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Globalizing Standard of Patent Protection in WTO Law and Policy Options for the LDCs: The Context of Bangladesh

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GLOBALIZING STANDARD OF PATENT PROTECTION IN WTO LAW AND POLICY OPTIONS FOR THE LDCS: THE CONTEXT OF BANGLADESH

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INTRODUCTION

This Article analyzes the globalizing standard of patent protection as adopted under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization (WTO) and possible options for the Least Developed Countries (LDCs)[1] such as Bangladesh against the experiences of Brazil, India, and South Africa with special reference to pharmaceutical patent issues. The developed member countries of the WTO negotiated mandatory protections for pharmaceutical products and processes in the TRIPS Agreement on the basis that such mandatory protections will provide the necessary incentives for continued pharmaceutical innovation. In contrast, the developing countries and LDCs argued that enacting patent laws that comply

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[1] "There are no WTO definitions of 'developed' or 'developing' countries." *Least-developed Countries*, Understanding the WTO: The Organization, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm (last visited Apr. 27, 2014). "The WTO recognizes as [LDCs] those countries which have been designated as such by the United Nations. There are currently 48 [LDCs] on the UN list, 33 of which to date have become WTO members." *Id.* According to the United Nations, LDCs are countries that exhibit the lowest indicators of socioeconomic development, with the lowest human development index (HDI) ratings of all countries in the world. A country is classified as an LDC if it meets three criteria based on low income (three-year average gross national income (GNI) per capita of less than $992, which must exceed $1,190 to leave the list), human resources weakness (based on indicators of nutrition, health, education and adult literacy) and economic vulnerability (based on instability of agricultural production, instability of exports of goods and services, economic importance of non-traditional activities, merchandise export concentration, handicap of economic smallness, and the percentage of population displaced by natural disasters). *Id.* However, countries "graduate" out of the LDC classification when indicators exceed these criteria. *Id.* See for details *Criteria for Identification and Graduation of LDCs*, UN-OHRLLS, http://unohrlls.org/about-ldcs/criteria-for-ldcs/ (last visited Apr. 27, 2014).

with the TRIPS Agreement may restrict production and supply of low-cost generic medicines by their local pharmaceutical industries or by the pharmaceutical industries in other developing countries, and hence could increase the price of pharmaceuticals to the point that pharmaceuticals may become inaccessible to their populations. Considering the costs and benefits of such a system, the implementation of the TRIPS Agreement will require a reorganization and restructuring of the intellectual property regime in the LDCs. Given the extent of the reorganization and the restructuring required, LDCs (of which Bangladesh is one) were granted an initial transition period until December, 31 2005,[2] which was later extended to July 1, 2013 to implement a TRIPS-compliant intellectual property regime within their domestic jurisdictions.[3] The extension was given after a request by the LDCs as a group, pursuant to Article 66.1 of the TRIPS Agreement. The group cited socio-economic, administrative and financial constraints and the need to create a viable technological base as reasons to justify the extension request. However, the transition period did not prove to be long enough for LDCs to introduce pharmaceutical patent protection and to take adequate measures to ensure access

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[2] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197, art. 65 (1994) [hereinafter TRIPS Agreement], *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (LDCs were given a ten-year period (until 2005) in which to become TRIPS-compliant.).

[3] The initial transition period for LDCs ended on December 31, 2005. Later, by a decision of the TRIPS Council on Tuesday, November 29, 2005, LDC members as a group were granted an extension of the transitional period for 7.5 years to apply the provisions of the TRIPS Agreement; that is, "until 1 July 2013, or until such a date on which they cease to be a least-developed country Member, whichever date is earlier." WTO COUNCIL FOR TRIPS, EXTENSION OF THE TRANSITION PERIOD UNDER ARTICLE 66.1 FOR LEAST-DEVELOPED COUNTRY MEMBERS (IP/C/40) ¶ 1 (Nov. 30, 2005), *available at* https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S001.aspx (search for Document Number 05-5671). The TRIPS Council took the decision following the request by the LDCs as a group, pursuant to Article 66.1 of the TRIPS Agreement, for a fifteen-year extension of the transition period in order for those LDCs to be able to apply the provisions of the Agreement. WTO COUNCIL FOR TRIPS, MINUTES OF MEETING HELD IN THE CENTRE WILLIAM RAPPARD ON 25-26 AND 28 OCTOBER, 29 NOVEMBER AND 6 DECEMBER 2005 (IP/C/M/49) ¶ 243 (Jan. 31, 2006), *available at* https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S001.aspx (search for Document Number 06-0444). The group had cited socioeconomic, administrative and financial constraints and the need to create a viable technological base as reasons duly motivating the request. *Id.* at ¶ 245. The Decision was negotiated between LDCs and some key developed countries during informal consultations and was adopted by the formal TRIPS Council meeting on November 29, 2005. *Id.* at ¶¶ 276, 285. However, during the consultations, several developed country members, particularly the United States, insisted that each LDC member should request an extension on an individual basis and that extensions would be granted on a case-by-case basis. *Id.* at ¶¶ 267–68.

to medicines; therefore, the Doha Declaration on the TRIPS Agreement and Public Health was adopted by the WTO Ministerial Conference of 2001 in Doha on November 14, 2001, which further extended the transitional period for LDCs to introduce pharmaceutical patent protection to January 1, 2016.[4] However, WTO members agreed on June 11, 2013 to further extend the deadline for LDCs until July 1, 2021 to protect IP under the TRIPS Agreement.[5] It is vital for the LDCs to utilize the transitional periods properly to update their patent law regimes and other supporting governmental policy options so that after the expiration of the transitional period, LDCs are able to balance pharmaceutical innovation and access to medicines.

During the TRIPS negotiations, it was argued that the principle of a balance of rights and obligations is required because IP owners need to undertake certain obligations in return for the exclusive rights conferred on them and also to allow governments to take remedial measures in the case of non-fulfilment of these obligations so that IPRs can promote industrial creativity to benefit society in general.[6] This principle was generally recognized in pre-existing IP conventions and in national laws of many countries.[7] "The acceptance of this principle was aimed at assuring the access of developing countries to modern technology, eliminating non-use, misuse or abusive use of

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[4] As per the Decision of the TRIPS Council to implement paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, LDCs shall be free to disregard the TRIPS disciplines on patents and undisclosed information with respect to pharmaceutical products, until 2016. *See* WTO, *Ministerial Declaration of 14 November 2001*, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration], *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm; WTO COUNCIL FOR TRIPS, EXTENSION OF THE TRANSITION PERIOD UNDER ARTICLE 66.1 OF THE TRIPS AGREEMENT FOR LEAST-DEVELOPED COUNTRY MEMBERS FOR CERTAIN OBLIGATIONS WITH RESPECT TO PHARMACEUTICAL PRODUCTS (IP/C/25) (June 1, 2002), WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm.

[5] However, this decision will not prejudice the extension of pharmaceutical patents granted under the Doha waiver, and LDCs can seek further extensions of that period. *See* WTO COUNCIL FOR TRIPS, EXTENSION OF THE TRANSITION PERIOD UNDER ARTICLE 66.1 FOR LEAST DEVELOPED COUNTRY MEMBERS (IP/C/64) (June 12, 2013), *available at* http://www.wto.org/english/tratop_e/trips_e/ta_docs_e/7_1_ipc64_e.pdf.

[6] Negotiating Group on TRIPs, Including Trade in Counterfeit Goods, *Meeting of Negotiating Group of 11-13 September 1989*, GATT Doc. MTN.GNG/NG11/15 ¶ 20 (Oct. 26, 1989), *available at* http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCsQFjAA&url=http%3A%2F%2Fwww.wto.org%2Fgatt_docs%2FEnglish%2FSULPDF%2F92080131.pdf&ei=XR9MU9m9AuiqyAHs0oGQBQ&usg=AFQjCNFvdhfireMHtd-bUZ3G43ICQKeoDg&sig2=RGcwDBsTNc_vgAHEL5_ezQ.

[7] *See* MICHAEL BLAKENEY, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A CONCISE GUIDE TO THE TRIPS AGREEMENT (INTELLECTUAL PROPERTY IN PRACTICE) (1998).

intellectual property rights, especially with a view to avoiding trade distortions, and allowing the flexibility in the intellectual property protection for the public interest and the developmental and technological needs of developing countries" and LDCs.[8]

Therefore, the principle of balance of rights and obligations could be used while also using other flexibilities of the TRIPS Agreement. It was further suggested that the TRIPS Agreement should take into account the application of the General Agreement on Trade and Tariffs (GATT) principle of securing a balance of rights and obligations among parties.[9] However, as in the case of the principle of public interest, the application of the principle of balance of rights and obligations was adopted with the lock of the consistency test. As worded in TRIPS Article 8.2, any measure taken under the umbrella of this article must be "consistent with" the provisions of the TRIPS Agreement.[10] Moreover, to what extent a practice is regarded as "unreasonably" restraining trade or "adversely" affecting the international transfer of technology, and to what extent a national response against such practices is regarded as an appropriate measure are ambiguous questions under this article. These unclear conditions leave room for interpretation but, otherwise, give rise to the difficulty in applying the principle of balance of rights and obligations. Considering the room for interpretation of TRIPS flexibilities and practices for countries like India, Brazil and South Africa, this Article explores possible options for Bangladesh while it complies with the patent provisions under the TRIPS Agreement.

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[8] Pham Hong Quat, How to Comply with the TRIPS and WTO Law: The New Challenges to Vietnam's Patent Legislation from WTO Dispute Settlement Practice 42 (Dec. 2006) (unpublished dissertation, Nagoya University), *available at* http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CC0QFjAA&url=http%3A%2F%2Fiprenforcement.most.gov.vn%2Fckfinder%2Fuserfiles%2Ffiles%2FHow%2520to%2520Comply%2520with%2520the%2520TRIPS%2520and%2520WTO%2520Law(2).pdf&ei=J5ZqU5ODPcSlyASb5ILADw&usg=AFQjCNHAkYdpepkK9NI9D8olsQH0fvqKYQ&sig2=KLYdAQBwvA1lG--qkVLowA.

[9] *See* Negotiating Group on TRIPs, Including Trade in Counterfeit Goods, Meeting of Negotiating Group of 10–21 September 1990, MTN.GNG.NG11/25 ¶ 8, *available at* http://www.wto.org/gatt_docs/English/SULPDF/92110158.pdf.

[10] TRIPS Agreement, *supra* note 2, art. 8.2.

Brazil, India, and South Africa used TRIPS flexibilities in different ways to change their national patent regimes to become TRIPS compliant,[11] but they experienced some difficulties with respect to the legislative measures they enacted.[12] However, the legislative provisions were found to be within the scope of the flexibilities of the TRIPS Agreement. Bangladesh, as an LDC, faces public health challenges including lack of access to medicine due to high cost and in some instances inadequate supply, but Bangladesh has the potential to become a substantial (global) producer of generic medicines. The need to balance these competing interests (pharmaceutical innovation and access to pharmaceuticals) highlights that there may be good grounds for Bangladesh to

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[11] For example, Brazil implemented a system of compulsory licensing. See Kenneth C. Shadlen, *The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Activism* 42 J. COMP. POL., Oct. 2009, at 41. Conversely, India's experience was very different. India entered the WTO in 1995 and went through a long amendment process to institute a TRIPS-compliant patent regime, which became effective on January 1, 2005. Prabhu Ram, *India's New "TRIPs-Compliant" Patent Regime: Between Drug Patents and the Right to Health*, 5 CHI.-KENT J. INTELL. PROP. 195, 195 (2006). The impact of stronger intellectual patent rights created problems for the larger Indian drug firms and greatly damaged the ability of smaller local firms to meet the rising costs of royalties and remuneration of experienced and efficient pharmacists and other technical people. *See* Stephen Barnes, Note, *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa*, 91 KY. L.J. 911, 924–25 (2003).

