WTO Joint Secretariat Workshop on Differential Pricing and Financing of Essential Drugs' Presented at the WHO/WTO Joint Secretariat Workshop on Differential Pricing and Financing of Essential Drugs. Hosbjor, April 11, 2011. http://www.cptech.org/ip/health/econ/jamie-hosbjor.html, (accessed 20 June 2016).

[48] R. P.Rozek, 'The Effects of Compulsory Licensing on Innovation and Access to Health Care', *The Journal of World Intellectual Property*, vol. 3, no. 6, 2000, p. 889.

sold by the local firms which could be passed off as originals) were on an average 60% more expensive than the original medicines which are marketed by the international laboratories.[49] Felix Rozanski opined that "…there are many fundamental problems in access to health services in developing countries that are unrelated to patents. These range from poor funding as a result of incorrect assignment of resources, to physical barriers, including lack of healthcare facilities, staff, equipment or distribution channels, as well as information asymmetries."[50] The Director of HIV Division of WHO stated in relation to the AIDS epidemic, "The real obstacle is the fragility of the health care systems. We have health infrastructure that is dilapidated, and supply chains that do not exist."[51]

The National Drug Policy of Bangladesh, 1982 echoed the comments made above. It revealed that maximum retail prices of finished drugs were fixed by the Ministry of commerce under the Essential Commodities Act and Orders. There was no agency for enforcement of prices at retail level; the prices of drugs fluctuated widely in the market according to demand and supply. Further, there was no control over the prices of pharmaceutical raw and packaging materials which contributed more than 60% of the prices at trade level. The same materials were imported from different sources by different manufacturers at widely variable prices ranging up to four times. It was further found that in the drug laws there was no provision for technology transfer and/or licensing agreement with foreign collaborators. Similarly, there was neither provision for protection of consumers from drug hazards nor there was protection of national interest in respect of patent rights of pharmaceutical substance.

---

[49] R. P.Rozek and R. Berkowitz, 'The Effects of Patent Protection on the Prices of Pharmaceutical Products: Is Intellectual Property Protection Raising the Drug Bill in Developing Countries?', *The Journal of World Intellectual Property*, vol. 1, no. 2, 1998, p. 179.

[50] F. Rozanski, *Developing Countries and Pharmaceutical Intellectual Property Rights: Myths and Realities*, edited, Stockholm Network, 2007, stockholm-network.org.
(accessed 14 May 2011).

[51] P. Reaney, 'Interview: Creaking health systems hampering Aids battle- WHO", *Reuters News Media*, 21 July 2006.

The impact of National Drug Policy of Bangladesh, 1982 (NDP, 1982) can be better understood from the findings of National Drug Policy of 2005 which are stated below:

- Following the guideline of NDP, 1982 Drug (Control) Ordinance, 1982 was promulgated and these two documents were applauded worldwide;
- Availability of essential drugs increased remarkably. The monetary value of which grew from TK. 1730 million in 1981 to 41000 million in 2002;
- The local pharmaceutical companies increased their share of production from 30% in 1970 up to more than 80% in 2002;
- Drug prices stabilized, increasing (practically a drop of price in real terms) by only 20%, compared to an increase of 179% in the consumer price index. This made drugs more affordable to consumers;
- Quality of products improved and the proportion of substandard drugs fell from 36% in 1970 to only about 2% in 2002;
- Volume of import of drugs and medicine in the country reduced drastically;
- Less dependency on import and prioritization of useful drugs saved the country approximately $600 million per year;
- A drug importing country Bangladesh turned into a drug exporting country.

In implementing the TRIPS' provisions through legislations Bangladesh should carefully protect and ensure sustainability of the above stated achievements. In realizing this goal Bangladesh should take the following steps:

i. Introducing a new drug policy in the light of implementing medicine patenting at the latest 2033 with a safety measure of implementing the medicine patenting[52] earlier on the

[52] Patent for both product and process medicine.

probability of graduating of Bangladesh from an LDC to a middle-income country by 2021[53] with attention to:

a. making the pharmaceutical industry capable of producing generic medicine or APIs from inception;[54]

b. determining and limiting the scope of MNCs in the production and marketing[55] of medicines including lifesaving drugs in Bangladesh; and

c. creating a viable technological base for transfer of technology to the medicine sector of Bangladesh.[56]

ii. Revisiting its PD Act and laws relating to medicine to exploit the TRIPS' flexibilities earmarked for LDCs and the same should be explicitly stated in the new drug policy.

iii. Make a roadmap to implement the TRIPS' provisions through legislative measures by 2021[57] and 2033 with strategies for implementing the roadmap in the new drug policy.

2.6 Other Consequences of Patenting Pharmaceutical Products

Under the existing Patents and Designs Act, 1911 the patent officials of Bangladesh are supposed to grant a patent on a medicine product or process if the application is valid and accompanied by all the criteria of patentability. The apprehensions of the Association of Bangladesh Pharmaceutical Industries regarding impact on reverse engineering method, marketing and exporting pharmaceutical products manufactured by using reverse engineering, TRIPS Council's waiver on exclusive marketing right of new pharmaceutical

[53] General Economics Division, Planning Commission Bangladesh, Perspective Plan of Bangladesh 2010-2021, Making Vision 2021 a Reality, Dhaka, Government of the People's Republic of Bangladesh, 2012, http://bangladesh.gov.bd/sites/default/files/files/bangladesh.gov.bd/page/6dca6a2a_9857_4656_bce6_139584b7f160/Perspective-Plan-of-Bangladesh.pdf , (accessed 20 March 2016).

[54] The National Drug Policy of Bangladesh 2005. [2005].

[55] Here marketing includes exclusive marketing right (EMR).

[56] This issue has been dealt separately in Chapter 5 of the thesis.

[57] The Council for TRIPS by its decision IP/C/64, 12 June 2013 extended the exemption period for implementing TRIPS' provisions till 1 July 2021 and IP/C/73, 6 November 2016 extended the exemption period of implementing TRIPS' provisions till 1 January 2033.

products by its manufacturer and Government's inability to reap the benefits of abstention from granting patent on pharmaceutical products are crucial issues and needs to be examined carefully.

It is viewed by this Author that, "[W]hen patent protection is provided for a pharmaceutical product or a drug formula, local manufacturers cannot use the method of reverse engineering in order to manufacture the product commercially or use the drug formula for commercial purpose. At best the local manufacturers can use such products or formula to invent a better product or formula by using reverse engineering. Since Bangladesh is an LDC it is not in a position to provide its local manufactures the technological or logistic support to conduct research on the patented products or formula of the multinational companies in order to produce better product or formula and in this way may reap the benefit of patenting pharmaceutical products or drug formula."[58]

It is noticed by this Author that, "[T]he existing practice of using reverse engineering of the pharmaceutical products or drug formula would be challenged by the multinational companies for the reverse engineering of their patented product and formula. The local manufacturers may lose the legal battle and would be compelled to withdraw their products or formula from national and international market and have to pay a huge compensation to the multinational company concerned. When the local manufacturers would require using the patented product or formula of a multinational company, they must get license from the company by paying huge foreign currency. Due to this, the price of the essential drugs may shoot up to several times than the existing price."[59]

---

[58] M. M. Murshed, 'TRIPS Agreement and Patenting of Pharmaceutical Products', *The Daily Star*, 19 August 2006, http://archive.thedailystar.net/law/2006/08/03/index.htm , (accessed 8 August 2016).

[59] ibid.

In a study conducted by the Centre for Policy Dialogue in Bangladesh it was found that the pharmaceutical industry in Bangladesh is the largest in the least developed countries, but it neither has the research capability to invent new pharmaceutical products, nor has the imitative capacity to reverse engineer patented drugs in order to develop competing generic products. Instead, the principal activity of the domestic industry is the final production of generic products using imported generic active ingredients. These products are sold primarily in the domestic market.

Under the TRIPS' Provisions the supply of generic ingredients may be cut off as a result of TRIPS requirement that the developing countries in which most of the generic producers reside have already provided patent protection to both process and product of medicine.[60] Due to the exemption in the transition period given to LDCs until 1 January, 2033, the exclusive rights for a new pharmaceutical product i.e. making, using, offering for sale, selling and importing for these purpose and for a new drug formula i.e. for use of the formula and the product obtained directly from the formula need not be provided by the LDCs. Therefore, Bangladesh is not required to provide exclusive rights to a multinational company for its any of its new pharmaceutical product or a new drug formula. But once patent protection is given by the patent office for such a product or formula, the government is bound to provide and ensure the exclusive rights of such a company.

2.7 Flexibilities under TRIPS and Scope of Maneuvering by Bangladesh

The TRIPS Agreement itself has provided some built-in flexibilities in striking a balance between incentive to inventors and right of access to medicine of public. The Member States

[60] T. V. Duzer, *TRIPS and Pharmaceutical Industries in Bangladesh: Towards a National Strategy*, in CPD Occasional Paper Series, [pdf] , Center For Policy Dialogue (CPD), Bangladesh, 2003, http://www.cpd.org.bd/pub_attach/op24.pdf , (accessed 14 May 2011).

particularly the developing countries and LDCs are at liberty to utilize some means and methods such as Research exception and BOLAR provision, Parallel imports and compulsory license etc. It is important to examine how far Bangladesh is and will be able to exploit these flexibilities under its existing legal framework of Patent law, what the existing gaps are and how such gaps should be addressed by the possible policy and legislative initiatives by the government.

2.7.1 Compulsory License and Government Use

The TRIPS Agreement allows compulsory licensing as part of the agreement's overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs. However, the term "compulsory licensing" does not appear in the TRIPS Agreement. Instead, the phrase "**other use without authorization of the right holder**" is mentioned.[61] Compulsory licensing is only a part of this since "other use" includes use by governments for their own purposes. Compulsory licensing and government use of a patent without the authorization of its owner can only be done under a number of conditions aimed at protecting the legitimate interests of the patent holders. Normally, the person or company applying for a license must have first attempted, unsuccessfully, to obtain a voluntary license from the right holder on reasonable commercial terms.[62] If a compulsory license is issued, adequate remuneration must still be paid to the patent holder.[63]

However, for "national emergencies", "other circumstances of extreme urgency" or "public non-commercial use" (or "government use") or anti-competitive practices, there is no need to

[61] The TRIPS Agreement, (1994), Article 31.
[62] The TRIPS Agreement (1994), Article 31 (b).
[63] The TRIPS Agreement (1994), Article 31 (h).

try for a voluntary license.[64] Compulsory licensing must meet certain additional requirements. In particular, it cannot be given exclusively to licensees (e.g. the patent-holder can continue to produce), and usually it must be granted mainly to supply the domestic market. Generally compulsory licensing procedures are burdensome and vague, thus, developing countries must fine-tune their laws to make the best use of it. Commission on Intellectual Property Rights (CIPR) has rightly observed that, "Developing countries should establish workable laws and procedures to give effect to compulsory licensing and provide appropriate provisions for government use."[65]

In the domestic Law of Bangladesh, section 22 of the Patents and Designs Act, 1911 provides for compulsory license. According to the provisions of section 22 an unsuccessful attempt to obtain a voluntary license is not a must in Bangladesh. There are no provisions for national emergency or other circumstances of extreme urgency, public non-commercial use or government use or anti-competitive practice etc. The Act is silent about whether the compulsory licensee got exclusive right or the patent holder can continue to produce and whether the license can be granted to supply the patented product to the domestic market only. Furthermore, under the Patents and Designs Act, 1911 of Bangladesh, High Court Division and the Government have concurrent jurisdictions on issuing compulsory license or revocation of a patent on the following situations:

a) Any person interested should present a petition to the Government which shall be left at the Department of Patents, Designs and Trade Marks, together with the prescribed fee.

[64] The TRIPS Agreement (1994), Art. 31 (b).

[65] Commission on Intellectual Property Rights (CIPR), *Integrating Intellectual Property Rights and Development Policy: Final Report of the Commission on Intellectual Property Rights*, Commission on Intellectual Property Rights (CIPR), London, Author, 2002, p. 44.

b) The allegation should be 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.

c) The parties must come to an arrangement between themselves and only in case of failure the Government may itself dispose of the petition or refer it to the High Court Division.

d) The Government or the High Court Division as the case may be must come to the conclusion that the demand for the patented article in Bangladesh is not being met to an adequate extent and on reasonable terms.

In such a case the patentee may be ordered to grant licenses on such terms as the Government or the High Court Division, as the case may be, may think just, or, if the Government or the High Court Division is of opinion that the demand will not be adequately met by the grant of license, the patent may be revoked by order of the Government or the High Court Division.

However, there is a further condition that an order of revocation shall not be made before the expiration of four years from the date of the patent, or if the patentee gives satisfactory reasons for his default. In this regard, the demand for a patented article shall not be deemed to have been met to an adequate extent and on reasonable terms-

(a) if by reason of the default of the patentee to manufacture to an adequate extent and supply on reasonable terms the patented article, or any parts thereof which are necessary for its efficient working, or to carry on the patented process to an adequate extent or to grant licenses on reasonable terms, any existing trade or industry or the establishment of any new trade or industry in Bangladesh is unfairly prejudiced, or

(b) if any trade or industry in Bangladesh is unfairly prejudiced by the conditions attached

by the patentee to the purchase, hire or use of the patented article or to the using or working of the patented process.

In exercising the compulsory license, the government of a particular country needs to be careful so that it does not violate the provisions of TRIPS. The TRIPS Agreement provides that governments can act to prevent patent owners and other right-holders of intellectual property from abusing intellectual property rights, "unreasonably" restraining trade, or hampering the international transfer of technology.[66]

Azam observed that although there are some limitations under section 22 of the Bangladesh Patents Designs and Trademarks Act, 1911 by which provisions for compulsory licensing can be done, however, the vagueness of terms like 'inadequacy' 'unreasonable terms' limitations on domestic use, referring issue to HCD and finally vagueness on ceiling of royalties have made the provisions complicated.[67] He further submitted that under existing legal framework of Bangladesh the provisions for compulsory licensing are cumbersome.[68] Section 22(1) of the PD Act provides three mandatory steps for presenting a petition for compulsory license or for revocation of a patent. These are:

i. presenting a petition to the DPDT together with the prescribed fee;

iii. alleging that the demand for a patented article in Bangladesh is not being met to an **adequate extent** and on **reasonable terms**; and

iii. praying for the grant of a compulsory license, or, in the alternative, for the revocation of the patent.

In the second step stated above two ambiguous terms "adequate extent" and "reasonable terms" have been used that will widen the scope of colourable exercise of administrative

[66] The TRIPS Agreement, 1995, Articles 8 and 40.

[67] M. M. Azam, 'Globalizing Standard of Patent Protection in WTO Law and Policy Option for LDCs: The Context of Bangladesh', *Chicago-Kent Journal of Intellectual Property,* vol. 13, no. 2, 2014, p. 430.

[68] ibid.

power despite of their complicated explanation given in section 22(5) of the PD Act. The provision does not provide any time limit for disposing of the petition for compulsory license or revocation of patent and the power of High Court Division in dealing with such petitions is substantially curtailed by executive decision of referring the petition to the High Court Division. Therefore, the High Court Division cannot entertain such petitions except such petitions are referred by the Government to the High Court Division.[69]

Thus, Bangladesh government or the High Court Division never issued compulsory license or revoked any compulsory license. Azam suggested that Bangladesh should follow the Indian approach. However, within the Indian way there are some challenges that India is facing now. In India, compulsory license has been applied for once under section 92 of Indian Patents Act, 1973 but it was rejected by the Indian authority due to non-fulfillment of statutory obligation, i.e. request from importing country.[70] Under the TRIPS regime compulsory licensing is predominantly for domestic use.[71] This may hamper the importing scope for the countries which do not have manufacturing capacity.

For addressing this issue, on 6 December 2005 the WTO General Council adopted the protocol amending the TRIPS Agreement and opened it for acceptance by Members.[72] In fact this Protocol aimed to ease the problem of effective use of compulsory license by the Members of the WTO having insufficient or no manufacturing capacities in the pharmaceutical sector initiated on the basis of the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Doha Declaration.[73] Basically this

[69] Patent and Design Act, 1911, [1911}, s. 22(2).
[70] K. M. Gopakumar, 'Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime', *The Law and Development Review,* vol. 3, no. 2, 2010, pp. 326-368.
[71] Ibid, Article 31(f).
[72] WTO General Council Decision no. WT/L/641, dated 6 December 2005.
[73] WTO, 'Responding to least developed countries' special needs in intellectual property' WTO, Geneva, Author, https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm,
(accessed 6 June 2015).

Protocol shall amend the TRIPS Agreement by inserting Article 31bis after Article 31 and by inserting the Annex to the TRIPS Agreement after Article 73. The Amendments include non-application of Articles 31(f), 31(h) and 31(f) of the TRIPS Agreement under certain conditions and imposed some conditions on issuing compulsory license.

A Member is at liberty to deposit an instrument of acceptance of the Protocol without having adopted domestic legislation implementing the Paragraph 6 System and the current deadline for depositing acceptances is 31 December 2017.[74] Bangladesh should examine the Protocol in deciding either to accept it in any of these manners or not to accept it at all, because acceptance of the Protocol might snatch the liberty of a Member to incorporate the provisions of compulsory license through its domestic legislation prioritizing its own national interest.

In 2003, the TRIPS Council adopted some waiver decisions that waived the restrictions for enabling the LDCs and other Members to issue compulsory license to export generic medicines to the Members with insufficient or no manufacturing capacities in the pharmaceutical sector. LDCs are eligible as the first category to use compulsory license for export to other LDCs without formal notifications. Other countries have committed not to apply these provisions except in the case of national emergency or extreme urgency or non-commercial public use.[75]

Bangladesh may follow the Brazilian way to reduce the price of patented life-saving pharmaceutical products. It has been experienced in Brazil that the Government issued compulsory license to produce the US patented AIDS drugs in Brazil. The US government imposed a heavy sanction on Brazil. Brazil reduced the price of an essential life-saving drug by using compulsory license, which has been followed by several other countries.

[74] WTO, "How to accept the protocol Amending the TRIPS Agreement", Geneva, Author https://www.wto.org/english/tratop_e/trips_e/accept_e.htm, (accessed 26 March 2016).
[75] ibid 71.

However, it must be remembered that the provisions of compulsory license must be enacted in compliance with the conditions provided in section 31 of the TRIPS Agreement. Under the TRIPS provisions the proposed user before getting license must seek authorization from the patentee on reasonable commercial terms and conditions and such effort must fall within a reasonable time. The scope and duration of such use also must be limited to the purpose for which it is authorized. The right holder must be paid adequate remuneration considering the economic value of the authorization. The issuance of compulsory license must be subject to the judicial review or review of an independent body. These are the core conditions among other conditions provided in section 31 of the TRIPS Agreement.[76]

For using the tool of compulsory license Bangladesh should provide for such legal provision which would enable her to use compulsory license in case of national emergency or extreme urgency or for non-commercial use without the consent of the patentee. In paying adequate compensation to the patentee on the economic value, the license rules should be framed keeping in view the economic status of Bangladesh. Since Bangladesh can manufacture generic drugs from API therefore, it should exploit the tool of compulsory license for keeping the price of essential medicines at a reasonably lower level which should be affordable to its low-income citizens. Therefore, to use the tool of compulsory license Bangladesh must amend the provisions of section 22 to make those compatible with the provisions of Article 31 of the TRIPS Agreement.

2.7.2 Research Exception and BOLAR Provision

Many countries use this provision to advance research and experiment to ensure the advancement in the field of science and technology. They allow researchers to use a patented invention for research, to understand the invention meticulously. In addition, some countries

[76] the TRIPS Agreement, 1995. S. 31.

allow manufacturers of generic drugs to use the patented invention to obtain marketing approval. For example, a manufacturer of generic drugs may obtain the approval from public health authorities of using the patented product without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision.[77]

The research exception or Bolar exception is significant for developing efficient alternative to protect public health and encourage R&D.[78] The Patents and Designs Act, 1911 does not provide any such provision for research exception and BOLAR provision as impliedly enshrined in Article 30 of the TRIPS Agreement. However, the existing patent Law of Bangladesh, under section 21 provides a scope for experimental use of patented invention. The language and process are ambiguous and complicated, and so it might not have any good impact in real effect.[79] To exploit this provision of TRIPS, Bangladesh may allow manufacturers of generic medicine to use the patented invention to obtain marketing approval without the patent owner's permission before the patent protection expires. The generic producers can then market their version as soon as patent protection expires. Thus, the proposed Patent Law of Bangladesh must specifically contain the provisions for Research experiment or Bolar Provisions.

2.7.3 Exhaustion of Rights and Parallel Import

A parallel import takes place when products marketed by the patent owner (or trademark- or copyright-owner, etc.) or with the patent owner's permission in one country and imported into another country without the approval of the patent owner. For example, suppose

[77]The TRIPS Agreement, 1995. Article 30.

[78] M. M. Azam, 'Globalizing Standard of Patent Protection in WTO Law and Policy Option for LDCs: The Context of Bangladesh', *Chicago-Kent Journal of Intellectual Property*, vol. 13, no. 2, 2014, p. 421.

[79] Ibid.

company A has a patented drug in the Republic of China and Bangladesh and it sells the drug at a lower price in the market of Bangladesh. If a second company buys the drug from Bangladesh and imports it into the Republic of China at a price that is lower than company A's price, in that case it would be a parallel import.

The provision for parallel import or grey import is not provided in the Patents and Designs Act, 1911. As it has been discussed earlier that a country can import a drug from a country where the drug is sold at a lower cost with the license of the patentee though it is patented in the importing country where the price of drug is higher than the country of export.

The legal principle here is "exhaustion", the idea that once company 'A' has sold a batch of its product, its patent rights are exhausted on that batch and it no longer has any rights over what happens to that batch. The TRIPS Agreement simply says that none of its provisions, except those dealing with the principle of non-discrimination ("national treatment" and "most-favoured-nation treatment"), can be used to address the issue of exhaustion of intellectual property rights in a WTO dispute. In other words, even if a country allows parallel imports in a way that another country might think violates the TRIPS Agreement; this cannot be raised as a dispute in the WTO unless fundamental principles of non-discrimination are involved. The Doha Declaration clarifies the issue in this way that Members can choose how to deal with exhaustion in a way that best fits their domestic policy objectives.[80]

The concept of parallel import depends on the 'exhaustion of right' or 'doctrine first sale'. Typically, there are three types of exhaustion, namely domestic, regional and international exhaustion. Under TRIPS, countries are at liberty to adopt policy supporting any exhaustion that is beneficial and relevant for them. Generally, an international exhaustion is good for

[80]The TRIPS Agreement, Article 6 and Doha Declaration, 2001, Paragraph5 (d).

developing countries or LDCs since it enables them to import from anywhere in the world.[81] Thus, policy measures should be implemented to make low-priced drugs freely available in all countries. Generic prescribing or substitution and parallel imports are two policy measures which will allow consumers to get easy access to low-priced, quality drugs.[82] Bangladesh may provide for parallel imports with the approach of international exhaustion in its patent law to make available essential drugs at a low cost.

2.8 Amendment of the Existing Patents Law of Bangladesh

Until Bangladesh enacts new Patents Law, it may be suggested that the following amendments may be made to the Patents and Designs Act, 1911 of Bangladesh:

a) Express provisions for exclusion from patentability should be inserted in the light of the provisions of TRIPS where medicines or drug should be excluded from patentability. It should be carefully drafted so that both process and product on medicines are excluded from patentability.
b) Provisions for parallel imports should be inserted.
c) Research Exception and Bolar Provision should be inserted in the Act;
d) The provisions of section 22 i.e. compulsory license should be redrafted in the light of TRIPS;
e) Infringements of patent should be expressly provided.

In addition, the following amendments may be made to the Patents and Designs Rules, 1933:

a) The detailed provisions for issuing compulsory license including determining adequate compensation to the patent holder should be provided;
b) Detailed provisions for parallel imports should be provided; and

[81] K. M. Gopakumar, 'Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime', *The Law and Development Review*, vol. 3, no. 2, 2010, p. 344.
[82] B. K, Lanza O, SR Kaur. 'Retail drug prices: the law of the jungle'. HAI News, April 1998, 1-16.

c) Detailed provisions for research exceptions and Bolar provision should be provided.

2.9 What Provisions should be Included in the Proposed Patent Law for Bangladesh?

As it has been discussed earlier Bangladesh has an age-old Patent Law, now to meet the current and future challenges, it should therefore be revised. In the process a new Patent Law has been in the drafting stage, has been updated many a times and upgraded but to be finalized. The latest draft that we have got is the Proposed Bangladesh Patent Act, 2015 (henceforth BPA). It is of great significance to understand how the patent law should be drafted to become TRIPS complaint protecting national interest. Furthermore, Bangladesh should fully exploit the transition period for LDCs that has been extended till 2033. Thus, in drafting a new patent law we should be careful about TRIPS flexibiliies to strike a balance between incentive for inventions and the right of public for exploiting new inventions. When such law shall be drafted, attention should be given to exploit the TRIPS flexibilities and exemptions on medicine patenting. In doing so specific attention should be given to the following:[83]

2.9.1 Patentability requirements and exclusion clause

Developing countries and LDCs those who do not have native patents of their own, typically limit the patentability by increasing thresholds and narrowing down the scope of patent. For instance, both Brazil and India have adopted similar types of approach.[84] Bangladesh may adopt a similar approach by incorporating patentability requirements, namely- novelty, inventive steps and industrial application along with exclusion clause.

---

[83] Bangladesh Law Commission, *Final Report on the Patents and Designs Act*, edited, www.lawcommissionbangladesh.org, 2003, (accessed 17 April 2015).

[84] M. M. Azam, 'Globalizing Standard of Patent Protection in WTO Law and Policy Option for LDCs: The Context of Bangladesh', *Chicago-Kent Journal of Intellectual Property*, vol. 13, no. 2, 2014, p. 421.

The Indian legislative measures in this regard has been best explained and interpreted in *Novartis AG V. Union of India and Others* case by the Supreme Court of India where three appeals have been disposed of by a single judgment.[85] In this case, the Indian Supreme Court has made an in depth analysis of the terms 'invention' and 'patentability' and explained how within the ambit of the TRIPS a Member of the WTO may best exploit its provisions to implement those through national legislation. This famous Indian case has been dealt here separately in understanding what the policy makers and legislators should consider in determining legislative policy and enacting a new patent law or amending the existing provisions of PD Act to be TRIPS compliant protecting the national interest.

2.9.1.1 Novartis AG case

The case implicated the patent of an anti-cancer drug Glivec. The brief history of the case is that the appellant Novartis filed the application for grant of patent for Imatainib Mesylate in beta crystalline from at the Chennai Patent Office on July 17, 1998. In the application, it claimed that the invented product, the beta crystal form of Imatinib Mesylate, has (i) more beneficial flow properties: (ii) better thermodynamic stability; and (iii) lower hygroscopicity than the alpha crystal form of Imatinib Mesylate. It further claimed that the aforesaid properties make the invented product "new" (and superior!) as it "stores better and is easier to process"; has "better processability of the methanesulfonic acid addition salt of a compound of formula I", and has a "further advantage for processing and storing".

The Assistant Controller of Patents and Designs heard and rejected the appellant application for grant of patent to the subject product by five separate, though similar, orders passed on January 25, 2006 on the five opposition petitions. In narrating the facts, the Court went on

[85] Novartis Ag Vs Union of India & Others, [2013], Civil Appellate Jurisdiction, Supreme Court of India, Nos. 2706-2716, [2013], SCC,
http://supremecourtofindia.nic.in/outtoday/patent.pdf,
(accessed 17 March 2016).

"At that time, the appellate authority under the Act had yet to become functional. The appellant, therefore, challenged the orders passed by the Assistant Controller in writ petitions filed directly before the Madras High Court. Apart from challenging the orders of the Assistant Controller, the appellant also filed two writ petitions (one by the appellant and the other by its Indian power of attorney holder) seeking a declaration that section 3(d) of the Act is unconstitutional because it not only violates Article 14 of the Constitution of India but is also not in compliance with "TRIPS". After the formation of the Intellectual Property Appellate Board (IPAB), the five writ petitions challenging the five orders of the Assistant Controller were transferred from the High Court to IPAB by order dated April 4, 2007, where these cases were registered as appeals and were numbered as TA/1 to 5/2007/PT/CH. The other two writ petitions assailing section 3(d) of the Act were finally heard by a Division Bench of the High Court and dismissed by the judgment and order dated August 6, 2007. The appellant did not take that matter any further."[86]

The appeals were dismissed by IPAB on June 26, 2009. Against the order of IPAB the appellant came directly to the Supreme Court of Indian under Article 136 of the Indian Constitution.

The following questions were determined in this case:

i. What is the true import of section 3(d) of the Patents Act, 1970?
ii. How does it interplay with clauses (j) and (ja) of section 2(1)?
iii. Does the product for which the appellant claims patent qualify as a "new product" which comes by through an invention that has a feature that involves technical

[86] Novartis Ag Vs Union of India & Others, [2013], Civil Appellate Jurisdiction, Supreme Court of India, Nos. 2706-2716, [2013], SCC. pp. 9-10, http://supremecourtofindia.nic.in/outtoday/patent.pdf, (accessed 17 March 2016).

advance over the existing knowledge and that makes the invention "not obvious" to a person skilled in the art? and

iv. In case the appellant's product satisfies the tests and thus qualifies as "invention" within the meaning of clauses (j) and (ja) of section 2(1), can its patentability still be questioned and denied on the ground that section 3(d) puts it out of the category of "invention"?

Aftab Alam J who is the Author Judge observed in the judgment that "[A]t the time of Independence, India's patent regime was governed by the Patents and Designs Act, 1911, which had provisions both for product and process patents. It was, however, generally felt that the patent law had done little good to the people of the country. The way the Act was designed benefited foreigners far more than Indians. It did not help at all in the promotion of scientific research and industrialization in the country, and it curbed the innovativeness and inventiveness of Indians."[87] Since both Bangladesh and India inherited same legal regime from the British and obviously, Bangladesh adopted the same law[88] at the time of its independence in 1971, the comments made above is very much relevant to the patent regime of Bangladesh. Aftab Alam J narrated the history of revision of the PDA after the independence of India through forming committees under the chairmanship of Justice (Dr.) Bakshi Tek Chand and Justice Ayyangar. India framed its new patent law namely, the Patents Act, 1970 based on the report of Justice Ayyangar. Subsequently, India came under the obligations of the TRIPS Agreement from January 1, 1995 as a founding Member of GATT and the Member of the WTO from its inception. Justice Aftab rightly observed "[t]he TRIPS Agreement is the most comprehensive multilateral agreement to set detailed minimum

[87] ibid 16.

[88] Bangladesh adopted the Patents and Designs Act, 1911 (Act No. II of 1911) by Laws Continuance Enforcement Order dated April 10, 1971 and subsequently by Bangladesh Laws (Revision and Declaration) Act, 1973 (Act No. VII of 1973). The PD Act has been so far 29 times amended and all amendments took place during British and Bangladesh periods.

standards for the protection and enforcement of intellectual property rights, and aims at harmonizing national intellectual property systems."[89]

India had to amend its Patents Act, 1970 in 2005 by the Patents (Amendment) Act, 2005 to be compliant with the TRIPS since it was under pressure from the USA and the EC and subsequently after finding of WTO Appellate Body that requested India to bring its legal regime for patent protection of pharmaceutical and agricultural chemical products into conformity with India's obligations under Article 70.8 and 70.9 of the TRIPS Agreement.[90] Aftab J made his detailed observations on the method of interpreting the TRIPS Agreement and application of the TRIPS' provisions to the national jurisdictions. He made a vital observation as to the enactment of the Patents (Amendment) Act, 2005 of India about the role of legislature and policy makers that run as follows:

"Parliament had an absolutely unenviable task on its hands. It was required to forge, within a very limited time, an Act that would be TRIPS compliant without, in any way, compromising on public health considerations. It is seen above that the TRIPS Agreement had aroused grave concerns about its impact on public health. India had learnt from experience the inverse relationship between product patents and the indigenous pharmaceutical industry, and its effects on the availability of essential drugs at affordable prices. It is also seen above that after the patent system in India barred the grant of patents for pharmaceutical and chemical substances, the pharmaceutical industry in the country scaled great heights and became the major supplier of drugs at cheap prices to a number of developing and under developed countries. Hence, the reintroduction of product patents in

[89] Novartis Ag Vs Union of India & Others, [2013], Civil Appellate Jurisdiction, Supreme Court of India, Nos. 2706-2716, [2013], SCC. p. 27,
http://supremecourtofindia.nic.in/outtoday/patent.pdf,
(accessed 17 March 2016).

[90] "India was taken twice to the WTO panel, first on a complaint by the USA (WT/DS50/AB/R, dated December 19, 1997) and the second time on a complaint filed by the European Communities (WT/DS79/R, dated August 24, 1998). The complaint by the USA was in regard to the absence, in India, of either patent protection for pharmaceutical and agricultural chemical products under Article 27 of the TRIPS Agreement…" Justice Aftab in Novartis AG Case.

the Indian patent system through the TRIPS Agreement became a cause of alarm not only in this country but also for some international agencies."[91]

The above observation provides a clear guideline that during policy decision of drafting a new patent law or an amendment of the existing patent law the policy makers and legislators of an LDC like Bangladesh should be careful on the following issues:

i. The law should be TRIPS Compliant without compromising on public health issues;

ii. The relationship between the product patents and the indigenous pharmaceutical industries is inverse; and

iii. product patents' effect on the availability of essential drugs at an affordable price.

The judgment meticulously found that while considering the amendment to the Patents Act, 1970, the Indian Parliament made the effort "to make the law not only TRIPS compliant but also to provide therein necessary and adequate safeguards for protection of public interest, national security, bio-diversity, traditional knowledge, etc. Opportunity is also proposed to be availed of for harmonizing the procedure for grant of patents in accordance with international practices and to make the system more user friendly."[92]

The judgment appreciated the speech of one of the opposition Members during the debate on the Bill of Patents (Amendment) Act, 2005 where the Member proposed to consider the following points to enrich the patent system of India:

i. limiting the scope of patentability to only new chemical entities;

ii. no patents for new usage and dosage of known drugs;

[91] Novartis Ag Vs Union of India & Others, [2013], Civil Appellate Jurisdiction, Supreme Court of India, Nos. 2706-2716, [2013], SCC. p.43, http://supremecourtofindia.nic.in/outtoday/patent.pdf, (accessed 17 March 2016).

[92] Novartis Ag Vs Union of India & Others, [2013], Civil Appellate Jurisdiction, Supreme Court of India, Nos. 2706-2716, [2013], SCC. p.39, http://supremecourtofindia.nic.in/outtoday/patent.pdf, (accessed 17 March 2016).

iii. retain pre-grant opposition in its original form;

iv. simple procedures with a time limit for grant of compulsory licenses;

v. immunity for generic drugs which are already available in the market; and

vi. introduction of ceiling on royalty to pharmaceutical companies.[93]

The above-mentioned guidelines may be considered by our policy makers and legislators during drafting and enacting stages of the new patent law or amendment of the existing PD Act.

J Aftab analyzed the definitions of the terms "capable of industrial application", "invention" and "inventive step" as provided in the amended Patents Act, 1970 of India by the amending Act of 2005[94] (IPA) in consideration for construing the meaning of "invention". He found that section 2(1)(j) requires that a product must satisfy the following three conditions for qualifying as an invention:

> "(i) It must be "new", that is to say it must not have been anticipated;
>
> (ii) Its coming into being must involve an "inventive step"; and
>
> (iii) It must be "capable of industrial application", that is to say it must be capable of being made or used in an industry [section 2(1) (ac)]."[95]

J Aftab explained the term "inventive step" as used in the IPA in the words, "…a feature of an invention that involves technical advance as compared to the existing knowledge, or having economic significance or both and that makes the invention not obvious to a person skilled in the art." He came to the finding that in order to qualify as "invention" in India, a product must satisfy the following tests:

---

[93] ibid 48.
[94] The Patents Act, 1970, [1970], s. 2(1) (ac), (j), and (Ja).
[95] Novartis Ag Vs Union of India & Others, [2013], Civil Appellate Jurisdiction, Supreme Court of India, Nos. 2706-2716, [2013], SCC. p.51, http://supremecourtofindia.nic.in/outtoday/patent.pdf, (accessed 17 March 2016).

"(i) It must be "new";

(ii) It must be "capable of being made or used in an industry"

(iii) It must come into being as a result of an invention which has a feature that:

(a) entails technical advance over existing knowledge;

Or

(b) has an economic significance

And

(c) makes the invention not obvious to a person skilled in the art."[96]

The existing PD Act of Bangladesh has not defined the terms "capable of industrial application" and "inventive step" only defines the term "invention" as ""invention" means any manner of new manufacture and includes an improvement and an alleged invention."[97] This definition leaves much uncertainty and gives wider scope of patentability of both process and product medicine. Evidently, two vital conditions of invention, i.e. innovative step and capable of industrial application are missing in this definition resulting in abuse of both product and process patents in medicine.

The BPA defines "invention" as ""invention" means an idea of an inventor which permits in practice the solution to a specific problem in the field of technology and it shall also include an invention relating to a product or a process."[98] This definition is almost a true copy of the definition provided in section 12 of the WIPO Model Law for Developing Countries 1979.[99] Manifestly this Model Law was drafted much earlier than TRIPS came into force in 1995.

[96] Novartis Ag Vs Union of India & Others, [2013], Civil Appellate Jurisdiction, Supreme Court of India, Nos. 2706-2716, [2013], SCC. p.52, http://supremecourtofindia.nic.in/outtoday/patent.pdf, (accessed 17 March 2016).

[97] the Patents and Designs Act, 1911, [1911], s 2(1) (8).

[98] The Bangladesh Patent Act, 2015 (Draft). [2015], s. 2(f).

[99] WIPO "WIPO Model Law for Developing Countries on Inventions-Vol. I Patents", Geneva, Author, 1979, s.12, ftp://ftp.wipo.int/pub/library/ebooks/ModelLaws/840e_vol_1.pdf, (accessed 19 March 2016).

Therefore, it did not have any opportunity to consider the TRIPS' provisions and thus it would be more prudent to rely on the legislative language for a new patent law or an amendment of the existing PD Act of Bangladesh followed in the Indian Patents Act, 1970 (IPA) in drafting the term "invention" that is judicially tested by the apex court of India.

The BPA follows the definition of the IPA for the term "inventive step" with little deviation. In defining the term "inventive step" IPA states "…technical advance as compared to the existing knowledge or having economic significance or both". But in defining the "inventive step" BPA states "…technical advance as compared to the existing knowledge **and** having economic significance or both."[100] This makes the definition of BPA a little confusing and unclear because of wrong use of conjunction "and" as underlined above. If "and" is used in this manner in that case subsequent use of "or" is merely a repetition of the earlier expression and redundant. The legislative drafters and policy makers should be very careful in constructing the legislative sentence in a provision of law as careless use of any word may bring subsequent confusion, abuse of law and multiplicity of litigations.

The True import of section 3(d) of IPA was the core issue in deciding the Novartis Case by the Indian Supreme Court. Section 3(d) runs as follows:

"Section 3. What are not inventions. – The following are not inventions within the meaning of this Act, —
(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
Explanation. —For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."[101]

In Bangladesh BPA incorporated the same provisions in section 4(1)(p) under the marginal note of subject matters not patentable. Therefore, whatever interpretation of section 3(d) of

[100] The Bangladesh Patent Act, 2015 (Draft), [2015], S. 3(3) provides the definition of "inventive step".
[101] The Patents Act, 1970, s.3 (d).

IPA is given by the Indian Supreme Court in Novartis AG case would be largely applicable to the provisions of BPA.

In the Novartis AG case the Author Judge found that the following changes took place in the amended version of section 3(d) of IPA:[102]

(i) Adds the words "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or" at the beginning of the provision;

(ii) Deletes the word "mere" before "new use"; and

(iii) Adds an explanation at the end of the clause.

The Author Judge found that "[t]he amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds."[103]

The Court puts special emphasis in interpreting the word "efficacy" that is the corner stone of section 3(d) of IPA. It states, ""[w]hat is "efficacy"? Efficacy means "the ability to produce a desired or intended result". Hence, the test of efficacy in the context of section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in the case of a medicine that claims to cure a disease, the test of efficacy can only be "therapeutic efficacy"."[104]

---

[102] Novartis Ag Vs Union of India & Others, [2013], Civil Appellate Jurisdiction, Supreme Court of India, Nos. 2706-2716, [2013], SCC. p.54,
http://supremecourtofindia.nic.in/outtoday/patent.pdf,
(accessed 17 March 2016).

[103] ibid 57.

[104] NOVARTIS AG vs UNION OF INDIA & OTHERS, [2013], CIVIL APPELLATE JURISDICTION, SUPREME COURT OF INDIA, Nos. 2706-2716, [2013], NC 90,
http://supremecourtofindia.nic.in/outtoday/patent.pdf,

The Court finally concluded that "…in case of chemicals and especially pharmaceuticals if the product for which patent protection is claimed is a new form of a known substance with known efficacy, then the subject product must pass, in addition to clauses (j) and (ja) of section 2(1), the test of enhanced efficacy as provided in section 3(d) read with its explanation." It held that "[i]n view of the findings that the patent product, the beta crystalline form of Imatinib Mesylate, fails in both the tests of invention and patentability as provided under clauses (j), (ja) of section 2(1) and section 3(d) respectively, the appeals filed by Novartis AG fail and are dismissed with cost. The other two appeals are allowed."

India is a developing country capable of producing generic medicines and has become a major supplier of drugs at cheap prices to several developing and under developed countries. The Indian Parliament and the Executive have done a great job in increasing the invention threshold by the amendments made in section 3(d) of IPA in the year 2005.

The Indian Supreme Court has given a landmark decision in Novartis AG case by holding that the patent product of Novartis, the beta crystalline form of Imatinib Mesylate marketed in India as the brand name Gleevec, failed in both the tests of invention and patentability as provided under clauses (j), (a) of section 2 (1) and section 3 (d) of IPA respectively. It establishes relationship amongst the terms "invention", "inventive step" and "what are not inventions" successfully and set a precedent of higher threshold of invention and a standard of patentability for chemical substances/pharmaceutical products that may be efficiently applied in an LDC like Bangladesh with limited capability of producing medicines from API for protecting its interest in the medicine sector during TRIPS compliance.

(accessed 17 March 2016).

2.9.2 Preventing 'Ever-greening' of Pharmaceuticals Patents

Most often pharmaceutical companies misuse the patents by seeking patent on known substance or incremental modifications as invention on the known substance.[105] This practice has been known as the 'Ever-greening' of Patent and this is done generally by forwarding 'frivolous claim'.

The BPA has rightly addressed the issue of frivolous claim as non-patentable substance.[106] Section 4(p) has the most significant explanation in order to limit the ever-greening of pharmaceutical patent. It has stated that "mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."

Thus, known substance and incremental modifications thereof if they do not provide any significant efficacy, is not patentable. Bangladesh, if it properly implements BPA provisions would be able to reap the benefits out of pharmaceuticals products where patent claims would be limited by exclusion of known products and incremental modifications of those known products. This may have great implications for a country like Bangladesh.

2.9.3 Pre-grant and Post-grant Opposition Procedures

[105] K. M. Gopakumar, 'Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime', *The Law and Development Review*, vol. 3, no. 2, 2010, p. 332.
[106] the Bangladesh Patent Act, 2015 (Draft), s. 4(h).

Developing Countries and LDCs which have great concerns regarding access to drugs for their citizens are willing to provide detail procedures so that patent claims can be restricted. This may be enhanced by providing as many possible opposition procedures by the concerned or interested parties. Under BPA, the Registrar may publish the patent application after 18 months or before that if the applicant allows to do so. After this publication, any person interested may oppose the application by showing valid grounds. This pre-grant opposition is provided in the BPA but it is unclear whether any post-grant opposition is possible under this Act.[107] It is further recommended that third party opposition or public interest opposition should also be included in the BPA so that any medicine patent application may be opposed on such grounds.

2.9.4 Invalidation of Patents

Revocation or invalidation of patents by the appropriate authorities is a great device to prevent misuse of patent, anti-monopoly, even mistakenly granted patents. In BPA it is stated that any interested person may apply to the competent court (District Judge's Court) for invalidation of patents by showing the valid grounds listed in the said Act.[108] It is unclear that whether the government is included under the term 'interested party' since the government itself has granted the patent previously. Thus, it is suggested that clear provision should be inserted in the BPA that enables government agencies to apply for invalidation of patents.