[12] For example, the Dispute Settlement Body (DSB) of the WTO set a panel, as requested by the United States, to go into the complaint about the patent laws of Brazil in 2001, which the United States said illegally required the local working of patents and enabled compulsory licensing of the patent or the authorization of imports of the patented product (parallel imports) without the authorization of the patent holder. *See Brazil – Measures Affecting Patent Protection*, Dispute Settlement: Dispute DS199, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm (last visited Apr. 27, 2014). However, due to huge public pressure and campaigns by public-health groups, both parties negotiated it outside the DSB. *See id.* Conversely, Indian patent law was challenged even in the Indian Court by an MNPC, Novartis, claiming that it was inconsistent with some of the provisions of the TRIPS Agreement. Rajshree Chandra, *The Role of National Laws in Reconciling Constitutional Right to Health with TRIPS Obligations: An Examination of the Glivec Patent Casein India*, *in* INCENTIVES FOR GLOBAL PUBLIC HEALTH-PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES 392–94 (Thomas Pogge, Matthew Rimmer, & Kim Rubenstein eds., 2010). Another major concern is the confiscation of generic Indian medicines used to treat illnesses such as AIDS and hypertension in several European countries, regarding which India and Brazil complained to the WTO saying that the European Union had wrongfully confiscated generic medicines. *See* Jennifer M. Freedman, *India, Brazil Complain at WTO Over EU Drug Seizures*, BUSINESS WEEK (May 12, 2010), http://web.archive.org/web/20100515054911/http://www.businessweek.com/news/2010-05-12/india-brazil-complain-at-wto-over-eu-drug-seizures-update3-.html (accessed by searching http://www.businessweek.com/news/2010-05-12/india-brazil-complain-at-wto-over-eu-drug-seizures-update3-.html in the Internet Archive index).

use the Indian, Brazilian, and South African experiences as a way to guide Bangladesh's legislative transition to a TRIPS-compliant patent regime. It is crucial for Bangladesh to use the experiences of Brazil, India, and South Africa to develop IPR policies that preserve the full complement of TRIPS flexibilities. In this regard, a comment by Rochelle Cooper Dreyfuss is worth noting: "These practices [of India, Brazil, South Africa, and other developing countries] achieve international recognition as they are defended in international courts and put on the agendas of international organizations."[13] Therefore, "domestic actors then may interpret the law in a particular way that allows them to offer a new approach that others may choose to emulate."[14] While evaluating the possible policy options for LDCs such as Bangladesh to balance pharmaceutical innovation and access to medicines against the experiences of Brazil, India, and South Africa for complying with the TRIPS-compliant patent law, relevant discussions, policies, and recommendations as formulated in the WHO have also been indicated.

This Article explores possible legislative and governmental intervention options for Bangladesh utilizing the experiences of Brazil, India, and to some extent, South Africa. It also reflects on the relevant policy issues and recommendations from the WHO. This Article uses legal doctrinal analysis, comparative review, and field research in Bangladesh using surveys and interviews to understand the perceptions of different stakeholders regarding different policy options available under the TRIPS Agreement.[15] The field research in Bangladesh analyzed in-depth the situation at the Department of Patents, Designs and Trade Marks (DPDT)[16] and the Directorate General of

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[13] Rochelle C. Dreyfuss, *The Role of India, China, Brazil and Other Emerging Economies in Establishing Access Norms for Intellectual Property and Intellectual Property Lawmaking* 13 (Inst. for Int'l Law and Justice, Working Paper No. 09-53, 2009), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1442785.

[14] Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP*, 18 J. INTELL. PROP. L. 447, 476 (2011).

[15] To encourage participation, the survey and interview participants were promised anonymity. The author has provided as much information regarding the interview and survey participants as possible. If you would like more information on the results of the field study, please contact the author.

[16] The present legislative regime relating to the patent and pharmaceutical industry in Bangladesh comprises the Drugs Act 1940, the Patents and Designs Act 1911 and the Patent and Design Rules 1933. In 2003, amendments were made to the Patents and Designs Act 1911 to establish the Department of Patents, Designs and Trade Marks (DPDT). DEPARTMENT OF PATENTS, DESIGNS AND TRADEMARKS (DPDT), http://www.dpdt.gov.bd/index.html (last visited Apr. 27, 2014). The DPDT is controlled by the Ministry of Industries and has jurisdiction to issue patents and designs. *Id.* The current patent law in Bangladesh with respect to patents is largely the same as it was in India, prior to changes in 1970.

Drug Administration[17] (DDA or DGDA)[18] to understand the ongoing role of the two important regulatory bodies during the TRIPS waiver periods and to understand their possible role in a post-TRIPS setting.

I. LEGISLATIVE OPTIONS FOR BANGLADESH

Using the Brazilian, Indian, and South African experiences, a number of legislative options should be considered by Bangladesh in order to introduce TRIPS-compliant patent law to help preserve Bangladesh's local pharmaceutical industry and to promote innovation and access to medicine. For the purposes of this Article, the legislative options include (i) having a high threshold for patentability and exclusion from patentability provisions, (ii) having a best mode patent disclosure and disclosure of origin, (iv) narrowing the scope of patent claims, (iv) providing exceptions to product patent rights such as early working, parallel imports, and research and experimental-use exceptions, (v) having a strong compulsory licensing mechanism, (vi) having prior-use exceptions, (vii) having pre-grant and post-grant oppositions (viii) making the duration of patent protection subject to exceptions, and (ix) not adopting overprotective enforcement provisions. Each of these options will be examined in turn.

A. High Threshold and Exclusion Clause

Under the TRIPS Agreement, patent protection must be granted for products and processes which are *new,* involve an *inventive step,* and are *industrially applicable*.[19] The definition of an *invention* itself constitutes a key aspect of any patent policy with implications in other areas, such as industrial

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[17] The Directorate of Drug Administration (DDA) was the national regulatory authority in Bangladesh, which was established back in 1976 under Ministry of Health and Family Welfare and empowered to regulate "Bangladesh's 838 manufacturers of allopathic, unani, ayurvedic, herbal, homeopathic, and biochemic manufacturers' products." JUDE NWOKIKE & HYE LYNN CHOI, ASSESSMENT OF THE REGULATORY SYSTEMS AND CAPACITY OF THE DIRECTORATE GENERAL FOR DRUG ADMINISTRATION IN BANGLADESH viii (Nov. 2012). The DDA was upgraded in January 2010 to the Directorate General of Drug Administration (DGDA). *Id.* at 8. It is responsible for the production, quality, registration, safety, efficacy, import, export, and distribution of pharmaceuticals based on the power delegated to it by the different pharmaceutical regulations. *See id.*

[18] Although the DDA upgraded to DGDA in 2010, most of the government documents have yet to be replaced with the new name. Hence, this Article used DGDA and DDA interchangeably, which does not signify any major differences between the activities of former DDA and the new DGDA.

[19] TRIPS Agreement, *supra* note 2, art. 27.1 (emphasis added) (providing that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application").

and public health policies. Therefore, with countries that are net importers of technologies, their priority should be to focus on narrowing the scope of patentability in addition to incorporating as many exceptions as possible under the national patent law in order to be able to develop and create a viable technological base. This also applies in the case of pharmaceutical products.

The TRIPS Agreement did not define the criteria for patent protection; therefore, these criteria can be interpreted and applied by member states in accordance with their national priorities and developmental goals.[20] For example, the TRIPS Agreement "does not specify the patenting of new uses of known products, including pharmaceutical drugs, thus allowing member countries the possibility of rejecting these new uses for lack of novelty, inventive step or industrial applicability."[21]

The TRIPS Agreement considers novelty to mean that the invention is not already part of an existing invention and represents an inventive step.[22] Considering the importance of having a high threshold for patentability in countries like Bangladesh, Tony VanDuzer stated:

> It is a common practice of patent owners in the pharmaceutical sector to seek to extend the effective duration of patent protection by obtaining a second later patent on a new mode of delivery of a patented drug (such as capsules instead of tablets) or some other small change in a patented product. Setting high standards for novelty and inventive step would help to ensure that a patent on a product was not, in effect, extended by a subsequent patent on a trivial improvement.[23]

Justifying the non-granting of patent for new uses or second uses, Correa stated:

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[20] *See* Mohammed El Said, *The Implementation Paradox: Intellectual Property Regulation in the Arab World*, 9 J. INT'L TRADE L. & POL'Y 221, 228 (2010).

[21] *Id.* at 229.

[22] *See id*. Article 27.1 reads:

> Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. 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.

Id. (footnote omitted).

[23] Tony VanDuzer, *TRIPS and the Pharmaceutical Industry in Bangladesh: Towards a National Strategy* 33–34 (CPD Occasional Paper Series, Paper 24, 2003) (footnote omitted), *available at* http://www.bdresearch.org/home/attachments/article/nArt/TRIPS_and_the_Pharmaceutical_Industry_in_Bangladesh.pdf. *See generally* Rajnish Kumar Rai, *Patentable Subject Matter Requirements: An Evaluation of Proposed Exclusions to India's Patent Law in Light of India's Obligations Under the TRIPS Agreement and Options for India*, 8 CHI.-KENT J. INTELL. PROP. 41 (2008).

> Such an invention relating to the use of a product may be deemed as non-patentable because it consists of the discovery of an existing property rather than a new development, or because it falls under the exclusion from patentability (allowed by the [TRIPS] Agreement and most national laws) of therapeutical methods.[24]

It is feared that awarding protection to new uses of medicines will stifle innovation and restrict the ability of pharmaceutical companies in the developing countries and the LDCs to produce advanced medications needed for eradicating local disease.[25] This requirement could also block the introduction of generics, particularly in those countries where pharmacy laws do not permit generic substitution and/or generic prescribing.[26] This will have anticompetitive consequences and result in higher prices of medications.

In this regard, the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) Report provides that:

> Governments should take action to avoid barriers to legitimate competition by considering developing guidelines for patent examiners on how properly to implement patentability criteria and, if appropriate, consider changes to national patent legislation.[27]

Again, the U.K. IPRs stated that:

> Most developing countries, particularly those without researchcapabilities, should strictly exclude diagnostic, therapeutic andsurgical methods from patentability, including new uses of known products.[28]

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[24] CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES 56 (2000).

[25] *See* CARLOS CORREA, GUIDELINES FOR THE EXAMINATION OF PHARMACEUTICAL PATENTS: DEVELOPING A PUBLIC HEALTH PERSPECTIVE – A WORKING PAPER iv–v 2006), *available at* http://ictsd.net/downloads/2008/04/correa_pharmaceutical-patents-guidelines.pdf.

[26] *See id.* at 1.

[27] WORLD HEALTH ORG., PUBLIC HEALTH, INNOVATION, AND INTELLECTUAL PROPERTY RIGHTS: REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH, 133 (2006) [hereinafter CIPIH REPORT], *available at* http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0CDMQFjAB&url=http%3A%2F%2Fwww.who.int%2Fintellectualproperty%2Fdocuments%2Fthereport%2FENPublicHealthReport.pdf&ei=z2BNU9SpNsK0ygGimYHwCg&usg=AFQjCNEFMHubzvISAJ2rJRIBo5C30qlw5w&sig2=WsHxEMok1PvQdsL7HORqsA.

[28] COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 50 (2002) [hereinafter INTEGRATING REPORT], *available at* http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf. Clare Short, the then British Secretary of State for International Development, established the Commission on Intellectual Property Rights in May 2001. *Id.* at i.