2.9.5 Incorporating flexibilities of TRIPS

It has been discussed earlier that there are several flexibilities under TRIPS Agreement that the countries should contextualize by their domestic laws. Among them, most prominent one is compulsory license. Under TRIPS and Doha Declaration, states are at liberty to use such

[107] The Bangladesh Patent Act, 2015 (Draft), s. 10 C.
[108] The Bangladesh Patent Act, 2015 (Draft), s. 16.

flexibilities for the purpose of access to medicine to their people. Thus, the Member States may use compulsory license by their domestic mechanisms. The BPA states that the provisions for compulsory license on several grounds, including public interests, nutrition and health issues, national emergency, etc.[109]

The other grounds may include misuse of patent, monopoly of patentee etc. Section 14(18) contains most significant provisions of compulsory license for exporting medicine to the countries that do not have any or enough manufacturing capacity. The application for compulsory license must be addressed to the Registrar along with a copy of request from the country that wants to import the medicine. However, the language of the section is not clear to show that whether such compulsory license can be used for commercial purpose or only should be used for non-commercial purpose. Again, there is no specific provision that which country would pay the reasonable compensation while invoking the section 14(18) of BPA. However, the positive aspect of this section is that it would nicely reduce the cumbersome procedures for compulsory licence that are available under existing Patents and Designs Act, 1911.

2.9.6 Provisions for Exhaustion of Rights and Parallel Exports

Exhaustion of rights of a patent holder where he first sells the products and thereafter imports that patented drug for the market where it is available at a cheap price is another way of meeting the challenges of access to drugs. The BPA has incorporated the provisions for exhaustion of rights and parallel import.[110] It postulates that importation in this process will

[109] The Bangladesh Patent Act, 2015 (Draft), s. 14.
[110] The Bangladesh Patent Act, 2015 (Draft), s. 3.

not infringe the rights of the patentee provided that it is done with the approval of the concerned authority of Bangladesh and it does not hamper the interests of the country.

However, it is not clear who is the concerned authority in this regard and what would generally prejudice the interests of the country. Further, what type of exhaustion would Bangladesh take, whether national, regional or international, is not clearly mentioned in the section. Bangladesh as an LDC, preferably needs to take international form of exhaustion so that it may allow any party interested to import from the international market where the price of patented drugs is cheap or comparatively lower than other jurisdictions.

2.9.7 Research Exceptions and Bolar provision

Early working exception popularly known as Bolar Provision is another method a country may use to further access to drugs. Section 32 of BPA incorporated research exception provisions stating that use of these would not infringe the right of the patentee, irrespective of their nationality. However, this provision is only applicable to individual research, for non-commercial purpose and with reasonable necessity. These types of restrictions and ambiguous terms may create complicated situations in a practical sense. Further, these terms do not have any clarifications under this Act.

2.9.8 The Provisions for Mail Box and Future Challenges

It is suggested that under TRIPS regime a mail box provision should be inserted in domestic mechanism so that the application for patent of medicine may be received with an assurance to give priority based on filing date and subject to the validity of the provisions made later, about the patentability of medicines or drug. At the existing status, Bangladesh government

has established a mailbox system but does not provide EMRs to drugs. Study shows that there are several patent applications already in the mail box.[111]

The BPA has also incorporated the mail box mechanism during the transitional period and further states that Act will be applicable after expiration of transitional period.[112] As per current standing, Bangladeshi medicine manufacturing companies barely have any patented drug of their own. On the other hand, foreign companies are submitting their applications in the mail box. It is plausible that, after a certain point in time when Bangladesh will need to provide patent, then the foreign companies will get the priority. Thus, the lion shares if not total patented drug market of Bangladesh, might go to the hands of foreign drug producing companies. This may lead to a great challenge regarding access to drug by local people.

2.10 TRIPS' Impact on Relevant Laws on Medicine of Bangladesh

The medicine or pharmaceutical sector is mainly regulated by the following laws in Bangladesh:

i. The Drugs(Control) Ordinance, 1982;
ii. The Drugs Act, 1940;
iii. The Drug Rules, 1945; and
iv. National Drug Policy, 2005.

The above stated laws have been discussed critically in the chapter of technology transfer of this thesis. However, harmonizing changes proposed in the draft patent law of Bangladesh with the laws on medicine has been briefly explored below.

---

[111] Secretariat, UNCTAD, *Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries: A Series of Case Studies*, [pdf], New York, UNCTAD, 2011, p. 72 http://apps.who.int/medicinedocs/documents/s19062en/s19062en.pdf, (accessed 6 June 2016).

[112] The Bangladesh Patent Act, 2015 (Draft), s. 33.

2.10.1 Harmonizing laws on medicine with Patent Law

To implement the TRIPS' provisions through patent law, Bangladesh should bring major changes in its patent regime. The BPA proposed the following key changes in the present regime:

i. Inclusion of important new definitions of "inventive step", "prior art", "parallel import", "compulsory license", "Biological resources" and "microorganism" and modifying the definition of "invention".

ii. Introduction of provisions for subject matters that are not patentable, patent rights of inventor, rights accrued through patent, compulsory license, illegally accessed genetic resources, special provisions regarding compulsory license in health sector, parallel imports, research exceptions, mailbox and exclusive marketing rights.

The provisions of parallel import of BPA should be reconciled with the provisions of prohibition of import of certain drugs[113] to avoid conflict of authority on importing patent drugs. The provisions for misbranded drugs in the Drugs Act may be needed to be reconciled with the definitions of invention and inventive step of BPA.[114]

The provisions of parallel import and compulsory license of BPA may be conflicting with the provisions of prohibition of manufacture, etc. of certain medicine, restriction of import of certain pharmaceutical raw materials, manufacture of drugs under licensing agreement and review of certain licensing agreement with foreign concerns provided in the Drugs (Control) Ordinance, 1982 and in the light of BPA the provisions of Drugs (Control) Ordinance should be harmonized. The concerned provisions of drug rules should also be amended in the light of above stated adjustments.

[113] THE DRUGS ACT, 1940 (Act no. XXIII of 1940), s.10. and The Bangladesh Patent Act, 2015 (Draft), s. 31.
[114] section 9 of the supra Act and section 2(f) and section 3(3) of the supra draft Act.

2.11 Summary and way forward

Being a WTO Member State, Bangladesh must abide by the TRIPS' obligations. Therefore, on the one side Bangladesh should abide by the rules of the TRIPS Agreement and on the other side in implementing the TRIPS provisions through its National legislation it must take the advantages given by the TRIPS Agreement. Thus, after exploring the issues, it may be concluded that at present Bangladesh must take the advantage of the exemption of not granting medicine patent till 1 Jan 2033 and at the same time should be prepared by both framing necessary laws and achieving technological advancement for the era of medicine patenting. Bangladesh must provide a right balance between incentive to the invention of medicines and right to access to such medicines. Bangladesh can derive benefit from the medicine patenting by adoption of appropriate legal measures.

In response to the current situation, Bangladesh may formulate a short-term plan and a long-term plan to subdue the challenge of medicine patenting. It may bring the amendments of the Patents and Designs Act, 1911 to exploit the flexibilities of the TRIPS Agreement. In addition, Bangladesh should also amend the Patents and Designs Rules, 1933 to make detailed provisions on compulsory license, parallel imports, research exceptions and Bolar provision etc.

Enacting a new Patent law would be the long-term action for which we may need a considerable time. However, it should be noted that today or tomorrow Bangladesh must revise its current Patent Law. The ambit of this chapter was limited to the TRIPS' impact on medicine patenting in Bangladesh and methods to harmonize relevant legal framework on medicine with the implementation of the TRIPS' provisions through legislative measures.

Neither the impacts of copyright law nor the trademark law on medicine has been explored in the study. If Bangladesh could achieve a balanced legal framework on medicine patenting, that might prevent any adverse impact on the access to drug and healthcare in Bangladesh and people would be able to get essential medicine in an affordable price even after 1 January 2033.

The next chapter investigates the options for Bangladesh to implement Article 27.3 (b) of the TRIPS Agreement through legislative measures. The chapter critically examines the protection of the seed industry of Bangladesh by patent or by an effective *sui generis* system or by any combination thereof in the light of international practice. At the same time, it explores the impact of implementation of the Article 27.3 on the medicinal plant, traditional knowledge and genetic resources of Bangladesh besides finding an interesting relationship between medicine patenting and protection of the medicinal plant or traditional medicine by a *sui generis* system.

Chapter 3: TRIPS Impact of Patenting Seed on Bangladesh and Relevant Issues

3.1 Introduction

Article 27 of the TRIPS Agreement states about the patentable subject matter and paragraph 1 of the Article provides scope of patenting for any invention, whether products or process, in all fields of technology, provided that they are new, involve inventive steps and are capable of industrial application.[115] For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.[116] Patents shall be available to and patent rights shall be enjoyable without discrimination as to the place of inventions, the fields of technology and whether products are imported or locally produced.[117] However, the whole regime of Patent under TRIPS is framed subject to the following provisions of the TRIPS agreement:

i. Paragraph 4 of Article 65;

ii. Paragraph 8 of Article 70; and-

iii. Paragraph 3 of this Article (Article 27).

Subparagraph 3(b) of Article 27 is relevant to this study and needs to be explained here. Other limitations of paragraph 1 have been examined at the appropriate chapter in the thesis. Subparagraph 3 (b) empowers the Member States to exclude from patentability-

i. plants and animals other than micro-organisms; and

ii. essentially biological processes to produce plants or animals other than non-biological and microbiological processes.

[115]the TRIPS Agreement, WIPO PUBLICATION No. 223 (E), Article 27, page 31.
[116]the TRIPS Agreement, footnote of paragraph 1 of Article 27.
[117]the TRIPS Agreement. Paragraph 1 of Article 27.

However, this Article 27.3(b) has imposed a mandatory obligation on the Members to provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The subparagraph provides a compulsory review of its own self four years after the date of entry into force of the WTO Agreement.[118]

The terms 'plants', 'micro-organisms', 'biological process', 'non-biological and microbiological processes' that are stated in subparagraph 3 (b) of Article 27 of the TRIPS Agreement are important to scrutinize how seeds are affected by the provisions of this subparagraph. These terms have been duly explained here to show that the term 'plant' includes seeds and seeds are a crucial issue to be carefully addressed in the national legislation, particularly, for an agro-based country like Bangladesh.

The TRIPS Agreement imposes on Members an obligation to provide protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.[119] Therefore, Bangladesh has the following options for providing protection of plant varieties including protection of seed, namely:

i. insert relevant provisions by amending the existing Patents and Designs Act, 1911 (PD Act);
ii. re-enact the PD Act in the light of subparagraph (b) of the paragraph 3 of Article 27 of the TRIPS Agreement;
iii. provide an effective sui generis system; and
iv. adopt any combination of sui generis system and patent protection.

[118]The WTO Agreement was concluded on April 15, 1994 and entered into force on January 1, 1995. Therefore, the review of subparagraph 3 (b) of Article 27 of the TRIPS Agreement was due on January 1, 1999-See WIPO PUBLICATION No. 223 (E), Page 13.
[119] The TRIPS Agreement. Article 27 (3) (b).

All these options have been specifically explored with due reference to the relevant Acts, Ordinances, Rules, Policies of Bangladesh including international and regional treaties, conventions, famous case laws of U.S., Canada and national legislations of Malaysia, Thailand and Sri Lanka.

3.2 Patentability of Seed under the Present Law of Bangladesh

In the interpretation clause of the PD Act the definitions of invention, manufacture and article are very relevant and of great significance in understanding the patentability of seed under the Act.[120] Under the PD Act the term invention is defined as ""invention" means any manner of new manufacture and includes an improvement and an alleged invention"[121], while the term manufacture "… includes any art, process or manner or producing, preparing or making an article, and also any article prepared or produced by manufacture"[122] and the term 'article' is defined as (as respects designs) "any article of manufacture and any substance, artificial or natural or partly artificial and partly natural".[123] Here evidently 'article' refers in respect of designs. But since the Act is silent about the word article used in the definition of manufacture, therefore, the same definition can be applied to interpret the word or term 'article' as used in the definition of manufacture. In Shanon Realities v. Ville de St. Michael, [1924] Ac 185 the Privy Council observed-

"Where the words of a statute are clear, they must, of course, be followed, but in their Lordships' opinion where alternative constructions are equally open, that alternative is to be chosen which will be consistent with the smooth working of the system which the statute

[120] Patents and Designs Act, 1911 (Act No. II of 1911), s 2.
[121] Patents and Designs Act, 1911 (Act No. II of 1911), the Bangladesh Code, Vol. VI. s. 2 (8).
[122] ibid, s. 2 (10).
[123] ibid, s. 2 (2).

purports to be regulating and that alternative is to be rejected which will introduce uncertainty, friction or confusion into the working of the system"[124]

For the application of definition of 'article' to interpret the term 'article' used in the definition of the term 'manufacture', the scope of alternative construction is equally open and such construction is consistent with the smooth working of the system which the PD Act purports to regulate.

Seeds are defined as ""Seeds" means any of the following classes of seeds used for sowing or planting -

(i) seeds of food crops including edible oil seeds and seeds of fruits and vegetables;
(ii) jute seeds;
(iii) cotton seeds;
(iv) seeds of cattle fodder;

and includes seedlings, and tubers, bulbs, rhizomes, root cuttings, all types of grafts and other vegetatively propagated materials of food crops or cattle fodder;".[125] Manufacture or productions of a new variety or developed variety of seed should be treated as invention under the PD Act. It can logically be inferred that the seeds are natural substances that should be treated as an 'article' under the PD Act. Manufacturing of a new variety or developed variety of seeds may include any art, process or manner or producing, preparing or making a seed. Such manufacture should be treated as new manufacture or an improvement of an earlier manufacture and thus, such manufacturing of seeds may be an invention.

The PD Act does not contain any compulsory provision that the applicant for patent must expressly demonstrate that the invention is new, involves innovative steps and capable of industrial application to grant a patent. However, the application form for patent (when the

[124] M. Islam, Interpretation of Statutes and Documents. Dhaka, Mullick Brothers, 2009, p. 74.

[125] The Seeds Ordinance, 1977 (Ordinance No. XXXIII of 1977), the Bangladesh Code, Vol. XX, s. 2 (j).

true or first inventor is the sole or joint applicant) as prescribed in the Patents and Designs Rules, 1933 provides that the applicant must declare that s/he is the true or first inventor thereof (for which patent is applied), the invention is not in use in Bangladesh by any other person.[126] These two provisions may be related to the novelty of the invention. Moreover, the patent may be revoked by HCD on the following grounds amongst others:

i. that the invention was not, at the date of the patent, a manner of new manufacture or improvement;

ii. that the invention does not involve any inventive step, having regard to what was known or used prior to the date of the patent;

iii. that the invention is of no utility.[127]

Therefore, if an invention does not have novelty, innovative steps and industrial application in that case the patent granted for such an invention may be revoked by the High Court Division by an appropriate proceeding before it.[128]

Microbiological process is patentable in Bangladesh and the Department of Patents, Designs and Trademarks (DPDT) has already granted such patent that is discovered from a list of patents gained from Pakistan Patent Office and Bangladesh Patent office published in the official website of Bangladesh Council of Scientific and Industrial Research (BCSIR), a government research institute.[129]According to the list, patents have been issued for "[a]

[126] Patents and Designs Act, 1911, s. 3 read with Patents and Designs Rules, 1933, r. 10 (1) and Form 1 of the schedule of the Rules, DPDT, http://www.dpdt.gov.bd/site/page/7a6a6fdb-70a1-4990-9a69-05c01ea3e0c4/Patent,
(accessed 22 April 2017).

[127] Patents and Designs Act, 1911 (Act No. II of 1911), s. 26 (1) (d), (e) and (f).

[128] ibid.

[129] Department of Patents, Designs and Trademarks, "List of Patents gained from Pakistan Patent Office and List of Patent so far gained from Bangladesh Patent Office", BCSIR, Dhaka, Author, http://bcsir.portal.gov.bd/sites/default/files/files/bcsir.portal.gov.bd/page/09aed8a0_b78f_4191_8b62_6c4c36679aca/Total_%20List_%20of%20_Patents.pdf ,
(accessed 4 August 2015).

process for isolating jute seed oil, strophanthidin and raffinose from seeds"[130], "a process for production of spinnable fibre from jute cuttings"[131], and "a process for microbiological upgrading of jute cutting for spinnable fibres"[132]etc. These are the obvious examples of microbiological process patents granted from Pakistan Patent Office and DPDT of Bangladesh.

Based on the above-mentioned argument, it shall not be less than just to conclude that the seeds may be patented under the present PD Act. Under Article 66.1 of the TRIPS Agreement Bangladesh is exempted from enforcing sub-paragraph 3 (b) of Article 27 of the Agreement, i.e. 'Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof, till 1 July 2021.[133]

In a list published by DPDT titled "Status of Patent Applications for Bangladesh (1972-2014)" it has been explored that during 1972-2014 total 7367 patent applications were filed which 7367 patents were granted to foreign applicants and only 1905 patents were granted to local applicants. The number of mail box applications is 1083.[134] The statistics indicate that granting patents on seeds, medicinal plants or microorganisms has been adversely affecting the local farmers, TK and medicine industry since MNCs may take the opportunity of getting their GM seeds as well as new plant varieties patented in Bangladesh. In that case farmers can easily be prevented from saving and sharing farm produced seeds or more adversely

[130]Ibid 118 Patent no. PP110064,
[131]Ibid 118 Patent no. PP 110185.
[132]ibid 118; Patent no. PP 1000003.
[133] Least developed country Members shall not be required to apply the provisions of the Agreement, other than Articles 3, 4 and 5, until 1 July 2021, or until such a date on which they cease to be a least developed country Member, whichever date is earlier. *Bangladesh to remain LDC until 2024: UN review*, http://bdnews24.com/economy/2015/11/26/bangladesh-to-remain-ldc-until-2024-un-review , 2015, (accessed 8 February 2016).
[134]Department of Patents, Designs and Trademarks, 'Status of Patent Applications for Bangladesh (1972 to 2014)' Dhaka, Author, 2015, http://dpdt.portal.gov.bd/sites/default/files/files/dpdt.portal.gov.bd/page/32948563_925f_4e88_9eb9_175ae3e90507/Patent%20statistics%20(1).pdf, (accessed 4 August 2015).

some of the traditional seeds and medicinal plants may be patented in the name of MNCS which will be a catastrophe in the agriculture as well as in medicine sectors of Bangladesh. Since Bangladesh is exempted from protecting its plant varieties according to Article 27.3(b) of TRIPS till 1 July 2021, therefore, the PD Act should be amended at once to exclude plant varieties, i.e. seed from the ambit of patentable subject matter by inserting a specific section with a marginal note "subjects not patentable".

3.3 The TRIPS Requirement on the Protection of Seed

The applicability of paragraph 3 (b) of Article 27 of the TRIPS Agreement for the protection of seed is an issue. In order to explore the issue, technical terms used in this paragraph, i.e. 'plants', 'micro-organisms', 'biological process', 'non-biological and microbiological processes' will be explained here. What protection to be conferred to seed by patent or by an effective sui generis system or by any combination thereof under the TRIPS Agreement is another important issue that will be examined in this section.

The TRIPS Agreement does not provide any interpretation of the terms 'plants', 'micro-organisms', 'biological process', 'non-biological and microbiological processes' used in paragraph 3 (b) of Article 27. Article IX clause 2 of the Agreement Establishing the World Trade Organization (WTO Agreement) provides:

> The Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements. In the case of an interpretation of a Multilateral Trade Agreement in Annex 1, they shall exercise their authority on the basis of a recommendation by the Council overseeing the functioning of that Agreement. The decision to adopt an interpretation shall be taken by a three-fourths majority of the Members.[135]

[135] WTO Agreement: Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 4 (1999), 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994) [hereinafter Marrakesh Agreement or WTO Agreement].

The Ministerial Conference and the General Council are the bodies established by Article IV clauses 1 and 2 of the WTO Agreement. Annex 1 of the WTO Agreement contains three Agreements, e.g. Annex 1 A-Multilateral Agreements on Trade in Goods, Annex 1 B-General Agreement on Trade in Service and Annexes and Annex 1C-Agreement on Trade-Related Aspects of Intellectual Property Rights (The TRIPS Agreement).

The TRIPS Agreement is a Multilateral Trade Agreement and is an integral part of the WTO regime, which Agreement is binding on all Members of the WTO.[136] Council for TRIPS is vested with the responsibility to oversee the functioning of the TRIPS Agreement and also to carry out functions assigned to the Council by the TRIPS Agreement and by the General Council.[137] Therefore, the Ministerial Conference and the General Council are to exercise their exclusive authority of interpreting the TRIPS Agreement on the recommendation of the TRIPS Council. So far the TRIPS Council has not recommended any interpretation for the terms used in paragraph 3 (b) of Art. 27.

In this backdrop as per the 'golden rule' of interpretation[138] the plain, literal and grammatical meaning of the terms 'plants', 'micro-organisms', 'biological process', 'non-biological and microbiological processes' should be accepted.[139] The term 'plants' is defined as "Plants, also called green plants (Viridiplantae in Latin), are multicellular eukaryotes of the kingdom Plantae. They form a clade that includes the flowering plants, conifers and other gymnosperms , ferns, clubmosses, hornworts, liverworts, mosses and the green algae. Plants exclude the red and brown algae, animals, the fungi, archaea and bacteria."[140]

---

[136]The WTO Agreement, Art. II clause 2.

[137] the WTO Agreement, Art. IV clause 5.

[138] "Generally all statutes are to be construed according to the plain, literal and grammatical meaning of the words and one should not import words into an enactment which are not there in it." Islam Mahmudul, *Interpretation of Statutes and Documents*, Dhaka, Mullick Brothers, 2009, p. 105.

[139] Fazle Rabbi v. Election Commissioner, [1992] 44 DLR (HCD) 14

[140] Plant, http://en.wikipedia.org/wiki/Plant ,
(accessed 9 May 2015).

The term ‘micro-organism’ is defined as “A microorganism (from the Greek: mikros, "small" and organismós, "organism") is a microscopic living organism, which may be single celled[141]or multi-cellular. Micro-organisms are very diverse and may include all the bacteria and archaea and almost all the protozoa. They also include some fungi, algae, and certain animals, such as rotifers. Many macroscopic animals and plants have microscopic juvenile stages. Some microbiologists also classify viruses (and viroids[/]) as microorganisms, but others consider these as nonliving.[142] EPO case law (T356/93) has established micro-orgnisms comprise “bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plant cells…including plasmid and viruses. The term ‘biological process’ is defined as the processes which are vital for a living organism to live. Biological processes are made up of any number of chemical reactions or other events that result in a transformation.”[143]

The term non-biological process is explained as follows in an FAO document:

“There is no clear dividing line between non-biological and microbiological processes. Generally, any method of genetic engineering may be regarded as being "non-biological". As non-biological one may consider in the first place processes the product of which could not have been created naturally, thus not covering conventional breeding methods.”[144] Since genetic engineering alters the genetic makeup of an organism therefore it is used in producing genetically modified organisms or GMOs and hence, it can be concluded that

[141] M. Madigan. et el., (ed.) Brock Biology of Microorganisms, 13th edn., UK, Pearson Education, p. 1096.
[142] Ed Rybicki, 'The classification of organisms at the edge of life, or problems with virus systematics', *South African Journal of Science*, vol. 86, 1990, pp. 182-186. And A. Lwoff, 'The Concept of Virus', *Journal of General Microbiology*, vol. 17, 1957, pp. 239-253.
[143]‘Biological Process’, http://en.wikipedia.org/wiki/Biological_process ,
(accessed 9 May 2015).
[144] R. S. Repetto and M. Cavalcanti, ‘Multilateral Trade Negotiations on Agriculture-A Resource Manual-Module 4-Provisions of the TRIPS Agreement Relevant to Agriculture (Part II)’, FAO, Rome, http://www.fao.org/docrep/003/x7355e/x7355e04.htm,
(accessed 26 July 2015).

non-biological process is the process by which GMOs can be produced. GM seed is one of the important GMOs that is to be protected under the TRIPS Agreement.

It can be logically interpreted from the above discussion that seed can be treated as a plant variety and it is to be protected under subparagraph 3 (b) of Art. 27 through patent(s) or an effective sui generis system or any combination thereof.

3.3.1 Protection of seed by patent under TRIPS

In order to be patentable a new variety of seed must fulfill the criteria of patentability under Art 27.1 of the TRIPS, i.e. it must be new, there must be an innovative step or it must be non-obvious and the inventions must be industrially applicable or useful. Since the TRIPS does not give an interpretation of the term 'invention', 'innovative step' and 'industrial application', it creates an interesting debate on interpreting these terms and their scope of application. India expressed view that, "… the lack of clear definitions of the conditions for patentability has left gray areas, in particular with respect to the definition of the term "invention" and the scope of patentable microorganisms and microbiological or non-biological processes. Leaving the issue purely at the discretion of Member States May give rise to a number of concerns."[145] On the other hand, Venezuela expressed a different view that "it should be left up to the domestic laws and practices of the national patent offices to define these matters. That freedom constitutes part of the flexibilities in the TRIPS Agreement."[146]

The examination of these opposite views as expressed by India and Venezuela in the light of the national legislations of Malaysia and Sri Lanka would be helpful in this respect. The

[145] WTO, 'Review of The Provisions of Article 27.3(B)
Summary of Issues Raised and Points Made' Council for Trade-Related Aspects of Intellectual Property Rights, Geneva, 9 March 2006, p 12, IP/C/W/369/Rev.1.

[146] ibid.

Malaysian Patent system is regulated by the Patents Act 1983 and the Patents Regulations 1986. Besides this, Malaysia also legislated a *sui generis* system for protecting plant varieties called the Protection of New Plant Varieties Act 2004. The Patents Act 1983 of Malaysia does not provide any provision for plant varieties protection through patent. Therefore, the issues of defining invention, novelty, innovative step and industrial application in the case of new plant varieties as per the said Patents Act 1983 do not arise in Malaysia.

The Protection of New Plant Varieties Act 2004 provides that, subject to the exceptions stated in sections 15 and 16, a plant variety shall be registered as a new plant variety and granted a breeder's right if the plant variety is new, distinct, uniform and stable.[147]

Despite this provision, farmers, local community or indigenous people may be granted breeder's rights for a new plant variety and such variety may be registered if it is bred or discovered and developed by them and if it is new, distinct and identifiable.[148] The Act provides specific interpretations of the terms, 'new', distinct', 'uniform', 'stable' and 'identifiable'[149]

On the other hand, the Patents Act 1983 left a grey area on patenting microorganism and biotechnological inventions *per se*.[150] The section on non-patentable invention of the Patents Act 1983 excludes man-made living micro-organisms, micro-biological processes and the products of such micro-organism processes.[151] No further explanation is given in the Act

[147]The Protection of New Plant Varieties Act, 2004, [2004], s. 14 (1). http://www.wipo.int/edocs/lexdocs/laws/en/my/my040en.pdf , (accessed 11 May 2015).
[148]ibid 136, section 14 (2).
[149]ibid 136, section 14 (3).
[150]"The PA, as it stands now, does not provide clear guidance on the patenting of biotechnological inventions per se. Although there are some exclusions on the matter, the current position in Malaysia with regard to inventions in the field of biotechnology is still vague." S. Ramachandaran, 'Patent Protection in Malaysia-A Basic Information Guide', Version 1.0, p. 10, 10 July, 2009. BIOTECHCORP,
[151]The Patents Act, Malaysia [1983] s. 13 (1) (b), http://www.wipo.int/edocs/lexdocs/laws/en/my/my053en.pdf , (accessed 12 May 2015).

about the patentability of biotechnological inventions including microorganisms. Such silence creates scope for confusion in patenting these inventions.

Sri Lanka does not have any *sui generis* system of the protection of plant varieties. It does not provide for patent protection or any combination of patent and sui generis system for the plant varieties as well. The Sri Lankan IP regime is governed by the Intellectual Property Act No. 36 of 2003[152] (Sri Lankan IP Act) that does not give any patent protection for plant varieties. Since Sri Lanka is not a least developed country, therefore, it must enforce Art 27.3 (b) as per the provisions of the TRIPS Agreement.[153] Sri Lanka has drafted a Bill titled "Protection of New Plant Varieties (Breeder's Rights) Sri Lanka 2001" that is yet to be enacted. .[154]

The Sri Lankan IP Act provides that patents granted for micro-organisms shall be subject to the provisions of this Act.[155] The Act does not provide any further clarifications in this regard.

Therefore, it can be concluded that the TRIPS's silence regarding the definition of invention, novelty, innovative step, industrial application, micro-organisms, non-biological and microbiological process creates some confusions which are reflected in different national legislations as well. It is worthwhile to mention that silence of TRIPS on this aspect gives the scope of Member States to define these terms to ensure their respective national interests in protecting seeds, micro-organisms and botanical inventions through patent law.

152The Intellectual Property, 2003, [2003], Act No. 36 http://www.wipo.int/edocs/lexdocs/laws/en/lk/lk004en.pdf , (accessed 12 May 2015).

[153]the TRIPS Agreement. Art. 65.2

[154] D. Hirimuthugodage, *Trade Related Intellectual Property Rights (TRIPS) Agreement and the Agriculture Sector in Sri Lanka,* Asia-Pacific Research and Training Network on Trade, 2011. http://www.unescap.org/sites/default/files/AWP%20No.%2092.pdf (accessed 14 June 2014).

[155]The Intellectual Property Act, 2003, [2003], s. 63 (3) (b).

3.3.1.1 Issues Raised Before the Council for TRIPS

On 9 March 2006, the Secretariat of the Council for TRIPS Agreement prepared a note on the summary of issues raised and points made by the Members of the WTO during the review process of Article 27.3 (b) (TRIPS Council Secretariat Report).[156] Some of the important issues and points are stated here to highlight the complexities that exist in interpreting the provisions of this Article which might be relevant in the context of Bangladesh while complying with TRIPS provisions.

The Secretariat's note explored that Brazil, raised an issue regarding the use of unreasonable low thresholds for novelty, inventive step and industrial application. It expressed the view that a lax criterion applied by some Members is undermining the patent system as a whole. Another important issue was raised by Kenya about "the distinction to be made between discoveries and inventions, and, in particular, what is required to satisfy the test of inventive step (or non-obviousness)."[157]

It was argued that, "by stipulating the patenting of micro-organisms and micro-biological processes, the TRIPS Agreement violates the basic tenet of patent law that, discoveries are not patentable, inventions are."[158] Malaysia expressed its view that, "there is need for a clear understanding of which stages of research into genetic resources, including genetic parts and components, constitute "discoveries" and which ones fulfil the requirements of being an invention."[159]

---

[156] WTO, 'Review of The Provisions of Article 27.3(B)
Summary of Issues Raised and Points Made' Council for Trade-Related Aspects of Intellectual Property Rights, Geneva, 9 March 2006, p 12, IP/C/W/369/Rev.1
https://www.wto.org/english/tratop_e/trips_e/ipcw368r1c1.doc,
(accessed 5 May 2017).

[157] ibid.

[158] ibid.

[159] ibid.

India raised questions that, "whether the mere act of isolation of genetic material from its natural state would satisfy the test of non-obviousness or of the inventive step."[160] Referring the negotiating history of the TRIPS Agreement India expressed the view that, "the TRIPS negotiators were not able to agree that the task of isolating a bacterium would satisfy the inventiveness test."[161] It was further stated by Brazil that, "whatever costly it may be today to isolate a micro-organism, in many instances, a discovery is better than an invention. Members should be able to limit the grant of patents in respect of micro-organisms to those that had been trans-genetically modified and satisfy the requirements of patentability."[162]

Responses to these issues and points from Members have been compiled by the Secretariat of the Council for TRIPS Agreement where it has been said that, "mere discoveries, not involving human interventions, are not considered patentable subject-matters."[163] Life-forms in their natural condition would not satisfy the criteria for patentability in the TRIPS Agreement. It has been argued that, "the subject-matter of a patent has involved sufficient human intervention, such as isolation or purification, and if the isolated or purified subject matter is not of a previously recognized existence, it is considered an invention. Plants,

[160] WTO, 'Review of The Provisions of Article 27.3(B) Summary of Issues Raised and Points Made' Council for Trade-Related Aspects of Intellectual Property Rights, Geneva, 9 March 2006, p 13, IP/C/W/369/Rev.1 https://www.wto.org/english/tratop_e/trips_e/ipcw368r1c1.doc, (accessed 5 May 2017).

[161] ibid.

[162] WTO 'The Relationship Between the Trips Agreement And The Convention On Biological Diversity Brazil', Geneva, 9 March 2006, IP/C/W/228. https://www.wto.org/english/tratop_e/trips_e/ipcw368_e.pdf, (accessed 20 Nov 2014).

[163] WTO, 'Review of The Provisions of Article 27.3(B) Summary of Issues Raised and Points Made' Council for Trade-Related Aspects of Intellectual Property Rights, Geneva, 9 March 2006, p 13, IP/C/W/369/Rev.1 https://www.wto.org/english/tratop_e/trips_e/ipcw369r1.doc (accessed 20 Nov 2014).

animals or micro-organisms and other genetic resources would have to be altered by the hand of man or produced by means of a technical process to satisfy the criteria of patentability."[164] Kenya argued that, "universal novelty should be introduced to prevent piracy of traditional knowledge."[165] India pointed out that, "some Members define novelty in a manner that does not recognize information available to the public using oral traditions outside their domestic jurisdictions."[166] Japan took the view that regarding patent obligations on micro-organisms in the TRIPS Agreement "the mere fact that a micro-organism or a gene has existed in nature does not mean that it has become known to the public and ceases to be "new" for patent purposes."[167]

Brazil and Zimbabwe raised questions that, "whether some patents claimed over micro-organisms adequately fulfill the requirements of industrial applicability as the usefulness of the inventions is often unclear even by the patent applicant."[168]

Switzerland in responding to the issues cited above stated that "if the criteria for patentability has not been properly applied, the patent system provides for opposition and revocation procedures to remedy such situations."[169] India opposed this view by raising the issue of "financial and other resource costs and delays involved in keeping track of such patents and using such procedures, especially where pre-grant opposition is not possible."[170]

From the above discussion, it is revealed that the core issues on patenting plant varieties and micro-organisms are as follows:

---

[164]The TRIPS Agreement, Art. 65.2.

[165] WTO, 'Review of The Provisions of Article 27.3(B) Summary of Issues Raised and Points Made' Council for Trade-Related Aspects of Intellectual Property Rights, Geneva, 9 March 2006, p 13, IP/C/W/369/Rev.1 https://www.wto.org/english/tratop_e/trips_e/ipcw369r1.doc (accessed 5 May 2017).

[166] ibid.

[167] ibid.

[168] Brazil, IP/C/W/228; Zimbabwe, IP/C/M/39, para 112.

[169] Switzerland, IP/C/M/26, para. 164.

[170] India, IP/C/W/161.

i. Use of unduly and reasonably low threshold of patentable conditions by the Members;

ii. Distinction between discovery and invention;

iii. Whether a mere act of isolation of genetic material from its natural state would satisfy the test of non-obviousness or of the inventive step?

iv. Whether the mere fact that a micro-organism or a gene has existed in nature does mean that it has become known to the public and ceases to be "new" for patent purpose?

v. If the criteria of patentability have not been fulfilled during application, whether opposition and revocation procedures of the patent system can cure such latches?

The conflicting views of the Members on the core issues show that even after a Member provides protection of plant varieties and micro-organisms by patents under the TRIPS Agreement there will remain scopes of confusions over many of the above-mentioned core issues and concerned national interests- traditional knowledge and farmers' rights may not even be protected in any justifiable manner. Such confusions can only be removed by an effective review of the provisions of the Article 27.3 (b) through the necessary interpretations of the patentable criteria for plant varieties, micro-organisms, plant, non-biological and microbiological processes that needed to be inserted in the TRIPS Agreement.

3.3.1.2 Protection of Medicinal Plant or Traditional Medicine vis-`a-vis Seed Patenting

Majority of the population of Bangladesh relies on traditional forms of medicine for everyday health care. WHO finds this proposition correct for most non-industrial countries.[171] Traditional medicine has been defined as "the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether

[171] O. Arihan and A. Mine GENÇLER ÖZKAN, 'Traditional Medicine and Intellectual Property Rights', *Journal of the Faculty of Pharmacy of Ankara*, vol. 36, no. 2, 2007, pp. 135-151.

explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses".[172] It is observed that "[P]roducts derived from traditional knowledge (TK) have benefited the pharmaceutical companies greatly, and indigenous knowledge of plants has played a significant role.".[173] Globally, almost 121 prescription drugs are made from plants of which almost half come from tropical lands.[174] The global market for plant based drugs has been estimated at $43 billion. There is an increasing trend for the use of herbal medicines globally.[175] Bangladesh has 734 species of different types of medicinal plant genetic resources (PGR).

Table1: Types, number of species, genera and families of the medicinal PGR in Bangladesh (Source: BNH).[176]

Types	No. of species	Number of genera	Number of families
Herbs	328	226	85
Shrubs	121	61	38
Trees	166	120	49

[172] WHO, 'General Guidelines for Methodologies on Research and Evaluation of Traditional Medicines', Geneva, Author, 2000.

[173] ibid 138.

[174] K. Moran, "Health: Indigenous Knowledge, Equitable Benefits" World Bank, *Indigenous Knowledge (IK) Notes No.15*, December, 1998.

[175] WHO, 'WHO Traditional Medicine Strategy 2002-2005'. Geneva, Author, 2002.

[176] M. K. A. Chowdhury, *Conservation and Sustainable Use Plant Genetic Resources in Bangladesh*, Dhaka, Bangladesh Agricultural Research Council, 2012, p. 175.

Shrubs/Trees	5	4	4
Climbers/herbs	85	58	24
Climbers/shrubs	29	23	17
Total	734	493	217

Bangladesh should carefully consider implications of implementation of Article 27.3(b) of TRIPS on the medicinal PGR. Bangladesh is to provide any of the three modes of protection to the plant varieties stated in this Article by June 2021, according to the latest decision of the TRIPS Council. The probable impact on medicinal plant for protecting plant varieties by patent has been highlighted in this section.

The Neem Tree grows in Bangladesh, India, Myanmar and Pakistan. All parts of the tree are used for their proven properties. It is known to have antifungal, antiviral and sedative properties. It is also purported to be an effective treatment for diabetes and infertility, as well as for parasitic infections. In 1995, the US Department of Agriculture and a pharmaceutical research company received a patent on a technique to extract an antifungal agent form the Neem Tree. The patent was eventually overturned in 2005 after the Indian Government responded to widespread public outcry and initiated legal action.[177] This is one of the examples of thousands of bio-piracy patents that will be used to restrict access to these traditional medicines by the Bangladeshi people and small-scale pharmacy business.

The existing PD Act of Bangladesh and seed and plant related relevant laws are incapable to protect its PGR and particularly medicinal PGR and traditional medicines from bio-piracy or

[177] 'AFN Environmental Stewardship Respecting and Protecting Mother Earth', http://www.afn.ca/uploads/files/env/ns_-_bio-piracy.pdf, (accessed 8 April 2016).

being patented elsewhere in the world by the MNCs like Monsanto. Even due to archaic provisions of the PD Act any MNC or foreign body or any person may obtain patent on any of our medicinal plants or traditional medicines. One burning example of bio-piracy is given above about patenting a technique to extract antifungal agent from Neem Tree which is a medicinal plant of Bangladesh.

The draft Biodiversity and Community Knowledge Protection Act of Bangladesh, 1998 provided a strong provision to protect medicinal Plant and traditional medicine in its Article 6.1 which is reproduced below:

> All the biological and genetic resources within the territory of Bangladesh, or originated in Bangladesh, as well as all related intellectual and cultural knowledge and practices among the people of the country, either existing in tangible forms or in various intangible forms and expressions, belong in perpetuity to the people of Bangladesh and is held for past, present and future of the country. Therefore, all such biological and genetic resources as well as all related intellectual and cultural knowledge and practices are being declared by this Act as wealth held in common and constitute the Common Property Regimes of the country and cannot, therefore, be alienated irrevocably nor can its enjoyment be impaired.[178]

The Bangladesh Biodiversity Act, 2017 (Act No. 2 of 2017) does not declare that all the biological and genetic resources within the territory of Bangladesh, or originated in Bangladesh, as well as all related intellectual and cultural knowledge and practices among the people of Bangladesh constitute common property regime of the country and does not impose any bar of irrevocable alienation or impairment of enjoyment of such property. This is a vital limitation of the newly enacted law. Incorporation of the draft Act's provisions in the enactment on common property regime would be more favourable to ensure the protection of

[178] Biodiversity and Community Knowledge Protection Act of Bangladesh, 1998, Text proposed by the National Committee on Plant Genetic Resources, article 6.1, http://www.farmersrights.org/pdf/asia/Bangladesh/Bangladesh-biodivknowdraft98.pdf (accessed 5 May 2012).

biodiversity, biological and genetic resources and community knowledge and their enjoyment by the people of Bangladesh.

The draft Plant Varieties Act, 1998 is supportive to the provisions of the draft Biodiversity and Community Knowledge Protection Act of Bangladesh and may play a substantial role in protecting medicinal PGR including all the PGR and traditional medicines. According to Article 7.8 of the draft Act an inventor of a new plant variety may apply for the protection of the variety. Article 6 of the Act defined new plant varieties as follows:

The New Plant Variety shall be a plant variety, which must have the following characteristics:

(a) be a new plant variety, in other words a hitherto nonexistent plant variety;

(b) be a plant variety with consistent specific traits;

(c) be a plant variety with stable specific traits; and

(d) be a plant variety with distinctive specific traits.

Therefore, an existing plant variety and a plant variety which does not have consistent, specific and distinctive traits cannot be considered as a new plant variety and thus cannot get protection under this Act and it can be commercially exploited.

Bangladesh is under an obligation besides TRIPS to protect its medicinal PGR and traditional medicine under CBD as provided in Article 6 (b)[179] and Article 8 (J)[180] since it is a contracting party of CBD. Therefore, it should go for enactment of the laws on PVR and Biodiversity and Community Knowledge Protection based on the draft Acts stated above.

---

[179] Article 6 (b) of CBD: "(b) Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies."

[180] Article 8 (J) of CBD: "Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices:"

3.3.2 Protection of Seed of Sui Generis System under TRIPS

The TRIPS Council Secretariat summarized the issues raised and points made by the Members regarding the provisions of the Article 27.3 (b) relating to the *sui generis* protection of plant varieties. It divided the issues and points into the following categories:

i. General issues;
ii. The views expressed about the elements of *a sui generis system*;
iii. The relationship between the TRIPS provision and the International Union for the Protection of New Plant Varieties of Plants (UPOV) Convention; and
iv. The relationship with traditional knowledge (TK) and farmer's rights.

Each of the above stated categories has been explained below.

3.3.2.1 General Issues

The TRIPS Council Secretariat summarized the general issues on the protection of plant varieties, "including whether or not such protection should be accorded and whether or not the provisions contained in Article 27.3 (b) are balanced or need to be amended."[181] About the question of why plant varieties should be protected, the point has been made by Japan and the United States that "such protection allows development of new technological solutions in the field of agriculture." [182] In the communication to the Council for TRIPS, Japan further clarifies the issue by pointing out that "it encourages the easy introduction of new varieties and ensures that breeders continue breeding effectively."[183] Japan and the USA also pointed out that "[A]dvances in the area, include the development of new crops with higher

[181] WTO, 'Review of The Provisions of Article 27.3(B) Summary of Issues Raised and Points Made' Council for Trade-Related Aspects of Intellectual Property Rights, Geneva, 9 March 2006, p 14, IP/C/W/369/Rev.1 https://www.wto.org/english/tratop_e/trips_e/ipcw369r1.doc (accessed 5 May 2017).
[182] Japan, IP/C/M/29, para.152, IP/C/M/40, para 98; United States, IP/C/W/162.
[183] Japan, IP/C/M/40, para. 98.

productivity and yields and with disease resistance."[184] Norway expressed the view that "strengthening plant varieties protection ensures a more efficient agriculture sector."[185]

Opposite concerns have been expressed by Mauritius on behalf of African Group, Zimbabwe and Kenya that, "the protection of plant varieties can have an adverse impact upon the fulfillment of the national goals of developing countries, in particular with regard to food security, health, rural development and equity for local communities whose traditional knowledge system has produced staple varieties, including varieties that have medicinal and biodiversity value."[186] Kenya suggested that, "plant variety protection could lead to excessive dependency on foreign commercial breeders, and that such persons could not always be relied upon."[187] Bangladesh expressed its view on the review of the Article 27.3(b) that can be summarized as follows:

"Review of Article 27.3 (b) has remained a priority for least-developed country Members. Farming was the main livelihood for the 75 per cent of the World's population living in rural areas. Article 27.3 (b) empowered the Members to choose their own *sui generis* system for the protection of plant varieties, including a system to accord due recognition to traditional knowledge and traditional practices and the right of farmers to save, use, exchange and sell seeds and other propagating materials, which was consistent with the ITPGRFA. Nothing in the TRIPS Agreement prevented Members from taking measures to ensure food security and safeguard farmers' livelihoods.