On one hand, "there is no agreed international standard of absolute novelty, and, within limits, the developing countries may pick and choose from among the different approaches recognized in the domestic patent laws."[29] However, the manner of dealing with the issue of the scope of patentability differs from one country to another because this issue heavily relies on each country's level of progress, development, and technological capability.

Furthermore, in addition to the flexibility awarded in drafting the patentability criteria, the TRIPS Agreement also provides for a number of exemptions which may be excluded from patentability. Article 27.2 of TRIPS states:

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health orto avoid serious prejudice to the environment, provided thatsuch exclusion is not made merely because the exploitation is prohibited by their law.[30]

The fact that the TRIPS Agreement does not define protect *ordre public* and morality gives member states additional room for flexibility.

The existing patent law of Bangladesh, the Patents and Designs Act 1911 (PDA), contains no legislative provision regarding the patentability of a pharmaceutical product and contains no provision detailing excluded categories of inventions. By defining thresholds for novelty so as to impose a significant requirement for novelty, Bangladesh could ensure that trivial improvements in technology would not receive patent protection. India adopted such an approach when it amended its Patent Act in 2005.[31] The Indian Patent Act now restricts the scope for granting patents based on frivolous claims.[32] The Indian Patent Act 2005 clarifies that an "inventive step" means a feature of an invention that "involves technical advances as compared to the existing knowledge or having economic significance or both."[33] It also provides a definition for "pharmaceutical substance" as being "a new entity involving one or more inventive steps."[34] Further, the Indian Patent Act 2005 provides that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy" is not patentable.[35]

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[29] J.H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. INT'L L. & POL. 11, 30 (1997).

[30] TRIPS Agreement, *supra* note 2, art. 27.2.

[31] *See* Reichman, *supra* note 29, at 93 n.62.

[32] K. Gopakumar, *Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime*, 3 LAW & DEV. REV. 326, 334 n.31 (2010).

[33] The Patents Act, 1970, § 2(ja), No. 39, Acts of Parliament, 1970 (India).

[34] *Id*. at § 2(ta).

[35] *Id*. at § 3(d).

In an attempt to ensure access to medicine, section 3(b) of the Indian Patent Act 2005 excludes from patentability "an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment."[36] Section 3(p) also excludes patenting of "an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components."[37] This provision is an attempt to avoid bio-piracy and ensure that traditional knowledge, whether handed down or developed, is incapable of being captured by patents. One interview participant commented that Section 3 of the Indian Patent Act 2005 is a powerful instrument to prevent frivolous patents and the abuse of traditional knowledge and resources in India.[38]

Given the absence of patentability and exclusion clauses in the existing patent law of Bangladesh, such legislative provisions should be considered by Bangladesh as it moves toward TRIPS compliance. Such legislative provisions are in compliance with the TRIPS Agreement, and are justified on the basis that limiting the availability of patents should promote competition in the local market.[39] However, in the 2010 Draft Patents and Designs Act of Bangladesh (Draft PDA)[40] there are provisions on patentable inventions[41] and exclusion from patentability.[42] Unlike the Indian patent law provisions, these provisions failed to utilize the high threshold of patentability options effectively because they lack a provision covering pharmaceutical substances, an exclusion clause pertaining

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[36] The Patents (Amendment) Act, 2005, § 3(b), No. 15, Acts of Parliament, 2005 (India).

[37] *Id.* at § 3(p).

[38] Email interview with a patent law academic in Delhi, India (Mar. 10, 2012).

[39] *See generally* Mohammad M. Azam & Kristy Richardson, *Trips Compliant Patent Law and the Pharmaceutical Industry in Bangladesh: Challenges and Opportunities*, LAWASIA J. 141 (2010).

[40] In 2001, a draft patent law was prepared by the Law Commission of Bangladesh in consultation with WIPO. It was not considered until 2007. Meanwhile, transitional periods for the introduction of TRIPS-compliant intellectual property law including patent law was extended for LDCs until July 2013, and the obligation to introduce pharmaceutical patents was extended until January 1, 2016 for LDCs. *Developing Countries' Transition Periods*, FACT SHEET: TRIPS and Pharmaceutical Patents, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm04_e.htm (last visited Apr. 27, 2014). This Draft was reviewed lightly in 2007, and it was under consideration by the Ministry of Law and Parliamentary Affairs of Bangladesh as the Draft Patents and Designs Act, 2010. It is translated by the Law Commission and Ministry of Law into national language "Bangla" with little revision and adopted a separate draft Act in "Bangla" for patents only as Bangladesh Patent Ain, 2012 (Bangladesh Patent Act, 2012). Unless this Draft is approved by the Parliament of Bangladesh, the existing Patents and Designs Act, 1911 will remain in force.

[41] Draft Patents and Designs Act, 2010 § 3, 2010 (Bangl.).

[42] *Id.* at § 4.

to mere improvement, and protection from abuse of traditional knowledge. The Draft PDA tried to extend the ambit of prior art under the definition of novelty:

> (2) Prior art in the case of an invention shall be taken to comprise-
>
> (a) all matter, whether a product, a process, information about either, or anything else, made available to the public anywhere in the world, by written or oral description, by use or in any other way, at any time prior to the filing or, as the case may be, the priority date, of the application for patent claiming the invention.[43]

However, this provision may not be effective without a specific exclusion clause; therefore, these provisions should be revised in light of the Indian Patent Act 2005.

Local pharmaceutical companies in Bangladesh view this provision as very important for generic producers and consumers because it will increase competition in the local market.[44] However, multinational pharmaceutical companies (MNPCs) argue that a high threshold for patentability will exclude local inventions from patentability, which would not benefit society.[45] The middle ground would suggest that such a provision will balance the need to maintain and support innovation with the need for access to pharmaceuticals.

B. Best Mode Disclosure and Disclosure of the Source of Genetic Resources and Traditional Knowledge

Because the aim of the patent regime is the disclosure of information and spread of knowledge, a "[l]ack of sufficient disclosure may be a reason for refusal result in the rejection of an application or invalidation of a patent."[46] Correa stresses that "[t]his requirement has particular importance in the chemical and pharmaceutical fields to enable the reproduction of the invention during the patent term (for instance, in the case of a compulsory license) or after patent's expiry."[47]

Article 29 of the TRIPS Agreement requires that an applicant for a patent disclose the invention "in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art."[48] This "may also require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date."[49]

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[43] *Id.* at § 5(2).

[44] Based on the survey data, this position has been supported by the majority of large, medium, and small local pharmaceutical companies in Bangladesh.

[45] This has been remarked by a CEO of an MNPC operating in Bangladesh.

[46] Correa, *supra* note 26, at 4.

[47] *Id.*

[48] TRIPS Agreement, *supra* note 2, art. 29.

[49] *Id.*

The absence of high disclosure requirements will have long-term negative implications upon innovation, technology transfer, and the dissemination of technology in the pharmaceutical sector in developing countries.[50] It will likely strengthen the monopolistic position of MNPCs by preventing local pharmaceutical companies from benefiting from the disclosed technical information and precluding efforts in research and development (R&D) based on that information.[51]

Section 4(2) of the PDA in Bangladesh simply provides that "a complete specification must particularly describe and ascertain the nature of the invention and the manner in which the same is to be performed."[52] Bangladesh should take advantage of Article 29 of the TRIPS Agreement by requiring disclosure of the best known mode for carrying out the invention and also that the disclosure enable the execution of all embodiments of the invention.

During an interview, one participant argued that, given the weakness of the existing provisions, patent applications in Bangladesh are typically ambiguous. Often it is difficult to ascertain a precise description of the invention, which ultimately frustrates the objective of granting of a patent in exchange for sufficiently disclosing the invention to contribute to technical learning and teaching.[53] One participant argued that the ultimate benefit of disclosure of an invention is the further development of that particular invention, which leads to increased competition in the marketplace; therefore, after the expiry of the patent term, competitors can enter the market with more viable options.[54]

Both India and Brazil have adopted the best mode disclosure approach. Section II, Article 24 of the Brazilian Industrial Property Law provides that the "specifications shall clearly and sufficiently describe the object, so as to permit its reproduction by a technician versed in the subject, and shall indicate, when

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[50] *Id.*

[51] *See generally* Bingbin Lu, *Best Mode Disclosure for Patent Applications: An International and Comparative Perspective*, 16 J. INTELL. PROP. RTS. 409 (2011), *available at* http://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID1938859_code381567.pdf?abstractid=1938859&mirid=1.

[52] Patents and Designs Act, 1911, § 4, effective Mar. 26, 1971 by virtue of the Laws Continuation and Enforcement Order of March 25, 1971, and adaptation of Existing Bangladesh Law Order of 1972. The Patents and Designs Act, 1911 is the same as Indian Patents and Designs Act, 1911 (No. II of 1911 (10 Pat. & T.M. Rev. 3697)).

[53] Interview with a pharmacist working in a leading local pharmaceutical company in Bangladesh, in Dhaka, Bangl. (Mar. 3, 2009).

[54] Interview with an examiner at the DPDT, in Dhaka, Bangl. (Mar. 1, 2009).

applicable, the best way of doing it."[55] On the other hand, section 10(4) of the Indian Patent Law in 1970 provides that every complete specification shall:

> a. fully and particularly describe the invention and its operation or use and the method by which it is to be performed;
> b. disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection.[56]

Therefore, Bangladesh should adopt a similar requirement to facilitate innovation and the development of competing products. It is worth noting that section 11 of the Draft PDA of Bangladesh included a provision which, in part, requires that:

> (4) Every complete specification-
>
> (a) shall fully and particularly describe the invention and the method by which it is to be performed;
> (b) shall disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection.[57]

Adoption of this provision would help the DPDT of Bangladesh to reject patent applications if the inventions are not sufficiently disclosed.

However, best mode disclosure does not necessarily require disclosure of origin, and hence may not prevent abuse of genetic resources and traditional. This led to a number of developing countries including by Brazil and India[58] to debate in the WTO the question of "whether and how patent applicants should be obliged to disclose the origin or source of the genetic resource and traditional knowledge used in an invention and provide evidence of prior informed consent and benefit sharing."[59] Because TRIPS Article 29 does not specifically required disclosure of origin, developing countries are requesting amendments to the

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[55] Lei No. 9.279 art. 24, de 14 de maio de 1996, Diario Oficial Da Uniao [D.O.U.] de 15.05.1996. (Braz.), translated in Brazil: Industrial Property Law, 14/05/1996, No. 9.279, http://www.wipo.int/wipolex/en/details.jsp?id=515 (last visited Mar. 24, 2014).

[56] The Patents Act, 1970, § 10(4), No. 39, Acts of Parliament, 1970 (India), *available at* http://ipindia.nic.in/ipr/patent/patent_2005.pdf.

[57] Draft Patents and Designs Act, 2010 § 11, 2010 (Bangl.).

[58] *See* WTO COUNCIL FOR TRIPS, ELEMENTS OF THE OBLIGATION TO DISCLOSE THE SOURCE AND COUNTRY OF ORIGIN OF BIOLOGICAL RESOURCE AND/OR TRADITIONAL KNOWLEDGE USED IN AN INVENTION (IP/C/W/429) 2 (Sept. 21, 2004), *available at* http://docsonline.wto.org/imrd/directdoc.asp?DDFDocuments/t/IP/C/W429.doc.

[59] *See* WTO PUBLIC SYMPOSIUM, DISCLOSURE REQUIREMENTS: INCORPORATING THE CBD PRINCIPLES IN THE TRIPS AGREEMENT ON THE ROAD TO HONG KONG ¶ 1 (Apr. 21, 2005), *available at* http://ictsd.org/downloads/2008/12/meeting-report.pdf.

TRIPS Agreement to ensure that the necessary requirements are incorporated into patent application procedures.[60]

On the other hand, Switzerland also made proposals relating to disclosure of origin to the WTO/TRIPS Council,[61] to the WIPO Working Group on Reform of the Patent Cooperation Treaty (PCT),[62] and to the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).[63] In Switzerland's opinion, "the provisions of the TRIPS Agreement provide for adequate flexibility with regard to a formal requirement to disclose the source. Accordingly, Switzerland does not consider it necessary to amend the TRIPS Agreement."[64] Consequently, it can be said that TRIPS Article 29 does not prevent the introduction of the requirement to

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[60] Tove Iren S. Gerhardsen, *Developing Countries Propose TRIPS Amendment on Disclosure*, INTELLECTUAL PROPERTY WATCH (June 1, 2006, 1:44 PM), http://www.ip-watch.org/2006/06/01/developing-countries-propose-trips-amendment-on-disclosure/.

[61] *See* WTO COUNCIL FOR TRIPS, ARTICLE 27.3(B), THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CBD, AND THE PROTECTION OF TRADITIONAL KNOWLEDGE (IP/C/W/400/Rev.1) (June 18, 2003), *available at* http://docsonline.wto.org/imrd/directdoc.asp?DDFDocuments/t/IP/C/W400R1.doc; *see also* WTO COUNCIL FOR TRIPS, FURTHER OBSERVATIONS BY SWITZERLAND ON ITS PROPOSALS REGARDING THE DECLARATION OF THE SOURCE OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS (IP/C/W/433) (Nov. 25, 2004), *available at* http://docsonline.wto.org/imrd/directdoc.asp?DDF Documents/t/IP/C/W433.doc.

[62] WORKING GROUP ON REFORM OF THE PATENT COOPERATION TREATY (PCT), WIPO, INTERNATIONAL PATENT COOPERATION UNION, PROPOSALS BY SWITZERLAND REGARDING THE DECLARATION OF THE SOURCE OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS (PCT/R/WG/4/13) (May 5, 2003) *available at* www.wipo.int/edocs/mdocs/pct/en/pct_r_wg_4/pct_r_wg_4_13.pdf; WORKING GROUP ON REFORM OF THE PATENT COOPERATION TREATY (PCT), WIPO, INTERNATIONAL PATENT COOPERATION UNION, PROPOSALS BY SWITZERLAND REGARDING THE DECLARATION OF THE SOURCE OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS (Doc PCT/R/WG/5/11 Rev.) (Nov. 19, 2003), *available at* http://www.wipo.int/edocs/mdocs/pct/en/pct_r_wg_5/pct_r_wg_5_11_rev.pdf.

[63] *See* WIPO INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY, AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE, AND FOLKLORE, FURTHER OBSERVATIONS BY SWITZERLAND ON ITS PROPOSALS REGARDING THE DECLARATION OF THE SOURCE OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS (WIPO/GRTKF/IC/7/INF/5) (Oct. 18, 2004), *available at* http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_7/wipo_grtkf_ic_7_inf_5.pdf.

[64] Felix Addor, WTO Public Symposium, ICTSD/CIEL/IDDRI/IUCN/QUNO Dialogue on Disclosure Requirements: Incorporating the CBD Principles in the TRIPS Agreement on the Road to Hong Kong: Switzerland's Proposals Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications and Switzerland's Views on the Declaration of Evidence of Prior Informed Consent and Benefit Sharing in Patent Applications 5 (Apr. 21, 2005), *available at* http://www.iprsonline.org/ictsd/docs/DOO6_Addor.pdf.

disclose the source within the national legislation.[65] In the context of Bangladesh during field studies, one participant argued that "in the absence of qualified and experienced examiners, best mode disclosure and disclosure of origin provisions would have little effect."[66]

However, in Bangladesh, neither the existing PDA nor the Draft PDA of 2010 includes any provision on the disclosure of origin. But the Draft Patent Law of 2012 states under section 15 that patents on genetic resources or traditional knowledge could be granted provided that the procedure of "relevant authority and related rules" is followed, and, before granting such patent, due consideration must be given to the issues of public order and morality.[67] But, there is no explanation or indication in the draft law regarding "relevant authority and rules," and also there is no existing authority or rules in Bangladesh that deal with the issues of genetic resources or traditional knowledge. Therefore, Bangladesh should amend the proposed law, preferably to include disclosure of origin as part of patent application requirement rather than in separate provision.

In addition to high-level disclosure, limiting the scope of patent claims may also be useful for Bangladesh.

C. Narrow the Scope of Patent Claims

In a 2003 report, Tony VanDuzer stated:

> The broader the claims that an inventor can make under [a patent] law, the wider the monopoly the inventor can obtain. Broad claims reduce the scope for competing products in the market, whereas narrow claims create greater opportunities for innovation and competition. National laws vary in the nature and breadth of claims permitted. In relation to pharmaceutical products claims can be restricted to the chemical structure or composition of a new product. . . . The TRIPS Agreement is silent on the form of and limits on allowable claims and so Bangladesh would be free to adopt a patent law that requires that pharmaceutical patent claims be limited to the precise chemical composition of the product.[68]

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[65] "A number of countries . . . have already [incorporated] disclosure of origin requirements (in different forms and conditions) in their domestic legislation, including in the Andean Community (Bolivia, Colombia, Ecuador, Peru and Venezuela), Brazil, Costa Rica, Denmark, India, Nepal, Norway and the African Union (53 African countries)." DISCLOSURE REQUIREMENTS: ENSURING MUTUAL SUPPORTIVENESS BETWEEN THE WTO TRIPS AGREEMENT AND THE CBD 9 (Martha Chouchena-Rojas et al. eds., 2005).

[66] Interview with an IP lawyer working as a legal adviser and practitioner at the Supreme Court, in Dhaka, Bangl. (Dec. 27, 2009).

[67] *See* Draft Patent Act, 2012 § 15, 2012 (Bangl.) (available only in Bangla), *available at* http://www.moind.gov.bd/index.php?option=com_docman&task=doc_download&gid=821&Itemid=236.

[68] Tony VanDuzer, *supra* note 23, at 33.

Section 4(3) of the PDA of Bangladesh provides that a specification, whether provisional or complete, must commence with the title, and in the case of a complete specification must end with a distinct statement of the invention claimed.[69] Based upon this provision, the law is not able to facilitate the narrowing of coverage of pharmaceutical patents, but rather encourages applications for broad patents. By way of comparison, Brazilian legislation provides that "[t]he claims shall be substantiated in the specifications, characterizing the particulars of the application, and clearly and precisely defining the subject matter that is the object of the protection."[70] During an interview, one participant argued that most of the pharmaceutical patents granted in Bangladesh prior to suspension of pharmaceutical patents in 2008 were based on broad claims, which in the future may restrict the production of generic pharmaceuticals.[71] Therefore, Bangladesh should adopt provisions similar to Brazil's that narrow the ability to claim a pharmaceutical patent so as to restrict patenting on broad claims. However, to encourage further development and innovation on any patented product, additional exceptions are necessary to facilitate generic competition and cheaper products for the consumers. Such exceptions include early working, a research and experimental use exception and parallel imports.

D. Provide Exceptions to Product Patent Rights

Patent rights are not absolute but rather are subject to certain limitations and exceptions. These limitations and exceptions are often designed to foster and promote technology transfer, to prevent the abuse of intellectual property, to foster research and innovation, and to protect public policy priorities including public health.

Article 30 of the TRIPS Agreement permits member countries to "provide limited exceptions to the exclusive rights conferred by a patent."[72] This article does not list the specific acts for which exceptions can be provided. What it says is that such exceptions should satisfy certain conditions that do not "unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[73] The TRIPS Agreement does not contain any explanation of the terms "limited exceptions," "unreasonably conflict" or "legitimate interests" and "hence the use of this

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[69] The Patents and Designs Act, 1911 § 4(3), 1911 (Bangl.).

[70] Lei No. 9.279 art. 25, de 14 de maio de 1996, Diario Oficial Da Uniao [D.O.U.] de 15.05.1996. (Braz.), translated in Brazil: Industrial Property Law, 14/05/1996, No. 9.279, http://www.wipo.int/wipolex/en/details.jsp?id=515 (last visited Mar. 24, 2014).

[71] Interview with a pharmaceutical researcher at the University of Dhaka, in Dhaka, Bangl. (Mar. 12, 2009).

[72] TRIPS Agreement, *supra* note 2, art. 30.

[73] *Id*.

provision depends on the interpretation of these conditions."[74] There are two exceptions used by India and Brazil in their legislative framework: (i) early working (Bolar exceptions) and research and experimental use and (ii) parallel importing.

E. Early Working (or Bolar Exceptions) and Research and Experimental Use

The early working exemption is commonly referred to as the "Bolar" provision or exception, as it derives from *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,[75] which concerned the manufacturing of generic pharmaceuticals. Bolar Pharmaceutical was the generic drug manufacturer and Roche Products was the pharmaceutical company that made and sold Valium, the active ingredient of which was patented.[76] Before the patent expired, Bolar used the patented chemical in experiments to determine if its generic product was the bioequivalent to Valium, and, therefore, could obtain U.S. FDA approval for its generic version.[77] Bolar argued that its use of the patented product was not an infringement based on the experimental use exception and that public policy favored the availability of generic drugs immediately following a patent's expiration.[78]

"The Court of Appeals for the Federal Circuit rejected Bolar's contention holding that the experimental use exception did not apply because Bolar intended to sell its generic product in competition with Roche's Valium after patent expiration and, therefore, Bolar's experiments had a business purpose," and did not qualify for the statutory exception.[79] The Court recognized that any change to the patent law needed to be made by Congress.[80]

Shortly after *Bolar Pharmaceutical* was decided, Congress passed a law permitting the use of patented products in experiments for the purpose of obtaining FDA approval.[81] As a result of this change, exceptions for early

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[74] Mohammad Monirul Azam & Yacouba Sabere Mounkoro, *Intellectual Property Protection for the Pharmaceuticals: An Economic and Legal Impacts Study with Special Reference to Bangladesh and Mali*, LE GRIOT DU DEVELOPPEMENT § 7.1.2 (June 1, 2012), http://legriotdudeveloppement.blogspot.com/2012/06/intellectual-property-protection-for.html.

[75] Roche Prods., Inc. v. Bolar Pharm. Co., 733 F. 2d 858 (Fed. Cir. 2006); *see* Anshull Mittal, *Patent Linkage in India: Current Scenario and Need for Deliberation*, 15 J. INTELL. PROP. RTS. 187, 193 (2010).

[76] *Bolar Pharm.*, 733 F.2d at 861.

[77] *Id*. at 861–62.

[78] *Id*. at 862.

[79] Mittal, *supra* note 75, at 193.

[80] *See id*.

[81] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 15 U.S.C. §§ 68(b)–(c), 70(b) (1994); 21 U.S.C. §§ 301, 355, 360cc (1994); 28 U.S.C. § 2201 (1994); 35 U.S.C. §§ 156, 271, 282 (1994)).

working gained momentum and now Bolar exceptions have been enacted in most jurisdictions.[82]

Importantly, the WTO Dispute Panel upheld the use of the Bolar exception as being in conformity with the requirements of the TRIPS Agreement in the Canada–E.U. dispute.[83] Supporting the inclusion of an early use exception, the CIPIH Report, recommended that:

> Countries should provide in national legislation for measures to encourage generic entry on patent expiry, such as the "early working" exception, and more generally policies that support greater competition between generics,

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[82] In the United States, this exemption is also technically called the § 271(e)(1) exemption or Hatch–Waxman exemption. K. Suresh Kumar, et al., *Patent Laws and Research Exemption Imperative—Do Scientists Have Enough Freedom to Operate?*, 99 CURRENT SCI. 1488, 1524 (2010). The U.S. Supreme Court considered the scope of the Hatch–Waxman exemption in *Merck v Integra*. Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005).