However, the patent provisions of the TRIPS Agreement allowed countries to recognize monopoly rights over individual genes and their characteristics, which negated farmers' rights over seeds and propagating materials with such genes and characteristics, reduced genetic

[184] Japan, I/P/C/M/29, para. 152, IP/C/M/40, para. 98; United States, IP/C/W/162.
[185]See Norway, IP/C/M/43, para. 52.
[186]See Mauritius on behalf of African Group, IP/C/W/206, Peru, IP/C/M/29, para. 175; Zimbabwe, IP/C/M/36/Add.1, para.201; Kenya, IP/C/M/40, para. 108.
[187]See Kenya, IP/C/M/28, para. 52.

diversity, made crops more vulnerable to pest attacks, and raised the cost of seeds and agricultural inputs to unaffordable levels for small farmers. It was further stated, although the TRIPS Agreement would not apply to least-developed countries until 2006, and 2016 for pharmaceutical products, the imposition of Article 27.3 (b) was already being threatened at least-developed countries through bilateral negotiations."[188]

Bangladesh further expressed its view that, "the review of Article 27.3 (b) should result in an amendment clarifying that no living organisms, including plants, animals and parts of plants and animals, gene sequences, and biological and other natural processes to produce plants, animals and their parts, should be patentable. In cases where they remain patentable, a provision should be incorporated into the TRIPS Agreement to the effect that patents must not be granted without the prior consent of the country of origin to affirm its compatibility with the CBD and ITPGRFA."[189]

The TRIPS Council Secretariat found two views on the issue on whether provisions in the TRIPS Agreement relating to the protection of plant varieties strike a right balance between right holders and other interests or not which includes:

i. Brazil, European Communities, Egypt, Malaysia, Mexico, Peru, Venezuela and Thailand were of the view that, "Article 27.3 (b) provides a certain degree of flexibility to Members in deciding on the most effective means of sui generis protection for plant varieties and that the *status quo* should be maintained."[190]

ii. Brazil, India, Kenya on behalf of the African Group, Thailand and European Communities expressed the view that, "while preserving the flexibility in Article

[188]The Representative of Bangladesh expressed his views in the TRIPS Council Meeting held on 18 November 2003.
[189]ibid.
[190]Brazil, IP/C/M/29, para.147; European Communities, IP/C/M/35, para.214; Egypt, IP/C/M/25, para.92; Malaysia, IP/C/M/29, para.206; Mexico, IP/C/M/26, para.76; Peru, IP/C/M/29, para.175; Venezuela, IP/C/M/29, para.200; Thailand, IP/C/M/42, para. 115.

27.3(b), clarification of the term "effective sui generis system" is needed."[191] While Zimbabwe on behalf of African Group opined that, "Members should confirm and lock in, by way of a decision, a common understanding that Members have the right and freedom to determine and adopt appropriate regimes."[192] The African Group was of the opinion that, "Members should also confirm a common understanding that regardless of what sui generis system is adopted for protecting plant varieties, non-commercial use of plant varieties, the system of seed saving and exchange as well as the selling among farmers, are rights and exceptions that should be ensured as matters of important public policy, among other things, to ensure food security and preserve the integrity of rural or local communities."[193]

The TRIPS Council Secretariat highlighted some specific suggestions and possible clarifications regarding the Article 27.3 (b) of the TRIPS Agreement which is summed up below:

i. European Communities suggested that, "reference could be made to the UPOV Convention in Article 27.3 (b)" [194];

ii. Kenya on behalf of the African Group suggested that, "a footnote should be inserted after the sentence on plant variety protection in Article 27.3(b), stating that any *sui generis* law for plant variety protection can provide for: (a) the protection of innovations of indigenous and local farming communities in developing countries, consistent with the CBD and the International Undertaking on Plant Genetic Resources; (b) the continuation of traditional farming practices including the right to save and exchange seeds, and sell farmers' harvest; and (c)

[191]Brazil IP/C/W/228; India, IP/C/M/25, para.70; Kenya, IP/C/M/28, para. 146, Kenya on behalf of the African Group, IP/W/163; Thailand, IP/C/M/25, para. 78; European Communities, IP/C/M/35, para. 214.
[192]African Group, IP/C/W/404, p.2; Zimbabwe, on behalf of the African Group, IP/C/M/40, para.79.
[193]African Group, IP/C/W/404, p.3.
[194]European Communities, IP/C/M/25, para. 74.

the prevention of anti-competitive rights or practices which threaten the food sovereignty of developing countries, as permitted by Article 31 of the TRIPS Agreement" [195];

iii. Peru, Zimbabwe and Malaysia suggested that, "the provisions permitting specific exceptions to plant variety rights should be included in the TRIPS Agreement covering, to the minimum, farmers' rights."[196] While Thailand made it specific by stating that "in particular to sow and share harvested seed of a protected variety, communities' rights and compulsory licensing where plant varieties are not available on reasonable commercial terms, in times of national emergency and in cases of public non-commercial use."[197]

TRIPS' silence on explaining an effective sui generis system can be used by the Members to legislate a sui generis law to protect their own plant varieties keeping in their respective national interest. However, it can be used negatively by donor States like the USA in creating pressures on the least developed countries to make law in protecting plant varieties upholding the interests of MNCs rather than protecting the interests of farmers, traditional knowledge and practices.

Among the suggestions given by the Members on Article 27.3 (b) Kenyan suggestion on behalf of the African Countries ought to be treated as the most suitable one to protect the interest of farmers, traditional knowledge and practices. By referring a convention like UPOV or CBD may not cover the specific interests of farmers or protect the traditional knowledge or practices. The Kenyan suggestion to insert footnote in Article 27.3 (b) regarding protection of innovations by indigenous and local farming communities of developing countries, traditional

[195]Kenya on behalf of the African Group, IP/C/W/163.
[196]Peru, IP/C/M/37/Add.1, para. 217; Zimbabwe, IP/C/M/40, para. 79; Malaysia, IP/C/M/40, para. 128.
[197]Thailand, IP/C/M/25, para78.

farming practices like save and exchange seeds and prevention of anticompetitive rights which threaten the food sovereignty of developing countries might be fruitful in preventing TRIPS plus agreement by which developed countries are compelling developing countries to provide more protection than the requirements of TRIPS Agreement on IP rights.

3.3.2.2 Elements of an Effective Sui Generis System

The TRIPS Council Secretariat sorted out a question raised by the Members as to what constitutes an "effective" system of *sui generis* protection for plant varieties for the purposes of Article 27.3 (b). In this respect, following two opposite views were expressed by some of the Members:

i. The United States expressed the view that, "there are specific criteria available to judge the effectiveness of a *sui generis* system" [198];

ii. India, Zimbabwe, the African Group and Kenya had the view that, "the TRIPS Agreement does not specify any criteria by which to judge whether a *sui generis* system is effective and therefore this should be left to the Members to decide."[199]

3.3.2.2.1 Criteria to Judge the Effectiveness of a Sui Generis System

The United States spelt out that to be effective, a *sui generis* system should possess the following basic characteristics[200]:

i. Clear identification of the nature of the subject matter;[201]

ii. Establishing entitlement of the property rights/ Conditions for granting protection; [202]

[198]United States, IP/C/W/209.

199India, IP/C/M/25, para.70; Zimbabwe, IP/C/M/36/Add.1, para. 201; African Group, IP/C/W/404, p.2; Kenya, IP/C/M/40, para. 108.

[200] United States, IP/C/W/209.

[201]Uruguay expressed that for sui generis system to be considered effective, protection should apply to all plant varieties throughout the plant kingdom (IP/C/M/28, para. 132) while opposite views were expressed that Article 27.3(b) only speaks of a sui generis system without providing specific details as to the plant varieties that should be protected (Peru, IP/C/M/32, para. 128), UPOV does not require protection of the entire plant kingdom (India, IP/C/M/29, para. 162; Thailand, IP/C/M/25, para.78).

iii. The rights with respect to the protected subject matter; [203]

iv. Limitations and exceptions to the rights of the right-holder; [204]

v. Farmers' privilege; [205]

vi. The period of application of rights; [206]

vii. Procedure to be followed by the potential right holder to obtain rights; [207] and

viii. Enforcement of rights. [208]

The opposite views expressed by certain Members against the view of the US about the basic characteristics of a *sui generis* system deserve due appreciation and apparently these

---

[202]The United States suggested four conditions for eligibility of protection of a plant variety, e.g. novelty, distinctiveness, uniformity and stability (IP/C/W/209). The opposite view was that these four conditions were beyond the determinants contained in existing models, e.g. UPOV and CBD (India, IP/C/M/29, para. 162.

[203]European Communities expressed the view that the right holder should at least be able to prevent third parties from carrying out certain acts in relation to the protected subject matter over a certain period of time and national treatment and MFN should be provided in law (IP/C/W/383, para. 77). The United States expressed that these rights are to be vested on the breeders or the persons specifically entitled through contract or law of succession (IP/C/W/209). Opposite view expressed that in this way farmers' rights that have been arisen through tradition and not through contracts or succession cannot be protected (India, IP/C/M/29, para. 162). In reply it was said that farmers' rights could be protected by other means but admitted that such protection is not an obligation under the TRIPS Agreement (Switzerland, IP/C/M/30, para. 166, IP/C/W/284.

[204] European Communities suggested that the limitations and exceptions should include experimental use, the right to use a protected variety for further breeding, compulsory licences and certain exceptions to the benefit of farmers (IP/C/W/383, para. 77). African Group emphasised on ensuring non-commercial use of plant varieties, the system of seed saving and exchange as well as selling among the farmers as matters of important public policy, ensure food security and preserve the integrity of rural or local communities (IP/C/W/404, p.3).

[205]European Communities, Switzerland and the Unites States stated that farmer's privilege was to allow farmers to replant on their own holdings propagating material of protected plant varieties that they have harvested on their holdings (EC, IP/C/M/25, para. 74, Switzerland, IP/C/M/29, para. 179; United States, IP/M/25, para. 71, IP/C/W/162). Kenya and African Group opposed this view that the farmers' privilege should not be limited to saving and re-planting the material only on a farmer's own holdings (IP/C/M/28, para. 114; African Group, IPC/W/404, p.3).

[206] The United States suggested that the rights should be granted for a period of 20 years and in cases of new varieties of trees and vines it should be 25 years (IP/C/W/209) while India opposed this view on the ground of non application of the provision of section 5, Part II of the TRIPS Agreement to plant varieties protection and UPOV system may have a different term of protection (IP/C/M/29, para. 162).

[207]European Communities expressed that an effective sui generis system should provide specific procedures and fees to obtain rights by right holders (IP/C/W/383, para. 77) and the US expressed that in doing so national treatment should be provided to a foreign national under Article 3 of the TRIPS Agreement (IP/C/W/209). This view was opposed by India which expressed that that sui generis models that reflect the practice of reciprocity rather than national treatment should not be deemed to be lowering the level of protectionor the effectiveness of the sui generis system (IP/C/M/29, para. 162).

[208]European Communities stated that to create an effective deterrent to infringement, the law should provide for legal and institutional implementation procedures (IP/C/W/383, para. 77). India expressed opposite view that effectiveness depends upon the enforceability of a right within a national legal system (IP/C/M/25, para. 70).

views have a strong basis.[209] On the literal reading of the provision of the Article 27.3 (b) it has been observed that the TRIPS Agreement does not provide any interpretation or explanation of the term 'effective' that creates a serious dilemma for the Members of the WTO where developed and developing countries particularly LDCs are sharply divided.

3.3.2.2.2 Opposite View on Adjudging Effectiveness of a Sui Generis System

Kenya in its communication with the TRIPS Council expressed that, "what constitutes an effective *sui generis* system to protect plant varieties under the TRIPS Agreement, is left to Members to determine and it further opined that the review of Article 27.3 (b) of the TRIPS should clarify that *sui generis* systems are domestic laws adopted to protect plant varieties within the context of important domestic goals and other international obligations."[210] Kenya also expressed the view that, "the concept of a "*sui generis*" system is inconsistent with a prescription of rights and duration or even models to be imposed on all WTO Members."[211] India expressed the view that, "the standards for patents might not necessarily be applicable, particularly for countries that have opted to create a *sui generis* system rather than relying upon patents or a combination of systems including patents."[212]

The views of Kenya and India hold strong grounds and require due attention by the developing countries as well as LDCs during the review process of Article 27.3 (b) of the TRIPS Agreement to protect the national interest, traditional knowledge and farmers' rights of these countries.

[209] Kenya and India have expressed articulated views regarding sui *generis system* that are opposed to the view expressed by the U.S.A.
[210]Kenya, IP/C/M40, para.109 and Kenya, IP/C/M/28, para. 142.
[211]Kenya, IP/C/M/28, para. 142.
[212]India, IP/C/M/29, para.162, Thailand, IP/C/M/42, para. 115.

3.4 Protection of Seed by Combination of Patent and Sui Generis System

Article 27.3(b) of the TRIPS Agreement empowers Members to provide for the protection of plant varieties by any combination of patents and an effective *sui generis* system that may be treated as the third option under the Article apart from protecting plant varieties by patents or by an effective *sui generis* system.[213] Definitely this third option of protecting plant varieties would provide more stringent protection for the plant varieties and Members are at liberty to choose this option as per their respective national stature. The US is one of the best examples which provides this dual protection for its plant varieties. The US system is briefly examined below with some important case references.

The US Plant Protection Act of 1930 (PPA) provided patents for developing plant varieties for asexually reproducing plants i.e. plants reproduced through propagation or grafting.[214] Under the Act distinctiveness and novelty were two basic criteria for patent protection of asexually reproduced plants for a period of seventeen years. This provision departed from the traditional requirements for patent protection, i.e. useful, non-obvious and novel that seems to be a lenient standard.[215]

The PPA encouraged privatization of seed industry in the US though seed was out of the ambit of the PPA. In 1970 the US enacted Plant Variety Protection Act (PVPA) that provided protection for sexual reproduction in plants, including seed germination. This Act provides for two exemptions, e.g. seed savings by farmers and for research purposes. The Act provides 'brown bag' exemption that empowers farmers to save, replant and resell protected seeds to

[213] "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." Second part of the subparagraph (b) of paragraph 3 of Article 27 of the TRIPS Agreement.
[214] See 35 U.S.C. § 161.
[215] H. Stein, 'Intellectual Property and Genetically Modified Seeds: The United States, Trade, and the Developing World', *Northwestern Journal of Technology and Intellectual Property*, vol. 3, no. 2, 2005, p. 165.

other farmers.[216] The PVPA may be recognized as the foundation of today's large agribusiness.

The PVPA gives rise to several judicial decisions that expanded the premises of patentability of plant varieties as well as biotechnological innovations. In *Diamond Vs. Chakrabarti*, the US Supreme Court rested the legal basis that would establish the United States as the global biotech patent leader. In this case, Burger, C.J., delivered the opinion of the Court, in which Stewart, Blackmun, Rehnquist, and Stevens, JJ, joined. Brennan, J., filed a dissenting opinion, in which White, Marshal, and Powell, JJ joined.

The brief fact of the case is that "[t]itle 35 U.S.C. § 101 provides for the issuance of a patent to a person who invents or discovers "any" new and useful "manufacture" or "composition of matter". Respondent filed a patent application relating to his invention of a human-made, genetically engineered bacterium capable of breaking down crude oil, a property which is possessed by no naturally occurring bacteria. A patent examiner's rejection of the patent application's claims for the new bacteria was affirmed by the Patent Office Board of Appeals because living things are not patentable subject matter under § 101. The Court of Customs and Patent Appeals reversed that rejection by reaching to a conclusion that the fact that micro-organisms are alive is without legal significance for purposes of patent law."[217] It was held in this case that a live, human-made micro-organism, is a patentable subject matter under § 101. Respondent's micro-organism constitutes a "manufacture" or "composition of matter" within the scope of that statute. It was also decided in this case that the patentee has produced a new bacterium with markedly different characteristics from automatically found in nature,

[216] ibid.

217 See Diamond v. Chakrabarty, 447 U.S. 303 (1980).

and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly, it is a patentable subject matter under § 101.[218]

The Court's liberal interpretation of the PPA and the enactment of the PVPA set a new standard for an invention that focused on not distinguishing between animate and inanimate objects, but rather between products of nature and the products of human effort.[219] Diamond v. Chakrabarty wide opened the door for broader definitions of what is patentable.

It was held by the Supreme Court of the United States in Asgrow Seed Company vs. Denny Winterboer[220] that in 1970, Congress passed the Plant Variety Protection Act (PVPA)[221], in order to provide developers of novel plant varieties with "adequate encouragement for research, and for marketing when appropriate, to yield for public the benefits of new varieties,".

In the case seed saving exemption for farmers was restricted to replant saved seeds on the farmers' own property. The ruling in the case manifests that the Supreme Court viewed seeds as a licensed commodity.[222] The Asgrow Seed Company case extends seed developers' (breeders) rights over farmers' rights particularly on the following issues:

i. Patent like protection has been extended to sexually reproduced plants, i.e. plants grown from seed parallel to the protection given to the asexually reproduced plants;

[218] ibid.
[219] J. P. Oczek, 'In the Aftermath of the "Terminator" Technology Controversy: Intellectual Property Protections for Genetically Engineered Seeds and the Rights to Save and Replant Seed', *Boston College Law Review,* vol. 41, no. 3, 2000, p. 627.
[220] Asgrow Seed v. Winterboer, 513 U.S. 179 (1995).
[221] See 84 Stat. 1542, 7 U.S.C. § 2321 et seq.
[222] K. Aoki, 'Weeds, Seeds and Deeds: Recent Skirmishes in the Seed Wars', *Cardozo Journal of International and Comparative Law,* vol. 11, no. 2, 2003, p. 247, 253.

ii. The developer of a novel variety can obtain PVPA coverage by acquiring a certificate through which owner gets exclusive rights for 18 years to exclude others from-

a. Selling the variety;
b. Offering it for sale;
c. Reproducing it;
d. Importing or exporting it; and
e. Using it in producing (as distinguished from developing) a hybrid or different variety there from.

In Asgrow Seed Company case more stringent protection is given to seed development by restricting the farmers reselling the seed to other farmers using 'brown bag' exemption of PVPA. Even the Patent Act does not provide such protection, because after the first sale the patentee loses his/her right over the patented product in respect of subsequent sale without infringing upon the patent according to the first sale doctrine.[223]

In 2001, the U.S Supreme Court extended protection to the sexually reproduced plant further by deciding that such plants are patentable by a utility patent in the case of *J.E.M. AG Supply v. Hi-Breed International*. The Court examined the different rights and types of protection afforded agricultural plants under each of the three applicable intellectual property systems (PPA, PVPA, and Utility Patent Act) and concluded that the enactment of the PPA and the PVPA did not remove plants from the more general coverage of the Utility Patent Act. The

[223] Adams v. Barke, 84 U.S. 453, 456-57 (1873).

decision of this case made the seed saving exceptions of PVPA infructuous as well as the intent of Congress of passing the PPA and PVPA has been substantially defeated.[224]

It can be concluded from the analysis of the U.S. protection of plant varieties by a combination of patent and the *sui generis* system that such a combination would create more favourable atmosphere for the plant breeders (MNCs) than farmers and such system would be a complex system that might give rise to a multiplicity of legal proceedings. This system might be useful for a developed country like the U.S, which is the pioneer of industrialization of seed and where MNCs are contributing a substantial part in the national economy. But an agro-based country like Bangladesh where more than 75 percent people live in the rural areas and depend on agriculture, will not be able to afford such a system for their livelihood.

3.5 Protection of Seed in Bangladesh

Bangladesh is largely an agro-based country where agriculture and forestry contribute 12.57 percent of total GDP.[225] This is the second largest sector after manufacturing and highest number of people work in the agriculture sector of the country. The Seed Policy-1993 of Bangladesh categorically stated that the "[q]uality seed is considered to be the basic input for increasing agricultural output and thereby achieving self-sufficiency in food production.". The legislative framework and National Policy on seed in Bangladesh will be examined and what changes to the law and policy are required to comply with that of the provisions of Article 27.3 (b) of the TRIPS Agreement will be explored below. Apart from the TRIPS' obligations there are other obligations imposed on Bangladesh by international and bilateral treaties/ conventions or contracts regarding seed which are to be delved into this section.

[224] H. Stein, "Intellectual Property and Genetically Modified Seeds: The United States, Trade, and the Developing World", Northwestern Journal of Technology and Intellectual Property, volume 3, issue 2, spring 2005, p.167.
[225] See at http://www.bbs.gov.bd/WebTestApplication/userfiles/Image/GDP/GDP_2013-14.pdf , (accessed 28 May 2015).

3.5.1 The Legislative Framework and Policy Regarding Seed in Bangladesh

Besides, the PD Act, Seeds Ordinance, 1977[226], the Seed Rules, 1998, the Seed Policy, 1993, Plant Quarantine Act, 2011 (Act no. 5 of 2011), National Institute of Biotechnology Act, 2010 (Act no. 10 of 2010), Competition Act, 2012 (Act no. 23 of 2012), the Safe Food Act, 2013 (Act no. 43 of 2013), the Agricultural Produce (Grading and Marketing) Act, 1937 (Act No. I of 1937), the Agricultural Pests Ordinance, 1962 (East Pakistan Ordinance No. VI of 1962), the Agricultural Produce Markets Regulation Act, 1964 (East Pakistan Act No. IX of 1964), the Geographical Indications of Goods (Registration and Protection) Act, 2013 (Act No.54 of 2013) and the Bangladesh Biodiversity Act, 2017 (Act no. 2 of 2017) deal expressly or implicitly with seed protection in Bangladesh. To ensure seed protection under 27.3(b) of the TRIPS Agreement the extent of legal regime of seed in Bangladesh which may be affected has been explored in this section.

3.5.1.1 Seeds Ordinance, 1977 (as amended up to date)-the Principal Legislation on Seed

Section 2 of the Ordinance provides for the interpretation clause, i.e. definitions, where the term 'seeds' is defined. This definition excludes seeds used for drugs and narcotics and includes seeds of food crops, edible oils, fruits and vegetables, fiber crops, flower and ornamental plants, forage crops. The definition further widens its scope by including seedlings, and tubers, bulbs, rhizomes, root cuttings, all types of grafts and other vegetatively/asexually propagated materials. Therefore, it can be safely inferred that the definition of 'seeds' includes both sexually and asexually reproduced plants.

The Drugs Act, 1940 defines drug which includes all medicines for internal and external use of human beings and animals. Therefore, medicinal plants are excluded from the ambit of the definition of the term 'seeds' that is opposed to the provision of Article 27.3 (b) and might be

[226]The Seeds Ordinance, 1977 (Ordinance no. XXXIII of 1977) has been subsequently amended in 1997 by the Seeds (Amendment) Act, 1997 and in 2005 by the Seeds (Amendment) Act, 2005.

detrimental to the national interest of Bangladesh. The exclusion of narcotics from the definition of 'seeds' may not be harmful to the national interest and the TRIPS Agreement also provides discretion to the Members for excluding 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 health.[227]

The term 'agriculture' has been defined in the Ordinance as "agriculture" means food and fiber crop production and includes horticulture". The term 'Seed Dealer' has been defined as "Seed Dealer" means a person or a company or an organization involved in the production of seeds or carrying on the business of importing, selling, hoarding for sale, bartering or otherwise supplying any seed of any kind or variety for agricultural purpose: Provided that, farmer producing or hoarding seeds partly for his own use and partly for sale in the local hats and bazars by himself or through any other person, in small quantities shall not be treated as Seed Dealer".[228]

Therefore, farmers' privilege of producing and selling seed to the other farmers has been maintained by the Ordinance and restrictions have been imposed on seed dealer i.e. MNCs who sell, import, barter, hoard, supply seeds for agricultural purpose, i.e. food and fiber crop production including horticulture.

The Ordinance vests power on the Government for regulating the quality of seed of any kind or variety that is to be sold and used for the purposes of agriculture. It specifically empowers the Government to notify seed of any kind or variety in the official gazette in consultation with the National Seed Board (the Board) to regulate the sale, distribution, bartering or otherwise supplying, and import of seed of such kind or variety. The Board is to approve and certify new varieties of non-notified crops developed by public or private agencies before

[227] The TRIPS Agreement, Article 27.2.
[228] Section 2(kk) of the Seeds Ordinance, 1977, clause (kk) was substituted by section 2 of the Seeds (Amendment) Act, 2005 (Act No. XXVI of 2005).

being released. The Board is empowered to approve and register new varieties of notified crops developed by public agencies before being released.[229]

A private agency must register with the Board varieties of non-notified crops that are locally developed or imported by it giving the prescribed cultivar description. The Board has wide power to prohibit sale, distribution of other specified kinds of the use of seed which is found harmful or potentially harmful to agriculture.[230] This is an unfettered power given to the Board to protect the interest of agriculture in Bangladesh. The Ordinance provided for a technical committee for examining a proposal to release new varieties of crops both notified and un-notified and to make its recommendations to the Board.

The Government may specify standards of seed quality in consultation with the Board.[231] The standard of seed quality includes:

i. germination percentage, purity percentage, moisture content and such other components of seed quality with respect to any seed of any kind or variety;

ii. the mark or label to indicate that such seed conforms to the standard specified in the Ordinance and the particulars which such mark or label may contain.

The Ordinance substantially regulates Seed dealers' business through registration and standardization.[232] It specifically provides for the labelling of seed packaging in containers. The label must contain, amongst other information minimum germination percentage, physical purity, name and address of the company and date of packaging. Thus, the label

[229] Section 5 of the Seeds Ordinance, 1977, section 5 was substituted by section 5 of the Seeds (Amendment) Act, 2005 (Act No. XXVI of 2005).
[230] the Seeds Ordinance, 1977 (Ordinance No. XXXIII of 1977), Bangladesh Code Volume XX, Sub-sections (4) and (5) of section 5.
[231] The Seeds Ordinance, 1977. [1977], S. 6 was substituted by section 4 of the Seeds (Amendment) Act, 1997 (Act No. XIII of 1997).
[232] The Seeds Ordinance, 1977. [1977], S. 7 was substituted by s. 5of the Seeds (Amendment) Act, 1997 (Act No. XIII of 1997).

displays the source of the seed besides it standard.[233] Such compulsory disclosure is conducive to maintain seed standard as well determining the origin of the seed.

Establishing the Seed Certification Agency (the Agency) is one of the most important provisions of the Ordinance that states several important functions of the Agency amongst which advising production, processing and quality control of seeds, post market quality control, certifying breeder and foundation seed, helping the Department of Agricultural Extension in the promotion and use of improved seeds of HYV's among farmers.[234]

The high breed seed is one of the main contributors to the dramatic rise in agricultural output during the last half of the 20th century.[235] Having less cultivable land, which is also shrinking at te rate of one percent (1%) every year with increasing need and demand of food, Bangladesh needs further promotion and use of improved seeds of HYV's and that calls for adequate legal protection for seed varieties. The Agency has power to grant certificate to seed dealers on seed of any kind or variety that conforms to the minimum limits of germination and purity specified in the Ordinance.[236]

The Seeds Ordinance, 1977 does not provide the rights of breeders as well as the farmers. It also does not specifically provide any protection for the traditional seeds used by the farmers from time immemorial. Bangladesh must overcome these drawbacks through appropriate legislative measures.

3.5.1.2 The Seed Rules, 1998-the Delegated Legislation to enforce the Seeds Ordinance

For carrying out the purposes of the Seeds Ordinance, the Government made Seed Rules in 1998 that provides amongst other the following important provisions:

---

[233] The Seeds Ordinance, 1977. [1977], S. 7A was inserted by s. 8 of the Seeds (Amendment) Act, 2005 (Act No. XXVI of 2005).

[234] The Seeds Ordinance, 1977. [1977], S. 8 was substituted by s. 9 of the Seeds (Amendment) Act, 2005 (Act No. XXVI of 2005).

[235] United States Department of Agriculture, *Improving Corn*, https://www.ars.usda.gov/oc/timeline/corn/ , (accessed 14 December 2014).

[236] The Seeds Ordinance, 1977. [1977], s. 9.

i. The functions of the Board, Seed Laboratory, Certification Agency;

ii. The manner of marking or labelling the container of seeds of any notified kind or variety;

iii. The requirements which may be complied with by a person carrying on the seed business; and

iv. The procedures of obtaining seed certificate and preferring appeal against a decision of the Seed Certification Authority.[237]

Since the Seeds Ordinance does not address the issues of preserving traditional seeds, farmers' rights and breeders' rights on seeds, the Rules are also silent or could not address these issues and the enforcement of such rights are at stake in Bangladesh. In this backdrop, it can be strongly inferred that Seed Rules are also not compliant with the provisions of the Article 27.3 (b) of the TRIPS Agreement to protect seeds in Bangladesh. The Government will not be able to bring positive changes in the Seed Rules to address this issue without bringing changes in the Seeds Ordinance. Because, subordinate legislation cannot go beyond the principal legislation.

3.5.1.3 The National Seed Policy 1993-Policy Instrument of GOB for Seed

The overall purpose of the National Seed Policy 1993 (the Policy) is to make the best quality seeds of improved varieties of crops conveniently and efficiently available to farmers with a view to increasing crop production, farmer's productivity, per capita farm income and export earnings.[238] The major objectives of the Policy are:

i. Breeding, developing and maintaining improved crop varieties with attention on suitability for high-input and high-output agriculture;

ii. Timely distributing among all farmers of high yielding varieties of improved quality of seeds that are resistant or tolerant to diseases and insect pests;

[237] ibid, s. 23.
[238] National Seed Policy-1993 of Bangladesh.

iii. Promoting public and private sector seed agency, technology for seed production, processing, storage and use of high quality seeds; and

iv. Monitoring, controlling and regulating the quality and quantity of seeds produced as well as development and commercialization of the seed industry.[239]

For achieving the above stated objectives, the Policy determines the following important strategies:

i. Strengthening institutional capacity of both public and private sectors of the seed industry, seed certification, quality control and testing facilities;

ii. Adopting seed technology for high-input and high-output agriculture;

iii. Promoting balanced development of the seed sector by providing equal opportunity to both public and private sectors; and

iv. Procedural simplification for importing high quality seeds.[240]

Neither the objective nor the strategies to achieve the objectives of the Policy require the enactment of any law or frame any rules for protecting traditional seeds, farmers' rights and breeders' interest in seeds. The development of the seed industry is crucial to the agricultural development of a country. It is more so for Bangladesh, because of the density of the population and scarcity of cultivable land and the low or unacceptable quality of food. Therefore, the seed policy should focus on developing seed industry. The seed industry consists of all enterprises that produce or distribute seeds and involves the following activities:

i. Plant breeding research;

ii. Seed production and multiplication;

iii. Processing and storage; and

iv. Marketing and distribution.[241]

The National Seed Policy of Bangladesh should specifically focus and extend its enthusiasm for the activities stated above. Moreover, biotechnology is a key factor in the agricultural development of the present times. Genetic engineering or modification techniques opened the

[239] ibid.
[240] National Seed Policy-1993 of Bangladesh.
[241] C. E. Pray and B. E. Ramaswami, *A Framework for Seed Policy Analysis in Developing Countries, International Food Policy Research Institute*, edited, Washington D.C., International Food Policy Research Institute, 1991.

door of enormous possibilities for the development of varieties of seeds. Our Seed policy should give due emphasis on these recent scientific developments with due caution in preserving the farmers' rights as well as protecting traditional seeds.

The Policy does not express any determination to bring legislative reform in the legal regime of seed to get rid of unnecessary laws and to introduce a regulatory system of a new genre that will encompass quality assurance mechanisms coupled with the facilitation of a vibrant and responsible seed industry.

The Policy should determine the following sectors like India[242] and Malaysia[243] as thrust sectors:

i. Varietal development and plant variety protection with specific emphasis on legislating and enforcing an effective sui generis system for intellectual property protection;
    a. The rights of farmers to save, use, exchange, share or sell farm produce of all varieties should be protected with reasonable restrictions.
ii. Seed Production;
iii. Quality Assurance;
iv. Seed distribution and marketing;
v. Infrastructure Facilities;
vi. Transgenic Plant Varieties where biotechnology will play a vital role in the development of the agriculture sector;
vii. Import of seeds and planting materials;

[242] National Seeds Policy, 2002, [2002], http://seednet.gov.in/Material/National%20Seed%20Policy,%202002.pdf , (accessed 8 June 2015).

[243] F. C. Ginibun and A. W. Ugap, *Current Status of the Integrated Seed Sector in Malaysia*, [pdf], Malaysia, Malaysian Agricultural Research and Development Institute, 2013, http://q.datakultur.se/~svalofco/wp-content/uploads/2012/12/Malaysia-Seed-Sector-Status-Paper.pdf , (accessed 19 January 2016).

viii. Export of seeds;

ix. Promotion of domestic seed industry to produce high yielding varieties and hybrid seeds;

a. Encouraging Membership of ISTA, OECD, ASSINSEL, WIPO;

x. Strengthening of the monitoring system;

xi. Establishment of centralized, integrated data management system that may contain database on seed supply and demand, imported seed and exported seed, online gene bank database, reporting the performance of the seed industry etc.

3.5.1.4 Plant Quarantine Act, 2011 (Act no. 5 of 2011)

The Plant Quarantine Act, 2011 was enacted in the context of international traffic in plants and plant products, for preventing the introduction of insects or pests into, and spread thereof within, Bangladesh and for the matters relating to phytosanitary and other measures incidental to these objectives. This Act contains provisions regarding interpretation stated in the preliminary chapter, establishment of a national plant quarantine authority and providing its functions, import plant, plant product, beneficial organism, soil or packaging materials into Bangladesh, pre export examination, prohibition of export of plant or plant products without phytosanitary certificate, containment and eradication of pests, offences and punishment for breaching certain provisions of the Act and some miscellaneous provisions like rule making power, removing ambiguity and repeal and savings etc.

The definition of “plants and plant products” includes seeds and live and dead parts of plants. The functions of the National Quarantine Authority, particularly regulating export and import of plants and plant products, inspection of plants and plants products in storage and transit, issuing phytosanitary certificate, reviewing and updating list of plants or plant

products the import of which is prohibited and restricted in Bangladesh, exchanging technical information etc. on plant protection with international, regional and other national plant protection organizations, complying with international agreements, protocols, conventions etc. on phytosanitary measures and the provisions of import and export regarding plants and plants products, containment and eradication of pests and provisions regarding offence and punishment for violating provisions of this Act are important in respect of protection of seed in Bangladesh.

The provisions regarding seizure and destruction of diseased plants and compensation for destruction of diseased plants are needed to be clarified with precision in the Act. The Act does not provide any specific provision regarding prohibition of importation, possession, seizure and destruction of noxious plants that are required for the protection of seeds in Bangladesh.[244]

3.5.1.5 National Institute of Biotechnology Act, 2010 (Act no. 10 of 2010)

National Institute of Biotechnology Act is enacted with the objective of providing law on establishing the National Institute of Biotechnology to facilitate research and development in biotechnology, creating skilled manpower and positive development and implement biotechnology at the national level. Since biotechnology is immensely important in the sector of agriculture, particularly plant biotechnology plays a significant role in producing GMOs as well as GM Food, this Act is important for seed protection in Bangladesh.

The term “Biotechnology” is defined in the Act as a technology to be applied for using living organism or part of organism to invent life (plant or animal or microorganism) with new variety or producing processed products or by-products from such life. Since plant is included

[244]The Plant Quarantine Act, 1976, [1976], sections 6, 13, 14, Act 167.

in the definition, therefore, it can be inferred that the definition attracts seed also.[245] The Act established the National Institute of Biotechnology that is, a body corporate having permanent seal and succession. The Institute has been assigned with several important functions. Among those determinations and attestation of genetically modified (GM) food and genetically modified organism (GMO) are relevant to the seed industry of Bangladesh. There should bea coordination among the National Seed Board, Seed Certification Agency established under the Seeds Ordinance, 1977 and National Institute of Biotechnology to specifically deal with the issues of seed invented or produced using biotechnology. = = =

3.5.1.6 Competition Act, 2012 (Act no. 23 of 2012)

The Competition Act, 2012 is enacted in the context of growing economic development of the Country to facilitate, ensure and maintain sound competition in the trade by preventing, controlling and eliminating anti-competition activities like collusion, monopoly and oligopoly situations, misuse of combination and dominant position.[246] This law is applicable to all commercial enterprises involved with purchase-sale, supply, distribution of any goods and services, and storage of any goods as in the case may be for commercial purposes.[247] The term 'goods' is defined in the Act as 'goods' defined in the Sale of Goods Act, 1930. The Sale of Goods Act defined goods as every kind of movable property other than actionable claims and money and the definition includes amongst others growing crops.[248] This definition is wide enough to include seed as goods.

[245] the Plant Quarantine Act, 2011 (Act no. V of 2011) [2011], s. 2(8), http://bdlaws.minlaw.gov.bd/ , (accessed 11 June 2015).
[246]Competition Act, 2012 (Act No. 23 of 2012), [2012], Preamble. http://bdlaws.minlaw.gov.bd/ , (accessed 12 June 2015).
[247] Section 3 of the Ibid Act.
[248]) (i) Competition Act, 2012 (Act No. 23 of 2012), [2012], s. 2 (1. http://bdlaws.minlaw.gov.bd/, (accessed on June 12, 2015.) And the Sale of Goods Act, 1930 (Act No. III of 1930), [1930], s. 2 (7), http://bdlaws.minlaw.gov.bd/ ,
(accessed 13 June 2015).

Since the Competition Act is applicable to seeds, it plays a significant role in purchasing, selling, supplying, distributing and storing of seeds in Bangladesh. This Act can be applied to prevent anti-competitive practices like monopoly, oligopoly, abuse of combination and dominant position in trading seeds by seed dealers, MNCs and other commercial enterprises. The provisions of the Act do not impede to impose reasonable restrictions to protect the rights of any person under any intellectual property law.[249] The patenting of seeds may create the 'unfettered monopoly' by the MNC's and eventually cage the farmer's right to seeds in the hands of the corporation.

The above situation requires an effective enforcement of the Act. So far the Government of Bangladesh (GOB) has not yet established the Competition Commission as required by the Act that is a key establishment for enforcing the Act. The provisions regarding constitution of the Commission, the appointment and removal of the Members of the Commission and their terms and conditions of service are not very suitable for an independent and effective commission.[250] The provision for administrative financial fine to be imposed by the Commission for abusing a dominant position could be very effective if the Commission could apply the provision impartially on due investigation.[251] The judicial sentence or fine to be imposed by the Commission for violating its order, direction or condition is apparently inadequate and may not serve the purpose of the Act.[252]

3.5.1.7 The Safe Food Act, 2013 (Act No. 43 of 2013)

Preamble of the Safe Food Act envisages the basic objective that this law is going to achieve and the reasons why this law is enacted. This Act holds that the right to safe food is integral

[249] The Competition Act, 2012 (Act No. 23 of 2012 of Bangladesh), section 15 (4).
[250] The Competition Act, 2012 (Act No. 23 of 2012), [2012] ss. 7,9 and 10, http://bdlaws.minlaw.gov.bd/ , (accessed 12 June 2015).

[251] ibid, section 20.
[252] ibid, section 24.

to the protection of health and human life, and this law also emphasizes on the scientific methods in ensuring safe foods by the process of production, distribution, sale, buy, export and import. The Act provides for special measures to ensure safe food that made the use of insecticides or any other harmful substances prohibited and punishable offence. Some of the relevant provisions of the Act that may affect seed related law are as follows:

Section 23 of the Act prohibits storage, marketing or selling of any food or food materials mixed with any pesticides or insecticides that may be dangerous to human health. If such food or food materials are produced from seeds germinated with the help of pesticides or insecticides harmful to human health in that case the storage, marketing and selling of such seed may be prohibited under the Food Safety Act, 2013.

If radioactive substance or heavy metal is found in any seed exceeding the acceptable standard, in that case also such seed may be prohibited under section 24 of the Act.

Section 31 is very important regarding GM seeds which provides that no one can produce, sell, distribute, export and import any novel food, functional food, organic food, and genetically modified or engineered food without getting approval in the prescribed manner under this law.

The provisions discussed above are to be scrutinized and duly appreciated in promulgating any law protecting seed or plant varieties in Bangladesh.

3.5.1.8 The Agricultural Produce (Grading and Marketing) Act, 1937 (Act No. I of 1937)

This Act provides for grading and marking of agricultural products. Section 2 (a) of the Act defines agricultural produce as follows:

"Agricultural produces" includes all produce of agriculture or horticulture and all articles of food or drink wholly or partly manufactured from any such produce, and fleeces and the skins of animals;

The schedule of the Act states 7 kinds of agricultural produces e.g. fruit, vegetables, dairy produces etc. Section 3 of the Act empowers government to frame rules for prescribing grade designations of the scheduled agricultural produces. Though this Act does not include seed in its schedule, the definition of agricultural produce is so wide that can easily attract seed within its ambit**.** Moreover, the Government may apply the provisions of the Act to any other agricultural product not included in the Schedule of the Act after consultation with the stakeholders. The object of grade designation is to ensure the quality of agricultural products. Therefore, this Act may play a vital role in controlling the quality of seeds as an agricultural product.

3.5.1.9 The Agricultural Pests Ordinance, 1962 (East Pakistan Ordinance No. VI of 1962)

The Agricultural Pests Ordinance, 1962 was promulgated to provide for the prevention of the spread of agricultural pests in Bangladesh. It defines crops that include all agricultural or horticultural crops and all trees, bushes and plants. The Act further defines 'infested crops' as the crop affected by any agricultural pest.[253] Since plants include seeds too, this Act has implications in the production, transport and sale of seeds. The law provides that the Government may prohibit any method of cultivation that may spread of agricultural pests either generally or with respect to any particular crop and it also empowers the government to prohibit transporting or sale of any infested crop.[254]

[253] The Agricultural Pests Ordinance, 1962, section 2 (e).
[254] ibid, section 3.

The Act makes it mandatory on the occupier of any land to take preventive measures in respect of any crop cultivated therein.[255] It further provides that the Inspector appointed by the Government has power to enter premises, seize and destroy infested crops or require the occupier or in-charge of the infested crop not to sell or dispose of or move the seized crop from a particular place without the written permission of the authority as may be prescribed by rules in this behalf.[256] The farmers, dealers or MNCs who produce/breed or sell seeds may be affected by the provisions discussed above.

3.5.1.10 The Agricultural Produce Markets Regulation Act, 1964 (East Pakistan Act No. IX of 1964)

This Act provides regulation of the purchase and sale of agricultural produce and of markets in which such produce is purchased and sold in Bangladesh. Section 2 (1) of the Act defines agricultural produce as follows:

"Agricultural produce" means an agricultural produce specified in the Schedule appended to this Act, and includes a produce of horticulture, arboriculture and animal husbandry so specified";

The Schedule includes, paddy, wheat, pulses and oilseeds amongst other kinds of seeds.

Under the Act, the government is empowered to notify markets with respect to a particular agricultural produce or produces. One must get a license to operate as a market functionary[257] in a notified market. The Director, Agricultural Marketing Department is to issue a license under the terms and conditions determined by him/her for one year to the market functionaries for operating in a notified market. Therefore, seed dealers or MNCs that deal

[255] ibid, section 4.
[256] ibid, section 6.
[257] Section 2 (6) of the Agricultural Produce Markets Regulation Act, 1964 states, ""market functionary" means any person who operates as a middle-man in connection with the purchase or sale of, or negotiation of a purchase or sale of, any agricultural produce, or in connection with the rendering of any services incidental to such purchase or sale, and includes a wholesaler, aratdar, stockist, weighman, measurer, sampler, jachandar, grader, commission agent, warehouse-man, broker and dalal;".

with seeds cannot operate in a notified market regarding a particular seed or seeds notified by the Government. The Act also empowers the government to constitute District Market Advisory Committee, which consists of 7 Members including representatives from the growers. This Advisory Committee has the power of arbitration between the purchaser and the seller of seeds amongst other agricultural producers as notified by the Government. Following disputes should be referred to the Advisory Committee for an amicable settlement:

(a) deviation from sample when the purchase is made by sample;

(b) deviation from standard when the purchase is made by a reference to an accepted standard;

(c) difference between the actual weight of a container and the standard weight;

(d) payment of the price;

(e) delivery of goods;

(f) damage of goods;

(g) admixture of foreign matters;

(h) the presence of moisture in excess of the natural moisture content; and

(i) such other matters as may be prescribed by rules.

The disputes referred above are not exhaustive and more disputes can be included through rules and procedures of dispute settlements, that also may be prescribed by rules.[258] However, the Act does not provide any binding effect of such arbitration or finality of such arbitration, which leaves the door open to a multiplicity of litigations.

[258] The Agricultural Produce Markets Regulation Act, 1964 (East Pakistan Act No. IX of 1964), [1964] s. 14, http://bdlaws.minlaw.gov.bd/print_sections_all.php?id=337 ,
(accessed 16 June 2015).

3.5.1.11 The Geographical Indications of Goods (Registration and Protection) Act, 2013 (Act No. 54 of 2013)

The Geographical Indications of Goods (Registration and Protection) Act, 2013 is enacted to provide for the registration and better protection of geographical indications relating to goods. The Act defined goods as an agricultural, natural or manufactured goods or any goods of handicraft or of industry and includes food staffs.[259] Geographical indications as defined in the Act includes agricultural goods originated in the territory of a country, or a region or locality in that territory, where a given quality, reputation, or other characteristic of such goods is essentially attributable to its geographical origin.[260] Therefore, GI may be attributed to the seeds as agricultural products and accordingly GI can be registered in respect of any variety of seed or seeds under the Act.[261] Once a seed is registered as GI under the Act it would get all protections conferred by the Act. The seed producers/breeders, dealers or MNCs that commercially produce or sell seeds may register them as authorized users of GI goods if a GI is registered in respect of the seed they deal with.[262] The authorized users of the seeds registered as GI shall get the following rights: [263]

i. to get redress under the Act for infringements of the GI seeds; and
ii. to use GI in respect of the seeds registered as GI.

3.5.1.12 Bangladesh Biodiversity Act, 2017 (Act no. 2 of 2017)[264]

This Act has been enacted due to the State obligation to fulfil one of the "Fundamental Principles of State Policy" enshrined in Art. 18 A of the Constitution of the People's Republic of Bangladesh which runs, "[T]he State shall endeavour to protect and improve the

[259]) The Geographical Indications of Goods (Registration and Protection) Act, 2013 (Act No. 54 of 2013), [2013] Section 2 (8), http://bdlaws.minlaw.gov.bd/bangla_all_sections.php?id=1136 , (accessed 16 June 2015).
[260] ibid, section 2 (9).
[261] ibid, sections 7 and 8.
[262] The Geographical Indications of Goods (Registration and Protection) Act, 2013 (Act No. 54 of 2013), [2013], section 10.
[263] ibid, section 18.
[264] Laws of Bangladesh, http://bdlaws.minlaw.gov.bd/bangla_all_sections.php?id=1203, (accessed 31 March 2017).

environment and to preserve and safeguard the natural resources, bio-diversity, wetlands, forests and wild life for the present and future citizens"[265] and its international obligation to conserve its biological diversity and to use its biological resources in a sustainable manner and to share equitable benefits from biological resources and the relevant knowledge arising out of such resources as a contracting party of the Convention on Biological Diversity (CBD). The Act will come in to force from the date of notification in the official gazette by the Government of Bangladesh.[266] The definition clauses provide definitions of biodiversity and biological resources amongst other which are akin to the definition of such terms provided by CBD. Sections 4 and 6 of the Act provide some restrictions on conducting activities and transferring research outcome and application for intellectual Property Rights regarding biodiversity. The majority provisions of the Act deal with constitution and powers of National Committee and other committees. The Act provides for punishment up to imprisonment for 5 years and fine up to 500,000/TK (five lac) for violating its provisions. The Act does not address the following issues[267] which are significant for protecting biodiversity and biological resources of Bangladesh:

i. declaring the sovereign rights of Bangladesh over its biodiversity;

ii. stating the human activities which reduce the biological diversity;

iii. providing definitions of 'biotechnology", 'country of origin of genetic resources", "country providing genetic resources", "domesticated or cultivated species" (very important for the protection of seed industry), "ecosystem", "ex-situ conservation", "genetic material", "genetic resources", "habitat", "in-situ conditions", "in-situ conservation", "protected area" and "technology";

[265] Article 18A was inserted by the Constitution (Fifteenth Amendment) Act, 2011 (Act XIV of 2011), section 12.
[266] Section 1 sub-section (2) of Bangladesh Biodiversity Act, 2017 (Act no. 2 of 2017).
[267] Convention on Biodiversity explicitly stated these issues amongst others to be addressed by each contracting party (Member) in its national legislation.

iii. community knowledge protection;

iv. identifying the components of biodiversity;

v. ex-situ conservation and in-situ conservation;

vi. impact assessment and minimizing adverse impacts;

vii. recognizing that technology includes biotechnology;

viii. access to and transfer of technology; and

ix. handling of biotechnology and distribution of its benefits.

In absence of the provisions regarding the above-mentioned issues in the Bangladesh Biodiversity Act, 2017, which Bangladesh is under an international obligation to address through its legislation as a contacting party of CBD, the Act merely increases the volume of the statute book rather contributing in protecting biodiversity and biological resources of Bangladesh and enable its people to enjoy these resources.

3.6 Protection of seed through International Conventions/Treaties/Agreement

Apart from the TRIPS Agreement Bangladesh is a Member of Convention on Biological Diversity (CBD).[268] Bangladesh signed and ratified CBD on June 5, 1992 and May 3, 1994 respectively, and became a party to the Convention on August 1, 1994. CBD has two protocols, namely Cartagena Protocol on Bio-safety (Cartagena Protocol) and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization (Nagoya Protocol).[269] The main objectives of the CBD are: [270]

[268]CBD was adopted on 5 June 1992 at the United Nations Conference on Environment and Development at Rio de Janerio, Brazil. The Convention came into force on 29 December 1993. Currently, 196 countries are contracting parties to CBD, available at www.cbd.int/information/parties.shtml, (accessed 24 June 2015).

[269] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity was adopted at the tenth meeting of the Conference of the Parties on 29 October 2010, in Nagoya, Japan, see www.cbd.int/abs/doc/protocol/nagoya-

i. Conservation of biological diversity;

ii. Sustainable use of its components; and

iii. Fair and equitable sharing of benefits arising out of the utilization of genetic resources from:

   a. Appropriate access to genetic resources; and

   b. Appropriate transfer of relevant technologies.

Amongst above stated three main objectives of the CBD, the third objective, i.e. fair and equitable sharing of benefits arising out of the utilization of genetic resources has substantial implications of seed. Cartagena Protocol and its supplementary Nagoya Protocol do not have any direct implication on seed. Therefore, these two protocols are not discussed here.

As a signatory of the WTO Agreement Bangladesh is by implication of law has become a party to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), that is an integral part of the WTO agreement and binding on Bangladesh.[271] SPS has a remarkable implication on the seed policy and seed related laws of Bangladesh.

Bangladesh is a signatory of the International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA) and it has also ratified the Treaty. Therefore, this Treaty is binding on Bangladesh. The basic objectives of PGRFA are:

i. To recognize the enormous contribution of farmers to the diversity of crops that feed the world;

ii. To establish a global system to provide farmers, plant breeders and scientists with access to plant genetic materials; and

---

protocol-en.pdf, (accessed 24 June 2015). Bangladesh signed and ratified Cartagena Protocol on May 24, 2000 and February 05, 2004 respectively and it entered into force for Bangladesh on May 05, 2004. Bangladesh has yet to sign and ratify the Nagoya Protocol.

[270] Convention on Biodiversity, Article 1.

[271] the WTO Agreement, Article II (2).

iii. To ensure that recipients share the benefits they derive from the use of these genetic materials with the countries where they have been originated.

Therefore, PGRFA has a vital role in formulating seed policy and seed related laws of Bangladesh.

Bangladesh is not a signatory of the International Convention for the Protection of New Varieties of Plants (UPOV) as revised at Geneva (Geneva Act 1991). But according to the agreement between Bangladesh and EC, Bangladesh is under obligation to make an endeavor to accede to the UPOV. The agreement has set time limit for Bangladesh to accede to UPOV by 1 January 2006, which is kept flexible. Still then Bangladesh is under pressure to accede to this International Convention. Under the same provision of the Agreement Bangladesh is to make an endeavor to accede to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977).[272]

3.6.1 Accession to UPOV Convention how far feasible

UPOV is the French acronym for the International Convention for the Protection of New Varieties of Plants (UPOV). The UPOV Convention was adopted in 1961 to ensure that Member states acknowledge the achievements of breeders of new plant varieties by making available to them exclusive property rights for a given period. Instead of using the patent system, there was a need to develop a system that was more adapted to the needs of plant breeders, i.e. continued access to plant varieties for breeding purposes. Therefore, it allowed wide exemptions from the property rights of breeders and for farmers. The Convention entered force in 1968 and has been revised several times since then, each time with more

[272] Cooperation Agreement between the European Community and the People's Republic of Bangladesh on Partnership and Development, L 118/48 [EN], Official Journal of the European Communities, 27.4.2001, Article 4, para 5 (b). http://trade.ec.europa.eu/doclib/docs/2016/september/tradoc_154979.pdf, (accessed 2 April 2017).

restricted exemptions for breeders and farmers. Today, most Member countries are either Member of the 1978 Act or the 1991 Act of UPOV.[273]

There are important differences between the 1978 and the 1991 Acts of UPOV regarding coverage, period, scope and exemptions.

i. The '78 Act covers plant varieties of nationally defined species or genera, whereas the '91 Act covers plant varieties of all genera and species.

ii. The protection period is minimum 15 years under the '78 Act and minimum 20 years under the '91 Act.

iii. The protection scope under the '78 Act is produced for the purposes of commercial marketing, offering for sale and marketing of propagating material of a protected variety. The '91Act adds, among other things, exporting, importing, and stocking for the above purposes of the protected material.

iv. Breeders are free to use a protected variety to develop a new variety under the '78 Act, but not if it requires repeated use of that variety. Under the '91 Act this exemption is restricted and, among other provisions, it is not allowed to produce varieties which are essentially derived from a protected variety or which are not distinguishable from such a variety.

v. Farmers are free to use their harvested material from a protected variety for any purpose under the '78 Act. Under the '91 Act, national governments are entitled to decide whether farmers shall be allowed -- within reasonable limits and

[273] GRAIN at www.grain.org/article/entries/2183-norway-says-no-to-upov-1991 , (accessed 4 August 2015).

> safeguarding the legitimate interests of the rights holder -- to reuse the harvest of protected varieties on their own land holdings without the authorization of the rights holder. It would not be allowed to exchange or sell such material.[274]

Norway is a Member of UPOV based on the 1978 Act and upholds its right to continue as a Member of UPOV based on that Act. In September 2005, the newly elected Norwegian government turned down a law proposal for Norwegian Membership in UPOV 1991. The basic reason for such a move was twofold:

i. It would limit the customary rights of farmers to save and reuse farm saved seeds and propagating material -- which they still practice to some extent.

ii. It would move the costs to the Norwegian farmers. They would have to buy propagating material for each season. For some species, they could reuse their farm saved seeds or potatoes upon payment of royalties each time (with exceptions for small-scale farmers regarding some crop species).[275]

1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV) shut the door of new Members to accede to the UPOV Conventions of 1961, 1972 or 1978 and it also limits the new Members' right to provide to the genera or species in the following manner:

[New Members of the Union] Each Contracting Party which is not bound by the Act of

[274] GRAIN at www.grain.org/article/entries/2183-norway-says-no-to-upov-1991 , (accessed 4 August 2015).

[275] GRAIN at www.grain.org/article/entries/2183-norway-says-no-to-upov-1991 , (accessed 4 August 2015).

1961/1972 or the Act of 1978 shall apply the provisions of this Convention,

(i) at the date on which it becomes bound by this Convention, to at least 15 plant genera or species and,

(ii) at the latest by the expiration of a period of 10 years from the said date, to all plant genera and species.[276]

On the other hand, UPOV, the intergovernmental organization established by UPOV Convention and FAO propagates opposite pictures. The Secretary-General of UPOV explained that "the introduction of the UPOV system of plant variety protection and Membership of the International Union for the Protection of New Varieties of Plants (UPOV) can open a door to economic development, particularly in the rural sector. […] An important conclusion is that the UPOV system of plant variety protection provides an effective incentive for plant breeding in many different situations and in various sectors, and results in the development of new, improved varieties of benefit for farmers, growers and consumers."[277]

The Second World Seed Conference held at the Headquarters of the Food and Agriculture Organization of the United Nations (FAO) in Rome, from September 8 to 10, 2009 concluded that "[…] countries are urged to participate in the internationally harmonized systems of the Organization for Economic Cooperation and Development (OECD), the International Union for the Protection of New Varieties of Plants (UPOV), the International Treaty on Plant and Genetic Resources for Food and Agriculture (ITPGRFA) and the International Seed Testing Association (ISTA). Participation in those systems will facilitate the availability of

[276]The UPOV Convention of 1991. Article 3 (2).
[277] UPOV, 'Report on the Impact of Plant Variety Protection', International Union for the Protection of New Plant Varieties of Plants (UPOV), 2005, p 3, http://www.upov.int/export/sites/upov/about/en/pdf/353_upov_report.pdf, (accessed 1 April 2017).

germplasm, new plant varieties and high quality seed for the benefit of their farmers, without which their ability to respond to the challenges ahead will be substantially impaired"[278]

Further argument has been placed in favour of UPOV of 1991 in the following manner:

The 1991 Act of the UPOV Convention contains in its Article 15 (1) (I) a compulsory exception to the breeder's right whereby the breeder's right does not extend to acts done privately and for non-commercial purposes. Therefore, activities of subsistence farmers, where these constitute acts done privately and for non-commercial purposes, are excluded from the scope of the breeder's right and such farmers' benefit from the availability of protected new varieties.

The provision in the 1991 Act of the UPOV Convention on "farm-saved seed" is an optional mechanism provided by the UPOV Convention (Article 15 (2)), under which Members of UPOV may permit farmers, on their own farms, to use part of their harvest of a protected variety for the planting of a further crop. Under this optional exception, Members of UPOV can adopt solutions, which are specifically adapted to their agricultural circumstances. However, this provision is subject to reasonable limits and requires that the legitimate interests of the breeder are safeguarded, to ensure there is a continued incentive for the development of new varieties of plants, for the benefit of society. For example, certain Members of UPOV apply the provision on farm-saved seed only to certain species and limit its application using criteria such as the size of the farmer's holding or the level of production.[279]

The differences sorted out by GRAIN between UPOV Conventions 1991 and 1978 should be carefully considered before taking any decision to accede to the UPOV Convention 1991

[278] www.worldseedconference.org ,
(accessed 4 August 2015).

[279] *Report of the Special Rapporteur on the right to food*, United Nations, 2009,
http://www.un.org/ga/search/viewm_doc.asp?symbol=A/64/170 ,
(accessed August 4, 2015).

despite arguments in its favour. Moreover, it is to be noted that none of the SAARC countries, including most the UN Members have acceded the Convention yet. Amongst the African countries, remarkably Kenya has acceded to UPOV Convention 1991. Considering all the pros and cons it would be wise for Bangladesh to wait further for coming to the decision of acceding to the Convention, notwithstanding the pressure of the EU and other developing partners.

3.6.2 SPS Agreement Crucial for Bangladesh

The Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement") entered force with the establishment of the World Trade Organization on 1 January 1995. It concerns the application of food safety and animal and plant health regulations.[280] Article 1.2 of the Agreement refers Annex A for definition and paragraph 1 of Annex A defines “Sanitary and Phytosanitary Measures”. Paragraph 1 (a) stated about measure to protect plant varieties from 4 kinds of threats, e.g. risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms. These measures are very crucial amongst all the measures stated in Paragraph 1. Bangladesh must carefully assess the measures for protecting its plant varieties from pests and diseases. In doing so Bangladesh is to take due consideration of Article 5 and 5.2 of the SPS Agreement. Article 5 does list certain factors that Members must consider when making a risk assessment.

Article 5.2 lists the relevant scientific and technical considerations, namely: “available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other

[280] www.wto.org/english/tratop_e/sps_e/spsund_e.htm ,
(accessed on August 6, 2015).

treatment." From this list, a risk assessment, for the purposes of the SPS Agreement, is not purely scientific (in the sense of laboratory science), but involves consideration of real-world factors that affect risk, such as climatic factors that could contribute to the proliferation of a pest; the vulnerability of an ecology such as that on an island state; the effectiveness of control mechanisms etc.

3.7 Legislative options for Bangladesh in protecting the seed

The PD Act of Bangladesh is an archaic law, amending of which may not give the desired results to achieve the target of exploiting the highest benefit from the flexibilities of the TRIPS Agreement. But to exploit the exemption from enforcing Article 27.3 (b) till July 1, 2021, Bangladesh might need to amend the PD Act to exclude plant varieties and seed from patenting as a short-term measure. However, On the other hand from the above discussion patent protection to the plant varieties may bring some adverse effect on the farmers, traditional knowledge and resources e.g. suing farmers by MNCs for the alleged protection of genetically engineered seed, infringement of farmers' rights to sell and exchange seeds produced by them, preservation of traditional seeds etc. We have also observed the difficulties of plant varieties protection through a combination of patent and sui generis system. Since Bangladesh is an agro based country, to protect its traditional seeds, knowledge and farmers' interests, it would be beneficial for the nation to go for an effective sui generis system for plant varieties protection through which seed, the fundamental ingredient of agriculture can be protected.

3.8 Summary and Way Forward

It has been revealed from the discussion in this chapter that seed is patentable under the PD Act and the DPDT has already issued a considerable number of patents to protect processes by using biotechnology. Since Bangladesh is exempted from protecting plant varieties under

Article 27.3 (b) till 1 July 2021, therefore, it should take immediate step by amending the existing PD Act to exclude plant varieties and seed from patenting. At the same time, it should take sufficient legal measures to protect its own plant varieties and seed.

The Geographical Indications of Goods (Registration and Protection) Act, 2013 may be helpful in this regard along with Seeds Ordinance, Seed Rules and Competition Law. In case of need Bangladesh should go for amending its Seed Ordinance and Competition Law to protect its national interest on seed. Bangladesh also should go for immediate enactment of a Plant Varieties Law to protect its PGR, medicinal PGR, traditional medicine, farmers' rights, seed industry and striking a balance between these interest and rights with the plant breeders' (MNCs) rights. The enactment will also ensure implementation of its obligation under CBD and TRIPS.

The next chapter reveals the impact of the TRIPS Agreement on software patenting. It examines the controversy on software patenting, status of software patenting in PD Act, software patenting in the US, EU and other Asian Countries, human rights issues involved with software patenting, scope of software protection in relevant laws of Bangladesh, recommendations for the proposed BPA. This chapter finds a relationship amongst software protection and protection of medicine and seed industries of Bangladesh through data protection in the fields of medicine and seed.

Chapter 4: The Impact of the TRIPS Agreement on Software Patenting in Bangladesh: Challenges and Way Forward

4.1 Introduction

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is a premier multilateral treaty which seeks to establish a common threshold for IPRs protection on one hand and to eliminate the trade barrier of IPRs on the other. Each Member state of the TRIPS has the obligation to provide legal means to protect the legitimate IPRs for its own nationals as well as for the nationals of the other Member states. Regarding the obligations, Least Developed Countries (LDCs) have been exempted for a certain period, currently until July, 2021. Bangladesh as a Member state of TRIPS and being an LDC is now enjoying the said exemption from TRIPS obligation. However, Bangladesh has already enacted some laws and is getting ready to enact and amend its legal instruments at par the TRIPS standards. Those measures will have huge impacts on the different sectors of Bangladesh, including booming software industry. Thus, impact assessment of such measures is a matter of great significance in order to have a sound legal framework that will strike a balance between the protection of national interests and TRIPS compliance.

In this backdrop, this chapter explores some key issues and concerns. Does TRIPS require software patenting? Is software patenting required besides copyright protection to ensure better protection of software? Is software patentable under the existing patent law of Bangladesh? Should Bangladesh provide software patenting in the light of the US, EU and Asian experience on software patenting to protect its software industry? How should Bangladesh enact its patent law to ensure a balance of convenience between national interest and that of MNCs? Should Bangladesh go for ‘restrictive’ or ‘flexible’ approach of software

patenting system? What are the main challenges that Bangladesh is going to face within the TRIPS periphery in patenting software? What other necessary changes should be brought in relevant laws and policies to ensure software protection? What measures and policy initiatives Bangladesh should take to overcome the challenges in this field? How those policies and measures would commensurate to the human rights norms? Finally, how does a delicate balance can be struck between protection of national interests and TRIPS compliance?

4.2 Development of Software Patenting

In the context of 21st century, intellectual creativities of human being are rapidly growing by the grace of technological advancement. New human creations related to technological fields open avenues to explore new opportunities as well as complicated legal challenges. The issues of suitable legal provisions and frameworks to protect and promote those creativities are of paramount importance. Software protection under the existing IPRs system is a complex and controversial matter since it does not exactly fit within the heretofore fields of classical intellectual property law.[281] This section attempts to explore the historical paths of software patenting system. In doing so, the section will first tend to explain the existing software protection mechanisms under current Intellectual Property System.

4.2.1 Software Protection under Prevalent IPRs System

In 1970's and 1980's there were extensive debates and discussions as to which fields of Intellectual Property Law cover computer software.[282] Despite those debates, currently, it is accepted that Copyright and Patent are the two main fields of Intellectual Property under

[281] J.H Reichman, 'The Know-How Gap in the TRIPS Agreement: Why Software Fared Badly', *Hastings Communications & Entertainment Law Journal,* vol. 17, 1995, p. 766.

[282] WIPO, 'Copyright Protection of Computer Software', Geneva, Author, http://www.wipo.int/copyright/en/activities/software.html , (accessed 4 June 2014).

which software should be protected. Copyright is a legal term used to describe the rights that creators have over their original literary and artistic works. The works covered by copyright range from books, music, paintings, sculpture and films, to computer programs, databases, advertisements, maps and technical drawings.[283] In software system there are two types of code, namely, the source code (human readable form) and object code (machine readable form). The combine effect of both the codes is that a set of instructions carried in a computer that brings about a certain result. Those instructions are emanated from source code and which is expressed in written form, it is therefore, logical to define software as being subject to copyright protection as a literary work.[284] Thus, Software should be protected under the umbrella of copyright.[285] Indeed, this approach is supported by the several international treaties.[286] However, since copyright only protects originality of expressions and not ideas, thus, software protection under the copyright regime suffers some intrinsic drawbacks. Most significantly, copyright cannot prevent second generation creators from recreating the same work or producing similar idea using different expressions.

On the other hand, Patent grants monopolistic right not only over the inventions but also inventive ideas. Unlike copyright, patent protection of the inventors can be challenged on the ground of the same ideas. The non-literal and functional aspects of software are claimed to be protected under patent. There is no dichotomy of idea and expression in patent law.[287] An

283 WIPO, 'What is Copyright?', Geneva, Author, http://www.wipo.int/copyright/en/ , (accessed 7 June 2014).

284 A. G. González, 'Software Patentability: Emerging Legal Issues', *WIPO Magazine*, no. 6, 2008, pp. 15-17.

285 Fenwick & West LLP, *Report on International Legal Protection for Computer Software*, [pdf], 2004 Updated edition, Computer & Internet Law, 2004, https://www.fenwick.com/FenwickDocuments/Software_Chart_2004.pdf , (accessed 10 July 2014).

286 Article 4 of the WIPO Copyright Treaty (WCT), Article 10 of the TRIPS Agreement, Article 1 of the European Council Directive 91/250/EEC on the Legal Protection of Computer Programs

287 A. G. González, 'Software Patentability: Emerging Legal Issues', *WIPO Magazine*, no. 6, 2008, pp. 15-17.

idea can be patented if it is novel, involves inventive steps, industrially applicable and not restricted by the exclusion clause under the patent law of a particular jurisdiction.

It is, however, settled that software can be protected by the copyright system. In contrast, there is a serious debate as to patentability of software program on the several aspects. Software programs are not patentable subject matters, at least not by any express provisions of international instruments. Software programs are typically composite of algorithm or mathematical codes; hence, do not fulfil the criteria of Invention which is a precondition of patentability. In addition, software patent creates a kind of 'trivial patent' where, in many cases, it lacks the threshold of inventive steps or standard of non-obviousness. Thus, it seriously hinders the SME's and open source development. Some critics also claimed that software patenting has a counterproductive impact on the small and medium software industries on one hand, and it furthers the anti-competitive practice in the market by creating almost unfettered monopoly on the other.[288]

On the other hand, software patenting has been supported due to several justifications. The software is compatible with all the requirements of patentability.[289] The source code and object code, in combination with each other, create some technical effects; therefore, this should be regarded as inventions. Moreover, these codes have enough inventive steps and huge industrial use. Software program requires considerable time and resources of the creator. If software is not patented, it will be an issue of 'free riding' which is contrary to the current intellectual property regime. Furthermore, functional technology and functional aspects of software can be protected suitably by patent as ideas. Thus, invariably software

[288] R. Hart et al., *The Economic Impact of Patentability of Computer Programs: Report to the European Commission*, [pdf], http://ec.europa.eu/internal_market/indprop/docs/comp/study_en.pdf , (accessed 30 June 2014).

[289] A. G. González, 'Software Patentability: Emerging Legal Issues', *WIPO Magazine*, no. 6, 2008, pp. 15-17.

programs should be protected by patent. If the software is protected under patent regime, it would enjoy a certain kind of suitable and extended protection than copyright.

4.2.2 Development of Software Patenting in the United States

The United States is the pioneer in granting software patents. Therefore, to overview the historical paths of software patenting we must take notice of the history of US Software patenting. The U.S. Patent and Trademark (USPTO) Office historically has been reluctant to grant patents on inventions relating to computer software. In the 1970s, the USPTO avoided granting any patent if the invention utilized a calculation made by a computer. Its rationale was that patents could only be granted to processes, machines, articles of manufacture, and compositions of matter. However, patents could not be granted to scientific truths or mathematical expressions, law of nature, natural phenomena, and abstract ideas. The USPTO viewed computer programs and inventions containing or relating to computer programs as mere mathematical algorithms, and not processes or machines. As such, software related inventions were considered non-statutory.[290]

In the 1980s, the Supreme Court forced the USPTO to change its position. It is the case of *Diamond vs. Diehr,* first instance in which the U.S. Supreme Court ordered the USPTO to grant a patent on an invention even though computer software was utilized. In that case, the invention related to a method for determining how rubber should be heated to be the best "cured." The invention utilized a computer to calculate and control the heating times for the rubber. However, the invention (as defined by the claims) included not only the computer program, but also included steps relating to heating rubber, and removing the rubber from the heat. The Supreme Court stated that in this case, the invention was not merely a mathematical algorithm, but was a process for melting rubber, and hence was patentable. This was true

[290] The History of Software Patents, Bit Law, www.bitlaw.com, (accessed 10 July 2014).

even though the only "novel" feature of this invention was the timing process controlled by the computer.[291]

Although ruling on the *Diamond Case* is a landmark, however, it does not open wholly the doors of software patenting. Around the same time of *Diamond Case*, there are three other cases[292] that paved the way for 'standardized' patentability test of software programs. Those three cases established the yardstick of patentability of software inventions by a test known as "Freeman-Walter-Abele Test". This test basically emphasizes on the utilitarian or practical aspect of the algorithm used in the software patenting. This utilitarian aspect of the algorithm was further liberalized by *State Street Bank and Trust Company v. Signature Financial Group, Inc.* case[293] in one hand and *Bilski v. Kappos cars*[294] on the other. Under the present mechanism, U.S. patent law holds the liberal approach on the patentability of the software programs, provided that they produce concrete, useful and tangible results.[295]

4.3 Overview of Software Patenting in EU

There are two sets of statute that govern the patent system in the EU. Firstly, European Patent Convention, (EPC) 1973 and secondly, the statute of each Member State of EU. Country specific legislations are almost up to the same standards as EPC and TRIPS.[296] EU patent system on software patenting has been developed through some landmarks judicial decisions and policies. The key historical development of software patenting in the EU is briefly discussed hereinafter.

---

291 The History of Software Patents, Bit Law, www.bitlaw.com, (accessed 15 July 2014).

[292]In re Freeman Case (1978), In re Walter Case (1980) and In re abele Case (1982)

[293]149 F.3d 1368 (Fed. Cir. 1998).

[294]561 U.S. 593 (2010).

295 T. Kaya, 'A Comparative Analysis Of The Patentability Of Computer Software Under The Trips Agreement: The U.S., The E.U., And Turkey', *Ankara Law Review,* vol. 4, no. 1, 2007, p. 43.

[296]ibid.

Under the current system, article-52 of EPC deals with the patent system. Article 52 (1) states the major three criteria for patentability of an invention, namely- novelty, inventive step and industrial application. Article-52 (2) specifically excludes some subject matters as non-patentable in which computer program along the others is explicitly mentioned. However, by the virtue of article 52 (3) computer programs or software are not under the sanction imposed by article 52 (2), hence patentable under EU law. It can fairly be stated that the Convention does allow for patent rights in software at present, albeit indirectly with somewhat obscure boundaries.[297]

The subject matter of software patent was not very clear cut, and with the passage of time it was developed by the judicial interpretation as well as State practice of the EU. For instance, 1985 EPO Guidelines for Substantive Examination relating to Computer Related Inventions outline the patentability of software and allow patents for computer program.[298] The issue was further elaborated by well-known Vicom Case,[299] where a method for enhancement of certain digitally processed images was rejected by Examination division on the ground, inter *alia* either it was a computer program or a mathematical method. However, the Board of Appeal reversed the decision and allowed patent assessing the technical effect of the invention as a whole.[300]

Furthermore, 'Inventive step' of software patent was a complicated issue to be resolved to determine patentability. The issue was addressed by the EPO under 'Problem-solution-

[297] C. D. Freedman, 'Software and Computer Related Business- Method Innovations: Must Europe Adopt American Patent Culture?', *International Journal of Law and Information Technology*, vol. 8, no. 3, 2000, p. 288.

[298] Guidelines for Examination in the European Patent Office, Part G, Chapter II-3.6 https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g.htm , (accessed 13 May 2017).

[299] (1987)2EPOR 74.

[300] Koch & Sterzel (1988) EPOR 72, In this case the principle was further reaffirmed.

approach'[301] –meaning the objective examination of technical problem and claimed solution- of each and individual claim. This problem-solving approach resulted in later almost similar yet distinct doctrine of 'Further technical effect'[302] by judicial interpretations in some famous cases.[303]

It was noticeable that EPO approach was not followed by the Member States uniformly. To resolve the issue as well as establish a uniform system for all Members, European Commission prepared a 'Proposal for a Directive of the European Parliament and of the Council on the Patentability of Computer-Implemented Invention' in 2002.[304] However, the proposal was rejected by the European Parliament in 2005. Thus, the Member States are free to determine the software patentability on judging 'technical effect' on a case by case basis under their own legislation. However, regarding European patent system the Members are bound to follow the guidelines of EPC and EPO. EU grants the patent for software subject to its own practice and policy, and recent developments in the EU have shown that patent protection for software is the midst of an expansion project.[305]

EPO position is best explained by the words "[a]s long as a software-related invention is of a technical character (in the sense of producing a technical effect) it will be eligible for patent protection. It does not matter that the essence of the invention falls into an excluded category, that is, that the technical character is found in a computer program."[306] The most recent version of the EPO Guidelines provides "[t]he basic patentability considerations in respect of

[301] C. D. Freedman, 'Software and Computer Related Business- Method Innovations: Must Europe Adopt American Patent Culture?', *International Journal of Law and Information Technology*, vol. 8, no. 3, 2000, p. 289.

[302] A computer program claimed by itself is not excluded from patentability if the program, when running on computer brings about or capable of bringing about a technical effect.,

[303] Case T 1173/97 and Case T 0935/97 in both the case IBM was a party.

[304] http://ec.europa.eu/prelex/detail_dossier_real.cfm?CL=en&DosId=172020 (accessed 25 July 2014).

[305] K. L. Durell, 'Intellectual Property Protection for Computer Software: How Much and What Form is effective?', *International Journal of Law and Information Technology*, vol. 8, no. 3, 2000, p. 241.

[306] C. Waelde, et al, *Contemporary Intellectual Property Law and Policy*, 3rd edn., London, Oxford University Press, 2014, p. 517.

claims for computer programs are in principle the same as for other subject-matter. While 'program for computers' are included among the items listed in Art. 52 (2), if the claimed subject-matter has a technical character it is not excluded form patentability by the provisions of Art. 52 (2) and (3)."[307] The EPO explained the relationship between the technical character and technical effect in the following manner:

Technical character is manifested by generating about a technical effect that changes the working of apparatus, products, or process achieved by technical means. Relevant technical effects that provide technical character to a computer program include:

(1) the control of an industrial process;

(2) the processing of data which represent physical entities; and

(3) the control of the internal functions of a computer itself or its interfaces.[308]

The EPO Guidelines further state that technical effect can be found in a computer program that:

(1) affects the efficiency or security of a process;

(2) governs the management of computer resources; or

(3) regulates the rate of data transfer in a communication link.[309]

The European trend on software patenting has been substantially changed by the Guidelines and now earlier prohibition on the patenting of computer program as such is illusory.

4.4 Trends and Issues of Software Patenting in Asian Countries

4.4.1 Jurisdictions of Japan and China

Japan is one the most influential countries in the fields of Intellectual Property. The standards for granting software patents were revised in 1993 in Japanese jurisdiction. The software

[307] C. Waelde, et al, *Contemporary Intellectual Property Law and Policy*, 3rd edn., London, Oxford University Press, 2014, p. 518.
[308] EPO Guidelines, Part G-II, para 3.6.
[309] ibid.

patenting system under the Japanese Patent Office is lenient in nature. Thus, Japanese Patent Office takes flexible approach in grating patent for software program. Per the Japanese Patent Law to be patentable an invention must be "highly advanced creation of technical ideas utilizing a law of the nature". Japan Patent Office has detailed guidelines on patentability[310] which outlined the claims can be patented if 'utilization of law of nature in information processing performed by software' and 'invention using hardware resources'. The Japanese approach has been adopted by the South Korea and Singapore.

The Chinese Patent Law provides the scope for software patenting, albeit not explicitly. Under the article 25 (2), rules and methods for intellectual activities are not patentable subject matter. Moreover, rule 2 of the Implementing Regulations describes an 'invention' as any new technical solution relating to a product, a process or an improvement thereof. The combine effect of article 25 and rule 2 forms the legal justification for software patenting. Under the Chinese system, software is not patentable *per se, rather it* is patentable when it produces any 'technical effect' or 'technical solution'.

4.4.2 Indian and Pakistani Jurisdictions

As per Indian patent law 'a mathematical or business method or a computer program *per se* (standing alone, in itself or by itself)' or algorithms are not an invention for purposes of the Patent Act.[311] In India, an amendment was attempted in 2004 to extend the scope of software patenting which has industrial application and can be used with hardware. However, because of objections both in and outside the parliament the provision was not incorporated while the amendment was passed in 2005. Despite this predicament, under the existing system 'a

310 Japan Patent Office Examination Guidelines that is divided into two segments, a) General Guidelines on Non-statutory Inventions, and b) Specialized Guidelines on Software Related Inventions. http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/1312-002_e.htm , (accessed 10 August 2014).

311 The Indian Patent Act, 1970 (as amended up to 2005), [1970, S.-3(k), http://www.wipo.int/wipolex/en/details.jsp?id=13104 , (accessed 10 August 2014).

computer program *per se* other than its technical application to industry or a combination with hardware' cannot be patented. Moreover, in 2005, the Indian Patent office published the Draft Manual of Patent Practice and Procedure, which gave guidelines on patentability of software inventions. It provides that any method executed by software without any technical means or any method executed by technical means but without any hardware support" would not be patentable.[312] The Indian approach to software patenting is not flexible rather strict in nature.

The Pakistani Patent Law contains the general patentability requirements, namely novelty, inventive steps and industrial application. It also excludes some subject matters from patentability.[313] Although it is not explicitly mentioned in the exclusion clause that computer program/ software cannot be patented, however, Intellectual Property Organization of Pakistan contained the guidelines that a computer program / software is non-patentable.[314]

4.5 Software Patenting under the TRIPS Agreement

The TRIPS Agreement has been adopted under the WTO regime by considering of effective promotion and adequate protection of IPRs on one hand, and to lessen or diminish the impediments or barriers in legitimate trading of IPRs on the other.[315] The TRIPS aims to achieve overall requirements, minimum thresholds of protection and dispute settlement mechanisms for the Member States in relation to IPRs. Thus, TRIPS provides the general framework for the protection of computer programs along with other intellectual properties.

---

[312] R. Negi, Remfry and Sagar, 'Business Method and Software Patent Trends in India', *Intellectual Asset Management*, no. 35, 2009, p. 102.

313 Article 7(2) and (3) specifically mentioned some subject matter and grounds that are not patentable. Scientific theories, mathematical method, business method, subject matter against public order and morality, etc are included in this section.

314 http://ipo.gov.pk/Patent/Default.aspx#UnPatentable%20Inventions%20In%20Pakistan , (accessed 11 August 2014).

[315] the TRIPS Agreement, 1994, Preamble, para-1.

4.5.1 Protection of Software under Copyright and Patent

Regarding patent, TRIPS has made a considerable progress over Paris Convention, 1883 which previously dealt with different aspects of industrial properties including patent. However, it did not explicitly solve the issue of patentability of computer program. In contrast, as far as the computer program is concerned, TRIPS contains a specific provision for the protection under the umbrella of copyright. Article 10 of TRIPS accommodates the protection for computer programs, whether in source or object code, as 'literary works' based on the same notion of the Bern Convention, 1886.

However, there are some intrinsic difficulties and practical hindrances in protecting computer programs under copyright due to its nature. TRIPS postulates that copyright protection shall extend to expressions and not the ideas, procedures, methods of operation or mathematical concepts as such. As TRIPS stands, copyright cannot prevent second generation creators from recruiting software by using the same source code or object code in different expressions. Thus, to protect content of software as an idea, there is a proposition that computer programs should be protected under patent system.

4.5.2 The TRIPS Requirements for Software Patenting

On the question of patentability, article 27 (1) of the TRIPS Agreement sets the minimum criteria. This provision acts as the basis for Member States to provide patent of any subject matter. Article 27 (1) of TRIPS states that:

> "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any invention, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of

industrial application.[316] 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."[317]

Article 27 (2) (3) of the TRIPS Agreement provides the flexibilities on the Member States not to provide patent in certain subject matters and any particular circumstances. Under the TRIPS provisions Members may exclude some inventions from patentability to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment subject to the conditions mentioned therein. Members may further exclude from patentability of followings

(a) diagnostic, therapeutic and surgical methods for the treatment of human or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes to produce plants or animals other than non-biological and microbiological process.

Article 27 of TRIPS establishes an overall scheme of patentability which acts as the bedrock for the Member States while enacting their national laws. According to TRIPS provisions 'Any inventions' 'whether products or process' relating to 'all fields of technology' are patentable if they are 'novel' involve to 'inventive steps' also 'industrially applicable' and are not excluded by the exception to patentability clause. TRIPS Agreement provides two kinds of exception to patentability under article 27 (2) and27 (3). In addition to TRIPS exclusion,

[316] [TRIPS Agreement note] For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

[317]Article 27 (1) of Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (1994), WIPO Publication No. 223(E).

generally patent is not granted to natural principles, scientific phenomena, abstract ideas and mathematical formulas.[318]

4.6 Patentability of Software in the Existing Laws of Bangladesh

4.6.1 Is Software Patentable under Existing Laws?

The Patents and Designs Act, 1911 (Act no. II of 1911) enacted during the British regime in Indian subcontinent is the law in force in Bangladesh. The issues relating to patent have been dealt with and regulated in Bangladesh by aforesaid Act. In accordance with this Law, Department of Patents, Designs and Trademarks (DPDT) under Ministry of Industries of Peoples' Republic of Bangladesh manages and administers the patent related affairs.

Under the present system, to be patentable, firstly a subject matter must be an invention. The Act narrowly defines the 'invention' as any manner of new manufacture and includes an improvement and an alleged invention. Manufacture is defined in the Act as "manufacture" includes any art, process or manner or producing, preparing or making an article, and also an article prepared or produced by manufacture.[319] Reading both the definitions together would attract a wide range of subject matters as patentable under the Act that may include software patenting. Although the Patents and Designs Act, 1911 enumerates procedure for patent application, however, it does not have any specific provision on subject matters which cannot be patented.[320] This is probably a grey area where the patent authority can exercise a wide range of discretionary power in dealing with any patent application.

Despite the non-specific provision for software patenting under the existing Patent Act, in reality, patent has been granted for computer program in Bangladesh. More precisely, patents

[318] United States Patent and Trademark Office, *Examination Guidelines for Computer-Related Inventions,* United States Patent and Trademark Office, 1996, https://www.uspto.gov/web/offices/com/sol/og/con/files/cons093.htm , (accessed 5 September 2014).

[319] See section 2 (10) ibid.

[320] M. M. Azam, *Intellectual Property WTO and Bangladesh*, 2nd edn., Dhaka, New Warsi Book Corporation, 2012, p. 175.

are granted in favour of computer programs, not as program *per see* rather as a method of some technical effects. Any software method that results in 'technical effect' is an invention and therefore a patentable subject matter. For instance, Bijoy Bangla typing software is protected by copyright in 1989 as original expression and later patented in 2004 under the Patents and Designs Act, 1911 as a method of producing technical effects.[321]

It is worthwhile to mention here that Patents and Designs Act, 1911 does not specifically provide any clarification on 'novelty', 'inventive steps' and 'industrial application'. However, it has incorporated the issues related to basic requirements of patent under the procedure for patent application, particularly in the portion of the specification. Thus, it is plausible that software program *per see* is not eligible to be patented under existing laws of Bangladesh. However, it can be patented as an idea or method when it produces technical effects. Though the official website of the Department of Patents, Designs and Trademarks does not give any data of software patenting or granting patents on any subject matter, however, it is revealed from a visit to the Department that it grants patents to the embedded software and so far, it has granted almost 100 patents for embedded software out of 239 applications.[322]

4.7 Initiation of Drafting New Patent Law

Owing to the old age patent Law along with its defects, on many aspects, it is greatly demanded from different corners to update, upgrade or totally reshape the existing patent Law of Bangladesh. Considering the justified issues and facts, Law Commission of Bangladesh visited the current status and coverage of the existing Patent Law. The

[321] WIPO, 'Localizing Technology: The Story of Bijoy' Geneva, Author, http://www.wipo.int/ipadvantage/en/details.jsp?, (accessed 5 September 2014).

[322] Embedded software is computer software, written to control machines or devices that are not typically thought of as computers. It is typically specialized for the particular hardware that it runs on and has time and memory Constraints-See http://en.wikipedia.org/wiki/Embedded_software , (accessed 9 April 2015).

Commission has finally proposed to substitute the present Act by a new enactment instead of suggesting amendments to the present patent Act. Thus, Bangladesh has proposed a draft Patents and Designs Act, 2001 to overcome the shortcomings of existing Patent Law as well as to fulfil TRIPS obligation. The draft Patents and Designs Law have been reviewed and revisited in several times by the different stakeholders, including WIPO experts, however, it is yet to be enacted by the parliament.

4.7.1 How Far Patentability of Software is addressed by Proposed Patent Law?

The current policy of Bangladesh government is heading towards establishing a country with digitized systems. It is rather intuitive that everyone is expecting technological advancements by the laws and policies of Bangladesh. Therefore, it is significant to examine that how far would technology be protected by the Proposed Patent Law. Investigating patentability of software is certainly an important issue in this regard.

4.7.2 Invention

On the question of patentability, the prime query is that whether the alleged subject matter is an invention or not. The patent Examination authority must deal with the issue in accordance with guidelines or rules laid down by the relevant legal framework. The Proposed Patent Law of Bangladesh has widened the definition of invention than that of existing one. It postulates 'an invention' as any new, sufficiently inventive and useful-

a. Art, process, method or manner of manufacture.
b. Machine, apparatus or other article.
c. A substance produced by manufacture and includes any new, sufficiently inventive and useful improvement of any of them, and an alleged invention. [323]

[323] Draft Patents and Designs Act, 2001 (the Act has been modified and revisited several times and yet to be passed), [2001], s. 16.

This wide definition of 'invention' has been endorsed by the WIPO experts and Bangladesh delegation in a discussion on 2003. The WIPO experts stated that this definition is acceptable and compatible with the TRIPS Agreement. On the question of patentability, The Proposed Law has incorporated the general three requirements, i.e. novelty, inventive steps, and industrial application.[324] In addition to, it has enlisted some subject matters as non-patentable.[325]

4.7.3 Novelty

Novelty has been clarified by the proposed Law as any inventions which do not fall under 'prior art'. The prior art means the publication of anything intangible form and already in use by the public before the application of patent by the inventor. Thus, the newness of a particular invention will be treated in relation to the state of the prior art. If the matter is already in the prior art, it will not be considered as novel and will not be eligible for a patent. The concept of prior art in relation to a particular invention denotes to existing knowledge and similar invention already known in that field.

4.7.4 Inventive Steps

Inventive steps in any invention mean an invention which involves technological sophistication or improvement, economic benefits or significance or both, then in the existing knowledge which was unknown to the person related to that field. There must be research and development to make a substantial difference from the existing knowledge. The invention must be non-obvious to a person skilled in the art to which the invention relates.[326] In the case of *Windsurfing International Inc vs. Tabur Maries (Great Britain) Ltd*,[327] Justice Oliver developed the test of inventive steps. He observed that to determine inventive steps of alleged

[324] Draft Patents and Designs Act, 2001, [2001], s. 3.
[325] The Proposed Draft Patent and Design Act, 2001, [2001], s 4.
[326] B.L., Wadehra, *Law Relating to Intellectual Property*, New Delhi, Universal Law Publishing, 2012, p. 6.
[327] 1985, RPC 59, 73.

invention, it should be considered that whether those differences constitute steps which would have been obvious to the man or whether they require any degree of invention. Thus, the basic notion of inventive steps is to consider how much difference has been made in an invention and how far it non-obvious to the person ordinarily skilled in the particular field.