> The Supreme Court held that the statute exempts from infringement *all* uses of compounds that are reasonably related to submission of information to the government under any law regulating the manufacture, use or distribution of drugs. In Canada, this exemption is known as the Bolar provision or Roche–Bolar provision, named after the case *Roche Products v. Bolar Pharmaceutical*. In the European Union, equivalent exemptions are allowed under the terms of EC Directives 2001/82/EC (as amended by Directive 2004/28/EC) and 2001/83/EC (as amended by Directives 2002/98/EC, 2003/63/EC, 2004/24/EC and 2004/27/EC).

Research Exemption, WIKIPEDIA, http://en.wikipedia.org/wiki/Research_exemption (last visited Apr. 16, 2014).

[83] Azam & Mounkoro, *supra* note 74; *see also* WTO, CANADA--PATENT PROTECTION OF PHARMACEUTICAL PRODUCTS (WT/DS114/R) 28 (Mar. 17, 2000), *available at* http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf.

> Article 30 of the TRIPS Agreement authorizes limited exceptions to patent rights for such things as research, prior user rights, and pre-expiration testing. Often called the 'research exception,' the provision is commonly used by countries to advance science and technology by allowing researchers to use a patented invention to gain a better understanding of the technology. In addition, countries also use the provision to allow manufacturers of generic drugs to apply for marketing and safety approval without the patent owner's permission and before the patent protection expires. The generic producers can then market the drug. This practice, often called the 'regulatory exception' or 'Bolar' provision, has been upheld as conforming to the TRIPS Agreement. . . . [The Panel also found] that manufacturing and stockpiling patented drugs prior to the exhaustion of patent protection is not a "limited exception" which can be exempted under Article 30.

Bryan Mercurio, *The Impact of the Australia-United States Free Trade Agreement on the Provision of Health Services in Australia*, 26 WHITTIER L. REV. 1051, 1065 n.39 (2005) (footnote and citation omitted).

> whether branded or not, as an effective way to enhance access by improving affordability.[84]

In addition to the Bolar exception, the "exception for research or experimental use of an invention also falls under the Article 30 category of exceptions.[85] This exception is extensively used in many national patent laws around the world.[86] It "allows the use of a patented product in experimentation, for both scientific as well as commercial purposes, without the consent of the patent holder. This exception plays a significant role in the process of encouraging innovation, dissemination of knowledge and transfer of technology."[87]

This kind of exception is important for maintaining and developing efficient alternatives to protect public health and to encourage innovation within the industry. The opportunity to use patented products for R&D purposes will enable the indigenous firms to be ready with efficient processes and use these whenever they are permitted to do so.

The existing patent law of Bangladesh under section 21 provides for experimental-use exceptions. However, the language and process as mentioned in the existing PDA is so ambiguous and complicated that it will have no positive effect. The law must be amended in a way to simplify the entry of generic pharmaceuticals into the market. The research and experimental provision:

> is very important for generic entry. It permits generic entry soon after the patents expire and hence allows the consumers to benefit from competition and lower prices without delay. In the absence of it, generic companies

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[84] CIPIH REPORT, *supra* note 27, at 24.

[85] MOHAMMED K. EL SAID, WORLD HEALTH ORG. & INT'L CTR. FOR TRADE & SUSTAINABLE DEV., PUBLIC HEALTH RELATED TRIPS-PLUS PROVISIONS IN BILATERAL TRADE AGREEMENTS: A POLICY GUIDE FOR NEGOTIATORS AND IMPLEMENTERS IN THE WHO EASTERN MEDITERRANEAN REGION 153 (2010), *available at* http://applications.emro.who.int/dsaf/dsa1081.pdf. See for details, CARLOS CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES (2000), *available at* http://apps.who.int/medicinedocs/pdf/h2963e/h2963e.pdf.

[86] *Id*. According to Musungu and Oh, "[n]ational laws reviewed in Latin American and Caribbean countries all contained provisions relating to the research or experimental use exception; in Asia, 85% of the national laws reviewed provided for this exception, although the figure is lower in Africa at 59%." CECILIA OH & SISULE MUSUNGU, THE USE OF FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES? 32 (Aug. 2005), *available at* http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf.

[87] El Said, *supra* note 85; *see also* CHRISTOPHER GARRISON, UNCTAD-ICTSD PROJECT ON IPRS AND SUSTAINABLE DEVELOPMENT, EXCEPTIONS TO PATENT RIGHTS IN DEVELOPING COUNTRIES 46, 49 (2006), *available at* http://ictsd.org/i/publications/11716/?view=document.

> will have to wait till [sic] the patents actually expire before they can start the tests necessary for getting regulatory approval.[88]

It will take time to get such approvals and without such an exception, "the patentee will effectively enjoy monopoly status even though there are no legal barriers to entry."[89] However, the Draft PDA tried to simplify the process stating that:

> [A]ny machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person for the sole purpose merely of experiment or research including the imparting of instruction to pupils.[90]

However, the exemption, as laid down in the Draft PDA of 2010, may not be enough if a generic producer wants to use it for experimental purposes leading to the collection of data to be submitted to the drug-approval authority for the production of on-patent drugs.[91] In the context of the terms of the legislative provision itself, guidance can be sought from section 107A(a) of the Indian Patent Act, which provides:

> [A]ny 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 . . .shall not be considered as an infringement of patent rights.[92]

In Bangladesh there are diverging opinions within the pharmaceutical industry regarding this. During interviews, most of the local pharmaceutical industry[93] strongly supported the inclusion of this provision to allow generic producers, whereas MNPCs[94] thought this may discourage investment and technology transfer in the pharmaceutical sector. One interview participant argued that, in

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[88] Azam & Mounkoro, *supra* note 74.

[89] *Id.*

[90] Draft Patents and Designs Act, 2010 § 48(c), 2010 (Bangl.).

[91] *See* Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act, 2005*, 1 INDIAN J. L. & TECH. 15, 30 (2005), *available at* http://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID942680_code339749.pdf?abstractid=764066&mirid=1.

[92] The Patent (Amendment Act) 2002, § 107A(a), 2002 (India).

[93] During the survey, most of the local pharmaceutical companies in Bangladesh irrespective of size (large, medium, or small) supported this provision.

[94] In the survey feedback, MNPCs did not answer this question, but during the interview MNPCs opposed this provision and considered that, in the long term, this may provide no benefits for Bangladesh.

the absence of a research and experimental-use provision, generic producers in Bangladesh will be restricted from experimenting with patented products.[95]

Arguably, the absence of a research and experimental-use provision encourages the high pricing of pharmaceuticals when given the monopoly of a patent holder. Therefore, the present provision in Bangladesh needs to be extended to include a similar provision to India's in order to facilitate generic entry of patented drugs as early as possible after the introduction of pharmaceutical patents in Bangladesh. As part of its transition to a TRIPS-compliant regime, the legislative option of including both an early working and a research and experimental-use exemption should be considered.

A further exemption that should be considered is the practice of permitting parallel imports.

F. Parallel Imports

The TRIPS Agreement provides that the patent owner has the exclusive right to prevent others not only from making, using or selling the invented product or process in the country, but also importing the product from other countries.[96] However, this right is subject to Article 6 of the TRIPS Agreement, which deals with the principle of "exhaustion."[97] "The principle of exhaustion states that once patentholders have sold a patented product, they cannot prohibit the subsequent resale [or import] of that product since their rights in respect of that market have been exhausted by the act of selling the product."[98] In regard to patent exhaustion as it relates to parallel imports, Sudip Chaudhuri wrote:

> Such imports of patented products without the consent of the patent holder in the importing country are known as parallel imports. This is very important in the pharmaceutical industry because the same patented medicine is often sold at different prices in different countries and hence parallel imports permit a country to shop around for the lowest price. The underlying justification of allowing parallel imports is that since the innovator has been rewarded through the first sale of the product, its patent rights have been "exhausted" and hence it should have no say over the subsequent re-sale.[99]

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[95] Interview with an official of a public health NGO, in Dhaka, Bangl. (Feb. 9, 2009).

[96] TRIPS Agreement, *supra* note 2, art. 28.1(a).

[97] TRIPS Agreement, *supra* note 2, art. 6.

[98] World Health Org., *Intellectual Property Protection: Impact on Public Health*, 19 WHO DRUG INFO. 236, 240 (2005), *available at* http://apps.who.int/medicinedocs/pdf/s7918e/s7918e.pdf.

[99] Sudip Chaudhuri, *Indian Generic Companies, Affordability of Drugs and Local Production in Africa with Special Reference to Tanzania* (Open University Research Centre on Innovation, Knowledge and Development, Working Paper No. 37, Sept. 2008), *available at* http://www.open.ac.uk/ikd/documents/working-papers/ikd-working-paper-37.pdf.

Article 6 of the TRIPS Agreement was further clarified by the Doha Declaration, which provided that each country was "free to establish its own regime for such exhaustion without challenge."[100]

There are three kinds of exhaustion regimes for the purpose of parallel imports: national, regional and international.[101] The United States has adopted "a national exhaustion principle whereby the patent owner has no control over the product once it is placed in the domestic market;" however, the patent holder "can exercise his rights outside the US market regarding the price and quantity of the product."[102] In contrast, the European Union has adopted a "regional exhaustion principle whereby the rights are exhausted within" the boundaries of the European Union.[103] By comparison, international exhaustion has no jurisdictional limit; the rights of the patent owner are exhausted once he has sold his product.[104] International exhaustion is consistent with the objective of Article 7 of the TRIPS Agreement.[105] The advantage of international exhaustion is that developing countries can scout for lower-priced patented products anywhere in

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[100] Doha Declaration, *supra* note 4, at ¶ 5(d); Chaudhuri, *supra* note 99.

[101] *See generally* Marco C.E.J. Bronckers, *The Exhaustion of Patent Rights under WTO Law*, 32 J. WORLD TRADE 137, 137–38 (1998).

[102] N. Lalitha, *Doha Declaration and Public Health Issues*,13 J. INTELL. PROP. RTS. 401, 404 (2008), *available at* http://nopr.niscair.res.in/bitstream/123456789/2026/1/JIPR%2013(5)%20401-413.pdf.

[103] *Id.*

[104] *Id.*

[105] *Id*. A submission to the World Health Organization stated:

> Article 7 is a key provision that defines the objectives of the TRIPS Agreement. It clearly establishes that the protection and enforcement of intellectual property rights do not exist in a vacuum. They are supposed to benefit society as a whole and do not aim at the mere protection of private rights" and should be utilized in a way for "the mutual advantage of producers and users of technological knowledge; social and economic welfare; and the balance of rights and obligations.

COUNCIL DISCUSSION ON ACCESS TO MEDICINES, TRIPS, DEVELOPING COUNTRY GROUP'S PAPER—SUBMISSION BY THE AFRICA GROUP, BARBADOS, BOLIVIA, BRAZIL, DOMINICAN REPUBLIC, ECUADOR, HONDURAS, INDIA, INDONESIA, JAMAICA, PAKISTAN, PARAGUAY, PHILIPPINES, PERU, SRI LANKA, THAILAND AND VENEZUELA (IP/C/W/296) ¶ 18 (June 19, 2001), *available at* http://www.wto.org/english/tratop_e/trips_e/paper_develop_w296_e.htm. Therefore:

> [e]ach provision of the TRIPS Agreement should be read in light of the objectives and principles set forth in Articles 7 and 8. Such an interpretation finds support in the Vienna Convention on the Law of Treaties (concluded in Vienna in 23, May 1969), which establishes, in Article 31, that "[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."