4.7.5 Industrial Application

An invention that accomplishes the criteria of novelty and inventive steps, but not industrially applicable, will not be eligible for a patent. Therefore, besides the aforesaid two preconditions it must also be industrially useful. The proposed Draft Patent Law of Bangladesh depicts industrial applicability of a particular invention if such invention is ready for or already used in any industry.[328] Usefulness is a significant element of justification and granting patents. The condition of industrial application requires that the invention should be something which can be made industrially or relate to an industrial process. Practical and commercial value has been a great consideration for development of the modern patent system.

4.7.6 Non Specification of software in Proposed Patent Law

Like the TRIPS Agreement, the Proposed Patent Law of Bangladesh does not have any specific provisions relating to patentability of computer program. It does not explicitly exclude the software from patentable subject matter either. Therefore, a conclusion can be drawn in favour of software patenting due to the wide definition of invention on one hand and replication of worldwide practiced general requirements of patentability on the other.

However, there might be scope of confusions under Proposed Law. For example, Proposed Law excludes 18 items from patentability on various grounds, including a discovery, scientific theory or mathematical method. Therefore, software patenting might be objected by

[328] The Draft Patents and Design Acts, 2012 [2012], S. 4(3),

arguing it as purely algorithm or mathematical issue due to obscure provision of Proposed Patent Law. It is overwhelmingly attributable that granting patents for mathematical algorithms would preclude others from performing the same process; hence, this should not be patented.[329]

Bangladesh is one of the booming developing nations in the software industry, outsourcing and ICT sectors. Therefore, it should adopt specific policy, whether it will go for 'flexible' or 'restrictive' approach in granting software patents. In doing so, it must strike a delicate balance between protection of national interests and safeguard to foreign giant software companies. There should be clear provisions on patentability of software, if affirmative, upon fulfilment of specific conditions. Due consideration and consultation may be given to worldwide practiced conditionals while setting up requirements of software patent in Bangladeshi Law.

4.8 Impacts of software patenting on Bangladesh

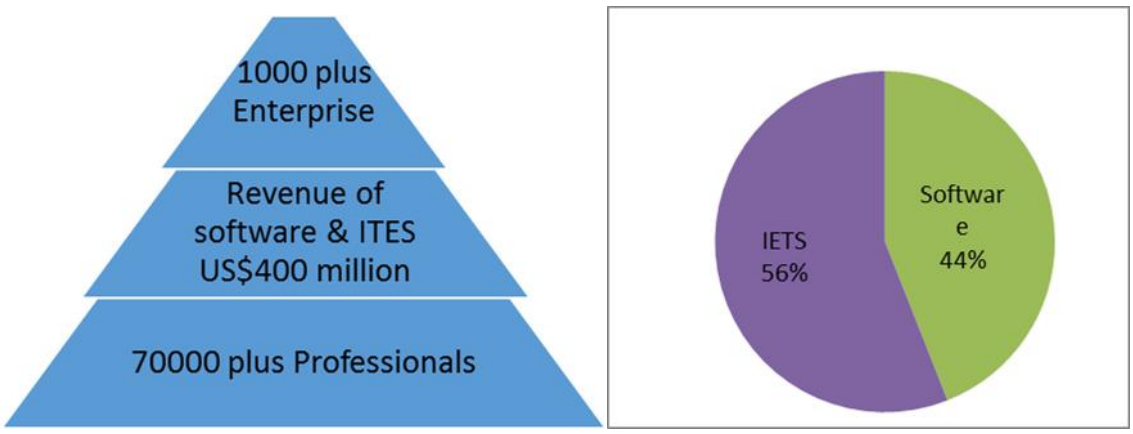
It is generally assumed that Bangladesh has great potential in ICT sectors. Software market of Bangladesh is not an infant. However, this is yet to be matured enough to fulfil the dream of digital Bangladesh. The government of Bangladesh has set the priority on Digital Bangladesh Vision and adopted the National Information and Communication and Technology Policy (NICT) of 2009. This policy has been updated by introducing NICT 2015.[330] It declares in its strategic themes to create legal framework conducive to conservation of IPR, online document transaction and payment. It also provides for development of telemedicine and health service management through utilizing sophisticated technology and encouraging highest use of ICT for increasing productivity in agriculture. Besides this, Access to

[329] T. Kaya, 'A Comparative Analysis Of The Patentability Of Computer Software Under The Trips Agreement: The U.S., The E.U., And Turkey', *Ankara Law Review,* vol. 4, no. 1, 2007, p. 22.
[330] Bangladesh Gazette, Extraordinary Copy, August 5, 2015.

Information Programme (a2i) of Bangladesh has opened new windows for the people.[331] Thus, in consonance with the government's vision of 'Digital Bangladesh', the country is heading towards a digitized system. Impact assessment form both negative and positive sides, may serve as the important way forward for the policy formulation on software patenting in Bangladesh.

4.8.1 Current Stature of Software Industry of Bangladesh

The software development sector appears to be the largest local value adding segments of IT industry of Bangladesh. The sector is booming with a relative young population of Bangladesh which has great potential to add value to the economy of the country.[332] Thus, Software Industry of Bangladesh is contributing to the country's economy on one hand, and creating new job opportunities for young graduates on the other. This new booming arena is even helping greatly our creative minds to be entrepreneurs and to create many jobs for others.



[331] The Access to Information (a2i) Programme at the Prime Minister's Office, with support from UNDP and USAID, was started in 2007 with the focus of bringing information and services to citizens' doorsteps and increasingly within the palms of their hands. It does so by harnessing modern ICTs, local knowledge and global best practices to establish both physical and virtual one-stop access points. See, http://www.bd.undp.org/content/bangladesh/en/home/operations/projects/democratic_governance/access-to-information--ll-.html ,
(accessed 9 November 2016).

[332] Data Collection of Bangladesh IT/ITES Industry, Final Draft, February, 2015, Published by Bangladesh Computer council and Ministry of Posts, Telecommunications and Information Technology, p2.

Total Human Resources Employed in Industry Revenue Proportion

Source: Bangladesh Association of Software and Information Services (BASIS)[333]

The snapshot of the ICT industry shows that the total industry size is estimated to be around US$400 million. Approximately 70,000 professionals, majority IT and other graduates are employed in the industry. Software industry generates the 44% of total yearly revenue. IT Enabled Service Companies earned 56% of yearly total revenue. The demand of software services is growing in different sector of Bangladesh. Banks, Corporations and other business and financial institutes cannot run their daily affairs without software system. RMG sector, Textile and Pharmaceuticals have huge demands for automated systems.

Moreover, the service sectors including education, healthcare and telecommunication are spending their money in adopting and maintaining the software system. In outsourcing/offshoring initiative, Bangladesh has made a considerable progress in both formal corporate and individual (freelancing) levels. In this process, it is developing a good number of IT experts, mostly from the student folk and attracting handsome revenue in the economy of the country. The government's policy on the tax exemption on income from this sector has furthered the involvement of our IT experts in this field.

4.8.2 Software Protection and its potential impacts on Bangladesh

The TRIPS has given the flexibilities on the state parties to formulate their policies to protect and promote IPRs. Bangladesh has an obligation to be TRIPS compliant country after the expiration of the transition period or after the cessation of the status of developing countries. The impact of the implementation of TRIPS will certainly be very huge due to the level of development, structure as well as the relevant sector of the particular country. Therefore,

[333] Bangladesh Association of Software and Information Services, 'Bangladesh Software and IT service Industry: Recent Trends and Dynamics', [pdf], http://www.basis.org.bd/resource/About_Industry.pdf , (accessed September 15, 2014).

before adopting the policy on Patents, Bangladesh needs to assess the impacts of TRIPS on concerned sector. Bangladesh is currently granting the protection to the software that is original and not modified or developed upon the existing software.[334]

It is believed that if software protection is accorded, it will encourage foreign direct investment (FDI) which ultimately will generate employment. For instance, Samsung has established Research &Development (R&D) Centre in Bangladesh where some Bangladeshi engineers have been employed. Protection of software by the legal regime might build a positive image of the country. The good impression on the image of the country may expedite export oriented economy of the country. Protection to the software program may be a useful way to encourage local innovators and industries to innovate and develop the indigenous products. Thus, it might have a big impact on the local development.

4.9 The Story of Bijoy as Case Study

The lesson learnt from the case of Bijoy Bangla Software is revolutionary for understanding the significance of protection and local innovation. Mostafa Jabbar, the proprietor of Bijoy, has developed the program for Bangla typing system which is highly acclaimed both within and beyond the country. Due to the protection by national IP Law, the story of Bijoy is a successful one.

Bijoy is copyrighted under the Bangladesh Copyright Act, 2000 as an expression. It is also accorded Patent as the method of new invention. Its design has been protected by the Patents and Designs Act, 1911. If Bijoy was not accommodated by such protection under different mechanisms of Domestic IP Laws of Bangladesh, it would have been copied by domestic and international competitors. For instance, Bijoy had an issue of dispute with Avro Keyboard layout which alleges that Avro has copied its layout system. Bijoy issued an administrative

[334]This is the current approach of the Patent Examination Office in Bangladesh of DPDT under the Ministry of Industries, People's Republic of Bangladesh.

notice to Avro by the Registrar of the Copyright Board. However, in later date the matter had been settled through the amicable solution between the parties.[335] If protection was not accorded, Bijoy would not have any option but to suffer piracy. The consequences of according protection under legal frameworks of Bangladesh are multiple. It has galvanized different versions of 'Bijoy Software' on one hand, and encouraged our local innovations on the other.

4.10 Present Scenario of Software Piracy in Bangladesh

The scenario of software piracy in Bangladesh is deplorable and alarming in many senses. Some studies showed that Bangladesh is within top five software pirated countries during the last several years. For instance, Global Software Piracy Study 2008, published in 2009 which conducted by International Data Corporation (IDC) revealed that with 92 percent software piracy in Bangladesh, the country ranked first in the Asian Pacific region and the second highest in the world.[336] Although the report has been challenged and protested by the Bangladeshi stakeholders.[337] It is rather acceptable in many aspects that, Intellectual Property Culture in Bangladesh is in a bad condition. The patent protection like other IPRs is not in very creditworthy condition. Thus, issues related to software piracy hamper the FDI and further development of this sector in Bangladesh. The International Property Rights Index, 2014 shows that the patent protection system is very weak in Bangladesh. Bangladesh ranked 97th globally out of 97 countries and 16th regionally out of 16 countries.

[335]WIPO, Localizing Technology: The Story of Bijoy, Genva, Author, http://www.wipo.int/ipadvantage/en/details.jsp?, (Accessed 17 September 2014).
[336] http://www.datasoft-bd.com/index, accessed on September 17, 2014.
[337] https://groups.yahoo.com/neo/groups/ict_of_bangladesh/conversations/topics/4944, (accessed 20 September 2014).

Table:2 The International Property Rights Index, 2014[338]

	Score	Globally	Regionally
Overall	2.6	97 of 97	16 of 16
Protection of Individual Property Rights	3.7	89 of 97	16 of 16
Patent Protection	3.2	97 of 97	16 of 16
Copyright Protection	1.0	79 of 80	15 of 15

The reasons are generally unchartered but not unknown. However, there are some obvious reasons for such a high rate of software piracy in Bangladesh. Availability of counterfeit copies of the software is certainly one of the prime causes in this regard. If someone buys a computer, our retailers generally install counterfeit programs in the computer without further asking anything for the buyers. This probably one of the key practices that hindrance overall development of IP culture in Bangladesh.

On the other hand, Bangladeshi users usually cannot afford the proprietary software. Thus, they often go for counterfeit software. Even the most government institutions and offices do not use the propriety genuine software. However, the study shows the different connotation "some people choose counterfeit to save money, but this 'ride-along' malware ends up putting a financial and emotional strain on both the enterprise and casual computer users alike'.[339]

[338] http://internationalpropertyrightsindex.org/country?c=Bangladesh , (accessed 20 September 2014).

[339] International Data Corporation (IDC) and Microsoft, *The Dangerous World of Counterfeit and Pirated Software*, 2013, https://news.microsoft.com/download/presskits/antipiracy/docs/IDC030513.pdf , (accessed 20 October 2014).

4.11 Human Rights Compatibility of the Software Patenting

4.11.1 Issues of Convergence and Divergence between HRs and IPRs

Human Rights (HRs) and Intellectual Property Rights (IPRs) were at odds and stranger to each other for a long time. However, it was in the recent past, World Intellectual Property Organization (WIPO) and United Nations High Commissioner for Human Rights (UNCHR) jointly investigated the interface between two disciplines.[340] The issue has been synthesized in two ways, firstly, IPRs fundamentally conflict with human rights. In some cases, even human rights are traded off due to the protectionism approach of private monopoly of IPRs holders. Secondly, there are several intersections between human rights and IPRs. Precisely, IPRs are the part of human rights; hence, there is no fundamental conflict. However, there may be a likelihood of *quid pro quo;* thus, we need to strike the balance between monopoly of the IPRs holders' in one hand and the interests of the consumers on the other.[341]

4.11.2 Human Rights Compatibility of Software Protection

Human rights compatibility of software protection like other IPRs is under scrutiny owing to their huge implications. Universal Declaration of Human Rights (UDHR), 1948 does not expressly depict IPRs as part of the human rights spectrum. However, article 27 of UDHR contains the requisite ingredients of possible convergence between human rights and IPRs. On one side, it says that everyone has the right to the protection of the moral and material interests resulting from scientific, literary or artistic production of which he is the author.[342] This notion delineates IPRs as part of the human rights and justifies the author's right to enjoy the material and moral benefits from his creation. The notion has been reiterated by article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR),

[340] WIPO, Intellectual Property and Human Rights, A Panel Discussion to commemorate the 50th Anniversary of the Universal Declaration of Human Rights, WIPO Publication No.762 (E), 1999.
[341] L. R. Helfer, 'Human Rights and Intellectual Property: Conflict or Co-existence?', *Minnesota Intellectual Property Review*, vol. 5, no. 1, 2003, p. 47.
[342] Universal Declaration of Human Rights (UDHR), 1948, Article 27(2).

1966. Intellectual Property Rights to a certain degree create a monopoly in favour of the right holders and excludes 'free riding' by the third parties.[343] In software, it is protected either by copyright as the expression or by patent as an idea or method of new invention. In both the systems, the author or the patentee has every human right to enjoy the material or moral benefits that arises out his creation. In this way, the whole paradigm of modern IPRs system is compatible with Human Rights Norms.

In another aspect, article 27 (1) of UDHR says that everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits. This is certainly an area on which the concerns and questions are placed to the extent of monopoly of IP right holders on the one hand, and access to enjoyment of scientific benefits and utilities by a human being on the other. In case of software patenting, the issues pertaining to access, utilization, right to education and information amidst others are under the active consideration from a human rights perspective.

4.11.3 Does Software Patenting Hamper Consumer's Freedom and Right to Information?

Freedom of ideas and expressions enjoys special stature both in the fields of Human rights and Intellectual Property Rights. Freedom of expression is one of the core human rights, on the hand, it is the cardinal *raison d'être*[344] for granting IPRs to a particular person or entity. The provision of the International Covenant on Civil and Political Rights (ICCPR), 1966, prescribes the significance of freedom of expression about receiving and imparting information in the following words:

[343] Md. R. Islam, 'Intellectual Property Rights and Developing or Least Developed Countries: Strategies for Policy Makers', *The Dhaka University Studies Part-F,* vol. 19, no. 1, 2008, p. 116

[344] The most important reason or purpose for someone or something's existence-English Oxford Living Dictionaries,
https://en.oxforddictionaries.com/definition/raison_d'%C3%AAtre ,
(accessed 13 March 2017).

> "Everyone shall have right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art or, through any other media of his choice."[345]

Likewise, the human rights aspect, Software system revolves around the different frontiers of human right's notion. This may range from freedom of expressions or ideas of freedom of receiving and disseminating information. Human rights based approach purports that private monopoly often hinders the legitimate collective right to information and right to know of the mass people. It must not be forgotten that IPRs are essentially granted not to augment the benefits of the business enterprises, not even the authors or inventors, rather it is granted an incentive for invention and gain for society at large. Thus, monopolistic system of software like other IPRs should not be allowed to trade off the collective right of the community.

In the case of *Microsoft Corporation vs. Commission of the European Communities (2007)*[346], the main accusation against the Microsoft was that it was abusing its dominant position in the market by restricting some key information about its software program. Although the main issue was related to the competition law, concern regarding the human right to information comes into play as a matter of fact. Microsoft was ordered to open the information related to the program to a certain degree that will ensure the balance between the right of information and interest of the Microsoft as holder of the IPRs. In this way, a delicate balance was tried between the human right of the consumers and the interests of the Multinational Corporation.

[345] The International Covenant on Civil and Political Rights (ICCPR), 1966. Article 19.
[346] T 201/04, the case was submitted in 2004 and decided in 2007.

In the above line of thought, it is argued that proprietary software does not allow the general users to know the information about source code. This hampers the right to information of the consumers. Due to the peculiar contingencies of this kind of software, users dictate to a certain degree of functions. In proprietary software, users are not allowed to utilize and customize the software as they wish to because of the functional settings. In this way, freedoms of the consumers are restricted or controlled by the multinational companies and big corporation. Thus, the human rights of common masses are being entrusted with the profits making machines of the corporate giants.

4.11.4 Does Software Patenting Hinder Right to Education?

In IP jurisprudence, it is well settled notion that patent is not granted solely for the benefits of the patentee rather for his disclosure and addition of new knowledge in a specific field. It is, therefore, a valid and legitimate expectation that patent will enrich the domain of public knowledge and promote further innovation. In Software patenting, particularly the proprietary software may shrink the relevant learning information for the students. For instance, in computer science if the students want to know everything how a specific program works. If the program is proprietary one, the teacher has nothing to do but to say sorry because the source code is secret.[347] Eventually, it hampers the educational process of future programmers and in the long run hindrances the development of software. The right to know and educational rights of common citizenry in general and future software developers in particular should not be traded off for just ensuring financial dividends to the big and Multinational Corporation.

[347] S. Richard, Free Software, p. 15.

4.11.5 Do Current Flexibilities in Software Protection Conducive for HRs Realization?

In replying aforesaid concerns from human rights perspective, it is intuitive that software patenting to some extent restricts the consumer's freedoms. This may stand in the way to freedom of information or freedom to use and utilize as they wish to. However, the cardinal consideration is to examine whether those restrictions are reasonable, just or arbitrarily imposed. Moreover, there are some inbuilt flexibilities within the software protection regimes. Furthermore, it is also attributable that free software system does not embark any blanket restriction. Therefore, consumers enjoy the freedom of tailoring them into their own way. So, current software systems are available with due alternatives for the consumers.

4.12 Compulsory Licensing' in Software Patenting

Compulsory license is an authorization given by the government for the use by a third party without the consent of the right-owner of a patent.[348] The TRIPS provision accommodates the scope for compulsory license under certain grounds.[349] As to the human rights concerns on software patenting, software can be compulsorily licensed in national emergency, extreme urgency, non-commercial use etc. State parties to TRIPS have the discretionary power to determine the situations in which compulsory license can be availed. The only restriction in this regard, is that such limitations should not unreasonably prejudice the legitimate interests of the patent holder.[350] Thus, compulsory licensing may be used to diminish or lessen the hardships of monopoly that may be by-products of software patenting. In this way, a balance can be drawn regarding human rights concerns towards software patenting.

[348] C. M. Correa, 'The TRIPS Agreement: How Much Room for Maneuver?', *Journal of Human Development*, vol. 2, no. 1, 2001, p. 87.
[349] The TRIPS Agreement (1994), Article 31.
[350] The TRIPS Agreement (1994), Article 30.

4.13 Doctrine of Fair Use' in Software Copyrights

In case of copyright, domestic laws of many countries provide the 'fair use' exceptions. This may be done without the prior consent of the author in situations like personal use, non-commercial use, use in educational and research purposes, etc.[351] This doctrine is incorporated with a view to diminishing the overweight of the monopolistic rights on the collective or individual rights of the people. The software can be protected by copyright alongside the patent system. Thus, 'fair use' doctrine may be as shield to reduce the impacts of such protection on right to information and right to education and many more.

4.14 Other Built-in Flexibilities

There are some built-in flexibilities within the system of software protection which may be harnessed to create checks and balances of the negative impacts of IPRs on human rights. In open source software (OSS),[352] unlike the proprietary software, source code is open and users have scope to use, adapt and modify in accordance with their needs.

Thus, this kind of software system provides the user's freedom of information, right to information and the right to education. In this process, it is compatible with the human rights to freedom, information and education. On the other hand, adopting a policy of economy pricing for developing countries or gratis copy for educational and research institutions in the case of proprietary software may be a useful way out to overcome the human rights challenges. Thus, the issues and concerns from human rights perspective towards protection of software under IPRs can be resolved by aforesaid built-in flexibility within protection systems.

---

[351] C. M. Correa, 'The TRIPS Agreement: How Much Room for Maneuver?', *Journal of Human Development,* vol. 2, no. 1, 2001, p. 85.

[352] It is a kind of software that may be protected by IPRs as well but with much flexibility to the users and it is therefore much user friendly than Proprietary Software. See, Klaus M. Schmidt and Monika Schnitzer, 'Public Subsidies for Open Source? Some Economic Policy Issues of the Software Market', *Harvard Journal of Law & Technology*, vol. 16, no. 2, 2003, p. 475.

4.15 Changes Required in Relevant Laws for Protection of Software

4.15.1 Scope of Software Protection in Relevant Laws of Bangladesh

The Bangladesh Copyright Act, 2000 specially accords copyright protection for computer program. The Patents and Designs Act, 1911 does not have any explicit provision as to the patentability or non-patentability of software program. However, in practice Department of Patents, Designs and Trademarks (DPDT) under Ministry of Industries has been granting patents for software program not *per see* but for those which produce technical effects. Thus, if the patent is granted to any software program, any piracy or counterfeits will be dealt under the existing Patent Law. On the other hand, if any, software program is protected by copyright, infringement will also be actionable under the Copyright Law of Bangladesh.

The scope of software protection in any other Laws, as supporting legal mechanisms, is of paramount significance to understand and formulate a holistic legal framework. The Information and Communication Technology Act, 2006 contain the software program as a subject matter of protection under computer system.[353] Any wilful and intentional damage done to the computer system, including software programs without the consent of the owner is a cybercrime under this Law. Thus, the provisions of said Law can be attracted in terms of cybercrimes relating to the software program.

Bangladesh has enacted some national legislations to tackle crimes which have global impacts. The Anti-Terrorism Act, 2009 and The Mutual Cooperation on Criminal Affairs Act, 2012 are worthwhile to discuss here. Software program are within the meaning of property under the purview of section 2 (14A) of the Anti-Terrorism Act, 2009.[354] Any terrorist activities are done with a view to destroying any property is punishable under the provisions of the said Act. On the other hand, by the Mutual Cooperation on Criminal Affairs

[353]the Information and Communication Technology Act, 2006. [2006], s. 2(14)

[354]Section 2 (14A) of the said the Act defines the property as tangible or intangible things whether situated in Bangladesh or outside.

Act, 2012 Bangladesh government is bound to cooperate with other countries to inquire, investigate and try criminal offences related to software subject to some conditions imposed in the law. Appropriate applications of these laws will be helpful in protecting national interest on software in Bangladesh.

4.15.2 Recommendations on Proposed Patent Law

A. On the patentability of Software

For TRIPS compliance, Bangladesh is under no specific obligation to declare the software program as patentable subject matter. The TRIPS itself does not specifically accord such protection and obligation. However, since Bangladesh is one of the booming developing nations in the software industry, outsourcing and ICT sectors, it should adopt the specific policy regardless of the fact whether it will go for 'flexible' or 'restrictive' approach in granting software patents. Bangladesh is currently granting patent for software which is originally not developed upon other software programs.

New Patent Law of Bangladesh should specifically contain the patentability of software upon the fulfilment of certain conditions. It should incorporate the general criteria of patent along with the exclusion clause. If the software is made specifically patentable subjects, there might be a challenge for Bangladeshi local software companies to compete with the MNC's in the domestic market. Bangladesh will be under obligation to give equal level of protection to its own nationals and other nationals under the TRIPS. To overcome the hurdle, our Law should also accommodate all the flexibilities of TRIPS like compulsory licensing, parallel imports, etc. Thus, the new Patent Law should be drafted in a way so that it can strike a delicate balance between protection of national interests and TRIPS' Compliance.

B. Compulsory licensing

Section 14 of the Proposed Draft of Bangladesh Patent Law, 2012 contains the provisions for compulsory licensing. The compulsory license can be made by the appropriate authority of the government on the ground of public interests, particularly for national security, health care, nutrition and national sector with economic significance. Compulsory License can also be granted upon the satisfaction of any judicial or executive magistrate on the issue that the monopoly of the patent holder has created unfair competition or the patent holder has misused the monopoly of the patent. An application for compulsory license can be made by any person to the government of Bangladesh. The government can order issue of compulsory license after hearing of the interested parties. On issuance of compulsory license, the government shall provide compensation to the Patent holder. It seems that the proposed Patent Law has nicely covered the provisions for 'Compulsory Licensing'.

C. Parallel Import

Section 31 of Proposed Draft Patent Law of Bangladesh allows the parallel import only if it does not prejudice the national interest and within the rules and regulations under this Law. Thus, it is *prima facie* perceivable that parallel import could be made under the proposed law in the cases where it is not prejudice to the interests of Bangladesh and within the purview of existing rules and regulations.

D. Exception to the Research and Experiments

Section 32 of Proposed Draft Patent Law of Bangladesh postulates that exemption from the infringement of the patent if it is used without the consent of the patent holders for research and experiment purposes. This is conducive to the research and development of the patent system. Non-specification of the educational use may create confusion. Thus, any use for educational purpose should also be mentioned as the ground of exception. However, there should be provisions for tackling the misuse of these exemptions.

4.16 On Preventing Software Piracy

Overall scenarios on the software piracy and prevention system in Bangladesh have been greatly affecting the image branding of the country which ultimately hampers foreign direct investment (FDI). Appropriate and effective steps should be adopted to strengthen the protection mechanisms on one hand, and stop the software piracy on the other. The implementation of the legal rules is very important in this regard. A special branch of law enforcing agency may be made so that they can quickly act in the software piracy. Our judges and lawyers should be trained to accord better justice system for any dispute related to software piracy.

4.17 On human rights compatibility of software patenting

In broad point of view, software patenting is compatible with human rights norms. However, there are certain situations where cautious approach should be taken to lessen the harshness of monopoly of software patenting. The Proposed Patent Law of Bangladesh should incorporate all those flexibilities so that the interests of the mass people can be protected. Our Patent law has a provision for compulsory licensing; our Copyright Law has 'Fair use' under the doctrine. The Proposed Patent Law should incorporate the provision to empower the government to require the software companies to issue software program for students and consumers in low price.

4.18 Summary and way forward

Software patenting is a controversial and disputed issue all over the world. Software is protected under the umbrella of copyright, patent and in some jurisdiction under data protection laws. What protection will be appropriate and adequate is still a matter of continuous research. However, protection of software under Patent results in some

advantageous position than other forms of protection. Thus, patent protection is accorded to the software program world-wide, albeit with different approaches.

The USPTO provides a wide range of patent protection for software or computer program, whereas a little bit restrictive approach is being followed by the EPO. Software is explicitly patentable subject matter under US patent law. EPO grants the patent protection only when it produces any 'technical effect'. Some Asian countries like Japan, South Korea and Singapore have adopted the US system in their own ways.

In 2004, India tried to amend its patent law to cover patent protection for software; however, it did not see the light. Currently, India provides software patent only when it is not *per se* rather having 'technical effect' in combination with any hardware support. In contrast, a Pakistan Patent system excluded software from patentable subject matter, thus, it does not allow patents for software. Bangladesh provides software patent only in a restrictive way. Our law does not specifically mention software as the patentable subject matter. However, patents are granted to the embedded software by DPTD in Bangladesh.

Bangladesh as Member State of TRIPS must adopt its patent system at par TRIPS standards. The TRIPS provision does not provide any explicit recognition on patentability of computer programs. Therefore, arguably it is claimed that software patenting should not be allowed under TRIPS. Conversely, it is also contended that software is a patentable subject matter under TRIPS since it is compatible to all criteria set by article 27. TRIPS provision stipulates that patents should be awarded for all inventions irrespective of their fields of technology.

Since software programs are within the meaning of 'inventions', these should be covered by the patents under the TRIPS framework. Moreover, TRIPS does not explicitly exclude computer programs from patentability, thus, patent protection should be extended to software under TRIPS. However, as it has been discussed before Member States of TRIPS accord the

patent protection for software program. Like the TRIPS Agreement, neither the existing Patents and Designs Act, 1911 nor the BPA has any specific provisions relating to patentability of computer program. Both the Laws do not explicitly exclude the software from patentable subject matter either. However, The Proposed Patent Law has widened the scope of the invention, and also specifically mentioned other general criteria of Patent. Therefore, a conclusion can be drawn in favour of software patenting due to the wide definition of invention on one hand and replication worldwide on the other.

In Bangladesh, currently patents are granted for software in 'restrictive approach'. In this 'restrictive approach' Multinational Companies (MNC's) do not have much problems in getting patents in comparison to domestic software companies. Thus, they apply to the DPDT in refereeing same diagram and formula of the other jurisdictions. In contrast, the 'restrictive approach' hinders the local innovation and development. Local software developers do not get patent for programs that are developed and they are under serious examination of patent criteria. In this way, local innovation and creativities are not encouraged by the present practice.

The software industry has great impacts on the different sectors of Bangladesh including revenue generation, youth employment, local innovation and entrepreneurship. The snapshot of the ICT industry shows that the total industry size is estimated to be around US$400 million. Approximately 70,000 professionals, majority of which are IT graduates along with other graduates, are employed in the industry.

Software industry generates the 44% of total yearly revenue handoff IT industry. On the other hand, IT Enabled Service Companies earned 56% of yearly total revenue. From aspect of protection mechanisms, present status of Bangladesh is rather frustrating than being satisfactory. Bangladeshi users have a common tendency to use pirated or counterfeit

software. Our market system is also largely accustomed to encourage the counterfeit software program. Protection frameworks and mechanisms are very much weak both from global to regional points of view. Overall scenario has been greatly affecting the image branding of the country which ultimately hampers foreign direct investment (FDI).

In broad perspective, software patenting is compatible with human rights norms. However, there are certain situations where cautious approach must be taken to lessen the harshness of monopoly of software patenting. This may be done by the way of compulsory licensing, Doctrine of fair use under Copyright Law, Private use for research and educational purpose, free and open source software, etc. Software companies should also sell the software program for students and consumers of LDCs in low price.

Next chapter explores the impact of patent system on transfer of technology in Bangladesh. It particularly focused on exploiting TRIPS' flexibilities on technology transfer to medicine, seed and software industry in Bangladesh while implementing the TRIPS' provisions through legislative measures.

Chapter 5: The Impact of TRIPS on Transfer of Technology to Bangladesh

5.1 Introduction

Article 7 of the TRIPS Agreement emphatically states one of its objectives as the transfer and dissemination of technology which should be achieved through protecting and enforcing intellectual property rights. This transfer and dissemination should benefit both the producers and users of technological knowledge. The entire process of achieving this objective should be done in a manner conducive to social and economic welfare, which must strike a balance between rights and obligations.

Article 8.1 of the TRIPS Agreement empowers Members to take measures in formulating or amending their laws and regulations to promote technological development provided such measures are consistent with the provisions of this Agreement.

Article 66.2 of the TRIPS Agreement specifically provides for technology transfer to the least-developed country Members. Under these provisions it is mandatory for developed country Members to provide incentives to enterprises and institutions in their territories for promoting and encouraging technology transfer to least-developed country Members to enable them to create a sound and viable technological base. Justifying this provision M Rafiqul Islam opined that "[t]his is due to the fact that MNCs own and control the supply of technology and they do not have any legal obligations to support developing countries' quest for it."[355]

The guiding principles of technology transfer as enshrined in Articles 7, 8 and technology transfer to the least-developed country Members (LDCs) in Article 66.2 of the TRIPS Agreement are the basis of the study of technology transfer in Bangladesh. The technology transfer is confined to medicine, seed and software in this chapter. Questions like what are

[355] M. R. Islam, *International trade law of the WTO*, New Delhi, Oxford University Press, 2006, p. 411.

the modes of technology transfer, How far the existing PD Act is conducive to the technology transfer, what are the basic laws of technology transfer and how far these laws are convenient in technology transfer to Bangladesh, what are the legal impediments in technology transfer to Bangladesh, what provisions should be incorporated in the draft Patents and Designs Act in order to make the technology transfer to Bangladesh convenient and how Bangladesh can best exploit the TRIPS flexibilities in enacting its Patent law and other relevant laws are explored here.

5.2 Brief Analysis of the TRIPS Provisions on Technology Transfer

The preamble of the TRIPS Agreement recognized the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations to enable them to create a sound and viable technological base. This recognition in the preamble is the guiding principle in interpreting other provisions of the TRIPS Agreement. It was held in *Sussex Peerage Case, (1844) 11 C1 & F85* that preamble is a key to open the minds of the makers of the Act, and the mischief which they intend to redress.[356]

Article 7 declares one of the objectives of the TRIPS Agreement as transfer and dissemination of technology that should be achieved through enforcement of intellectual property rights. Paragraph 19 of the Doha Ministerial Declaration reiterated that "[i]n undertaking [the work outlined in this paragraph], the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension."[357]

[356] M. Islam, *Interpretation of Statutes and Documents*, Dhaka, Mullick Brothers, 2009, p. 163.
[357] P. K. Yu, 'The Objectives and Principle of the TRIPS Agreement', *Houston Law Review*, vol. 46, no. 4, 2009, p. 979. And World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Ministerial Declaration].

Article 8.1 of the TRIPS Agreement enables Members to adopt necessary measures to promote public interest in the sector of technological development amongst others in formulating and amending their laws and regulations. But at the same time the enabling provision is restricted by a proviso that such measures are to be consistent with the provisions of this Agreement. Literal interpretation of this proviso is that the measures must not be conflicting with any of the provisions of the TRIPS Agreement.

Article 66.2 of the TRIPS Agreement created an obligation on the developed country Members to provide incentives for technology transfer to the least-developed country Members. But the way how the provisions are incorporated in this sub-Article appears to be ambiguous and difficult to implement. Because the developed country Members are required to provide incentives to enterprises and institutions in their territory for promoting and encouraging technology transfer to least-developed country Members with the objective of enabling the LDCs to create a sound and viable technological base.

In providing the incentives, the developed country Members do not need to make any agreement with the concerned LDC Member for transferring technology and as per the provisions of this sub-Article incentives must go to the enterprises and institutions in the territory of the developed country Members.

Therefore, the interested LDC Member that needs to create a sound and viable technological base must enter an agreement with the concerned MNC or private or public enterprise or institution of the concerned developed country Member. Such MNC or private or public enterprise or institution may not be interested to assist the LDC Member in creating a sound and viable technological base for such Member without protecting the maximum commercial interest of the MNC or enterprise or institution. This attitude of the MNC or public or private enterprise or institute may become a stumbling block in technology transfer to the LDCs.

Though the Doha Ministerial Conference has reaffirmed the mandatory nature of Article 66.2, but it is observed that "the obligation of developed-country WTO Members stops at the provision of incentives. The governments of those countries may not and should not be expected to intervene in the transfer of technology, because technology in developed countries is mostly controlled by private companies. Governments may not confiscate and transfer it to LDCs."[358]

Article 66.2 does not specify the incentives that should be provided by the developed country Members to create a sound and viable technological base for LDCs. It is rightly pointed out that "since Article 66.2 does not specify exactly what these incentives must look like or how extensive they must be, developed countries are essentially free to answer such questions on their own."[359]

Another important aspect raised by the scholars is that Article 66.2 is not limited to the IPR-related mechanism for promoting technology transfer. Andrew Michaels viewed that "Article 66.2 does not mention IPRs specifically, so developed countries are not limited to IPR-related mechanisms for promoting ITT."[360] This view may be exploited in favour of Bangladesh to adopt measures necessary to promote technological development in formulating and amending its laws and regulations.

Article 67 provides for a mandatory provision that developed country Members are to provide technical and financial cooperation in favour of developing and least-developed country Members under certain conditions. The cooperation under this Article includes assistance in the preparation of laws and regulations on the protection and enforcement of

---

[358] Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights*, 3rd edn., Alphen aan den Rijn, The Netherlands, Kluwer Law International, 2010, p. 706-707.

[359] M. Andrew, 'International Technology Transfer And Trips Article 66.2: Can Global Administrative Law Help Least-developed Countries Get What They Bargained For?', *Georgetown Journal of International Law*, vol. 41, no. 1, 2009, p. 223.

[360] ibid; ITT means International Technology Transfer.

intellectual property rights as well as on the prevention of abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel. The meaning of technical cooperation cannot be limited to the fields stated in the Article. Therefore, it can be inferred that the meaning of technical cooperation may be extended to the transfer of technology.

IP law experts found a relationship between Article 66.2 and 67. It is opined that "[w]hile assistance as required by Article 67 can be helpful in implementing Article 66.2, developed countries should make clear the full extent of the flexibility allowed under TRIPS in educating administrators from developing nations, especially LDCs."[361]

Between Article 66.2 and 67 we find two sharp distinctions. Firstly, in Article 66.2 incentives should be provided to develop a sound and viable technological base for LDCs and not for other developing countries. But in 67 developed country Members are in obligation to provide technical cooperation in favour of developing and least-developed country Members. Secondly, Article 66.2 does not provide for any agreement between developed country Members and LDC Members for transfer of technology. But Article 67 provides for a request and mutually agreed terms and conditions for providing technical cooperation by developed country Members to the developing and least-developed country Members.

It can be settled from the above discussion that the TRIPS Agreement provided for technology transfer in its preamble, Articles 7, 8, 66.2 and 67 and to understand the paradigm of technology transfer in adopting measures necessary to promote technology transfer in Bangladesh by formulating or amending laws and regulation, these provisions of the TRIPS Agreement should be scrutinized by the legislative drafters and lawmakers.

[361] M. Andrew, 'International Technology Transfer And Trips Article 66.2: Can Global Administrative Law Help Least-developed Countries Get What They Bargained For?', *Georgetown Journal of International Law*, vol. 41, no. 1, 2009, p. 223.

5.3 The meaning and modes of technology transfer

In a policy brief of ICTSD, technology transfer is broadly interpreted to comprise training, education and know how including any capital component.[362] The Policy Brief further stated New Zealand's view on the modes of technology transfer using the view of UN definition as follows:

i. Physical objects or equipment;

ii. Skills and human aspects of technology management and learning;

iii. Designs and blueprints which constitute the document-embodied knowledge on information and technology; and

iv. Production arrangement linkages within which technology is operated.

To get a fair understanding of the term technology transfer, comprehending the meaning of technology is important. Technology is "[t]he systematic knowledge for the application of a process that results in the manufacture of a product or the delivery of a service."[363] The term technology is further explained in the UNCTAD Report of 2014 as "[t]echnology does include the entrepreneurial expertise and professional know-how to deliver products and services (UNCTAD, 1985)."[364] Citing Burgelman et al. (2008) the Report further explains that "[t]echnology refers to the theoretical and practical knowledge, skills, and artefacts that can be used to develop products and services as well as their production and delivery

[362] S. Moon, Meaningful Technology Transfer to the LDCs: A Proposal for A Monitoring Mechanism for TRIPS Article 66.2, in Policy Brief No. 9, [pdf], International Centre for Trade and Sustainable Development (ICTSD), 2011, http://www.ictsd.org/downloads/2011/05/technology-transfer-to-the-ldcs.pdf , (accessed 19 March 2016).
[363] UNCTAD "Transfer of Technology and Knowledge Sharing for Development: Science, Technology and Innovation Issues for Developing Countries", Geneva, Author, www.unctad.org, (accessed 4 December 2015).
[364] ibid.

systems. Technology can be embodied in people, materials, cognitive and physical processes, plant, equipment and tools."[365]

The way how the term technology is explained by a UN body like UNCTAD is very wide that further extends the scope of technology transfer. The UNCTAD Report defines technology transfer as "the transfer of systematic knowledge for the manufacture of a product, for the application of a process or for the rendering of a service and does not extend to the mere sale or lease of goods".[366]

Following five modes of technology transfer emerge from this definition:[367]

i. The assignment, sale and licensing of all forms of industrial property, except for trademarks, service marks and trade names when they are not part of technology transfer transactions;

ii. The provision of know-how and technical expertise in the form of feasibility studies, plans, diagrams, models, instructions, guides, formulae, basic or detailed engineering designs, specifications and equipment for training, services involving technical advisory and managerial personnel, and personnel training;

iii. The provision of technological knowledge necessary for the installation, operation and functioning of plant and equipment, and turnkey projects;

iv. The provision of technological knowledge necessary to acquire, install and use machinery, equipment, intermediate goods and/or raw materials which have been acquired by purchase, lease or other means;

[365] UNCTAD "Transfer of Technology and Knowledge Sharing for Development: Science, Technology and Innovation Issues for Developing Countries", Geneva, Author, www.unctad.org, (accessed 4 December 2015).
[366] ibid 1.
[367] ibid 2.

v. The provision of technological contents of industrial and technical cooperation arrangements (UNCTAD, 1985).

The above-mentioned modes of transfer of technology have been stated in the Draft International Code of Conduct on the Transfer of Technology negotiated by UNCTAD in 1985.[368] These modes do not include diffusion of technological knowledge among the developing countries and development of technological capabilities of developing countries. The problem of a developing country particularly an LDC like Bangladesh is that it does not have necessary R&D programs, adequate public and private research laboratories and universities and a sound basis of technical skills and human capital. The absences of these basic features of sound technological base creates a 'technological distance' of Bangladesh from the global frontier.[369]

The legal aspect of technology transfer is explained in the way that in a technology transfer, a technology assignor transfers its technology to an assignee under a legal process.[370] The assignor and assignee are the subjects of technology transfer and the object of technology transfer is "technical achievement, which is a technical solution resulting from the utilisation of scientific knowledge, information and experience, and relating to products, processes, materials and their improvement, including patents, patent applications, technical secrets (know-how), computer software, integrated circuit layouts and new varieties of plants,

[368] Development, United Nations Conference on Trade and, *Transfer of Technology and Knowledge Sharing for Development: Science, Technology and Innovation Issues for Developing Countries*, [pdf], UNCTAD, 2013, http://unctad.org/en/PublicationsLibrary/dtlstict2013d8_en.pdf , (accessed 4 December 2015).

[369] K. Saggi, K. E. Maskus and B. Hoekman, *Transfer of Technology to Developing Countries: Unilateral and Multilateral Policy Options*, edited, World Bank Policy Research Working Paper 3332, 2004, http://elibrary.worldbank.org/doi/abs/10.1596/1813-9450-3332 , (accessed 12 December 1015).

[370] W. Zhang and G. Wang, 'An Overview of Technology Transfer Including Patent Licences and Know-how Licences in China', European Intellectual Property Review vol. 35, iss. 3, 2013, pp. 138-142.

etc."[371] This definition of technology transfer is more conducive to the intellectual property law than the definition given by the UNCTAD Report. However, this definition is also short of disseminating technology and creation of technological base for developing country necessary for technology transfer.

5.4 Need assessment of Technology Transfer for Bangladesh

TRIPS Agreement (the Agreement) itself does not provide any specific description of technology transfer. It also does not provide for any scope of need assessment for technical cooperation in favour of developing and least-developed country Members to be provided by the developed country Members.[372] However, the Agreement itself provides some broad guidelines on transfer of technology in its preamble, Articles 7, 8, 66 and 67 as discussed in section 5.1 of this chapter. The Council for TRIPS decided on 29 November 2005 that "…the least-developed country Members will provide to the Council for TRIPS, preferably by 1 January 2008, as much information as possible on their individual priority needs for technical and financial cooperation in order to assist them taking steps necessary to implement the TRIPS Agreement."[373]

The Council also decided that, "[d]eveloped country Members shall provide technical and financial cooperation in favour of least-developed country Members in accordance with Article 67 of the Agreement in order to effectively address the needs identified in accordance with paragraph 2."[374]

[371] W. Zhang and G. Wang, 'An Overview of Technology Transfer Including Patent Licences and Know-how Licences in China', European Intellectual Property Review vol. 35, iss. 3, 2013, pp. 138-142.
[372] the TRIPS Agreement, Article 67.
[373] *Bangladesh to remain LDC until 2024: UN review*, http://bdnews24.com/economy/2015/11/26/bangladesh-to-remain-ldc-until-2024-un-review , 2015,
(accessed 28 November 2015).
[374] ibid.

Responding the decision of the Council for TRIPS, Bangladesh submitted its needs by communicating to the Council amongst other countries like Sierra Leone, Uganda, Rwanda, Tanzania, Senegal, Mali and Madagascar. How effectively Bangladesh could communicate its needs for technical and financial cooperation and how far such communication succeeded in getting cooperation on technology transfer from developed country Members in comparison to some of those countries which communicated their needs according to the Councils' decision are very vital issues for Bangladesh that are carefully scrutinized here. What should be the modes of technology transfer to create a sound and viable technological base for Bangladesh is another crucial issue that is also considered in this section.

5.4.1 Effectiveness and success of the Communication of Bangladesh

Bangladesh submitted its communication to the Council for TRIPS in March 2010 stating its priority needs for financial and technical cooperation under the TRIPS Agreement. The communication stated in its action matrix formulation of an IP policy, encouragement and commercialization of creation and innovation: creation and innovation and technology transfer and Centre of Excellence for R&D, improve legal systems, strengthening of the IP Institutions: strengthening existing IP institutions, improve service delivery of the IP institutions, IP enforcement, IP education and protection of folklore, traditional knowledge and cultural expressions.[375]

Since the TRIPS Agreement, WTO and WIPO have not given any standard or specific definition of technology transfer; therefore, a reasonably standard definition has already been explored from other sources like reports, policy papers, scholarly articles and communications of various research organizations, researchers and countries. The

[375] "Priority Needs for Technical and Financial Cooperation", Communication from Bangladesh, IP/C/W/546, 23 March 2010, available at https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/7_2_ipcw546_e.pdf , (accessed 29 November 2015).

effectiveness and success of the Needs Communication of Bangladesh have been examined here in the light of a standard communication of another LDC and that explored reasonably standard definition of technology transfer.

Sierra Leone communicated its needs for financial and technical assistance to the Council for TRIPS on September 28, 2007 within the deadline given by the Council. The relevant part of the Communication is as follows:

"Under the cluster on innovation, technology transfer and use of IP as a development tool, the specific needs identified are: development of a domestic innovative and creative base; improving business education and awareness about IP management for Small and Medium-sized Enterprises (SMEs); development of a Patent Information Service to support innovation and technology transfer; and development of a multi-disciplinary IP policy teaching capacity in the University of Sierra Leone."[376]

Bangladesh determines its insufficient IP infrastructure to achieve adequate gain from the knowledge based world and keen to develop its own R&D. It stated in its Communication that "Bangladesh has potential for innovation and creation, but unfortunately it has not been able to develop an appropriate IP regime."[377]

The inadequate R&D in Bangladesh is evident in the statement that "Research and Development (R&D) in the public sector cannot cope with the rising market demand. Major industrial sectors in Bangladesh like jute, ready-made garments (RMG) and pharmaceuticals could not grow properly, inter alia, due to the absence of need-based and appropriate R&D

---

[376] *Factual Overview on Technical and Financial Cooperation for LDCs Related to the TRIPS Agreement: Identifying and Responding to Individual Priority Needs of LDCs*, [pdf], World Trade Organization, 2013, https://www.wto.org/english/tratop_e/trips_e/ldc_overview_08.05.2013_full.pdf,

(accessed 5 January 2016).

[377] "Priority Needs for Technical and Financial Cooperation", Communication from Bangladesh, IP/C/W/546, 23 March 2010.

facilities."[378] The Communication revealed that the technologies used in Bangladesh are mostly imported and the scope of technology transfer is extremely limited. It also stated about the significance of low patent registration at the local level.

Low private sector investment in R&D, inadequate government grants for public research institutions in facilitating R&D, under valuation and the insignificant reward of scientists and professionals who work in the innovation process have been pointed out as barriers to the technology transfer in Bangladesh in the Communication. The strengthening of R&D for ensuring food security and fulfilling the needs of emerging agro-food processing industries has been emphasised in the Communication. Foreign Direct Investment's role in technology transfer is given due importance in the Communication. It highlighted the dire necessity of Bangladesh to conclude technology transfer agreements with other countries particularly in the field of pharmaceutical products, key manufacturing industries and agriculture.[379]

The communication raised question about the effectiveness of Article 66.2 of the TRIPS Agreement in technology transfer though it makes mandatory for developed countries to provide incentives to create a sound technological base for an LDC like Bangladesh. The pharmaceutical industries in the past made unsuccessful approach to several international pharmaceutical companies for technology transfer for production of some essential medicines in exchange of granting exclusive marketing rights for a certain period as the Communication categorically stated.

---

[378] ibid.

[379] "Only a few research organizations, such as the Bangladesh University of Engineering Technology (BUET), Bangladesh Agricultural Research Institute (BARI) and Bangladesh Rice Research Institute (BRRI) have technology transfer agreements with some international organizations. BUET has technology transfer agreements with the Asian Institute of Technology (AIT) of Thailand and some other international research organizations. BARI has research agreements with Australian research institutions, the International Maize and Wheat Improvement Centre (CIMMYT), the Asian Vegetable Research and Development Centre (AVRDC) etc. and BRRI has a technology transfer agreement with the International Rice Research Institute (IRRI)." See "Priority Needs for Technical and Financial Cooperation", Communication from Bangladesh, IP/C/W/546, 23 March 2010.

As discussed above the needs of Sierra Leone and Bangladesh appear to be a bit different. Bangladesh did not identify its need to create a sound technological base for itself directly. But in emphasizing on strengthening in R&D in jute, RMG, pharmaceuticals, agro-food processing and making more technology transfer agreements with other countries, it indirectly indicates the need of creating a sound technological base for the Country. On the other hand, Sierra Leon identified its need for developing a domestic innovative and creative base which amounts to the creation of a sound technological base for Sierra Leon. Therefore, on this point Sierra Leon's approach is found more direct and akin to the spirit of Article 66.2 of the TRIPS Agreement. Sierra Leon omitted the reference for the need of FDI in technology transfer while Bangladesh categorically mentioned it in its Communication. The need of FDI in technology transfer is not expressly stated in Articles 66.2 and 67 of the TRIPS Agreement and this is also not stated explicitly in the UNCTAD definition of technology transfer and in the expert's definition as stated earlier. Both Sierra Leon and Bangladesh did not clearly state any particular mode of technology transfer as stated in the UNCTAD Report[380] in their respective communication.

Since the submission of the Communication to the TRIPS Council in 2010 Bangladesh achieved some progress in attaining few of the needs assessed by it. It has enacted the Geographical Indications Act, 2013 and initiated Patent Bill 2012 to formulation of a new law. However, it has yet to address some key needs such as:

i. the formulation of a national intellectual property policy and strategy despite being in the process of amending some key IP laws. The restructuring of national IP institutions;
ii. the delivery of training and awareness-raising to targeted actors such as policy makers, the judiciary, police and custom officials; and

[380] United Nations Conference on Trade and Development, *Transfer of Technology and Knowledge Sharing for Development: Science, Technology and Innovation Issues for Developing Countries*, [pdf], UNCTAD, 2013, http://unctad.org/en/PublicationsLibrary/dtlstict2013d8_en.pdf , (accessed 4 December 2015).

iii. development of IP related legal instruments aimed at genetic resources.[381]

Bangladesh reported in the WTO National Symposium, 2012 that the Swiss government has responded positively to its request for the formulation of a national IP strategy and policy, including the conduct of some awareness-raising and training programmes.[382] Swiss Government's response is encouraging, but not adequate for technology transfer to Bangladesh or for creating a sound and viable technological base for Bangladesh in order to enable it for receiving technology from the developed countries.

5.5 Technology Transfer in Pharmaceutical Industry of Bangladesh a Challenge of 21st Century

It is already revealed from the Need Assessment Report[383] that Bangladesh requested for cooperation on technology transfer in the pharmaceutical sector at the cost of exclusive marketing right to the MNCs which has been turned down. Despite this fact, Bangladesh achieved a remarkable progress in producing and exporting active pharmaceutical ingredients (APIs) that has been highly appreciated by UNCTAD and Pharmaceutical companies like Square Pharmaceuticals Ltd (Square), Beximco Pharmaceuticals Ltd (BPL) have a remarkable number of transfer of technology agreement with MNCs.[384]

Given the achievement of Bangladesh in the Pharmaceutical sector, it has been revealed that the pharmaceutical industry of Bangladesh does not have the capability to produce APIs from

[381] *Factual Overview on Technical and Financial Cooperation for LDCs Related to the TRIPS Agreement: Identifying and Responding to Individual Priority Needs of LDCs*, [pdf], World Trade Organization, 2013, p. 45 https://www.wto.org/english/tratop_e/trips_e/ldc_overview_08.05.2013_full.pdf , (accessed 5 January 2016).

[382] ibid.

[383] "Priority Needs for Technical and Financial Cooperation", Communication from Bangladesh, IP/C/W/546, 23 March 2010.

[384] For example, Roche has recently announced a technology transfer agreement with BPL for the production of a second-line human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) medicine, saquinavir Fortovaseor Invirase). UNCTAD Secretariat, *Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries: A Series of Case Studies*, [pdf], New York, UNCTAD, 2011, http://apps.who.int/medicinedocs/documents/s19062en/s19062en.pdf, p. 65, (accessed 17 December 2015).

inception.[385] It is observed that production of APIs constitutes a significant portion of inputs needed to manufacture any drug and it is further observed that "[m]ost firms import APIs from an advanced intermediate stage and perform the last few stages of API production in-house. However, the ability of firms to reverse-engineer drugs completely and manufacture APIs within the country will be critical to make their exports more competitive vis-à-vis the branded generic firms from China and India, from where most APIs for Bangladeshi pharmaceuticals are currently sourced."[386] Here lies the key challenge for Bangladesh in the 21st Century to compete with China and India in producing and exporting generic drug that will not be possible if Bangladesh fails to achieve the capability of producing APIs from the scratch.

In order to face the challenge Bangladesh has to ensure technology transfer from developed foreign countries/ MNCs providing due importance in:

(i) establishing production capacity;

(ii) expanding product portfolios to include several new product categories; and

(iii) technological upgrading of the kind required to produce good-quality medicines at reasonable cost.[387]

5.5.1 The Legal Framework of Technology Transfer in Medicine Sector

Apart from the PD Act technology transfer in the pharmaceutical sector is regulated largely by the following laws:

---

385 UNCTAD Secretariat, *Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries: A Series of Case Studies*, [pdf], New York, UNCTAD, 2011, http://apps.who.int/medicinedocs/documents/s19062en/s19062en.pdf, p. 65, (accessed 17 December 2015).

386 ibid.

387 ibid 81.

v. The Drugs(Control) Ordinance, 1982;

vi. The Drugs Act, 1940;

vii. National Drug Policy, 2005;

viii. Export Policy, 2012-2015;

ix. The Imports and Exports (Control) Act, 1950 (Act No. XXXIX of 1950);

x. The Import Policy Order, 2012-2015;

xi. Competition Act, 2012;

xii. Public Private Partnership Act, 2015;

xiii. Customs Act, 1969;

xiv. Bangladesh Export Processing Zones Authority Act, 1980.

PD Act has itself some inbuilt provisions that are instrumental in the transfer of technology.[388] None of the aforementioned laws have any direct implication with the PD Act. Still, these laws have some key provisions that might play a pivotal role in the transfer of technology in medicine, seed and software. Besides PD Act, Bangladesh might take recourse of these laws to facilitate transfer of technology in these sectors. The relevant provisions of these laws have been analysed below in order to get an appropriate picture of the strength and weakness of the legal framework of transfer of technology in Bangladesh.

5.5.1.1 The Drugs (Control) Ordinance, 1982

The preamble of the Ordinance states that the Ordinance is to control manufacture, import, distribution and sale of drugs. The term 'drug' has been widely defined in the Ordinance, which include the meaning of drug as stated in the Drugs (Control) Act, 1940 as well as any substance exclusively used or prepared for use in accordance with the Ayurvedic, Unani and

[388] the PD Act, sections 21 (2), 21 A, 22, 23 and 72.

homeopathic or Biochemic system of medicine.[389] The Drugs (Control) Act, 1940 defines a drug as follows:

""Drug" includes-

(i) all medicines for internal or external use of human beings or animals, and all substances intended to be used for or in the treatment, mitigation or prevention of diseases in human beings or animals, not being medicines and substances exclusively used or prepared for use in accordance with the Ayurvedic, Unani, homeopathic or Biochemic system of medicine,

(ii) diagnostic, abortive and contraceptive substances, surgical ligatures, sutures, bandages, absorbent cotton, bacteriophages, adhesive plasters, gelatine capsules and antiseptic solutions,

(iii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals,

(iv) any substance, mentioned as monograph in any of the editions of the British Pharmacopoeia or the British Pharmaceutical Codex or the United States Pharmacopoeia or the National Formulary of the United States or the International Pharmacopoeia, whether alone or in combination with any substance exclusively used in the Unani, Ayurvedic, homeopathic or Biochemic system of medicine and intended to be used for any of the purposes mentioned in sub clauses (i), (ii) and (iii), and

(v) any other substance which the Government may, by notification in the official Gazette, declare to be a "drug" for the purposes of this Act;".[390]

[389] the Drugs (Control) Ordinance, 1982, section 3 (1) (d).
[390] the Drugs (Control) Act, 1940. [1940], s. 3 (b).

The term ‘drug’ how defined in the Drugs (Control) Act is very wide and inclusive. Indian drugs and cosmetics are mostly controlled by the Drugs and Cosmetics Act, 1940 (Act No. 23 of 1940) of India, while Malaysian medicines are controlled by the Control of Drugs and Cosmetics Regulations 1984 framed under Section 28 (1) of the Sale of Food and Drugs Ordinance 1952.

The definition of drug as stated in Indian Drugs and Cosmetics Act is almost similar to that of the Drugs (Control) Act of Bangladesh. However, most distinctly the Indian Act does not include the substance mentioned in any of the editions of the British Pharmacopoeia or the British Pharmaceutical Codex or the United States Pharmacopoeia or the National Formulary of the United States or the International Pharmacopoeia in the definition of drug. Searching the answer for the cause of such non-inclusion Malaysian law has been explored and it was found that Malaysia also does not include such substance. The Control of Drugs and Cosmetics Regulations did not give a detailed definition of a drug. Instead, it gives the definition of the product as follows:

"Product" means

(a) a drug in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a medicinal purpose; or

(b) a drug to be used as an ingredient of a preparation for a medical purpose.[391]

The definition of drug is very important for IP protection of the medicine as well as technology transfer in pharmaceuticals. One example of Uruguay will make the issue clear. A study on the Impact of Intellectual Property on the Pharmaceutical Industry of Uruguay by the WIPO revealed that-

[391] The Control of Drugs and Cosmetics Regulations 1984, [1984], Regulation 2 (C), http://www.pharmacy.gov.my/v2/sites/default/files/document-upload/control-drugs-and-cosmetics-regulation-1984.pdf ,
(accessed 22 December 2015).

"Concerning IP protection, two out of three products in our dataset contain an active ingredient protected with at least one patent granted in the US. Totaling about 58.5 US dollars, the average price for these products is roughly 12 dollars higher than the overall average. Additionally, the market structure for these products does not appear to be markedly different, with numbers of varieties and competitors being close to the overall average. Patent protection in Uruguay – either sought or granted – affects a considerably lower proportion of products in the market. About 6.5% of them have an active ingredient for which patent protection has been sought in Uruguay and in roughly half of those cases (3.4%) was the patent granted. Where a patent was pending or granted, prices are substantially higher than the overall one, averaging 110 and 113 US dollars, respectively."[392]

The above stated situation explains why India and Malaysia excluded from the definition of drug, the substance mentioned in any of the editions of the British Pharmacopoeia or the British Pharmaceutical Codex or the United States Pharmacopoeia or the National Formulary of the United States. Therefore, Bangladesh may think about redefining 'drug' in the light of Indian and Malaysian experience as well as guideline given by the WHO.

In addition to the term 'drug', Indian Drugs and Cosmetics Act, 1940 defines patent or proprietary medicine as follows:

""patent or proprietary medicine" means, —

(i) in relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (a);

[392] WIPO, "Study on the Impact of the Intellectual Property on the Pharmaceutical Industry of Uruguay", Committee on Development and Intellectual Property", Geneva, Author, CDIP/13/INF/5, (accessed 5 May 2014).

(ii) in relation to any other systems of medicine, a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorized in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board constituted under section 5;"[393]

The Drugs Act, 1940 defines patent or proprietary medicine and the definition differs substantially from the definition provided in the Indian law. The definition in the Drugs Act, 1940 of Bangladesh does not include Ayurvadic or Unani Tibb like the Indian one.[394]

Neither the Drugs Act, 1940 nor the Drugs (Control) Ordinance, 1982 of Bangladesh defines medicine. But section 5 of the Drugs (Control) Ordinance, 1982 provides for the compulsory registration of all kinds of medicine which includes Homeopathic and Biochemic medicines with the licensing authority for manufacturing, sale, import or distribution and such registration unless cancelled earlier remains valid for 5 years. The licensing authority must get recommendation of the Committee for registering any medicine. The purpose of registration is to ensure the safety, efficacy and usefulness of the manufactured or imported medicines. Section 9 of the Drugs (Control) Ordinance, 1982 provides for restriction on import of certain pharmaceutical raw materials. It specifically provided that "[n]o drug, semi-finished bulk drug] or pharmaceutical raw material shall be imported except with the prior approval of the licensing authority."[395] This empowers the licensing authority to restrict import of drugs or API. Discretionary use of such power might be challenging for the development of the local pharmaceutical industry.

[393] The Drugs and Cosmetics Act, 1940, [1940], s.3 (h).
[394]However, rule 55-59 of the Drug Rules, 1945 framed under the Drugs Act, 1940 deal with packaging, registration and renewal of registration of the patent or proprietary medicine. Rule 62-64 of the Bengal Drugs Rules, 1946 also deal with packaging, labelling and packing of patent or proprietary medicine.
[395] The comma and the words ", semi-finished bulk drug" were inserted by section 3 of the Drugs (Control) (Amendment) Act, 2006 (Act No. IV of 2006).

Sections 10 and 12 of the Drugs (Control) Ordinance, 1982 have been provided specifically to facilitate transfer of technology in the medicine sector. Section 10 provides for manufacture of drugs under licensing agreement and section 12 provides for power of government to review of certain licensing agreement with foreign concerns.

Section 10 (a) empowers licensing authority to approve a foreign manufacturer to manufacture any drug under licensing agreement with any manufacturer in Bangladesh if the drug is its research product and is registered under the same brand name in any of the countries specified under sub-section (1A) of section 5. The Indian Drugs and Cosmetics Act, 1940 does not provide for such a provision. This provision should be exploited for transfer of technology in Bangladesh.

Section 15 of the Drugs (Control) Ordinance makes it mandatory for every manufacturer of drug to follow the good practices in the manufacture and quality control of drugs recommended by the World Health Organization. Therefore, every manufacturer of drug in Bangladesh must follow the good manufacturing practices (GMP)[396] provided by WHO. Such a provision impacts positively in improving the quality of drug and thereby should play a vital role in increasing export of medicine from Bangladesh.

5.5.1.2 The Drugs Act, 1940

The preamble of the Act provides that this Act is formulated to regulate import, export, manufacture and sale of drugs in Bangladesh. The definition of manufacture, the provision relating to import and export of drugs and misbranded drugs are important for technology transfer in pharmaceutical industry of Bangladesh. The term manufacture is defined as

[396] "GMP covers all aspects of production from the starting materials, premises, equipment, and quality testing to the training and personal hygiene of staff." See "Managing Access to Medicine and Health Technologies", Chapter 6, Management Science for Health, http://apps.who.int/medicinedocs/documents/s19577en/s19577en.pdf , (accessed 26 December 2015).

““manufacture” in relation to any drug includes any process or part or stage of process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug with a view to its sale and distribution, but does not include the compounding and dispensing or the packing of any drug in the ordinary course of retail business or on a prescription of a registered medical practitioner or dentist or of a veterinarian, and ‘to manufacture’ shall be construed accordingly;”[397]

The Indian Drugs and Cosmetics Act, 1940 also provides almost similar definition of manufacture with only one exception, i.e. it added cosmetic with drug. The term manufacture only means process of making etc. of drugs with a view to selling or distributing it. The term manufacture deliberately excluded drugs prepared or produced by manufacture. Therefore, patent system of Bangladesh provides for process patent and not product patent for medicine. Though PD Act provides for both product and process patenting, for medicine the scope of patentability is limited to the process patent due to the definition of manufacture in the Drugs Act, 1940.

The term ‘misbranded drug’ as defined in the Indian Drugs and Cosmetics Act, 1940 is slightly different from the definition of the term as provided in the Drugs Act, 1940 of Bangladesh. The Indian law does not include the following clauses that are included in the Bangladeshi law:[398]

> “(a) if it is an imitation of, or substitute for, or resembles in a manner likely to deceive, another drug, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or
>
> (b) if it purports to be the product of a place or country of which it is not truly a product;

[397] The Drugs Act, 1940, [1940], s. 3 (bc).
[398] ibid, section 17.

or

(c) if it is imported under a name which belongs to another drug; or

(d)if the label or container bears the name of an individual or company purporting to be the manufacturer or producer of the drug, which individual or company is fictitious or does not exist."[399]

In fact, Indian law was amended in 1982 through Act no. 68 of 1982 and section 17, 17 A and 17B were inserted to provide misbranded drugs, adulterated drugs and spurious drugs. These newly inserted sections provided all the provisions that the Drugs Act, 1940 of Bangladesh provided and in addition the Indian law covers some more aspects like deeming a drug as adulterated if it consists any filthy, putrid or decomposed substance.[400] Apart from this a drug shall be deemed to be adulterated by the Indian law in the following events:[401]

i. if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or
ii. if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
iii. if it bears or contains, for the purposes of colouring only, a colour other than one which is prescribed; or
iv. if it contains any harmful or toxic substance which may render it injurious to health; or
v. if any substance has been mixed therewith so as to reduce its quality or strength.

The aforesaid provisions are not provided in the Bangladeshi law. Inclusion of these provisions in the Drugs Act, 1940 of Bangladesh would make our drugs more efficacious,

[399] The Drugs Act, 1940 (Act No. Xxiii of 1940). [1940], s. 9.
[400] The Drugs and Cosmetics Act, 1940, [1940], section 17 A (a).
[401] ibid.

safe and of standard quality. Besides this Bangladesh may follow WHO good manufacturing practices for pharmaceutical products: main principles.[402]

5.5.1.3 National Drug Policy 2005

The Policy echoed following objectives[403] which have direct or indirect implications in the transfer of technology to the medicine industry of Bangladesh:

i. to encourage foreign manufacturers to invest, manufacture and sell drugs in Bangladesh with corresponding assurance of transfer of new technology and technical knowledge in the country;

ii. to ensure no discrimination is made between the local and multinational companies, which have manufacturing plants in Bangladesh while applying the principles of this policy;

iii. to encourage both local and multinational manufacturers to establish full-fledged Research & Development (R&D) facilities in the country;

iv. to allow manufacturers to manufacture, distribute and sell drugs by their Generic or Formulary names and Trade or Brand names (except in Homeopathic medicines) as appropriate for best identity of the product;

v. to encourage investors to set up facilities for manufacturing pharmaceutical raw materials in the country;

vi. to encourage collaboration between universities, research institutes and manufacturers for undertaking basic and applied research in medicine, pharmacy, biochemistry, genetic engineering and biomedical sciences.

The objective number 1 stated above is subsequently qualified by stating that foreign and multinational companies will be allowed to invest and manufacture drugs in Bangladesh if

[402] See WHO Technical Report Series, No. 961, 2011, Annex 3.
[403] The National Drug Policy of Bangladesh 2005. [2005].

they have at least three of their original research drug products registered in at least two of the following countries: USA, UK, Switzerland, Germany, France, Japan and Australia.[404]

The objective number 1 is further qualified by indicating the area of production that to encourage transfer of technology, the foreign investors will be encouraged to produce locally active pharmaceutical ingredients of their innovative lifesaving drugs.

In the objective and elements of the policy section, the policy explicitly stated that concerted efforts of all the manufacturers to adopt current good manufacturing practices (CGMP) will ensure adequate quantities of safe, efficacious and useful drugs, in the country at affordable prices.

The Policy further stated unequivocally that Drugs Act, 1940 and Drugs (Control) Ordinance, 1982 are quite old and they should be updated through necessary amendments to keep pace with newer developments in the drugs sector. Similarly, the Rules framed under the above Act and Ordinance should also be updated and integrated into one set of Rules. The Policy focused on amending other laws to make those compatible with the drug laws in order to implement the Policy.

One of the fundamental shortcomings of the National Drug Policy 2005 of Bangladesh is that it does not provide any clear guide line of realizing the objective of transfer of technology in the drug sector like that of Malaysia. Malaysian National Medicine Policy, 2nd Edition, 2012 clearly stated as follows[405]:

i. Technical collaboration and partnership shall include all areas in regulatory practices, training and human resource development, medicines accessibility, quality use, and research and development.

[404]National Drug Policy 2005, [2005] p-6.
[405] Malaysian National Medicines Policy, 2nd Edition, 2012, http://www.pharmacy.gov.my/v2/sites/default/files/document-upload/buku-dunas.pdf , (accessed 29 December 2015).

ii. Effective networking shall be established to provide a framework for exchange and sharing of information.

iii. Referencing against best practices and standards shall be established and reviewed regularly.

iv. Partnerships, coordination & cooperation with all relevant stakeholders shall be strengthened.

The Malaysian Policy also provides specific guidelines on implementing the TRIPS Agreement that, "[i]ntellectual Property (IP) protection shall be in line with international standards, where the Malaysian Patent Laws are compliant with Trade Related aspects of Intellectual Property Rights (TRIPS) obligations. However, to address the public health needs, flexibilities under the TRIPS Agreement shall be used and the Doha Declaration on the TRIPS Agreement and Public Health shall be implemented."[406] The guideline puts due emphasis on using TRIPS' flexibilities and implementation of Doha Declaration on the TRIPS Agreement and Public Health which are indispensable for a developing country like Bangladesh to incorporate in its patent regime to be implemented in 2033 in providing medicine patenting.

5.5.1.4 Export Policy 2015-18

The preface of the Policy declares the pharmaceutical industry as one of the emerging prospective industries of Bangladesh. The Policy emphatically states that one of the objectives of this policy is to help in developing necessary infrastructures and even forward and backward linkage if necessary for encouraging, producing and marketing exportable goods.

[406] Malaysian National Medicines Policy, 2nd Edition, 2012.

The objective of the Policy indicates the willingness of the GOB to make necessary technological improvement in the pharmaceutical industry amongst other exportable industries. Paragraph 4.16 of the Policy states about R&D in a vague term like the National Board of Revenue will examine the possibility of duty free import of machinery and instruments for R&D by export oriented industry and at the recommendation of the Export Promotion Bureau the research institutions may be considered eligible for this advantage.

A separate sub-chapter has been dedicated in the Policy for pharmaceuticals. It stated that to import raw material for medicine, it would examine the possibility of introducing a pass book procedure or different procedure. It adds further that initiative will be taken to establish a common lab and active pharmaceutical ingredient park at Dhaka and Chittagong. The Policy declared the pharmaceutical sector as one of the highest priority sectors. But it does not provide a specific way forward to ensure the sustainable development in exporting pharmaceutical products in the context of global trade liberalization and the TRIPS regime. Attention should be given as to how the pharmaceutical industry can produce generic medicine and API from scratch, to compete with India and China in the export market of pharmaceutical products.

5.5.1.5 Import Policy Order, 2012-2015

Paragraph 24 (6) of the Import Policy Order, 2012-2015[407] deals with raw materials and packing materials for the pharmaceutical industry under the heading of prescribed conditions for import of industrial items. It provided for a block list duly approved by the Director, Drug Administration, which is to contain the specification of raw and packing materials,

[407] The GOB made and issued this order in exercise of the powers conferred by section 3(1) of the Imports and Exports (Control) Act, 1950 (Act XXXIX of 1950), English text is available at http://pflanzengesundheit.jki.bund.de/dokumente/upload/98e82_bd3-import_policy_order_12-15.pdf , (accessed 7 January 2016).

value and quantity according to the annual production program of government approved and recognized pharmaceutical industries.

A pharmaceutical producing company may only import the raw materials up to the quantity and value stated in the block list. If for a particular raw material, permission of any other authority apart from the Director, Drug Administration is needed as per the Order, in that case such permission is to be duly obtained.

Customs authority is to release the raw materials on the basis of import-invoice and analysis report of the raw materials certified by the Director, Drug Administration or government approved internationally reputed pre-shipment inspection agent regarding the quantity, value and quality of each item. These provisions are very important in the manufacture of pharmaceutical products and R&D because the pharmaceutical industry is under compulsion to be restricted within the block list and cannot go beyond it even if the transfer of technology requires any particular raw material necessary for producing a particular lifesaving medicine.

5.6 Technology Transfer to Seed Industry of Bangladesh

Quality seed is a prime and a basic agro ingredient for producing more crops and ensuring food security. The seed industry of Bangladesh largely depends on the public sector and recently some N.G.Os and MNCs have started entering into the industry by supplying some good seeds. Some good seeds are also being produced at the initiative of private individuals.[408]

However, the seed policy of Bangladesh is more than twenty-two years old, which had been framed in 1993 before the TRIPS Agreement was finalized. The relevancy and efficacy of the Seeds Ordinance, 1977, Seed Rules, 1998, National Agriculture Policy 2013 and National

[408] National Agriculture Policy 2013, http://www.moa.gov.bd/site/view/policies/Policy , (accessed 7 January 2016).

Seed Policy 1993 in transferring technology to the seed industry of Bangladesh in the light of TRIPS' compatibility have been examined along with the Import Policy Order, 2012-2015 and Export Policy 2015-2018. The Seeds Act, 2013 (Draft)[409] and the Protection of the Plant Varieties Act of Bangladesh, 1998 (Draft) are being examined in the light of technology transfer to the seed industry of Bangladesh as per the TRIPS Agreement.

5.6.1 The Seeds Ordinance, 1977

The preamble of the Ordinance states that this law has been promulgated to provide for regulating the quality of certain seeds for sale and for matters connected therewith. The Ordinance does not provide any provision of GM seeds which are a vital source of food security throughout the world currently and specifically in a country like Bangladesh where the ratio of cultivable land in respect of the population is remarkably low. Section 17 of this Ordinance deals with import and export of seeds where the standard of seed quality and necessity of specific labelling have been provided for import and export of seeds with other requisite conditions. It is also provided that registered seed growers may be permitted to import small quantities of such varieties not approved by the National Seed Board (NSB) for the purpose of research and adaptability testing.

The Ordinance also provides some sporadic provisions on R&D like establishment of government seed laboratory or vesting executive power to declare any seed laboratory as the government seed laboratory,[410] empowers Seed Certification Agency to advise seed producers on production, processing and quality control of seeds[411] and helping DAE in the promotion and use of improved seed of HYV's among farmers. The Ordinance itself may be

[409] Available at http://sca.portal.gov.bd/sites/default/files/files/sca.portal.gov.bd/law/eda82ac3_005b_49b5_9e7e_8449d9205930/5.The%20Seeds%20Act%202013%20(draft)-%20For%20your% , (accessed 12 January 2016).
[410] The Seeds Ordinance, 1977 of Bangladesh, section 4.
[411] ibid, section 8 (2) (a).

amended to provide for detailed provisions relating to the technology transfer in the field of genetically modified seeds, and other quality seed as well as development of R&D of seed in Bangladesh.[412]

5.6.2 The Seed Rules, 1998

The Government of Bangladesh made the Seed Rules on being empowered under section 23 of the Seeds Ordinance, 1977. Though these rules have been made to carry out the purposes of the Ordinance, the rules have not provided any detailed description of the research and development of seed as sporadically provided in the Ordinance. The rules also do not provide any provisions for technology transfer in GM seed and other quality seed. Rule 5 provides the functions of the Government Seed Laboratory which are basically related to seed testing and no provisions provided for research by producing new varieties of seed or quality seeds. The government is empowered to assign any other function on the Government Seed Laboratory than expressly provided in the rule.[413] Under this provision the government may assign function like producing a high yielding variety of seed or quality seed on the Government Seed Laboratory.

5.6.3 National Agriculture Policy 2013[414]

One of the main objectives of the National Agriculture Policy 2013 is to invent new variety of crop and sustainable cultivation technology through research and training. The Policy has a separate section on research and development (R&D). It emphasized on a well-coordinated research plan and declared one of the tactics of facing multifarious challenges of R&D is

[412] the Seeds Ordinance, 1977, section 8 (2) (h).
[413] Seed Rules, 1998, Bangladesh Gazette, Extra Ordinary Copy, July 13, 1998, S.R.O, No. 33-LAW/98.
[414] Available at http://moa.portal.gov.bd/sites/default/files/files/moa.portal.gov.bd/policies/2b1e1832_541c_492e_9764_c2b3c8db5317/Final_NAP%202013_web.pdf , (accessed 19 January 2016).

inventing high yielding, adversity tolerant, rapid growing and less input dependent crop varieties.

The Policy declared to encourage private individual/ enterprise to take reproduction of plant programme and produce or import foundation seed by private individual or company to develop or extend government approved crops. However, it does not provide any specific measures to realize the objectives or any concrete methods for transfer of technology in seed sector and R&D of seed industry of Bangladesh.

5.6.4 National Seed Policy 1993

The National Seed Policy of Bangladesh does not specifically mention any provision for R&D and transfer of technology (TT) in the seed sector. However, some of the provisions of the Policy stated about R&D and TT indirectly and these may facilitate R&D and TT to some extent despite the Policy is itself outdated and needed massive change to be up dated. In the section of development and promotion of improved seed varieties it is stated in the policy that "Improved varieties of seeds and planting materials should be procured and introduced in the country by allowing their import, especially through private seed entrepreneurs. For this purpose, business contracts, including joint ventures, are to be encouraged between private enterprises and foreign seed companies." This provides scope of TT in the seed sector of Bangladesh. The Policy needed to be updated to incorporate specific provisions on R&D and transfer of technology in the seed industry of Bangladesh.

The National Seed Policy (NSP) also provides functions for National Agriculture Research System (NARS)[415] and Bangladesh Agricultural University (BAU) which might facilitate

[415] DAE will be responsible for promoting newly involved superior crop varieties. For this purpose, DAE will:
1) monitor the farmer's response/demand for varieties and transmit farmer's preferences to the NSB so that adjustments to production of breeder and foundation seed can be made;
2) promote new varieties among farmers through demonstration plots; - See paragraph 11.6 of the NSP available at http://faolex.fao.org/docs/pdf/bgd149127.pdf ,
(accessed 19 January 2016).

R&D to some extent.[416] The NSP is required to make the functions of these research organizations more specific, clear and updated by spelling out distinct emphasis on TT and R&D of the Seed industry of Bangladesh.

Malaysia has developed its agriculture industry to a remarkable stage[417] and its economy is flourishing very rapidly. It has taken several measures to develop its seed industry, which may be summed up as follows:

i. Conducive Policy for the development of seed industry

The Malaysian Government has included development of Seed Industry into its Economic Transformation program as one of the Entry Point Programs, EPP, 14 in the National Key Economic Area (NKEA) under Agriculture. The objectives of EPP 14 are to ensure adequate supply of quality seed and to develop superior crop variety of local and export market needs.[418]

ii. Capacity building to strengthen the Seed Industry

The higher education institution like university, college and polytechnics are encouraged to introduce plant breeding and seed technology into the curriculum

---

[416]BAU will undertake the following:

1) Establish/strengthen a course in seed technology, which would cover all aspect of the seed industry from seed breeding to its multiplication and distribution, seed policy and seed industry development;

2) Develop its seed pathology laboratory as a National Seed Health Laboratory which will, besides supporting the university's teaching functions, regularly review the seed quarantine requirements and develop seed technology necessary for the production of healthy seed.

3) Promote the technology and production of inoculum for legume seeds in both public and private sectors. -See paragraph 11.8 of NSP.

[417]Agriculture in Malaysia makes up Twelve percent of the nation's GDP. Sixteen percent of the population of Malaysia is employed through some sort of agriculture. -See Wikipedia at https://en.wikipedia.org/wiki/Agriculture_in_Malaysia , (accessed 19 January 2016).

418 Florence C. Ginibun and Amyita Witty Ugap, *Current Status of the Integrated Seed Sector in Malaysia*, [pdf], Malaysia, Malaysian Agricultural Research and Development Institute, 2013, http://q.datakultur.se/~svalofco/wp-content/uploads/2012/12/Malaysia-Seed-Sector-Status-Paper.pdf , (accessed 19 January2016).

and the institutions are fostered to develop networking with the International Seed Federation (ISF), International Seed Testing Association (ISTA) and the Asia Pacific Seed Association (APSA).

iii. Development of Seed Industrial Zone.

iv. Strengthen the Implementation of Seed Quality Control.

v. Establishment of Integrated Data Management System.

The Malaysian example is cited here just to give an example of a comprehensive approach to develop a seed industry of a Nation from where Bangladesh may learn a lesson to revisit its Seed Policy, Seed Ordinance, Seed Rules and other relevant laws and policies.

5.6.5 Import Policy Order, 2012-2015[419]

The Government of Bangladesh issued this Order in exercise of the powers conferred by section 3 (2) of the Imports and Exports (Control) Act, 1950 (Act XXXIX of 1950. The term "plant and product" have been defined in the Order as plant species or products originates from plant or live and dead portion of plant with seeds, reproductive of plant source, Germplasm, processed or unprocessed source of plant which for their characteristics or for the process able to carry, transmit and spread diseases and packing materials and cotton.

Since the seeds have been included as plant and product, import of seed falls within the purview of this Order. Sub paras (30) and (31) of para 26 of the Order state provision applicable to import of potato seeds and rice seeds respectively. Following provisions are to be complied with for importing both the seeds:

i. A Phytosanitary certificate from the exporting country is needed;

[419] http://pflanzengesundheit.jki.bund.de/dokumente/upload/98e82_bd3-import_policy_order_12-15.pdf , (accessed 25 January 2016).

ii. Quarantine certificate is to be produced from exporting country as well as Plant Protection Authority of Bangladesh before the Customs Authority; and

iii. An import permit issued by the Plant Protection Authority at the time of opening L/C.

In addition to these provisions for importing hybrid rice seeds the phytosanitary certificate should state that the seed is purified with hot water treatment and with approved pesticides. The implications of these provisions in transfer of technology of seed should be assessed correctly in complying with the TRIPS provisions through legislation in Bangladesh.

5.6.6 Export Policy 2015-2018

The Agro-producing sector has been declared in the Policy as an emerging prospective sector and special incentives have been declared for the development of this sector. One of the main objectives of the Policy is to increase the export of plant and product. This very objective indicates the intention of the policy makers is to enhance the quality production of Agro product as well as seeds in Bangladesh. The National Revenue Board is to consider the tax free import of equipment and machineries for R&D at the request of the Export Promotion Bureau.[420]

The Policy declared some special measures for the development of the agriculture sector like encouraging contract farming for producing plant and product, organizing training programmes for the producers and exporters of plant and product, allocating government land for the producers of plant and product etc.[421] These incentives and objective are conducive to the technology transfer under the TRIPS Agreement. However, the GOB must take appropriate initiative to make a road map for implementing these policies by framing necessary law, rules and regulations regarding agriculture and seed.

[420] the Export Policy 2015-2018 of Bangladesh, para 4.16.
[421] ibid, para 5.8.

5.6.7 The Draft Plant Varieties Act of Bangladesh

The Draft Plant Varieties Act of Bangladesh was drafted in 1998 by the National Committee on Plant Genetic Resources (NCPGR). The Committee simultaneously drafted another Act called Biodiversity and Community Knowledge Protection Act of Bangladesh and in the commencement clause of the Draft Plant Varieties Act of Bangladesh it is clearly stated that both the Acts shall come into force together.[422]

The scope of the Draft Plant Varieties Act emphatically stated that the scope of this Act should strictly limited to the commercial transaction of plant varieties as long as it does not violate the rights of the Communities stipulated in Biodiversity and Community Knowledge Protection Act of Bangladesh.[423]

The newly enacted Bangladesh Biodiversity Act, 2017 does not stipulate any right of the communities. Therefore, either the Act should be amended to provide rights of the communities or the Draft Plant Varieties Act should be redrafted to protect the rights of the communities and make it at par with the Biodiversity Act.

The application of the Draft Act is limited to the plant varieties which are registered and permitted to be used for economically gainful purpose and newly innovated plant varieties intended to be used by the inventor or owner of the inventor for monitory gains.[424] The areas where the Draft Act shall not affect the communities have been clearly demarcated by specific terms. As for example the Draft Act shall in no way affect the rights of farmers to have unencumbered access to biological and genetic resources of Bangladesh and related knowledge, intellectual practices and culture.[425] This Draft Act also shall not limit the rights

[422] Plant Varieties Act of Bangladesh (Draft), Text proposed by the National Committee on Plant Genetic Resources [1998], Article 2, http://www.farmersrights.org/pdf/asia/bangladesh/bangladesh-pvpdraft98.pdf, (accessed 26 January 2016).
[423] ibid, Article 3.
[424] ibid, Article 3 (3).
[425] ibid, Article 3 (5).

of farmers as innovators and the right to be recognized as such and awarded individually or as a group, or both, for the innovation.[426] This provision is conducive to the R&D and might facilitate transfer of technology in the seed sector, if the newly enacted Bangladesh Biodiversity Act, 2017 incorporated the provisions relating to the farmers' rights.

The executing agency of the Draft Act is named as National Biodiversity Authority and this authority is to constitute an independent and autonomous body to be known as Bio-safety Council with the competent citizens of Bangladesh. The Draft Act is silent about the number of Members of the Authority, their qualifications and selection or election procedure. No such provision is provided in the Bangladesh Biodiversity Act, 2017 to create any independent and autonomous body like National Biodiversity Authority. The Act rather provided for a National Committee on Biodiversity largely dominated by bureaucrats.[427]

The proposed Act states about the characteristics of new plant varieties. Under the general provisions it states on the right to apply protection for new plant variety. It also declares innovation of all new plant varieties in any National Public Research Institution as property belonging to the people of Bangladesh and any innovation done with the financial support of the State or with resources from public finance or development fund will also be considered common property.

The Draft Act states the scopes of application for the innovators, eligibility and inability for application, rejection of applications, procedure and granting of the application, dispute settlement, period of plant protection, citation of award for new plant variety and revocation of certificate and permit.

[426] ibid, Article 3 (7).
[427] Bangladesh Biodiversity Act, 2017, s. 8(1).

The draft law specifically provided for commercial transaction of seed.[428] The provision protected the common biological and genetic resource of the people of Bangladesh as well as all the knowledge, culture and practice of cultivation at all times and in perpetuity.

The Draft Act imposes specific requirements for improvement or development of a common indigenous plant variety and a wild plant variety or any part of the plant variety for commercial purposes.[429] The rights of the recipients of the certificate of the new plant variety and when such rights are not applicable are also enumerated by the Draft Act.[430] Farmers' rights are enshrined in the Draft Act and it provides for the constitution of a plant variety development fund.

Comparing the Draft Act with the similar Act of an emerging economic power and agriculturally developed country like Malaysia, it is found that the Draft Act of Bangladesh is lacking in providing some important provisions regarding issuance of compulsory license, infringement of the breeders' rights (certificate holder of a new plant variety) and remedies, offenses, punishment and enforcement provisions. Inserting these provisions in the Plant Varieties Act to be enacted in future, would be beneficial to technology transfer in the seed sector of Bangladesh which will protect the national interest on the one hand by using TRIPS flexibility like using compulsory license and on the other hand this will ensure MNCs' investment for R&D and technology transfer.

5.6.8 The Seeds Act, 2013 (Draft)[431]

The draft Seeds Act followed the stereo type provisions like the age-old Seeds Ordinance, 1977. It is also lacking the provisions on GM seeds and R&D of the seed industry. The draft

[428] the Draft Plant Varieties Protection Act of Bangladesh (1998), Article 20.
[429] ibid, Article 20 (8).
[430] ibid, Article 21.
[431] http://sca.portal.gov.bd/sites/default/files/files/sca.portal.gov.bd/law/eda82ac3_005b_49b5_9e7e_8449d9205930/5.The%20Seeds%20Act%202013%20(draft)-%20For%20your% ,
(accessed 12 January 2016).

law does not address the issues like use of seeds by small farmers, exchange of farm saved seeds and sell off farm saved seed which are significantly necessary for technology transfer and fair use of seeds.

5.7 Technology Transfer to the Software Industry of Bangladesh

Starting from a low base, ICT export earnings have gained some momentum during the Sixth Five Year Plan, growing from $ 246.5 million in FY2010 to $444.8 million in FY2014.[432] The global software market is more than US $ 600 billion[433] and compares to this huge market the software export earnings of Bangladesh is yet to attain any remarkable position. However, the growth of ICT sector of Bangladesh shows the immense opportunity of Bangladesh in this untapped sector in making its mark in the global software market. Given this fact GOB emphasizes technology transfer in the ICT sector in its National Information and Communication Technology (ICT) Policy-2015.[434]

This section will explore how far existing PD Act is conducive to the technology transfer of the software industry of Bangladesh and to what extent the relevant laws like ICT Act, 2006, Cyber Security Act, 2015 (Draft), E-Service Act, 2014 (Draft), ICT Policy-2015, Industrial Development and Innovation Act, 2012 (Draft), Bangladesh Patents Act, 2015 (Draft) are tuneful to the TRIPS' provisions of technology transfer as enshrined in Article 66.2 and 67 of the TRIPS Agreement.