Id. at ¶ 17.

the world.[106] Research conducted in a number of countries supports this claim. In Kenya, for example, it was found that "parallel importation reduced the price of first-line anti-retroviral medicines to one-third of the price of the patented version."[107]

In this regard, the Report on the Commission of Intellectual Property Rights (U.K.) stated:

> Developing countries should not eliminate potential sources of low cost imports from other developing or developed countries. In order to be an effective pro-competitive measure in a scenario of full compliance with TRIPS, parallel imports should be allowed whenever the patentee's rights have been exhausted in the foreign country. Since TRIPS allows countries to design their own exhaustion of rights regimes (a point restated at Doha), developing countries should aim to facilitate parallel imports in their legislation.[108]

Moreover, the CIPIH Report, Recommendation 4.19, states that "[d]eveloping countries should retain the possibilities to benefit from differential pricing, and the ability to seek and parallel import lower priced medicines."[109]

In the context of Bangladesh, one pharmaceutical market expert argued that "international exhaustion will be of no benefit for Bangladesh; rather, it will increase counterfeiting and low-quality medicine in the local market."[110] He also indicated that allowing cheaper medicines from other alternative sources may jeopardize the entire pharmaceutical market in Bangladesh with regard to the institutional and infrastructural limitation of the DDA because it would open flood gates of different products making it impossible for the DDA to inspect and monitor all the possible cheaper pharmaceutical products.[111] However, one public health activist in Bangladesh argued that due to fear of counterfeiting, one cannot shut the door to opportunities; rather, counterfeiting can be prevented if the proper steps are taken.[112] She further remarked that in the absence of parallel imports it will create a monopoly and may threaten the adequate supply and access to affordable pharmaceuticals.[113]

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[106] Lalitha, *supra* note 102.

[107] Rohit Malpani, *All Costs, No Benefits: How TRIPS-plus Intellectual Property Rules in the US–Jordan FTA Affect Access to Medicines* 11 (Oxfam Briefing Paper No. 102, Mar. 21, 2007), *available at* http://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf.

[108] INTEGRATING REPORT, *supra* note 28, at 52.

[109] *See* CIPIH REPORT, *supra* note 27, at 124.

[110] This remark was made by an official of a leading MNPC operating in Bangladesh during an interview, in Dhaka, Bangl. (Feb. 1, 2009).

[111] *Id.*

[112] Interview with a policy analyst of an international NGO working in Bangladesh, in Dhaka, Bangl. (Mar. 1, 2012).

[113] *Id.*

The PDA of Bangladesh does not contain any provisions dealing with the legality or otherwise of parallel imports. Brazilian patent law also does not support international exhaustion.[114] However, the Indian Patent Act (under section 107) allows parallel imports and permits the import of patented drugs at the lowest available price in the global market (international exhaustion). Section 107A(b) of the Indian Patent Act provides: "Importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights."[115]

The Draft PDA of Bangladesh (2010), section 92 included the following provision:

> *Meaning of Use of Invention for Purposes of Government*
> (1) For the purposes of this chapter, an invention is said to be used for the purposes of government if it is made, used, exercised or vended for the purposes of the government or a government undertaking.
> (2) Without prejudice to the generality of the provisions of sub-Section (1) of this Section:
> (a) the importation, by or on behalf of the government, of any invention being a machine, apparatus or other article covered by a patent granted before the commencement of this Act, for the purposes merely of its own use; and
> (b) the importation, by or on behalf of the government, of any invention being a medicine or drug covered by a patent granted before the commencement of this Act:
> (i) for the purpose merely of its own use; or
> (ii) for the purpose of distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the government or in any other dispensary, hospital or other medical institution that the government may, having regard to the public service that such other dispensary, hospital or medical institution render, specify in this behalf by notification in the Official Gazette, shall also be deemed, for the purposes of this Chapter, to be use of such invention for the purposes of Government.[116]

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[114] *See* ESTHER M. FLESCH ET AL., REPORT Q 156 IN THE NAME OF THE BRAZILIAN GROUP: INTERNATIONAL EXHAUSTION OF INDUSTRIAL PROPERTY RIGHTS (XXXVIIIth World Intellectual Property Congress in Melbourne, Mar. 23–30, 2001), *available at* https://www.aippi.org/download/commitees/156/GR156brazil.pdf; *see also* Shamnad Basheer & Mrinalini Kochupillai, *TRIPS, Patents and Parallel Imports: A Proposal for Amendment*, 2 INDIAN J. INTELL. PROP. L. 63(2009), *available at* http://www.nalsar.ac.in/IJIPL/Files/Archives/Volume%202/4.pdf.

[115] 2005 Patent (Amendment) Act, No. 15 § 92(1), 2005 (India).

[116] Draft Patens and Designs Act, 2010 § 92, 2010 (Bangl.).

Again, Draft Patent Ain (Law) 2012 of Bangladesh included a similar provision, which also authorized individuals to parallel import with permission from a duly empowered authority provided the individuals comply with the rules framed for such authorization.[117]

This provision is ambiguous and only allows government institutions and duly-authorized institutions or individuals to make use of parallel imports. The existing patent act of Bangladesh (the PDA, 1911*)* and also draft PDA 2010 requires a notification from duly-empowered authority or government whereas draft patent law of 2012 requires complying with clumsy administrative rules for obtaining permission for parallel imports. Considering the bureaucratic hurdles and delayed procedures typically faced when making a notification or getting an authorization, along with the dysfunctional government health services, this provision will have no positive effect on the availability or accessibility of cheaper generic drugs in Bangladesh; therefore, Bangladesh should permit parallel importing by anyone based on the principle of international exhaustion and should adopt clear and transparent procedures for granting parallel imports within a reasonable time.

The Indian parallel-imports regime has some defects. For example: "importation of patented products by any person from any person who is duly authorised under the law to produce and sell or distribute the product."[118] Therefore, it may restrict the importation of cheaper drugs unless the exporter is duly authorized by law to produce, sell, or distribute such drugs. Shamnad Basheer explained this problem with an example: suppose India's patent laws prohibit production of a drug that is under a valid patent but Bangladesh's laws do not. These drugs are available via import from a Bangladeshi drug producer because there is no pharmaceutical patent in Bangladesh, and, therefore, the drug producer in Bangladesh does not need any authorization from the patent holder.[119] However, under the existing provision in India, an Indian importer may be barred from importing from Bangladesh because of a potential violation of Article 28 of the TRIPS Agreement[120] as the goods produced in Bangladesh by a third party did not have authorization from the patent holder, were not distributed by the patent holder, and the patent right has not been exhausted. In this situation, there will be complications when trying to import drugs from cheaper sources that may also trigger unnecessary legal hurdles and litigation for violation of the TRIPS provisions. Therefore, Basheer suggested the following amendment to be included as section 107B, in the existing Patent Act of India:

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[117] Draft Patent Ain (Law), 2012 § 31, 2012 (Bangl.).

[118] 2005 Patent (Amendment) Act § 107A(b), 2005 (India).

[119] Shamnad Basheer & Mrinalini Kochupillai, *supra* note 114, at 66–74.

[120] *See* TRIPS Agreement, *supra* note 2, art. 28.1 (stating in a pertinent part that "a patent owner shall have the exclusive right to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product").

> 107B. Exhaustion of Rights
>
> (1) For the purposes of this Act, the rights of a patentee or anyone claiming through such patentee shall be exhausted after a patented article has been sold once anywhere in the world (including within India), by or with the authorization of such patentee.[121]

This suggestion seems to be more logical because the first sale[122] of a product anywhere in the world by the patent holder would be considered an exhaustion of rights and, therefore, it could be imported from anyone and from anywhere in the world. Bangladesh should use this approach when drafting its parallel-importation to ensure access to medicine at the best possible price. Allowing for the parallel import of pharmaceuticals may be an effective tool to force patent holders to sell their protected pharmaceuticals at reasonable and affordable prices.[123]

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

G. Strong Compulsory Licensing Mechanism

The issues of compulsory licensing were:

> brought to the forefront of the international debate about intellectual property and public health policy in January 1998, after the Executive Board of the World Health Assembly adopted a resolution urging the member states to put public health above commercial interests and to review their options under TRIPS to safeguard access to essential drugs.[124]

While the TRIPS Agreement does not use the term "compulsory license," Article 31 of the TRIPS Agreement permits "use without authorization of the right holder" and includes both use by third parties and government use.[125] The

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[121] Basheer & Kochupillai, *supra* note 114, at 84–85.

[122] "Exhaustion of rights, or the doctrine of first sale, is inherent to IPRs and a necessity in bringing about legal certainty in downstream markets. Thomas Cottier, *The Exhaustion of Intellectual Property Rights - A Fresh Look*, 39 IIC INT'L REV. INTELL. PROP. & COMPETITION L. 755, 755 (2008).

[123] *See* Krithpaka Boonfueng, *Parallel Imports in Pharmaceuticals: Increase Access to HIV Drugs*, THAILAND LAW FORUM (July 19, 2001), http://www.thailawforum.com/articles/hivdrugs1.html.

[124] WILLIAM W. FISHER III & CYRILL P. RIGAMONTI, THE SOUTH AFRICA AIDS CONTROVERSY: A CASE STUDY IN PATENT LAW AND POLICY 12 (Feb. 10, 2005), *available at* http://cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf; *see also* WORLD HEALTH ASSEMBLY EXECUTIVE BOARD RES., WORLD HEALTH ORGANIZATION, REVISED DRUG STRATEGY (EB 101/R.24) 2 (Jan. 27, 1998), *available at* http://apps.who.int/gb/archive/pdf_files/EB101/pdfangl/angr24.pdf.

[125] TRIPS Agreement, *supra* note 2, art. 31.

Doha Declaration clarified the WTO's position on compulsory licensing by providing that "each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."[126]

Article 31 of the TRIPS Agreement dealing with compulsory licensing does not clarify the grounds under which a compulsory license can be given. However, as stated in another article:

> [C]ertain conditions listed in the Article will have to be satisfied. These include: (i) that authorization of such use will have to be considered on its individual merits, (ii) that before permitting such use (except in such cases as situations of national emergencies, extreme urgency, public non-commercial use), the proposed user will have to make efforts over a reasonable period of time to get a voluntary license on reasonable commercial terms, (iii) that the legal validity of the compulsory licensing decision and the remuneration will be subject to judicial or other independent review, and (iv) that the compulsory licenses can be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur.[127]

Nevertheless, there are some "[l]ess controversial grounds for issuing compulsory licences as contemplated in TRIPS itself" such as "[t]o correct anticompetitive practices," "[n]ational emergenc[ies] or other situations of extreme urgency, including public health crises, and" "[p]ublic non-commercial use, such as to provide health care to the poor."[128]

"In all these circumstances, TRIPS Article 31 permits a Member to grant compulsory licences without first having to make efforts to obtain a licence from the patent owner [under] reasonable commercial terms and conditions."[129] However, even in these cases the TRIPS Agreement requires the payment of "adequate remuneration in the circumstances of each case, taking into account the economic value of the [licence]."[130]

In the PDA of Bangladesh, there is also a provision dealing with the issue of compulsory licenses. Section 22 of the PDA provides:

> (1) Any person interested may present a petition to the government which shall be left at the Department of Patents, Designs and Trade Marks, together with the prescribed fee, **alleging that the demand for a patented article in Bangladesh is not being met to an**

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[126] Doha Declaration, *supra* note 4, at ¶ 5(b).

[127] Azam & Mounkoro, *supra* note 74; *see also*TRIPS Agreement, *supra* note 2, art. 31.

[128] VanDuzer, *supra* note 23, at 36.

[129] *Id.*

[130] *Id.* (quoting TRIPS Agreement, *supra* note 2, art. 31). For details, see Swarup Kumar, *Compulsory Licensing Provision Under TRIPS: A Study of* Roche vs. Natco *Case in India vis-à-vis the Applicability of the Principle of Audi Alteram Partem*, 7 SCRIPTED 135 (2010).