[432] Seventh Five Year Plan: FY 2016-FY2020, http://www.plancomm.gov.bd/wp-content/uploads/2015/11/7FYP_after-NEC_11_11_2015.pdf, (accessed 2 March 2016).

[433] "The global software market had total revenues of $617.5bn in 2014, representing a compound annual growth rate (CAGR) of 10.9% between 2010 and 2014." 'Software Global Industry Guide', http://www.reportlinker.com/p0191925-summary/Software-Global-Industry-Guide.html, (accessed 2 March 2016).

[434] Serial no. 99 of the Action Plan, National Information and Communication Technology Policy-2015, Bangladesh Gazette, Extra Ordinary Copy, August 5, 2015.

5.7.1 Patents and Designs Act, 1911

It is already revealed in this study that the PD Act covers software patenting and DPDT provides software patents in Bangladesh. Section 23 of the PD Act facilitates technology transfer. Though it does not do that expressly for software, the same may be invoked to facilitate technology transfer to the software industry of Bangladesh. One may seek relief under this section because the patented article or process is manufactured or carried on exclusively or mainly outside Bangladesh. After inquiry if the Government is satisfied that-

The allegations are correct and the applicant is prepared and is in a position;

i. to manufacture or carry on the patented article or process in Bangladesh; and

ii. 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 either-

i) forthwith, or

ii) after such reasonable interval, as may be specified in the order, unless in the meantime it is shown to its satisfaction that the patented article or process is manufactured or carried on within Bangladesh to an adequate extent; or

(b) ordering the patentee to grant a license to the applicant which may be a license exclusive to him or otherwise as the Government may direct.

At least three major loopholes are apparent in this section, e.g. how the inquiry shall be conducted? How long Government may take to conclude the inquiry and what are the reasonable terms on which patentee may refuse to grant license? Neither the PD Act nor the Patents and Designs Rules, 1933 provides any clear answers to these questions which are

crucial to determine an effective application of this section. The PD Act or rules framed thereunder provides no time limit to dispose of an application filed under this section.

The provisions of compulsory licenses and revocation as enshrined in section 22 (5) (a) (b) are to some extent affable to technology transfer in the software industry of Bangladesh. The provisions run as follows:

> "(5) For the purposes of this section the demand for a patented article shall not be deemed to have been met to an adequate extent and on reasonable terms-
>
> (a) if by reason of the default of the patentee to manufacture to an adequate extent and supply on reasonable terms the patented article, or any parts thereof which are necessary for its efficient working, or to carry on the patented process to an adequate extent or to grant licenses on reasonable terms, any existing trade or industry or the establishment of any new trade or industry in Bangladesh is unfairly
>
> prejudiced, or
>
> (b) if any trade or industry in Bangladesh is unfairly prejudiced by the conditions attached by the patentee to the purchase, hire or use of the patented article or to the using or working of the patented process."[435]

Though the provisions relate to the patented article, it also includes the patented process and thus software should be attracted under the purview of the provisions of paragraph (a) of sub-section (5) of section 22 of the PD Act. If firstly, patentee defaults to carry on the patented process to an adequate extent or to grant licenses on reasonable terms for which any existing trade or industry or the establishment of any trade or industry in Bangladesh is unfairly prejudiced and secondly, if any trade or industry in Bangladesh is unfairly prejudiced by the conditions attached by the patentee to the using or working of the patented process in that case subject to the conditions stated in section 22, the Government or the High Court Division as the case may be, may issue compulsory license on such terms as the Government or the High Court Division, as the case may be, may think just, or the patent may be revoked.[436] The provisions of compulsory licenses and revocation have some shortcomings

[435] Patents and Designs Act, 1911 (Act No. II of 1911) [1911], s.22 (5) (a) (b).
[436] Patents and Designs Act, 1911 (Act No. II of 1911) [1911], s. 22 (4).

like using ambiguous words 'adequate extent' and 'reasonable terms' and stating no time limit for disposing a petition filed under section 22 of the PD Act.

It will be examined now how far these issues are addressed by the Draft Bangladesh Patent Act, 2015.

5.7.2 Bangladesh Patent Act, 2015 (Draft)

The draft Act does not provide any specific provisions for directly facilitating technology transfer to the software industry of Bangladesh. However, the draft Act incorporates some favourable provisions for technology transfer to the software industry of Bangladesh under the caption of 'rights accrued through patent', compulsory license and research exception.[437]

Paragraph (5) of sub-section (4) (a) of section 12 of the Draft Act provides for ouster of patent's rights on any exclusive research action regarding patented invention. This will open the door of technology transfer from the MNCs' patented invention in Bangladesh.

Under section 14 of the Draft Act a compulsory license may be issued for public interest and especially where it is necessary for the development of important economic sector, national security, nutrition and health. The Export Policy 2015-2018 and ICT Policy-2015 have given due emphasis on ICT and software.[438] Software is also relevant to the public interest, national security, nutrition and health. The Draft Act deliberately tries to make the provisions of compulsory license compliant with the TRIPS' provisions.[439]

---

[437] Sections 12, 14 and 32 of the Patents Act, 2015 (Draft) provide for 'rights accrued through patent', compulsory license and research exceptions. The Draft Act is in Bangla and obtained from an official of DPDT on condition of anonymity.

[438] One of the strategic themes of the ICT Policy, 2015 is strengthening exports under which several objectives have been declared like making strong marketing and branding for ICT goods and services in the global market, providing special privilege for increasing export and creating industry friendly policy and appropriate environment and for supports to ICTs creating necessary supporting legal framework for preserving IPRs, online document transfer, transaction and payment. Pp 6270-6271 of Bangladesh Gazette, Extraordinary copy, August 5, 2015. ICT has been declared as a rising prospective sector in the Export Policy 2015-2018, See preamble of the Export Policy 2015-2018, Bangladesh Gazette, Extraordinary Copy, September 9, 2015.

[439] The provisions of Article 31 of the TRIPS Agreement have been incorporated in section 14 of the Draft Patents Act, 2015. For example, sub-section (2) of the draft Act provides for each application for CL should be considered on its individual merits, the invention can only be used for the purpose for which license is issued

However, the draft Act's provisions, like the PD Act have not provided any time limit for disposal of the application for compulsory license (CL) and not addressed some crucial issues like the contents of the application for CL, scope of CL, e.g., the period for which the license is granted, the time limit within which the beneficiary of CL shall begin to work the patented invention in Bangladesh etc., the limitations of CL, e.g., CL shall be limited to the supply of the patented invention predominantly in Bangladesh.[440]

Section 32 of the Draft Act provides for the research exception. Sub-section (1) of this section stipulates that for reasonable purpose of submission of data or personal and non-commercial use under any law enforce for the time being in any other country or Bangladesh making, constructing, use or import of any patented invention shall not be treated as violation of patent rights if that law regulates production, making, use or import of the said product. The provisions are unclear and indefinite. The sub-section does not disclose the name of any product about which reference is made at the end of this sub-section. Therefore, in order to make an effective use of the provision of research exception the concept should be well explained with favourable conditions in the provision of law. Indian example may be cited here which is comparatively better than the provision of Bangladeshi Draft Act. The Indian Patents Act's provisions run as follows:

"Certain Acts not to be considered as infringement. —For the purposes of this Act, —
(a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related 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;"[441]

---

and its patent holder should be paid compensation as determined by the Government and these provisions are akin to paragraphs (a), (c) and (h) of Article 31 of the TRIPS Agreement.

[440] The Patents Act, 1983 (Act 291) (as amended up to 16 August 2006), [1983, s. 52 and 53, https://www.jpo.go.jp/shiryou_e/s_sonota_e/fips_e/pdf/malaysia/patents_act.pdf, (accessed 4 March 2016).

[441] The Patents Act, 1970 (39 of 1970), [1970], S. 107 A (a), http://www.wipo.int/edocs/lexdocs/laws/en/in/in065en.pdf, (accessed 6 March 2016).

The provisions stated above are more clear and unambiguous and favourable to the national interest than those stated in the Draft Act of Bangladesh. Notably the Indian provision deliberately excluded the condition of non-commercial use and inserted the provision of selling of patented invention that may not be treated as infringement of patent rights if it falls within the purview of section 107 A (a) of the Indian Patent Act. Besides this provision the Indian Act more precisely provided for research exemption/exception as follows:

"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 purpose merely of experiment or research including the imparting of instructions to pupils;".[442]

India has taken advantage of both for research purpose and commercial use of a patented product subject to some legal requirements. But the US has strictly limited the use of patented invention to non-commercial and only for research purpose. It was held by the Federal Circuit that research exemption is only available for idle curiosity and philosophical use.[443]

5.7.3 Technology Transfer in ICT Related Laws of Bangladesh

The Information and Communication Technology Act, 2006 (ICT Act) provides some important measures like legal recognition of electronic record, defining computer data[444] that includes software also, Controller's power to announce protected systems[445], penalty for damage to computer, computer system, etc.[446] and punishment for tampering for computer

[442] the Patents Act, 1970 of India (39 of 1970), [1970], section 47 (3).
[443] Madey v Duke University 307 F.3d 1351 (Fed. Cir. 2002).
[444] Section 2 (10) of the ICT Act defines computer data as " "data" means a representation of formation, knowledge, facts, concepts or instructions which are being prepared or have been prepared in a formalized manner, and is intended to be processed, is being processed, or has been processed in a computer system or computer network, and may be in any form including computer printouts, magnetic or optical storage media, punch cards, punched tapes or stored **internally** in the memory of the computer;".
[445] the ICT Act (Act No. 39 of 2006), s. 47.
[446] ibid section 54.

source code.[447] These provisions of the ICT Act though not directly influence the transfer of technology to the software industry, may play a vital role in TT to the software industry of Bangladesh by curbing software piracy and cybercrimes.

The draft Cybersecurity Act, 2015 provides measures for national cybersecurity and for the prevention, detection, response and prosecution of cybercrimes and other related matters. It defines computer data, computer program, computer system, computer network, critical infrastructure, malware etc. It made punishable unlawful access to a computer, unlawful interception of communications, unauthorized modification of computer program or data, system interference, computer related forgery, computer related fraud, identity theft and impersonation, cybersquatting, cyber terrorism etc. It also provides for protection of critical infrastructure.[448] These provisions may be congenial for software protection in Bangladesh and protecting national interest regarding highly secured software vital to national security and technology transfer to this sector subject to providing well drafted provisions to strike a balance amongst preserving fundamental rights, human rights, personal data safety and national security as well as business interest of the local software industry and MNCs.

The draft National E-Service Act, 2014 provides for creating an authority called 'National E-Service Authority'. The draft Act vests on the Authority the powers amongst others by declaring information and technology (IT) system as protected IT system and appointing IT Auditor to audit application software for providing e-service by authorized e-service providers.[449] Proper exercise of such powers may create a favourable condition for transferring technology to the software sector of Bangladesh.

---

[447] ibid section 55.
[448] The draft Cybersecurity Act, 2015, [2015], www.ictd.gov.bd, (accessed 8 March 2016).
[449] The draft National E-Service Act has been referred to the budget doc. at paragraph 6.11, http://www.mof.gov.bd/en/budget/15_16/mtbf/en/28_ICT_English.pdf, (accessed 9 March 2016).

5.8 Summary and Way Forward

This chapter embodied the impact of patent system on transfer of technology with specific reference to medicine, seed and software industries of Bangladesh. The introductory section envisaged the guiding principles of technology transfer as enshrined in Articles 7, 8 and technology transfer to the least-developed country Members in Article 66.2 of the TRIPS Agreement as the basis of the study of technology transfer (TT) to Bangladesh. This chapter briefly analyzed the TRIPS' Provisions on TT with scholars' views on the effectiveness of Article 66.2 of the TRIPS. Attention is given on the controversial issue of providing incentives by the developed country Members to the LDCs to create a sound and viable technological base through public and private enterprises of the respective developed country Member. The meaning and modes of TT have been critically examined to find a way out for Bangladesh and LDCs for determining policy needs on TT.

The Need assessment to TT for Bangladesh is determined in this chapter based on the TRIPS Council's decision and communications of Bangladesh to the Council on technology transfer. The effectiveness of the Communications of Bangladesh has been assessed in comparison to the communication of Sierra Leon. The entire gamut of laws and policies on TT in pharmaceutical industry of Bangladesh has been examined to incorporate the TRIPS flexibilities in the proposed Patent law of Bangladesh.

The legal regime and policies of technology transfer on and relevant to seed have been scrutinized to find out necessary changes in the legal and policy regime of TT on seed to implement the TRIPS' provisions using TRIPS' flexibilities. This chapter also seeks to analyze TT to the software industry of Bangladesh. The legal and policy framework of software industry of Bangladesh have been examined carefully in the light of good practices of the USA and leading Asian Countries like Malaysia and India.

Chapter 6: Conclusion

This thesis explores the challenges and way forward for Bangladesh and LDCs having similar socio-economic background to be TRIPS compliant while protecting national interest in the thrust sectors of medicine, seed and software as well as technology transfer to these sectors through legislative measures. Neither this thesis attempts to adjudge the fairness of the TRIPS Agreement nor it tries to examine the acceptability and judiciousness of the decision of the Government of Bangladesh to accept the WTO Agreement and thereby accepting the TRIPS Agreement.[450]

This work has provided a comprehensive legislative and policy roadmap for implementing TRIPS' provisions in Bangladesh through legislative measures to protect its national interest on medicine, seed, software and technology transfer to these thrust sectors. Findings of this study are equally important for Bangladesh and LDCs having similar socio-economic background.

The thesis has sought to find out the way of implementation of Article 27 of TRIPS through patent law of Bangladesh or by an effective sui generis system as the case may be by using the flexibilities of TRIPS to protect medicine, seed and software as well as technology transfer to these sectors of Bangladesh and extent of harmonizing the legal regimes on medicine, seed and software and technology transfer to these sectors apart from patent law for implementing the TRIPS' provisions in Bangladesh through legislative measures. While covering these issues, the thesis has addressed a range of discrete but interrelated subjects including:

[450] The WTO Agreement, Article XIV Cl. 1.

(a) Is medicine patenting possible under the present Patents and Designs Act, 1911 (PD Act) of Bangladesh?

(b) What are the TRIPS requirements on medicine patenting that should be incorporated in the patent laws of Bangladesh which is to be introduced before January 2033?

(c) How and when the TRIPS' flexibilities, e.g. compulsory license, research exception and BOLAR provisions, Exhaustion of rights and parallel import can be incorporated in the patent laws of Bangladesh for protecting its national interest on medicine?

(d) How far paragraph 3 (b) of Article 27 of TRIPS can be implemented in Bangladesh to protect its seed industry and farmers' interest?

(e) How the flexibilities of TRIPS can be used in the best possible manner to implement the TRIPS' provisions with a view to protect seed industry and farmers' rights through legislative measures by Bangladesh?

(f) What are the obligations imposed on Bangladesh through international convention/treaty/agreement for protecting plant varieties/ seed through legislative measures and should Bangladesh acceded to the UPOV?

(g) How far seed related legal regime will be affected for implementing the TRIPS' provisions through legislative measures to protect seed industry of Bangladesh?

(h) Does TRIPS require software patenting?

(i) Is software patenting required besides copyright protection to ensure better protection of software?

(j) Is software patentable under the existing patent law of Bangladesh?

(k) Should Bangladesh provide software patenting in the light of the US, EU and Asian experience on software patenting to protect its software industry?

(l) How and when the patent law of Bangladesh will be craved to be amended or newly introduced in protecting software industry of Bangladesh?

(m) What other relevant laws and policies need to be changed besides patent law in order to ensure the protection of software industry of Bangladesh?

(n) What are the modes of technology transfer and how far Article 66.2 of TRIPS is suitable for technology transfer to the LDCs?

(o) What changes are needed to incorporate the TRIPS' flexibilities on technology transfer in the Patent law to be newly introduced in 2021 and 2032 for protecting software and medicine respectively?

(p) What provisions are needed to incorporate the TRIPS' flexibilities on technology transfer in an effective *sui generis* system for protecting plant varieties/seed?

(q) What changes should be brought to harmonize the legal and policy regime on medicine, seed and software with the patent law to implement the TRIPS provisions for transfer of technology in these sectors?

This chapter outlines the main findings of this thesis and contemplates the future work that is required to build upon and revitalize those findings.

6.1 Medicine Patent under the PD Act

In Bangladesh, patents are granted under The Patents and Designs Act, 1911 which was enacted during the colonial rule. The Act has defined invention in such a way that it does not apparently bar to patent pharmaceutical inventions in Bangladesh. Additionally, section 2 (10) of the same section defines "manufacture" includes any art, process or manner or producing, preparing or making an article, and also any article prepared or produced by manufacture. Thus, reading the invention and manufacture clauses together would

affirmatively accept that new manufacture may include pharmaceutical inventions. Therefore, both product and process patent can be granted under the present PD Act of Bangladesh which were stopped by executive orders after 2006 when foreign pharmaceutical companies obtained as many as 40 patents on their drug formulas. Bangladesh need to amend its PD Act immediately to provide legal basis to enjoy the transitional period for not granting patent for pharmaceutical product patent till 2032 and for pharmaceutical process till 2021 as per the decisions of the council for TRIPS.[451]

6.2 TRIPS Requirements on Medicine Patenting

Under Article 27 of TRIPS, the Member States need to provide medicine patenting if those products are inventions, involve inventive steps and have industrial application. Furthermore, TRIPS also postulates that no discrimination can be made to the subjects of patents with regard to fields of technology and place of the inventions. Therefore, TRIPS makes it mandatory for providing both product and process patent for medicine on the Member States. Being an LDC, Bangladesh is exempted from providing patent for pharmaceutical products till 2032 and pharmaceutical process till 2021.[452]

6.3 Adopting TRIPS flexibilities in the Patent law of Bangladesh for Medicine

This thesis explores how far Bangladesh is and will be able to exploit TRIPS' flexibilities like compulsory license, parallel imports and BOLAR Provision under its existing legal framework of patent law. The thesis also explores the existing gaps in the policy and how such gaps should be addressed by the possible policy and legislative initiative of the Government of Bangladesh.

[451] decisions of the Council for TRIPS of 6 November 2015 (IP/C/73) and 11 June 2013 (IP/C/64) respectively.
[452] ibid.

6.3.1 Exploiting Compulsory license

The existing provisions of the PD Act of Bangladesh for issuing compulsory license or revocation of patent are indefinite, cumbersome, time consuming and not favorable for judicial interference. Bangladesh like other developing countries should establish workable laws and procedures to give effect to compulsory licensing and provide appropriate provisions for government use.[453]

Under the TRIPS regime compulsory licensing is predominantly for domestic use.[454] This may hamper the importing scope for the countries which do not have manufacturing capacity.

For addressing this issue, on 6 December 2005 the WTO General Council adopted the protocol amending the TRIPS Agreement and opened it for acceptance by Members.[455] Bangladesh accepted the protocol on 15 March 2011.[456] Because of acceptance of the Protocol, Bangladesh may not have the privilege to incorporate the provisions of compulsory license through its domestic legislation prioritizing its own national interest.

For using the tool of compulsory license Bangladesh should provide for such legal provision which would enable her to use compulsory license in case of national emergency or extreme urgency or for non-commercial use without the consent of the patentee. In paying adequate compensation to the patentee on the economic value, necessary license rules under section 77 of the PD Act should be framed keeping in view the economic status of Bangladesh.

---

[453] Commission on Intellectual Property Rights (CIPR), *Integrating Intellectual Property Rights and Development Policy: Final Report of the Commission on Intellectual Property Rights*, London, CIPR, 2002, p. 44.
[454] Agreement on Trade-Related Aspects of Intellectual Property Rights, article 31(f).
[455] See WTO General Council Decision no. WT/L/641, dated 6 December 2005.
[456] WTO, Intellectual Property: TRIS and Public Health, www.wto.org/english/tratop_e/trips_e/amendment_e.htm, (accessed 7 April 2017).

6.3.2 Adopting Provisions for Exhaustion of Rights and Parallel Exports

The BPA incorporated provisions for exhaustion of rights and parallel export. However, it needs to clarify concerned authority, and matters prejudicial to the interest of the country and to adopt international form of exhaustion. Bangladesh as LDCs, preferably need to take international form of exhaustion so that it may allow any party interested to import from the international market where the price of patented drugs is cheap or comparatively lower than other jurisdictions.

6.3.3 Incorporation of Research Experiment or Bolar Provisions

In order to exploit this provision of TRIPS Bangladesh may allow manufacturers of generic medicine to use the patented invention to obtain marketing approval without the patent owner's permission and before the patent protection expires. The generic producers can then market their version as soon as patent protection expires. Thus, the proposed Patent Law of Bangladesh must specifically contain the provisions for Research experiment or Bolar Provisions.

6.3.4 Introduction of Exhaustion of Rights and Parallel Import

Generic prescribing or substitution and parallel imports are two policy measures which, according to the authors, will allow consumers easy access to low-priced, quality drugs.[457] Bangladesh may provide for parallel imports with an approach of international exhaustion in its patent law taking policy decision to make essential drugs available at a low cost.

[457] B. K, Lanza O, Kaur SR. Retail drug prices: the law of the jungle. HAI News, April 1998, 1-16.

6.4 The way of implementing Article 27.3(b) for Protecting Seed Industry in Bangladesh

This thesis finds that the seed can be treated as a plant variety and it is to be protected under Article 27.3(b) of the TRIPS Agreement through patents or an effective sui generis system or any combination thereof. This dissertation has treated each of the options for protecting plant variety separately and derived specific findings therefrom.

6.4.1 Protection of seed by patents

This thesis revealed that the core issues on patenting plant varieties and micro-organisms which are as follows:

i. TRIPS is silent in defining invention, novelty, innovative step, industrial application, micro-organisms, non-biological and micro-biological processes;

ii. Use of unduly and reasonably low threshold of patentable conditions by the Members;

iii. Distinction between discovery and invention;

iv. Whether a mere act of isolation of genetic material from its natural state would satisfy the test of non-obviousness or of the inventive step?

v. Whether the mere fact that a micro-organism or a gene has existed in nature does mean that it is known to the public and ceases to be “new” for patent purpose?

vi. If the criteria of patentability have not been fulfilled during application, whether opposition and revocation procedures of the patent system can cure such latches?

The conflicting views of the Members on the core issues show that even after a Member provides protection of plant varieties and micro-organisms by patents under the TRIPS Agreement scopes of confusions will remain over many of the aforementioned core issues

and concerned national interests, traditional knowledge and farmers' rights may not even be protected in any justifiable manner. Such confusions can only be removed by an effective review of the provisions of the Article 27.3 (b) through the necessary interpretations of the patentable criteria for plant varieties, micro-organisms, plant, non-biological and microbiological processes which are necessary to be inserted in the TRIPS Agreement. Thus, Bangladesh may take a step to review Article 27.3(b) before the TRIPS Council to settle these issues for itself as well as for its fellow LDC Members.

6.4.2 Protection of seed by an effective *sui generis* system under TRIPS

TRIPS' silence on explaining an effective sui generis system can be used by the Members to legislate a *sui generis* law to protect their own plant varieties keeping up their respective national interest. However, it can be used negatively by donor States like the USA in creating pressures on the least developed countries to make law in protecting plant varieties to uphold the interests of MNCs rather than to protect the interests of farmers, traditional knowledge and practices.

The Kenyan suggestion to insert footnote in Article 27.3 (b) regarding protection of innovations by indigenous and local farming communities of developing countries, traditional farming practices like save and exchange seeds and prevention of anticompetitive rights which threatens the food sovereignty of developing countries might be fruitful in preventing TRIPS plus agreement by which developed countries are compelling developing countries to provide more protection than the requirements of TRIPS Agreement on IP rights.

6.4.3 Protection of Seed by a combination of patent and *sui generis* system

This thesis finds from the analysis of the U.S. protection of plant varieties by a combination of patent and the sui generis system that such combination would create more favorable atmosphere for the plant breeders (MNCs) than for the farmers and such a system would be a

complex system that might give rise to a multiplicity of legal proceedings. This system might be useful for a developed country like the U.S which is the pioneer in industrialization of seed and where MNCs are contributing substantially in the national economy. But an agro-based country like Bangladesh where more than 75 percent people live in the rural areas and depend on agriculture will not be able to afford such a system for their livelihood.

6.5 Best use of Flexibilities of TRIPS through legislative measures by Bangladesh

Bangladesh is exempted to protect its plant varieties according to Article 27.3(b) of the TRIPS till 1 July, 2021. Therefore, the PD Act should be amended at once to exclude plant varieties, i.e. seed from the ambit of patentable subject matter by inserting a specific section with marginal note "subjects not patentable". Bangladesh is under an obligation besides TRIPS to protect its medicinal PGR and traditional medicine under CBD as provided in Article 6 (b)[458] and Article 8 (J).[459] It is a contracting party of CBD. Therefore, it should go for enactment of the laws on PVR based on the draft Plant Varieties Act, 1998.

6.6 Effect on relevant legal regime on seed in implementing TRIPS

The Seeds Ordinance, 1977 is the principal legislation on seed that defines seed excluding seeds used for drugs and narcotics. On the other hand, the Drugs Act, 1940 defines drug which includes all medicines for internal and external use of human beings and animals. Therefore, medicinal plants are excluded from the ambit of the definition of the term 'seeds' that is opposed to the provision of Article 27.3(b) and might be detrimental to the national

[458] Article 6 (b) of CBD: "(b) Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies."

[459] Article 8 (J) of CBD: "Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices:"

interest of Bangladesh. The Seeds Ordinance, 1977 does not provide the rights of breeders or the farmers. It also does not specifically provide any protection for the traditional seeds used by farmers from time immemorial. Bangladesh must overcome these drawbacks through appropriate legislative measures.

For carrying out the purposes of the Seeds Ordinance the Government made Seed Rules in 1998 under section 23 of the Ordinance. The Seeds Ordinance does not address the issues of preserving traditional seeds, farmers' rights and breeders' rights on seeds. Therefore, the Rules are also silent or could not address these issues and enforcement of such rights is at stake in Bangladesh. In this backdrop, it can be strongly inferred that Seed Rules are also not complying with the provisions of the Article 27.3 (b) of the TRIPS Agreement to protect seeds in Bangladesh. The Government will not be able to bring positive changes in the Seed Rules to address this issue without bringing change in the Seeds Ordinance. This is due to the fact that subordinate legislation cannot go beyond the principal legislation.

The overall purpose of the National Seed Policy 1993 (the Policy) is to make the best quality seeds of improved varieties of crops conveniently and efficiently available to farmers with a view to increasing crop production, farmers' productivity, per capita farm income and export earnings. Neither the objective nor the strategies to achieve the objectives of the Policy require to enact any law or frame any rules for protecting traditional seeds, farmers' rights and breeders' interest in seeds. Genetic engineering or modification technics opened the door of enormous possibilities for new developed varieties of seeds. Our Seed policy should put due emphasis on these recent scientific developments with due caution to preserve the farmers' rights and to protect traditional seeds.

The Policy should determine the following sectors like India[460] and Malaysia[461] as thrust sectors:

i. Varietal development and plant variety protection with specific emphasis on legislating and enforcing an effective sui generis system for intellectual property protection;

   a. The rights of farmers to save, use, exchange, share or sell farm produce of all varieties should be protected with reasonable restrictions.

ii. Seed Production;

iii. Quality Assurance;

iv. Seed distribution and marketing;

v. Infrastructure Facilities;

vi. Transgenic Plant Varieties where biotechnology will play a vital role in the development of agriculture sector;

vii. Import of seeds and planting materials;

viii. Export of seeds;

ix. Promotion of domestic seed industry to produce high yielding varieties and hybrid seeds;

   a. Encouraging Membership of ISTA, OECD, ASSINSEL, WIPO;

x. Strengthening of the monitoring system;

[460] National Seeds Policy, 2002 of India, http://seednet.gov.in/Material/National%20Seed%20Policy,%202002.pdf , (accessed 8 June 2015).

[461] F. C. Ginibun and A. W. Ugap, *Current Status of the Integrated Seed Sector in Malaysia*, [pdf], Malaysia, Malaysian Agricultural Research and Development Institute, 2013, http://q.datakultur.se/~svalofco/wp-content/uploads/2012/12/Malaysia-Seed-Sector-Status-Paper.pdf , (accessed 19 January 2016).

xi. Establishment of centralized, integrated data management system that may contain database on seed supply and demand, imported seed and exported seed, online gene bank database, reporting the performance of the seed industry etc.

The Plant Quarantine Act, 2011 was enacted, in the context of international traffic in plants and plant products, for preventing the introduction of insects or pests into, and for spreading thereof within Bangladesh and for the matters relating to phytosanitary and other measures incidental and ancillary to these objectives. The provisions regarding seizure and destruction of diseased plants and compensation for destruction of diseased plants are needed to be clarified with precision in the Act. The Act does not provide any specific provision regarding prohibition of importation, possession, seizure and destruction of noxious plants that are required for the protection of seeds in Bangladesh.[462]

National Institute of Biotechnology Act is enacted with the objective of providing law on establishing the National Institute of Biotechnology to facilitate research and development in biotechnology, to create skilled manpower and positive development and to implement biotechnology at the national level. The Institute has been assigned with several important functions including the determinations and attestation of genetically modified (GM) food and genetically modified organism (GMO) which are relevant to the seed industry of Bangladesh. There should be a coordination among the National Seed Board, Seed Certification Agency established under the Seeds Ordinance, 1977 and National Institute of Biotechnology to specifically deal with the issues of seed invented or produced using biotechnology.

The Competition Act, 2012 is enacted in the context of growing economic development of the Country to facilitate, ensure and maintain sound competition in the trade by preventing,

[462] The Plant Quarantine Act, 1976 (Act 167) [1967], ss. 6, 13, 14.

controlling and eliminating anti-competition activities like collusion, monopoly and oligopoly situation, misuse of combination, and dominant position.

Since the Competition Act is applicable to seeds, it plays a significant role in purchasing, selling, supplying, distributing and storing of seeds in Bangladesh. This Act can be applied to prevent anti-competitive practices like monopoly, oligopoly, abuse of combination and dominant position in trading seeds by seed dealers, MNCs and other commercial enterprises. The provisions of the Act do not impede to impose reasonable restrictions to protect the rights of any person under any intellectual property law.[463] The patenting of seeds may create the 'unfettered monopoly' by the MNC's and eventually cage the farmer's right to seeds in the hands of the corporation.

The Safe Food Act, 2013 emphasizes the use of scientific methods in ensuring safe foods by the process of production, distribution, sale, purchase, export and import. If Food or food materials produced from seeds germinated with the help of pesticides or insecticides harmful to human health, in that case the storage, marketing and selling of such seed may be prohibited under section 23 of the Food Safety Act, 2013. If radioactive substance or heavy metal is found in any seed exceeding the acceptable standard, in that case such seed may be prohibited too under section 24 of the Act. Section 31 is very important regarding GM seeds which provides that no one is allowed to produce, sell, distribute, export and import any novel food, functional food, organic food, and genetically modified or engineered food without getting approval in the prescribed manner under this law. These provisions of the Safe Food Act are to be scrutinized and duly appreciated in legislating any law protecting seed or plant varieties in Bangladesh.

[463] the Competition Act, 2012 (Act No. 23 of 2012), s. 15 (4).

The Agricultural Pests Ordinance, 1962 was promulgated to provide for the prevention of the spread of agricultural pests in Bangladesh. Since plants include seeds too, this Act has implications in the production, transport and sale of seeds. The law provides that the Government may prohibit any method of cultivation that may spread of agricultural pests either generally or with respect to any particular crop and it also empowers the government to prohibit transporting or sale of any infested crop.[464] The farmers, dealers or MNCs who produce/breed or sales seeds may be affected by the provisions of this Act and these may be duly considered in a legislation protecting seed or plant varieties maintaining the interest of farmers as well as national interest of Bangladesh.

The Geographical Indications of Goods (Registration and Protection) Act, 2013 is enacted to provide for the registration and better protection of geographical indications relating to goods. GI may be attributed to the seeds as agricultural products and accordingly GI can be registered in respect of any variety of seed or seeds under the Act.[465] Once a seed is registered as GI under the Act it would get all protections conferred by the Act.

The seed producers/breeders, dealers or MNCs that commercially produces or sells seeds may register them as authorized users of GI goods if a GI is registered in respect of the seed they deal with.[466] MNCs right of authorized users under this Act might be conflicting with the national interest of Bangladesh on traditional seeds and farmers' rights on such seeds provided by other laws and proposed Plant Varieties Act. This should be carefully resolved in taking appropriate legislative measures.

[464] the Agricultural Pest Ordinance, 1962, s.3.
[465] the Geographical Indications of Goods (Registration and Protection) Act, 2013, ss.7 and 8.
[466] ibid s.10.

The newly enacted Bangladesh Biodiversity Act, 2017 does not provide for the common property regime[467] of the Country and does not impose any bar of irrevocable alienation or impairment of enjoyment of such property. This is a vital limitation of the newly enacted law. Incorporation of the draft Act's provisions in the enactment on common property regime would be more favourable to ensure the protection of biodiversity, biological and genetic resources that include seed too and community knowledge and their enjoyment by the people of Bangladesh.

6.7 Protection of Seed under international convention/treaty/agreement

Bangladesh signed and ratified CBD on June 5, 1992 and May 3, 1994 respectively, and became a party to the Convention on August 1, 1994. The third objective of CBD, i.e. fair and equitable sharing of benefits arising out of the utilization of genetic resources has substantial implications to seed. As a signatory of the WTO Agreement Bangladesh is by implication of law has become a party to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). This is an integral part of the WTO agreement and binding on Bangladesh.[468]

SPS has a remarkable implication on the seed policy and seed related laws of Bangladesh. Bangladesh is a signatory of the International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA) and it has also ratified the Treaty. Therefore, this Treaty is binding on Bangladesh. PGRFA has a vital role in formulating seed policy and seed related laws of

[467] All the biological and genetic resources within the territory of Bangladesh, or originated in Bangladesh, as well as all related intellectual and cultural knowledge and practices among the people of Bangladesh constitute common property regime of the country- The draft Biodiversity and Community Knowledge Protection Act of Bangladesh, 1998, Article 6.1.

[468] the WTO Agreement, Article II (2).

Bangladesh since one of the objectives of it is to establish a global system to provide farmers, plant breeders and scientists with access to plant genetic materials.

UPOV is the French acronym for the International Convention for the Protection of New Varieties of Plants (UPOV). There are important differences between the 1978 and the 1991 Acts of UPOV regarding coverage, period, scope and exemptions. The differences sorted out by GRAIN between UPOV Conventions 1991 and 1978 should be carefully considered before taking any decision to accede to the UPOV Convention 1991 despite arguments in its favour.

Moreover, it is to be noted that none of the SAARC countries, including the majority of the UN Members, has acceded to the Convention yet. Amongst the African countries, remarkably Kenya has acceded to UPOV Convention 1991. Considering all the pros and cons it would be wise for Bangladesh to wait further to come up with the decision for acceding the Convention despite the pressure of the EU and other developing partners.

6.8 TRIPS on software patenting

This thesis finds that TRIPS provision does not provide any explicit recognition on patentability of computer programs. Arguably it is claimed that software patenting should not be allowed under TRIPS. Conversely, it is also contended that software is a patentable subject matter under TRIPS since it is compatible to all criteria set by article 27. Article 27 (1) of TRIPS stipulates that patents should be awarded for all inventions irrespective of their fields of technology. Since software programs are within the meaning of ‘inventions’, it should be covered by the patents under the TRIPS framework.

6.9 Software patenting for better protection of software besides copyright

TRIPS postulates that copyright protection shall extend to expressions and not the ideas, procedures, methods of operation or mathematical concepts as such. As TRIPS stands, copyright cannot prevent second generation creators from recruiting software by using the same source code or object code in different expressions. Thus, in order to protect content of software as an idea, there is a proposition that computer programs should be protected under patent system.

6.10 Patentability of software under PD Act

The thesis has explored that software program *per see* is not eligible to be patented under existing laws of Bangladesh. However, it can be patented as an idea or method when it produces technical effects. The official website of the Department of Patents, Designs and Trademarks does not give any data of software patenting or granting patents on any subject matter. However, it is revealed from a visit to the Department that it grants patents to the embedded software and so far it has granted almost 100 patents for embedded software out of 239 applications.[469]

6.11 Should Bangladesh provide software patenting?

Bangladesh is one of the booming developing nations in the software industry, outsourcing and ICT sectors. Therefore, it should adopt the specific policy, irrespective of the matter whether it will go for 'flexible' or 'restrictive' approach in granting software patents. Under the TRIPS. Bangladesh does not have any specific obligation to provide patent protection for a software program.

[469]Embedded software is computer software, written to control machines or devices that are not typically thought of as computers. It is typically specialized for the particular hardware that it runs on and has time and memory constraints-See http://en.wikipedia.org/wiki/Embedded_software ,
(accessed 9 April 2015).

However, Bangladesh is currently getting patent for software which is originally not developed upon other software programs. In this 'restrictive approach' Multinational Companies (MNC's) do not have much problem to get a patent because their products are already protected by several other countries. Thus, they apply to the DPDT in refereeing same diagram and formula of the other jurisdictions. Prima facie they are accorded protection due to the fact that their precedents have already been protected in other jurisdictions. In contrast, the 'restrictive approach' hinders local innovation and development. Local software developers do not get patent for programs that they develop and they are under serious examination of patent criteria. In this way, local innovation and creativities are not encouraged by the present practice.

New Patent Law of Bangladesh should specifically contain the patentability of software upon the fulfilment of certain conditions. It should incorporate the general criteria of patent along with the exclusion clause. If the software is made specifically patentable subjects, there might be a challenge for Bangladeshi local software companies to compete with the MNC's in the domestic market. According to 'Principle of Nationality' of the TRIPS, Bangladesh is under an obligation to give equal level of protection to its own and other nations. To overcome this hurdle our Law should also accommodate all the flexibilities of the TRIPS like compulsory licensing, parallel imports, etc. Thus, the new Patent Law should be drafted in a way so that it can strike a delicate balance between protection of national interests and TRIPS Compliance.

6.12 Relevant laws and policy implications for protecting software

The Information and Communication Technology Act, 2006 contain the software program as a subject matter of protection under computer system.[470] Any wilful and intentional damage done to the computer system, including software programs, without the consent of the owner

[470] The Information and Communication Technology Act, 2006, [2006], S. 2(14)

is a cybercrime under this Law. Thus, the provisions of said Law can be attracted in terms of cybercrimes relating to the software program.

Bangladesh has enacted some national legislations to tackle crimes which have global impacts. The Anti-Terrorism Act, 2009 and The Mutual Cooperation on Criminal Affairs Act, 2012 may play a significant role in protecting software and preventing software related crimes both nationally and internationally. Software program are within the meaning of property under the purview of section 2 (14A) of the Anti-Terrorism Act, 2009.[471] Any terrorist activities done with a view to destroying any property is punishable under the provisions of the said Act.

On the other hand, by virtue of the Mutual Cooperation on Criminal Affairs Act, 2012 Bangladesh government is bound to cooperate with other countries to inquire, investigate and try criminal offences related to software subject given some conditions imposed in the law. Appropriate applications of these laws will be helpful in protecting national interest of software in Bangladesh.

6.13 Modes of technology transfer and relevant provisions of TRIPS

In a policy brief of ICTSD, technology transfer is broadly interpreted to comprise training, education and know how including any capital component.[472] The thesis finds three basic modes of technology transfer from the UNCTAD definition i.e. transfer of systematic knowledge for manufacturing products, for application of a process and for rendering of a service. These modes do not include diffusion of technological knowledge among the developing countries and development of technological capabilities of developing countries.

[471]Section 2 (14A) of the said the Act defines the property as tangible or intangible things whether situated in Bangladesh or outside.

[472] S. Moon, *Meaningful Technology Transfer to the LDCs: A Proposal for A Monitoring Mechanism for TRIPS Article 66.2,* in Policy Brief No. 9, [pdf], International Centre for Tradeand Sustainable Development (ICTSD), 2011, http://www.ictsd.org/downloads/2011/05/technology-transfer-to-the-ldcs.pdf, (accessed 9 January 2016).

The problem of a developing country particularly an LDC like Bangladesh is that it does not have necessary R&D programs, adequate public and private research laboratories and universities and a sound basis of technical skills and human capital. The absences of these basic features of sound technological base creates a 'technological distance' of Bangladesh from the global frontier.[473]

The preamble of the TRIPS Agreement recognized the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations to enable them to create a sound and viable technological base. This recognition in the preamble is the guiding principle in interpreting other provisions of the TRIPS Agreement.

Article 7 declares one of the objectives of the TRIPS Agreement as transfer and dissemination of technology which should be achieved through enforcement of intellectual property rights. Paragraph 19 of the Doha Ministerial Declaration reiterated that "[i]n undertaking [the work outlined in this paragraph], the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension."[474]

Article 8.1 of the TRIPS Agreement enables Members to adopt necessary measures to promote public interest in the sector of technological development amongst others in formulating and amending their laws and regulations. But at the same time the enabling provision is restricted by a proviso that such measures are to be consistent with the provisions

[473] K. Saggi, K. E. Maskus and B. Hoekman, *Transfer of Technology to Developing Countries: Unilateral and Multilateral Policy Options,* [pdf], World Bank Policy Research Working Paper 3332, 2004, http://elibrary.worldbank.org/doi/abs/10.1596/1813-9450-3332 , (accessed 19 December 2015).

.

[474] P. K. Yu, 'The Objectives and Principle of the TRIPS Agreement', *Houston Law Review,* vol. 46, no. 4, 2009, pp. 979 and World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Ministerial Declaration].

of this Agreement. Literal interpretation of this proviso is that the measures must not be conflicting with any of the provisions of the TRIPS Agreement.

The Doha Ministerial Conference has reaffirmed the mandatory nature of Article 66.2. But it is observed that "the obligation of developed-country WTO Members stops at the provision of incentives. The governments of those countries may not and should not be expected to intervene in the transfer of technology because technology in developed countries is mostly controlled by private companies. Governments may not confiscate and transfer it to LDCs."[475]

Article 66.2 does not specify the incentives that should be provided by the developed country Members to create a sound and viable technological base for LDCs. It is rightly pointed out that "since Article 66.2 does not specify exactly what these incentives must look like or how extensive they must be, developed countries are essentially free to answer such questions on their own."[476]

Another important aspect raised by the scholars is that Article 66.2 is not limited to the IPR-related mechanism for promoting technology transfer. Andrew Michaels viewed that "Article 66.2 does not mention IPRs specifically, so developed countries are not limited to IPR-related mechanisms for promoting ITT."[477] This view may be exploited in favour of Bangladesh to adopt measures necessary to promote technological development in formulating and amending its laws and regulations.

---

[475] Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights*, 3rd edn., The Netherlands, Kluwer Law International, 2010, pp. 706-707.

.

[476] A. Michaels, 'International Technology Transfer And Trips Article 66.2: Can Global Administrative Law Help Least-developed Countries Get What They Bargained For?', *Georgetown Journal of International Law*, vol. 41, no. 1, 2009, p. 223.

[477] A. Michaels, 'International Technology Transfer And Trips Article 66.2: Can Global Administrative Law Help Least-developed Countries Get What They Bargained For?', *Georgetown Journal of International Law*, vol. 41, no. 1, 2009, p. 223. ITT means International Technology Transfer.

6.14 Incorporating TRIPS flexibilities on Technology Transfer in the Patent law

The PD Act does not specifically provide for any provision for technology transfer or R&D in Bangladesh. However, the patent system has got some inbuilt mechanism i.e. providing complete specification of the invention,[478] transmission of copies of specifications[479] etc. that may facilitate technology transfer and R&D in Bangladesh.

The BPA provides specific provisions for exemption for research besides disclosure of complete specification, inspection of register containing specification and publication of e-gazette. Section 32 of BPA incorporated research exception provisions stating that use of which would not infringe right of the patent, irrespective of their nationality. However, this provision is only applicable to the individual research, non-commercial purpose and with reasonable necessity. These types of restrictions and ambiguous terms may create complicated situations in practical sense. Further, these terms do not have any clarifications under this Act.

6.15 Effective sui generis system for technology transfer to seed industry

The Draft Plant Varieties Act of Bangladesh was drafted in 1998 by the National Committee on Plant Genetic Resources (NCPGR). The application of the Act is limited to the plant varieties which are registered and permitted to be used for economically gainful purpose and newly innovated plant varieties intended to be used by the inventor or owner of the inventor for monitory gains.[480] The areas where the Act shall not affect the communities have been clearly demarcated by specific terms. As for example the Act shall in no way affect the rights of farmers to have unencumbered access to biological and genetic resources of Bangladesh

[478] the PD Act, s 5(1)(a).
[479] ibid, s. 72.
[480] the Plant Varieties Act of Bangladesh (1998) (Draft), article 3 (3).

and related knowledge, intellectual practices and culture.[481] This Act also shall not limit the rights of farmers as innovators and the right to be recognized as such and awarded individually or as a group, or both, for the innovation.[482] This provision is conducive to the R&D and will facilitate transfer of technology in the seed sector.

Comparing the draft Act with the similar Act of an emerging economic power and agriculturally developed country like Malaysia, it is found that the draft Act of Bangladesh is lacking of providing some important provisions regarding issuance of compulsory license, infringement of the breeders' rights (certificate holder of a new plant variety) and remedies, offenses, punishment and enforcement provisions. Inserting these provisions would be beneficial to technology transfer in the seed sector of Bangladesh that will on the one hand protect the national interest by using TRIPS flexibility like using compulsory license and on the other hand assure MNCs in investing for R&D and technology transfer.

6.16 Harmonizing the legal and policy regime for TT

This thesis finds that India and Malaysia excluded the substance mentioned in any of the editions of the British Pharmacopoeia or the British Pharmaceutical Codex or the United States Pharmacopoeia or the National Formulary of the United States from the definition of drug. Therefore, Bangladesh may think about redefining 'drug' in the light of Indian and Malaysian experience as well as guideline given by the WHO. The Drugs Act, 1940 defines patent or proprietary medicine and the definition differs substantially from the definition provided in the Indian law. The definition in the Drugs Act, 1940 of Bangladesh does not include in the definition of patent or proprietary medicine, Ayurvadic or Unani Tibb like the

[481] ibid, article 3 (5).
[482] ibid, article 3 (7).

Indian one.[483] Bangladesh may consider of including Ayurvadic or Unani Tibb that constitute a considerable part of health service in Bangladesh particularly in the rural area.

The control vests on the licensing authority under section 9 of the Drugs (Control) Ordinance, 1982 to restrict import of drugs or API might be challenging for the interest of the local pharmaceutical industry and thereby might obstruct the development of the local pharmaceutical industry.

Sections 10 and 12 of the Drugs (Control) Ordinance, 1982 have been provided specifically to facilitate transfer of technology in the medicine sector. Section 10 provides for manufacture of drugs under licensing agreement and section 12 provides for power of government to review of certain licensing agreement with foreign concerns. Section 10 (a) empowers licensing authority to approve a foreign manufacturer to manufacture any drug under licensing agreement with any manufacturer in Bangladesh if the drug is its research product and is registered under the same brand name in any of the countries specified under sub-section (1A) of section 5. The Indian Drugs and Cosmetics Act, 1940 does not provide for such a provision.

Section 15 of the Drugs (Control) Ordinance makes it mandatory for every manufacturer of drug to follow the good practices in the manufacture and quality control of drugs recommended by the World Health Organization. Therefore, every manufacturer of drug in Bangladesh must follow the good manufacturing practices (GMP)[484] provided by WHO.

---

[483]However, rules 55-59 of the Drug Rules, 1945 framed under the Drugs Act, 1940 deal with packaging, registration and renewal of registration of the patent or proprietary medicine. Rules 62-64 of the Bengal Drugs Rules, 1946 also deal with packaging, labelling and packing of patent or proprietary medicine.

[484] "GMP covers all aspects of production from the starting materials, premises, equipment, and quality testing to the training and personal hygiene of staff." See "Managing Access to Medicine and Health Technologies", Chapter 6, Management Science for Health, available at http://apps.who.int/medicinedocs/documents/s19577en/s19577en.pdf , (accessed 26 December 2015).

Indian law was amended in 1982 through Act no. 68 of 1982 and section 17, 17 A and 17B were inserted to provide misbranded drugs, adulterated drugs and spurious drugs. These newly inserted sections provided all the provisions that the Drugs Act, 1940 of Bangladesh provided and in addition the Indian law covers some more aspects like deeming a drug as adulterated if it consists any filthy, putrid or decomposed substance.[485] Definitely, inclusion of these provisions in the Drugs Act, 1940 of Bangladesh would make our drugs more efficacious, safe and of standard quality. Besides this Bangladesh may follow WHO good manufacturing practices for pharmaceutical products: main principles.[486]

One of the fundamental shortcomings of the National Drug Policy 2005 of Bangladesh is that it does not provide any clear guide line of realizing the objective of transfer of technology in the drug sector like that of Malaysia. The Malaysian Policy also provides specific guidelines on implementing the TRIPS Agreement that " [i]ntellectual Property (IP) protection shall be in line with international standards, where the Malaysian Patent Laws are compliant with Trade Related aspects of Intellectual Property Rights (TRIPS) obligations. However, to address the public health needs, flexibilities under the TRIPS Agreement shall be used and the Doha Declaration on the TRIPS Agreement and Public Health shall be implemented."[487]

The guideline provides due emphasis on using TRIPS' flexibilities and implementation of Doha Declaration on the TRIPS Agreement and Public Health which are indispensable for a developing country like Bangladesh to incorporate in its patent regime to be implemented in 2033 in providing medicine patenting.

The preface of the Export Policy 2015-18 declares the pharmaceutical industry as one of the emerging prospective industries of Bangladesh. The Policy declared the pharmaceutical sector as one of the highest priority sectors. But it does not provide a specific way forward to

[485] The Drugs and Cosmetics Act, 1940, [1940] s. 17 A (a).
[486] WHO Technical Report Series, No. 961, 2011, Annex 3.
[487] ibid.

ensure the sustainable development in exporting pharmaceutical products in the context of global trade liberalization and the TRIPS regime. Attention should be given as to how the pharmaceutical industry would can produce generic medicine and API from scratch to compete with India and China in the export market of pharmaceutical products.

Paragraph 24 (6) of the Import Policy Order, 2012-2015[488] deals with raw materials and packing materials for the pharmaceutical industry under the heading of prescribed conditions for import of industrial items. A pharmaceutical producing company may only import the raw materials up to the quantity and value stated in the block list as provided in the Order. Customs authority is to release the raw materials based on import-invoice and analysis report of the raw materials certified by the Director, Drug Administration or government approved internationally reputed pre-shipment inspection agent regarding the quantity, value and quality of each item. These provisions are very important in the manufacture of pharmaceutical products and R&D because the pharmaceutical industry is under compulsion to be restricted within the block list and cannot go beyond it even if the transfer of technology requires any specific raw material for producing a certain lifesaving medicine.

The Seeds Ordinance, 1977 itself may be amended to provide for detailed provisions relating to the technology transfer in the field of genetically modified seeds, and other quality seed as well as development of R&D of seed in Bangladesh.[489] The Seed Rules, 1998 also do not provide any provisions for technology transfer in GM seed and other quality seed. Rule 5 provides the functions of the Government Seed Laboratory, which are basically related to seed testing and no provisions provided for research by producing new varieties of seed or quality seeds. The government is empowered to assign any other function on the Government

[488] The GOB made and issued this order in exercise of the powers conferred by section 3(1) of the Imports and Exports (Control) Act, 1950 (Act XXXIX of 1950), English text is available at http://pflanzengesundheit.jki.bund.de/dokumente/upload/98e82_bd3-import_policy_order_12-15.pdf , (accessed 7 January 2016).

[489] the Seeds Ordinance, 1977 (Ordinance No. XXXIII of 1977), section 8 (2) (h).

Seed Laboratory than expressly provided in the rule.[490] Under this provision the government may assign function like producing a high yielding variety of seed or quality seed on the Government Seed Laboratory.

One of the main objectives of the National Agriculture Policy 2013 is to invent new variety of crop and sustainable cultivation technology through research and training. The Policy has a separate section on research and development (R&D). However, it does not provide any specific measures to realize the objectives and no concrete methods for transfer of technology in seed sector and R&D of seed industry of Bangladesh.

The National Seed Policy 1993 of Bangladesh does not specifically mention any provision for R&D and transfer of technology (TT) in the seed sector. However, some of the provisions of the Policy stated about R&D and TT indirectly and these may facilitate R&D and TT to some extent despite the Policy is itself outdated and requires massive change to be up dated.

Like Malaysia Bangladesh also may take measures to formulate conducive seed policy for the development of seed industry and to make capacity building to strengthen the seed industry by developing networking with the International Seed Federation (ISF), International Seed Testing Association (ISTA) and the Asia Pacific Seed Association (APSA). It can also develop a seed industrial zone and establish an integrated data management system like Malaysia.

The Import Policy Order 2012-15 imposed some preconditions on importing rice and potato seeds e.g., the requirements of obtaining phytosanitary certificate, quarantine certificate and import permit from appropriate authorities. In addition to these provisions for importing hybrid rice seeds, the phytosanitary certificate should state that the seed is purified by hot water treatment and approved pesticides. The implications of these provisions in transfer of

[490] Seed Rules, 1998, Bangladesh Gazette, Extra Ordinary Copy, July 13, 1998, S.R. O. No. 33-LAW/98.

technology of seed should be assessed correctly in complying with the TRIPS provisions through legislation in Bangladesh.

The Agro-producing sector has been declared in the Export Policy 2015-18 as an emerging prospective sector and special incentives have been declared for the development of this sector. One of the main objectives of the Policy is to increase the export of plant and product. This very objective indicates the intention of the policy maker to enhance the quality production of Agro-product as well as seeds in Bangladesh.

The National Revenue Board is to consider the tax-free import of equipment and machineries for R&D at the request of the Export Promotion Bureau.[491] The incentives and objectives declared in the Policy are conducive to the technology transfer under the TRIPS Agreement however, the GOB must take appropriate initiative to make a road map for implementing these policies by framing necessary law, rules and regulations regarding agriculture and seed.

The Information and Communication Technology Act, 2006 (ICT Act) provides some important measures like legal recognition of electronic record, defining computer data[492] that includes software also, Controller's power to announce protected systems,[493] penalty for damage to computer, computer system, etc.[494] and punishment for tampering for computer source code.[495] These provisions of the ICT Act though not directly influence the transfer of technology to the software industry, may play a vital role in TT to the software industry of Bangladesh by curbing software piracy and cybercrimes.

---

[491] the Export Policy 2015-2018 of Bangladesh, para 4.16.

[492] Section 2 (10) of the ICT Act defines computer data as " "data" means a representation of formation, knowledge, facts, concepts or instructions which are being prepared or have been prepared in a formalized manner, and is intended to be processed, is being processed, or has been processed in a computer system or computer network, and may be in any form including computer printouts, magnetic or optical storage media, punch cards, punched tapes or stored internally in the memory of the computer;".

[493] the ICT Act (Act No. 39 of 2006), section 47.

[494] ibid, section 54.

[495] The ICT Act (Act No. 39 of 2006), section 55.

The draft Cybersecurity Act, 2015 provides measures for national cybersecurity and for the prevention, detection, response and prosecution of cybercrimes and other related matters. It defines computer data, computer program, computer system, computer network, critical infrastructure, malware etc. and made punishable some computer related offences like unauthorized modification of computer program or data, system interference, computer related forgery, computer related fraud, identity theft and impersonation, cybersquatting, cyber terrorism etc. These provisions may be congenial for software protection in Bangladesh and protecting national interest regarding highly secured software vital for national security and technology transfer to this sector subject to strike a balance amongst preserving fundamental rights, human rights, personal data safety and national security as well as business interest of the local software industry and MNCs.

The draft National E-Service Act, 2014 provides for creating an authority called 'National E-Service Authority'. The draft Act vests on the Authority the powers amongst others by declaring information and technology (IT) system as protected IT system and appointing IT Auditor to audit application software for providing e-service by authorized e-service providers.[496] Proper exercise of such powers may create a favourable condition for transferring technology to the software sector of Bangladesh.

6.17 Future Work

The flexibilities within the TRIPS Agreement are broadly grouped into four categories: (1) subject-matter which qualifies for protection; (2) scope of the protection; (3) modes of IPR enforcement; and (4) matters of administration.[497] As far as TRIPS' flexibilities concerned this thesis explored the first two categories of flexibilities. The third and fourth categories of

[496] The draft National E-Service Act has been referred to the budget doc. at paragraph 6.11, available at http://www.mof.gov.bd/en/budget/15_16/mtbf/en/28_ICT_English.pdf,
(accessed 9 March 2016).

[497] Ng-Loy Wee Loon, 'Exploring flexibilities within the global IP standards', *Intellectual Property Quarterly*, no. 2, 2009, pp. 162-184.

flexibilities have remained unexplored in the context of Bangladesh particularly for medicine, seed and software.

The implementation of the TRIPS' provisions through legislation will not only substantially change the patent regime of Bangladesh but also will affect the relevant laws and policies that deal with medicine, seed and software. This thesis examines this vast legal regime with a limited scope on the TRIPS' flexibilities of subject-matter which qualifies for protection and scope of protection. But how the TRRIPS' flexibilities regarding modes of IPR enforcement and matters of administration can be exploited in harmonizing this huge legal regime with the TRIPS Agreement with attention to protect the national interest on medicine, seed and software is left unexplored for future studies.

The human rights issues in implementing the TRIPS' provisions through national legislation particularly related to medicine and seed and technology transfer to these sectors have not been examined in this thesis. These are very crucial issues and may be explored in future.

Protocol Amending the TRIPS Agreement that aims to permanently incorporate into the TRIPS Agreement additional flexibilities to grant special compulsory licenses for the export of medicines, referred to as the "Paragraph 6 System" which remains open for acceptance till 31 December 2017 needs an in-depth study to adjudge its suitability for an LDC like Bangladesh. However, this study briefly examined it.

Bangladesh is under obligation to make an endeavor to accede to the UPOV convention due to an agreement with EU. The impact of such accession on the plant varieties particularly on the seed industry of Bangladesh should be assessed intricately. Special emphasis should be given on the impact of such accession on the legal regime of the seed or plant varieties including the draft Plant Varieties Act of Bangladesh in future studies. As a signatory of the WTO Agreement Bangladesh is by implication of law has become a party to the Agreement

on the Application of Sanitary and Phytosanitary Measures (SPS). This is an integral part of the WTO agreement and binding on Bangladesh.[498] SPS has a remarkable implication on the seed policy and seed related laws of Bangladesh. An extensive study is needed to be conducted on this issue in future to find out the policy gap in implementing the SPS in Bangladesh protecting our national interest on the seed industry.

This study briefly examined the impact of software patenting on the medical and agricultural data protection. A detailed examination in this regard would be helpful for Bangladesh in protecting its medical and agricultural database.

The world might undergo some seismic changes with the advent of mega-regional trade agreement like the Trans-Pacific Partnership (TPP) and the Transatlantic Trade and Investment Partnership (TTIP). Consequently, these may change the multilateral trading system and may have a potential to reduce the role of WTO as the mediator of commercial relations amongst nations. In this backdrop, this study puts due emphasis on the need of future study of legal impact of mega-regionals on Bangladesh in the fields of medicine, seed and software. Confidentiality of TPP's negotiations makes it more vulnerable for an LDC like Bangladesh that entails the necessity of a comprehensive study to determine the legal and policy issues to be addressed by Bangladesh in protecting its interest on medicine, seed and software and taking a policy decision about joining such agreements.

Investor-state arbitration claim is a great challenge for effective implementation of the TRIPS Agreement's flexibilities through domestic legislation for an LDC like Bangladesh. Recent trend shows companies are increasingly challenging domestic decisions pursuant to bilateral and multilateral agreements that provide protection to foreign investors and permit them to bring the investor - State dispute. In these disputes companies, may not only challenge the

[498]the WTO Agreement, Article II (2).

patentability standards they disagree with, but also exceptions to patent rights (flexibilities), even where these exceptions are permissible under TRIPS. Bangladesh as an LDC should take sufficient legal measures in protecting its national interest in medicine, seed and software before entering any such bilateral or multilateral agreements. Since this is a recent trend and Bangladesh is in transition to implement TRIPS, the MNCs are yet to file any such dispute against Bangladesh. Therefore, this study has not explored this issue. But in a very short time Bangladesh will require policy guidelines and in depth study on the investor-state arbitration emerging from bilateral and multilateral treaties to protect its medicine, seed and software industries.

This thesis endeavours a thorough analysis on the TRIPS' impact on the technology transfer to the medicine, seed and the software industries of Bangladesh. However, it does not analyse the impact of TRIPS on foreign direct investment (FDI) in these sectors of Bangladesh. An exhaustive study in this regard would be immensely beneficial for Bangladesh to determine policy gaps in the legal regimes of medicine, seed and software necessary to expedite FDI in these sectors.

This thesis finds legislative options for Bangladesh to amend and enact its patent law as well as an effective *sui generis* system to exploit TRIPS' flexibilities in incorporating TRIPS' provisions by 2021 and 2032 as the case may be, for protecting its medicine, seed and software industries and harmonizing legal regimes relevant to medicine, seed and software as well as transfer of technology to these sectors in the course of implementation of the TRIPS provisions through legislation. However, there are scopes to fine tune the findings and further improve those in the light of the changing needs of the society in the course of time.

Bibliography

A. Books

Azam, Mohammad Monirul, *Intellectual Property WTO and Bangladesh*, 2nd edn., Dhaka, New Warsi Book Corporation, 2012.

Bessen, J. and M. J. Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk*, Princeton, Princeton University Press, 2008.

Carvalho, Nuno Pires de, *The TRIPS Regime of Patent Rights*, 3rd edn., Alphen aan den Rijn, The Netherlands, Kluwer Law International, 2010.

Correa, Carlos M., *Intellectual Property Rights, the WTO, and Developing Countries: the TRIPS Agreement and Policy Options*, London, U.K., Zed Books, 2000.

Das, J.K., *Intellectual Property Rights*, Kamal Law House, 2008, https://books.google.com.bd/books?id=7MXZXwAACAAJ.

Grubb, Philip W., *Patents for Chemical, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy*, 4th edn., New Delhi, Oxford University Press, 2005.

Islam, Mahmudul, *Interpretation of Statutes and Documents*, 1st edn., Dhaka, Mullick Brothers, 2009.

Islam, M. Rafiqul, *International trade law of the WTO*, New Delhi, Oxford University Press, 2006.

Islam, M. Towhidul, *TRIPS Agreement of the WTO: Implications and Challenges for Bangladesh*, Newcastle, U.K., Cambridge Scholars Publishing, 2013.

Matthews, Duncan, *Globalising Intellectual Property Rights: The TRIPS Agreement*, London, U.K., Rouledge, 2002.

Merger, Robert Patrick et el., *Patent Law And Policy: Selected Statutes, Rules And Treaties*, 2005 edn., New York City, LexisNexis, 2005.

Merges, Robert Patrick and John Fitzgerald Duffy, *Patent Law and Policy: Cases & Materials*, New York City, LexisNexis, 2002.

Narayanan, Parameswaran, *Intellectual Property Law*, Kolkata, Eastern Law House, 2007.

Organization, World Intellectual Property, *Collection of Documents on Intellectual Property*, WIPO Worldwide Academy, 2003.

———, *The Enforcement of Intellectual Property Rights: A Case Book*, 2nd edn., WIPO,

2008.

Sender, Marta P., *Cross-border Enforcement of Patent Rights: An Analysis of the Interface Between Intellectual Property and Private International Law*, Oxford Private International Law Series, New Delhi, Oxford University Press, 2002.

Spence, Michael, *Intellectual Property*, New York City, Oxford University Press, 2007.

Wadehra, B.L., *Law Relating to Intellectual Property*, New Delhi, Universal Law Publishing, 2012.

B. Articles

Abbot, Fredrick M., 'The WTO Medicine Decision: World Pharmaceutical Trade and the Protection of Public Health', *The American Journal of International Law,* vol. 99, 2005, pp. 317-358.

Adams, Christopher P and Van V Brantner, 'Estimating the Cost of New Drug Development: Is it really $802 Millions?', *Health Affairs,* vol. 25, no. 2, 2006, pp. 420-428.

Adelman, Martin J. and Sonia Baldia, 'Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India', *Vanderbilt Journal of Transnational Law,* vol. 29, 1996.

Aoki, Keith, 'Weeds, Seeds and Deeds: Recent Skirmishes in the Seed Wars', *Cardozo Journal of International and Comparative Law,* vol. 11, no. 2, 2003, pp. 247-331.

Azam, M. M., 'Globalizing Standard of Patent Protection in WTO Law and Policy Option for LDCs: The Context of Bangladesh', *Chicago-Kent Journal of Intellectual Property,* vol. 13, no. 2, 2014.

Basheer, Shamnad, 'India's Tryst with TRIPS: The Patents (Amendment) Act 2005', *The Indian Journal of Law and Technology,* vol. 1, 2005, pp. 15-46.

Basheer, Shamnad, and Prashant Reddy, "Ducking' TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d)', *National Law School of India Review,* vol. 20, no. 2, 2008, pp. 131-155.

Bhatt, Tina S., 'Amending TRIPS: A New Hope for Increased Access to Essential Medicines', *Brooklyn Journal of International Law,* vol. 33, no. 2, 2008, pp. 597-628.

Bohrer, Robert A., 'Reach-through claims for drug target patents: Rx for pharmaceutical policy', *Nature Biotechnology,* vol. 26, 2008, pp. 55-56.

Bower, Jane, and Julian C. Sulej, 'The Indian Challenge: The Evolution of a Successful New Global Strategy in the Pharmaceutical Industry', *Technology Analysis & Strategic*

Management, vol. 19, no. 5, 2007, pp. 611-624.

Bruce, Lindsay, 'Defending Value and Maximising Profitability of Innovative Pharmaceuticals Over Their Entire Life Cycles', *International Journal of Medical Marketing,* vol. 3, no. 3, 2003, pp. 195-197.

Charfoos, Aaron D., 'How Far Have We Come, and Where Do We Go From Here: The Status of Global Computer Software Protection Under the TRIPS Agreement', *Northwestern Journal of International Law & Business,* vol. 22, no. 2, 2002, pp. 261-290.

Correa, Carlos M., 'The TRIPS Agreement: How Much Room for Maneuver?', *Journal of Human Development,* vol. 2, no. 1, 2001, pp. 79-107.

Durell, Karen Lynne, 'Intellectual Property Protection for Computer Software: How Much and What Form is effective?', *International Journal of Law and Information Technology,* vol. 8, no. 3, 2000, pp. 231-262.

Freedman, C. D., 'Software and Computer Related Business- Method Innovations: Must Europe Adopt American Patent Culture?', *International Journal of Law and Information Technology,* vol. 8, no. 3, 2000, pp. 285-309.

González, Andrés Guadamuz, 'Software Patentability: Emerging Legal Issues', *WIPO Magazine,* no. 6, 2008, pp. 15-17.

Gopakumar, K. M., 'Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime', *The Law and Development Review,* vol. 3, no. 2, 2010, pp. 326-368.

Goswami, Garima, 'Software Patents and the Current Trends', *International Journal of Computer Science & Communication,* vol. 1, no. 1, 2010, pp. 39-41.

Helfer, Laurence R., 'Human Rights and Intellectual Property: Conflict or Co-existence?', *Minnesota Intellectual Property Review,* vol. 5, no. 1, 2003, pp. 47-61.

Islam, Md. Rizwanul, 'Intellectual Property Rights and Developing or Least Developed Countries: Strategies for Policy Makers', *The Dhaka University Studies Part-F,* vol. 19, no. 1, 2008.

Kaya, Talat, 'A Comparative Analysis Of The Patentability Of Computer Software Under The Trips Agreement: The U.S., The E.U., And Turkey', *Ankara Law Review,* vol. 4, no. 1, 2007, pp. 43-81.

Michaels, Andrew, 'International Technology Transfer And Trips Article 66.2: Can Global Administrative Law Help Least-developed Countries Get What They Bargained For?',

Georgetown Journal of International Law, vol. 41, no. 1, 2009, p. 223.

Moss, Carrie, 'The Integrated Approach: A Solution to Patent Subject Matter Eligibility Standards in the Software Context', *Journal of Intellectual Property Law,* vol. 21, no. 2, 2014, pp. 341-377.

Murshed, Md. Mahboob, 'IPRS Compatibility with Human Rights: Striving for a Right Balance', *The Dhaka University Studies Part-F,* vol. 17, no. 1, 2006.

Negi, Ritushka, Remfry and Sagar, 'Business Method and Software Patent Trends in India', *Intellectual Asset Management*, no. 35, 2009, pp. 102-104.

Oczek, Jeremy P., 'In the Aftermath of the "Terminator" Technology Controversy: Intellectual Property Protections for Genetically Engineered Seeds and the Rights to Save and Replant Seed', *Boston College Law Review*, vol. 41, no. 3, 2000, pp. 627-657.

Prutzman, L. Donald, 'United States Patent Protection for Computer Software', *International Law Practicum,* vol. 19, no. 1, 2006, pp. 45-52.

Reichman, Jerome H., 'The Know-How Gap in the TRIPS Agreement: Why Software Fared Badly', *Hastings Communications & Entertainment Law Journal,* vol. 17, 1995, pp. 763-794.

Rozek, Richard P. and Ruth Berkowitz, 'The Effects of Patent Protection on the Prices of Pharmaceutical Products: Is Intellectual Property Protection Raising the Drug Bill in Developing Countries?', *The Journal of World Intellectual Property,* vol. 1, no. 2, 1998, pp. 179-243.

Schmidt, Klaus M. and Monika Schnitzer, 'Public Subsidies for Open Source? Some Economic Policy Issues of the Software Market', *Harvard Journal of Law & Technology,* vol. 16, no. 2, 2003, pp. 473-505.

Sun, Haochen, 'The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health', *European Journal of International Law*, vol. 15, no. 1, 2004, pp. 123-150.

Tomar, David K., 'A Look into the WTO Pharmaceutical Patent Dispute between the United States and India', *Wisconsin International Law Journal,* vol. 17, 1999, pp. 579-603.

Tully, Danielle L., 'Prospects for Progress: The TRIPS Agreement and Developing Countries after the Doha Declaration', *Boston College International and Comparative Law Review,* vol. 26, no. 1, 2003, pp. 129-143.

Weissman, Robert, 'A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries', *University of Pennsylvania Journal of International Law*, vol. 17, no. 4, 1996, pp. 1069-1125.

Whobrey, Brittany, 'International Patent Law and Public Health: Analyzing Trips' Effect on Access to Pharmaceuticals in Developing Countries', *Brandeis LiveJournal*, vol. 45, 2006.

Wilson, Clark A. D., 'The TRIPS Agreement: Is It Beneficial to the Developing World, or Simply a Tool Used to Protect Pharmaceutical Profits for Developed World Manufactures', *Journal of Technology Law & Policy*, vol. 10, 2005.

Yu, Peter k., 'The Objectives and Principle of the TRIPS Agreement', *Houston Law Review*, vol. 46, no. 4, 2009, pp. 979-1046.

C. Web Sources

Bangladesh to remain LDC until 2024: UN review,

http://bdnews24.com/economy/2015/11/26/bangladesh-to-remain-ldc-until-2024-un-review, 2015,

(accessed 8 February 2016).

Factual Overview on Technical and Financial Cooperation for LDCs Related to the TRIPS Agreement: Identifying and Responding to Individual Priority Needs of LDCs, edited, World Trade Organization, 2013, https://www.wto.org/english/tratop_e/trips_e/ldc_overview_08.05.2013_full.pdf., (accessed 8 May 2016).

Report of the Special Rapporteur on the right to food edited, United Nations, 2009, http://www.un.org/ga/search/viewm_doc.asp?symbol=A/64/170,

(accessed 16 June 2016).

Agriculture, United States Department of, *Improving Corn*, https://www.ars.usda.gov/oc/timeline/corn/,

(accessed 9 November 2016).

Ahmed, Ikteder, *Report on discussion between Bangladesh delegation and WIPO experts on proposed Patents and Designs Act, Trade Marks and Merchandise Marks Act, Copyright Act, 2000 and other subjects of intellectual property rights within the purview of WTO*, edited, Ministry of Law, Justice and Parliamentary Affairs, 2003, http://www.lc.gov.bd/reports/65.pdf.,

(accessed 9 November 2016).

Arihan, Okan and A. Mine GENÇLER ÖZKAN, 'Traditional Medicine and Intellectual Property Rights', *Journal of the Faculty of Pharmacy of Ankara*, vol. 36, no. 2, 2007, pp. 135-151. http://dergiler.ankara.edu.tr/dergiler/24/546/6744.pdf,

(accessed 1 April 2017).

Baghdadi-Sabeti, Guitelle and Fatima Serhan, *'WHO Good Governance for Medicine Program: An Innovative Approach to Prevent Corruption in the Pharmaceutical Sector'*, edited, World Health Organization, 2010, http://apps.who.int/medicinedocs/documents/s17550en/s17550en.pdf.,

(accessed 1 April 2017).

Bakels, Reinier and P. Bernt Hugenholtz, *The Patentability of Computer Programs: Discussion of European-level Legislation in the Field of Patents for Software*, in Directorate-General for Research Working Paper, edited, EU Parliament, 2002, http://www.europarl.europa.eu/RegData/etudes/etudes/join/2002/322357/DG-4-JURI_ET(2002)322357_EN.pdf.,

(accessed 8 November 2016).

Bangladesh Computer Council and Bangladesh Ministry of Posts, Telecommunications and Information Technology, *Data Collection of Bangladesh IT/ITES Industry*, edited, BCC and Ministry of Posts, Telecommunications and IT (BD), 2015, http://lict.gov.bd/publishdocs/doc_2015-03-02-11-46-29_54f3f935b3dea.pdf., (accessed 8 May 2016).

Berunudez, Jorge A.Z. and Maria Auxiliadora Oliveira, *Intellectual Property in the Context of WTO TRIPS Agreement: Challenges for Public Health*, edited by Jorge A.Z. Bermudez and Maria Auxiliadora Oliveira Berunudez, Rio de Janeiro, WHO/ PAHO Collaborating Centre for Pharmaceutical Policies, 2004.

http://www.who.int/intellectualproperty/submissions/Trips_ingles%20nova%20versao%2020

05.pdf,
(accessed 1 April 2017).

Condon, Bradly and Tapen Sinha, 'Global Diseases, Global Patents and Differential Treatments in WTO Law: Criteria for Suspending Patent Obligations in Developing Countries', *Northwestern Journal of International Law & Business*, vol. 26, no. 1, 2005, pp. 1-42.
http://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1615&context=njilb,
(accessed 1 April 2017).

Corporation, International Data Corporation (IDC) and Microsoft, *The Dangerous World of Counterfeit and Pirated Software*, edited, 2013, https://news.microsoft.com/download/presskits/antipiracy/docs/IDC030513.pdf.,
(accessed 20 March 2017).

Correa, Carlos, *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, edited, Geneva, The South Centre, 2000, http://www.eldis.org/vfile/upload/1/document/0708/DOC9006.pdf.,
(accessed 1 April 2017).

Council, European Economic, *Legal Protection of Computer Programs*, in 91/250/EEC, edited by European Economic Council, 1991, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31991L0250:EN:HTML., (accessed 16 November 2016).

Development, United Nations Conference on Trade and, *Transfer of Technology and Knowledge Sharing for Development: Science, Technology and Innovation Issues for Developing Countries*, edited, UNCTAD, 2013, http://unctad.org/en/PublicationsLibrary/dtlstict2013d8_en.pdf.,
(accessed 16 March 2017).

Duzer, Tony Van, *TRIPS and Pharmaceutical Industries in Bangladesh: Towards a National Strategy*, in CPD Occasional Paper Series, edited, Center For Policy Dialogue (CPD), Bangladesh, 2003, http://www.cpd.org.bd/pub_attach/op24.pdf.,
(accessed 14 March 2011).

Ginibun, Florence C. and Amyita Witty Ugap, *Current Status of the Integrated Seed Sector in Malaysia*, edited, Malaysia, Malaysian Agricultural Research and Development

Institute, 2013,
https://www.researchgate.net/publication/255821432_COUNTRY_REPORT_Current_Status_of_Seed_Industry_in_Malaysia.,
(accessed 6 January 2016).

Hart, Robert et al., *The Economic Impact of Patentability of Computer Programs: Report to the European Commission*, edited,
http://ec.europa.eu/internal_market/indprop/docs/comp/study_en.pdf.,
(accessed 8 March 2016).

Hirimuthugodage, Dilani, *Trade Related Intellectual Property Rights (TRIPS) Agreement and the Agriculture Sector in Sri Lanka*, edited, Asia-Pacific Research and Training Network on Trade, 2011.
https://www.econstor.eu/bitstream/10419/64314/1/656432152.pdf,
(accessed 1 April 2017).

Khondker, H. Bazlul and Sonia Nowshin, *Developing National Intellectual Property Policy for Bangladesh: An Assessment of National Intellectual Property System (Draft)*, edited, World Intellectual Property Organization, 2013,
http://dpdt.portal.gov.bd/sites/default/files/files/dpdt.portal.gov.bd/policies/0b84dc51_4a40_4333_ab01_66b4be436e26/IP%20Policy.KS.pdf.,
(accessed 9 November 2016).

Law Commission, Bangladesh, *Final Report on the Patents and Designs Act*, edited, www.lawcommissionbangladesh.org, 2001,
(accessed 20 March 2017).

LLP, Fenwick & West, *Report on International Legal Protection for Computer Software*, edited, 2004 Updated edn, Computer & Internet Law, 2004,
https://www.fenwick.com/FenwickDocuments/Software_Chart_2004.pdf.,
(accessed 12 February 2016).

Moran, Katy, *Health: Indigenous Knowledge, Equitable Benefits*, in Indigenous Knowledge (IK) Notes, edited, World Bank, 1999,
https://openknowledge.worldbank.org/handle/10986/10823.,
(accessed 12 March 2016).

Murshed, Md. Mahboob, 'TRIPS Agreement and Patenting of Pharmaceutical Products', *The Daily Star*, 19 August, 2006 2006,

http://archive.thedailystar.net/law/2006/08/03/index.htm.,
(accessed 16 April 2016).

Nitta, Itaru, *Patents and Essential Medicines: An Application of the Green Intellectual Property Project*, edited, School of International Service, American University, Washington. D.C. and Wakabayashi Intellectual Property Law, http://www.who.int/intellectualproperty/submissions/ITARUNITTA.pdf., (accessed 18 March 2016).

Office, Japan Patent, *Examination Guidelines for Patent and Utility Model in Japan*, edited by Japan Patent Office, 2015, http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/1312-002_e.htm.,
(accessed 9 February 2016).

Office, United States Patent and Trademark, *Examination Guidelines for Computer-Related Inventions*, edited by United States Patent and Trademark Office, 1996, https://www.uspto.gov/web/offices/com/sol/og/con/files/cons093.htm.,
(accessed 10 April 2016).

Organization, World Health, *General Guidelines for Methodologies on Research and Evaluation of Traditional Medicines*, edited, World Health Organization, 2000, http://apps.who.int/iris/bitstream/10665/66783/1/WHO_EDM_TRM_2000.1.pdf., (accessed 10 August 2015).

'Global Health Strategy on Public Health, Innovation and Intellectual Property (Agenda 11.6)', *Sixty-First World Health Assembly*, Geneva, 2008, http://apps.who.int/gb/ebwha/pdf_files/WHA61-REC1/A61_REC1-en.pdf., (accessed 11 August 2015).

———, *Good Governance for Medicines, Progress Report 2010*, edited, World Health Organization, 2010, *http://www.who.int/medicines/areas/policy/goodgovernance/GGM2010ProgressReport.pdf*.,
(accessed 11 November 2015).

———, *Health System Financing, The Path to Universal Coverage*, in The World Health Report, edited, WHO, 2010, http://www.who.int/whr/2010/whr10_en.pdf?ua=1., (accessed 8 November 2015).

———, *WHO Model List of Essential Medicines, 16th List (Updated)*, edited, 2010,

http://www.who.int/medicines/publications/essentialmedicines/Updated_sixteenth_adult_list_en.pdf.,
(accessed 28 September 2015).

———, *WHO Traditional Medicine Strategy 2002-2005*, edited, World Health Organization, 2002,
http://www.wpro.who.int/health_technology/book_who_traditional_medicine_strategy_2002_2005.pdf.,
(accessed 20 April 2016).

Organization, World Intellectulal Property, *Conference on Intellectual Property and Public Policy Issues*, WIPO/IPGC/GE/09/INF/1, Geneva, 2009.
http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ipgc_ge_09/wipo_ipgc_ge_09_inf_1.pdf,
(accessed 1 April 2017).

Organization, World Intellectual Property, *Intellectual Property and Human Rights, A Panel Discussion to commemorate the 50th Anniversary of the Universal Declaration of Human Rights*, edited, WIPO Publication, 1998,
http://www.wipo.int/mdocsarchives/WIPO_UNHCR_IP_PNL_98/WIPO_UNHCR_IP_PNL_98_INF%205_E.pdf.,
(accessed 18 July 2015).

Pray, Carl E. and Bharat E Ramaswami, *A Framework for Seed Policy Analysis in Developing Countries, International Food Policy Research Institute*, edited, Washington D.C., International Food Policy Research Institute, 1991.
http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.225.3579&rep=rep1&type=pdf,
(accessed 1 April 2017).

Rights, Commission on Intellectual Property, *Integrating Intellectual Property Rights and Development Policy: Final Report of the Commission on Intellectual Property Rights*, edited, London, CIPR, 2002.
http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf,
(accessed 1 April 2017).

Rozanski, Felix, *Developing Countries and Pharmaceutical Intellectual Property Rights: Myths and Realities*, edited, Stockholm Network, 2007.
http://www.stockholm-

network.org/downloads/publications/Developing_Countries_and_Intellectual_Property_Rights_Myth_and_Reality_6.pdf,
(accessed 15 April 2015).

Rozek, Richard P., 'The Effects of Compulsory Licensing on Innovation and Access to Health Care', *The Journal of World Intellectual Property*, vol. 3, no. 6, 2000, pp. 889-917.
http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2000.tb00158.x/epdf?r3_referer=wol&tracking_action=preview_click&show_checkout=1&purchase_referrer=onlinelibrary.wiley.com&purchase,
(accessed 1 April 2017).

Saez, Catherine, *What Does WTO Extension For LDCs To Enforce IP Mean For Pharmaceuticals?* edited, Intellectual Property Watch, 2013, http://www.ip-watch.org/2013/08/02/what-does-wto-extension-for-ldcs-to-enforce-ip-mean-for-pharmaceuticals/.,
(accessed 12 July 2015).

Saggi, Kamal, Keith E. Maskus and Bernard Hoekman, *Transfer of Technology to Developing Countries: Unilateral and Multilateral Policy Options*, edited, World Bank Policy Research Working Paper 3332, 2004, http://elibrary.worldbank.org/doi/abs/10.1596/1813-9450-3332.,
(accessed 22 June 2015).

Secretariat, UNCTAD, *Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries: A Series of Case Studies*, edited, New York, UNCTAD, 2011, http://apps.who.int/medicinedocs/documents/s19062en/s19062en.pdf.,
(accessed 2 August 2015).

Secretariat, WHO, *Public Health, Innovation, and Intellectual Property: Progress made by the Intergovernmental Working Group*, edited, World Health Organization, 2007, http://www.who.int/phi/A60_27-en.pdf.,
(accessed 28 October 2015).

Secretariat, WHO and the WTO, *WTO Agreements and Public Health, A Joint Study by the WHO and the WTO Secretariat*, edited, World Trade Organization / World Health Organization, 2002, https://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf.,

(accessed 6 October 2015).

Services, Bangladesh Association of Software and Information, 'Bangladesh Software and IT service Industry: Recent Trends and Dynamics', http://www.basis.org.bd/resource/About_Industry.pdf.,

(accessed 1 April 2017).

Uddin, M. Kamal, *Draft Report on Innovation and Intellectual Property Policy and Strategy for Bangladesh*, edited, World Intellectual Property Organization, 2012, http://dpdt.portal.gov.bd/sites/default/files/files/dpdt.portal.gov.bd/policies/04745374_f547_4d92_ba38_1299e50d98b1/IP%20Policy.MKU.pdf.,

(accessed 14 July 2015).

UNAIDS, *Global AIDS Response Progress Report (GARPR): Annual Progress Report Bangladesh*, edited, www.unaids.org, 2015, http://www.unaids.org/sites/default/files/country/documents/BGD_narrative_report_2015.pdf.,

(accessed 15 March 2016).

D. International Instruments

1. The Universal Declaration of Human Rights, (UDHR) 1948
2. The International Covenant on Civil and Political Rights, (ICCPR) 1966
3. The International Covenant on Economic, Social and Cultural Rights, (ICESCR) 1966
4. The Paris Convention for the Protection of Industrial Property, 1883
5. The Bern Convention for the Protection of Literary Works, 1886
6. The European Patent Convention, (EPC) 1973
7. WIPO Copyright Treaty (WCT), 1996
8. Agreement between the World Intellectual Property Organization and the World Trade Organization (1995).

9. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (1994).
10. Paris Convention for the Protection of Industrial Property (1967).
11. WTO Understanding on Rules and Procedure Governing the Settlement of Disputes (1994).
12. Patent Cooperation Treaty (1970)
13. Technical Barriers to Trade Agreement (1995)
14. Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)
15. Declaration on the TRIPS Agreement and Public Health, DOHA WTO MINISTERIAL 2001: TRIPS WT/MIN (01) /DEC/2, 20 November 2001
16. Ministerial Declaration: Ministerial Conference 4th Session, Doha 9-14 November, 2001, WT/ MIN (01) /DEC/1.

E. Bangladeshi Legislations

1. Constitution of the People's Republic of Bangladesh (as amended up to September 17, 2014)
2. Bangladesh Biodiversity Act, 2017 (Act no. 2 of 2017) [2017]
3. The Drugs (Control) Ordinance, 1982 (Ordinance No. VIII of 1982) [1982]
4. The Drugs Act, 1940 (XXIII of 1940) [1940]
5. Anti-Terrorism Act, 2009 (Act No. 16 of 2009) [2009]
6. The Information and Communication Technology Act, 2006 (Act no. 39 of 2006) [2006]
7. Money Laundering Prevention Act, 2012 (Act no. 5 of 2012) [2012]
8. Mutual Cooperation Regarding Matters Related to Crime Act, 2012 (Act no. 4 of 2012) [2012]
9. The Laws Continuance Enforcement Order dated April 10, 1971, [1971]

10. Bangladesh Laws (Revision and Declaration) Act, 1973 (Act No. VII of 1973) [1973]
11. The Patents and Designs Act, 1911 (Act No. II of 1911) as amended up to 2005. [1911]
12. The Patents and Designs Rules, 1933 [1933]
13. The Copyright Act, 2000 [2000]
14. The Copyright Rules, 2002 [2002]
15. The Bangladesh Draft Patents and Designs Act, 2001 [2001]
16. The Draft Patents and Designs Act, 2012 [2012]
17. The Draft Bangladesh Patent Act, 2015 [2015]
18. National Institute of Biotechnology Act, 2010 (Act no. 10 of 2010) [2010]
19. Competition Act, 2012 (Act no. 23 of 2012) [2012]
20. The Safe Food Act, 2013 (Act no. 43 of 2013) [2013]
21. The Agricultural Produce (Grading and Marketing) Act, 1937 (Act No. I of 1937) [1937]
22. The Agricultural Pests Ordinance, 1962 (East Pakistan Ordinance No. VI of 1962) [1962]
23. The Agricultural Produce Markets Regulation Act, 1964 (East Pakistan Act No. IX of 1964) [1964]
24. The Geographical Indications of Goods (Registration and Protection) Act, 2013 (Act No.54 of 2013) [2013]
25. The Seeds Ordinance, 1977 (Ordinance No. XXXIII of 1977) [1977]
26. Seed Rules, 1998 [1998]
27. The Import Policy Order, 2012-2015 [2015]
28. The Seeds Act, 2013 (Draft) [2013]
29. The Plant Varieties Act, 1998 (Draft) [1998]
30. Biodiversity and Community Knowledge Protection Act, 1998 (Draft) [1998]

F. Bangladeshi Policy

1. National Drug Policy 2005,
2. The National Drug Policy of Bangladesh 1982
3. National Agriculture Policy 2013
4. The Seed Policy 1993
5. Export Policy 2015-18
6. National Information and Communication Technology Policy-2015

G. Foreign Legislations

1. Intellectual Property Act (Act No. 36 of 2003 of Sri Lanka) [2003]
2. Patents Act 1983 [1983]
3. The Pakistan Patent Ordinance, 2000. [2000]
4. Japanese Patent Act, 1959 as amended up to 2008, [2008]
5. Patent Law of the People's Republic of China as amended up to 2008 [2008]
6. Plant Quarantine Act, 1976 of Malaysia, Laws of Malaysia, Act 167. [1967]
7. The Indian Patent Act, 1970 as amended up to 2005 [2005]
8. The Patents (Amendment) Act, 2005 of India [2005]
9. U.S. Patent Act-35 USCS Sects. 1-376
10. Canadian Patent Act JUS-96-460-01