> **adequate extent** and **on reasonable terms** and praying **for the grant of a compulsory license**, or, **in the alternative**, for the **revocation of the patent.**
>
> (2) The government shall consider the petition, and **if the parties do not come to an arrangement between themselves** the government may, as it thinks fit **either dispose of the petition itself** or **refer it to the High Court Division for a decision.**[131]

As emphasized, there are some limitations within section 22 in the context of meeting the needs of the local pharmaceutical industry and in ensuring access to medicine. The first limitation is that the section only applies where a situation is one of inadequacy and unreasonable terms. These terms are not defined in the PDA so there is uncertainty as to the extent of these terms. The second limitation is that there is no expert body to deal with a compulsory license application; there is only a referral to the High Court Division. The third limitation is that the section only applies to domestic need; therefore, local generic producers in Bangladesh may not take the opportunity to export to countries having no manufacturing capacity or countries in extreme need of pharmaceuticals. The fourth limitation is that the section does not provide any clear indication as to royalties or a ceiling on the royalties in the case of a compulsory license. The absence of a clear provision on royalties may give rise to higher claims for royalties and related litigation,[132] which could arguably create a degree of uncertainty. The fifth limitation is that the section does not prescribe any time limit for the conclusion of the proceedings. The sixth limitation is that the section does not provide that a compulsory license can be issued on the grounds of public interest, a health emergency, or for public non-commercial use. Further, section 23(3) of the PDA states that "No order revoking a patent shall be made . . . which is at variance with any treaty, convention, arrangement or engagement with any foreign country."[133] Such a provision may be used to prevent the issue of a compulsory license or revocation of a patent to argue that Bangladesh is breaching the TRIPS Agreement or any other bilateral free trade and investment agreement. Thus, patent-holders could take advantage of the cumbersome procedure and frustrate the efforts of interested enterprises in getting compulsory licenses. Despite having a

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[131] The Patents and Designs Act, 1911 § 22, 1911 (Bangl.) (emphasis added).

[132] *See generally* F. M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, (CMH Working Paper Series, Paper No WG4:1, June 2001), *available at* http://library.cphs.chula.ac.th/Ebooks/HealthCareFinancing/WorkingPaper_WG4/WG4_1.pdf.

[133] The Patents and Designs Act, 1911 § 23(3), 1911 (Bangl.).

compulsory license provision, the government of Bangladesh has never issued a compulsory license for patented drugs.[134]

These limitations should be removed and the PDA amended to incorporate a viable compulsory licensing mechanism. In this regard, the legislative examples of India and Brazil may be useful. Both India and Brazil have included compulsory licensing mechanisms within their legislative regime. Such legislation has the potential to not only ensure access to medicines, but also enable local generic producers to export and supply generic pharmaceuticals to other poor countries, countries without manufacturing capacity or to those in urgent need of medicines.[135]

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

> (2) If the Central Government is satisfied, in respect of any patent in force, in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary that compulsory licences should be granted at any time after the sealing thereof to work the invention, it may make a declaration to the effect, by notification in the *Official Gazette* . . . .[136]

Again to allow exportation under a compulsory license, section 92A of the Indian Patent Act states:

> (1) Compulsory licence shall be available **for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity** in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence have been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.[137]

Bangladesh should adopt a similar provision to allow local generic producers to exploit the opportunity to export cheap generic medicines to other countries that have no manufacturing capacity or that are facing an extreme health emergency. It is also interesting to note that the Indian Patent Act includes a provision listing the prime objectives for granting a patent for pharmaceuticals. In the event of a violation of any of these provisions, grounds

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[134] Interview with a deputy registrar at the Department of Patents, Designs and Trademarks, in Dhaka, Bangl. (Mar. 7, 2012).

[135] *See generally* CECILIA OH & SISULE MUSUNGU, THE USE OF FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES? (Aug. 2005), *available at* http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf.

[136] The Patents (Amendment) Act, 2002, § 92(1), 2002 (India).

[137] The Patents (Amendment) Act, 2005 § 55, 2005 (India) (emphasis added).

for the issue of a compulsory license could be raised. In this regard, section 83 of the Indian Patent Act provides:

> Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely:
>
> (a) that patents are granted **to encourage inventions and to secure** the **Public-health Safeguards in Indian Patents Act** that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
> (b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
> (c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;
> (d) That **patents granted do not impede protection of public health and nutrition and should act as instruments to promote public interest,** especially in sectors that are of vital importance for the socioeconomic and technological development of India;
> (e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;
> (f) that the patent right is not abused by the patentee or person deriving title or interest on-patent from the patentee, and the patentee or a person deriving title or interest on-patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and
> (g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.[138]

By inserting the above section, the Indian government validated its present actions and any future actions as a measure to protect the public interest. In particular, sections 83(d) and (e) are adopted from the objectives and principle clause of the TRIPS Agreement,[139] which validates government actions based upon the socioeconomic conditions of the country. Bangladesh should adopt a similar provision as a proactive measure so that it can validate future actions to protect the public interest and the socioeconomic interest and developmental goals of the country.

However, commentary on the Indian compulsory licensing regime has highlighted a limitation of the section because there is no clear detail regarding the requirement to pay royalties. Gopakumar stated that "gaps in the law take

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[138] The Patents (Amendment) Act, 2002 § 39, 2002 (India) (emphasis added).
[139] TRIPS Agreement, *supra* note 2, arts. 7–8.

away the effectiveness of a compulsory license regime under the Patents Act. As a result, during the last five years only one application was filed for the issuance of a compulsory license in India."[140]

In this respect, to speed up the process of issuing compulsory licenses in the case of an emergency situation, either an administrative body should be created to deal with the application or a provision enacted to empower the government itself to issue a compulsory license without application. In this respect, Article 71 of the Brazilian Industrial Property Law provides:

> In cases of **national emergency or of public interest, as declared in an act of the Federal Executive Power,** and provided the patentholder or his licensee does not fulfil such need, **a temporary and non-exclusive compulsory license for exploiting the patent may be granted, ex officio,** without prejudice to the rights of the respective titleholder.[141]

This provision empowers the Brazilian government to issue a compulsory license if negotiations between parties fail.[142] Such a legislative option should be considered by Bangladesh as part of its TRIPS-compliant legislative regime. In the Draft PDA 2010, Bangladesh tried to use the Indian option, but the provision needs clarification[143] because it is not clear whether exports can be made to non-WTO member countries or those that do not have pharmaceutical patents or

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[140] Gopakumar K. M., *Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime*, 3 LAW & DEV. REV. 326, 341 (2010).

[141] Lei No. 9.279 art. 71, de 14 de maio de 1996, Diario Oficial Da Uniao [D.O.U.] de 15.05.1996. (Braz.), translated in Brazil: Industrial Property Law, 14/05/1996, No. 9.279, http://www.wipo.int/wipolex/en/details.jsp?id=515 (last visited Mar. 24, 2014) (emphasis added).

[142] Brazil used this provision to threaten with compulsory licenses in order to gain substantial price reductions on several occasions. *See* Shanker, Daya, Fault Lines in the World Trade Organization: An Analysis of the TRIPS Agreement and Developing Countries (2005) (unpublished Ph.D. Thesis, University of Wollongong), *available at* http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCsQFjAA&url=http%3A%2F%2Fro.uow.edu.au%2Fcgi%2Fviewcontent.cgi%3Farticle%3D1497%26context%3Dtheses&ei=m09dU6ikMur4yQH3g4Fo&usg=AFQjCNEP1wTUDCL12JwtBwpV-uKSL3rQEw&sig2=nucm-B0lqD76mPlNEaNASw.

[143] Draft Patents and Design Act, 2010, § 84, 2010 (Bangl.).

patents of a particular drug.[144] As the law currently stands, the issue of compulsory licenses is still determined by the courts, like in India, rather than by any specific executive body, like in Brazil. The court procedure in Bangladesh is overly long, costly, and complicated; therefore, this may discourage potential applicants from applying for compulsory licenses.

In this regard, the IPR Commission in the United Kingdom stated that "an important barrier to compulsory licensing in developing countries is the absence of straight forward legislative and administrative procedures to put it into effect."[145] In addition, the CIPIH Report recommended:

> Countries should provide in their legislation powers to use compulsory licensing, in accordance with the TRIPS agreement, where this power might be useful as one of the means available to promote, inter alia, research that is directly relevant to the specific health problems of developing countries.[146]

Therefore, Bangladesh should follow the Brazilian approach of issuing compulsory licenses and establish an expert body to deal with compulsory licensing issues within the shortest possible time to speed up the production of generic drugs in case of public-health crises. As the TRIPS Agreement does not prohibit administrative decision-making on compulsory licenses and government use of patents, establishment of an expert administrative body could speed up the issue of compulsory licenses and could also avoid prolonged litigation, as the legal systems in most developing countries and LDCs, including Bangladesh, are already overburdened.

Further, the issue of reasonable remuneration is not clearly defined; therefore, bargaining over this issue may also unnecessarily delay the procedure of issuing compulsory licenses. In this case, Bangladesh could perhaps adopt the Canadian approach of fixing royalties based on the United Nations' Human

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[144] Although it is not clarified in the Draft Patents and Design Act 2010, the Draft Patent Act of 2012 under section 14(18) provides that compulsory licenses can be granted for pharmaceutical exports to countries having inadequate or no manufacturing capacity. *See* Draft Patent Act, 2012 (available only in Bangla), *available at* http://www.moind.gov.bd/index.php?option=com_docman&task=doc_download&gid=821&Itemid=236. However, the draft law of 2012 included a separate provision in section 30 that compulsory licenses including pharmaceutical export licenses could not be granted in Bangladesh unless the August 30th TRIPS amendment becomes effective in Bangladesh. *See id.*

[145] INTEGRATING REPORT, *supra* note 28, at 8.

[146] CIPIH REPORT, *supra* note 27, at 176.

Development Index (HDI)[147] with a slight modification. The same formula should be used based on ranking of the country where the manufactured drugs under the compulsory license are to be exploited, because the Canadian model only accounts for exports based on the destination of the drugs (the importing country).[148] Bangladesh still holds a very low ranking in the HDI, and most of the exporting destinations of Bangladeshi pharmaceutical products are still in the

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[147] "The Human Development Index (HDI) is a measure of life expectancy, literacy, education, and standard of living for countries worldwide. It is a standard means of measuring well-being, especially child welfare." CENTRE FOR ENVIRONMENT EDUCATION, SUSTAINABLE DEVELOPMENT: AN INTRODUCTION 17 (2007). It is used to determine whether the country is a developed, a developing, or an under-developed country, and also to measure the impact of economic policies on quality of life. *Id.* The origins of the HDI are found in the annual Human Development Reports of the United Nations Development Programme (UNDP). Sakiko Fukuda-Parr, *The Human Development Paradigm: Operationalizing Sen's Ideas on Capabilities*, 9 FEMINIST ECON. 301, 303 (2003). It was devised by economist Mahabub-ul Haq in 1990 with the explicit purpose "'to shift the focus of development economics from national income accounting to people centered policies.'" *Id.* (citation omitted). For more information, see *Human Development Index (HDI)*, Human Development Reports, UNITED NATIONS DEVELOPMENT PROGRAMME, http://hdr.undp.org/en/statistics/hdi (last visited Mar. 24, 2014).

[148] According to James Love:

> In 2005, Canada proposed royalty guidelines for the export of medicines under the Jean Chrétien Pledge to Africa Act, which implements the WTO waiver of Article 31(f) of the TRIPS Agreement. The Canadian royalty guidelines are a sliding scale of the generic sales price. The rate depends entirely upon the location of the importing market and the rank of the importing country in the [United Nations Human Development Index] (UNHDI). The formula is one, plus the number of countries on the UNHDI, minus the importing country's rank on the UNHDI, divided by the number of countries on the UNHDI, multiplied by 0.04. The rate is then applied to the generic sales price.
>
> With 177 countries currently in the UNHDI index, the royalty rate can be expressed as: Royalty rate = 0.04 * [(178)–rank importing country]/177.

JAMES LOVE, REMUNERATION GUIDELINES FOR NON-VOLUNTARY USE OF A PATENT ON MEDICAL TECHNOLOGIES 72 (2005), *available at* http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf. During the time of adoption of this royalty approach in 2004, the top rate was 4% of the generic sales price for Norway, as it was the number one country in the HDI in 2004, and the lowest rate was 0.02% for Sierra Leone as it was lowest ranking country in the HDI in 2004. *Id.* See for details MOHAMMAD MONIRUL AZAM, REVISITING THE CLIMATE CHANGE NEGOTIATION UNDER THE UNFCCC: IN SEARCH OF EFFECTIVE FRAMEWORK FOR NEGOTIATION AND TECHNOLOGY TRANSFER (2009), *available at* http://www.conference.unitar.org/yale/sites/conference.unitar.org.yale/files/Paper_Azam.pdf.

lower level of the HDI.[149] With this modification, Bangladesh would be able to produce drugs locally using compulsory licenses, or it could use compulsory licenses for exporting by paying the minimum fixed royalties without any cumbersome bargaining.

Furthermore, the government of Bangladesh may need to modify existing provisions that regulate "local working" of the patent or related provisions concerning patented products manufactured or processes used outside of Bangladesh. Section 23 of the PDA provides that:

> (1) At any time not less than four years after the date of a patent granted under this Act, any person may apply to the Government for relief under this section on the ground that the patented article or process is manufactured or carried on exclusively or mainly outside Bangladesh.
> (2) The Government shall consider the application, and, if after inquiry it is satisfied-
>
> (a) that the allegations contained therein are correct; and
> (b) that the applicant is prepared, and is in a position, to manufacture or carry on the patented article or process in Bangladesh; and
> (c) that the patentee refuses to grant a license on reasonable terms, then, subject to the provisions of this section, and unless the patentee proves that the patented article or process is manufactured or carried on to an adequate extent in Bangladesh, or gives satisfactory reasons why the article or process is not so manufactured or carried on, the Government may make an order
> (d) revoking the patent. . . .[150]

The existing patent law of Bangladesh does not contain any definition of the term "manufactured or carried on exclusively or mainly outside Bangladesh" as mentioned in section 23 of the PDA. This absence of a definition may result in varied and ambiguous interpretations. Again, section 23 of the PDA requires that four years should lapse from the date of granting of a patent and only then can one apply for the revocation of patents on the ground of "non-working in the territory" of Bangladesh.[151] Therefore, the ambiguity of the existing provision and the four year requirement will delay the entry of cheaper local pharmaceuticals. This will allow the MNPCs to enjoy a monopoly for their patented pharmaceuticals without any transfer of technology and investment for local manufacture as they will rely on the manufacturing facilities outside of

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[149] The ranking of Bangladesh in the HDI of 2010 was 129. UNITED NATIONS DEV. PROGRAMME, HUMAN DEVELOPMENT REPORT 2010, THE REAL WEALTH OF NATIONS: PATHWAYS TO HUMAN DEVELOPMENT, 145 (2010), *available at* http://hdr.undp.org/sites/default/files/reports/270/hdr_2010_en_complete_reprint.pdf. For the HDI of other countries, see *id.* at 143–46.

[150] The Patents and Designs Act, 1911 § 23, 1911 (Bangl.).

[151] *Id*.

Bangladesh. In this regard, section 84 of the Indian Patent Act[152] and Article 68 of the Brazilian Industrial Property Act (1996)[153] may be models for Bangladesh, which so far have successfully resisted the pressure of the United States and MNPCs.[154]

The Indian Controller of Patents, while disposing of an application for compulsory license in *Natco Pharma Ltd. v. Bayer Corp.*,[155] clarified the issue of working of the patent in the territory of India. The Controller noted that the term "worked in the territory of India" had not been defined in the Indian Patent Act, and so he needed to interpret the term with regard to "various International Conventions and Agreements in intellectual property," the 1970 Patent Act and the legislative history.[156] The Controller, using Article 27(1) of the TRIPS Agreement and Article 5(1)(A) of the Paris Convention, supported an interpretation that failure to manufacture in India supported the grant of a compulsory license to Natco stating that: "[p]atents are not granted merely to enable patentees to enjoy a monopoly for importation of the patented article" and that "the grant of a patent right must contribute to the promotion of technological innovation and to the transfer and dissemination of technology."[157]

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[152] 2005 Patent (Amendment) Act § 84, 2005 (India):

> Compulsory licences. –
>
> (1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely–
>
> (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India.

[153] Lei No. 9.279 art.68, de 14 de maio de 1996, Diario Oficial Da Uniao [D.O.U.] de 15.05.1996. (Braz.), translated in Brazil: Industrial Property Law, 14/05/1996, No. 9.279, http://www.wipo.int/wipolex/en/details.jsp?id=515 (last visited Mar. 24, 2014):

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

[154] *See generally* Daya Shanker, *India, the Pharmaceutical Industry and the Validity of TRIPS*, 5 J. WORLD INTELL. PROP. 315 (2002); *see also* Daya Shanker, *Brazil, Pharmaceutical Industry and the WTO*, 5 J. WORLD INTELL. PROP. 53 (2002).

[155] Compulsory License Application No. 1 of 2011, Application for Compulsory License Under Section 84(1) of the Patents Act, 1970 in Respect of Patent No. 215758, Natco Pharma Ltd. v. Bayer Corp. (Mar. 9, 2012), *available at* http://www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf.

[156] *Id.* at 39–45.

[157] *Id.* at 43.

Therefore, considering the experiences of India, the government of Bangladesh may adopt the following provision on the working of the patent in the territory of Bangladesh:

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

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

During the interview, most of the participants argued that Bangladesh should have strong compulsory licensing mechanisms.[158] However, one participant argued that compulsory licenses are not a viable option as they will discourage technology transfer and foreign direct investment in Bangladesh.[159] Another participant commented that the provision alone is not enough if the procedure is complicated and results in an inordinate delay in issuance of compulsory licenses.[160] Using the experiences of India and Brazil, if Bangladesh can include a compulsory license provision in its future amended patent law that avoid clumsy and complicated procedures, it will help ensure access to pharmaceuticals in the event of a public-health emergency in Bangladesh and provide a competitive advantage to its local pharmaceutical industry when exporting to any other country having low or no manufacturing capacity.

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[158] During interviews, the issues of compulsory licensing were supported by most of the executives of local pharmaceutical companies irrespective of size (large, medium, and small). That support was echoed by public health NGOs and local researchers.

[159] Interview with a policy analyst of an MNPC operating in Bangladesh, in Dhaka, Bangl. (Mar. 09, 2012).

[160] Interview with a policy analyst of an international NGO working in Bangladesh, in Dhaka, Bangl. (Mar. 10, 2012).

Similarly, Bangladesh should include a prior-use exception to protect local producers within the pharmaceutical industry.

H. Prior-use Exceptions

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

> Generic versions of patented medicine can continue to be manufactured in India provided that: (1) the generic manufacturer was producing and marketing the product prior to January 1, 2005; (2) the generic manufacturer made significant investment in the production and marketing for the product; and, (3) a reasonable royalty is paid to the patent holder.[161]

During field studies in Bangladesh, a majority of the participants strongly supported the inclusion of a prior user rights provision similar to India's.[162] However, one participant argued that this kind of provision will discourage foreign direct investments and transfer technology in Bangladesh.[163]

The Indian example of prior-user rights has some weaknesses. It may be challenged by the patent holder on a number of grounds, such as it was not exploited prior to January 1, 2005 or prior to introduction of pharmaceutical patents, investment is not sufficient (as there is no indication in the law, how much investment is to be considered as sufficient), or the reasonable royalty rate may be challenged. These weaknesses may create barriers for generic production. In this case, the Brazilian provision should perhaps be replicated in Bangladesh, which has no such limitations. Such an exception is contained in Article 45 of Brazil's Industrial Property Law and provides that:

> A person who in good faith, prior to the filing or priority date of a patent application, was exploiting the object thereof in this country, shall be

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[161] THE WORLD BANK, PUBLIC AND PRIVATE SECTOR APPROACHES TO IMPROVING PHARMACEUTICAL QUALITY IN BANGLADESH 15 (Mar. 2008), *available at* http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2008/09/01/000334955_20080901071115/Rendered/PDF/451900NWP0Box31uality0no2301PUBLIC1.pdf.

[162] This has been mentioned by a number of large, medium, and small pharmaceutical companies in Bangladesh and was also supported by officials at the patent office and directorate general of drug administration, Bangladesh.

[163] Interview with CEO of an MNPC operating in Bangladesh, in Dhaka, Bangl. (Mar. 9, 2012).

> assured the right to continue the exploitation, without onus, in the same manner and under the same conditions as before.[164]

While the above legislative options go towards defining the matters of patentability and exceptions, a provision related to patent application objection procedure should also be included.

I. Pre-grant and Post-grant Opposition

Pre-grant and post-grant opposition "is an important way to assist and encourage public interest groups and local generic pharmaceutical companies to oppose attempts by others" who seek patents.[165] An opposition provision is currently contained in Bangladesh under section 9(1) of the PDA, which provides:

> Any person may, on payment of the prescribed fee, at any time within **four months from the date of the advertisement of the acceptance of an application,** give notice at the Department of Patents, Designs and Trade Marks of opposition to the grant of the patent on any of the following grounds, namely:
>
> (a) that the applicant obtained the invention from him, or from a person of whom he is the legal representative or assign; or
> (b) that the invention has been claimed in any specification filed in Bangladesh which is or will be of prior date to the patent, the grant of which is opposed; or
> (c) that the nature of the invention or the manner in which it is to be performed is not sufficiently or fairly described and ascertained in the specifications; or
> (d) that the invention has been publicly used in any part of Bangladesh or has been made publicly known in any part of Bangladesh; or
> (e) that the complete specification describes or claims an invention other than that described in the provisional specification, and that such other invention either forms the subject of an application made by the opponent for a patent, which if granted would bear a date in the interval between the date of the application and the leaving of the complete specification, or has been made available to the public by publication in any document published in Bangladesh in that interval; **but on no other ground**.[166]

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[164] Lei No. 9.279 art. 45, de 14 de maio de 1996, Diario Oficial Da Uniao [D.O.U.] de 15.05.1996. (Braz.), translated in Brazil: Industrial Property Law, 14/05/1996, No. 9.279, http://www.wipo.int/wipolex/en/details.jsp?id=515 (last visited Mar. 24, 2014).

[165] Mohammad Azam & Kristy Richardson, *Pharmaceutical Patent Protection and Trips Challenges for Bangladesh: An Appraisal of Bangladesh's Patent Office and Department of Drug Administration*, 22 BOND L. REV. 1, 8 (2010).

[166] The Patents and Designs Act, 1911 § 9(1)), 1911 (Bangl.) (emphasis added).

As emphasized above and in a study by Azam and Richardson, objections to the provision are limited by two conditions. The first limitation "is that the objection must be made within four months of the advertisement of the acceptance of the application."[167] The second limitation is that the objection can only be based on the grounds provided by section 9(1).[168] It further stated that "[i]f defects in the patent application are revealed, or identified after the four month period, no objection can be raised against the patent application. In other words, the existing legislative regime does not permit any type of post-grant opposition."[169] "This is in contrast to the legislative equivalent in India which not only contains eleven grounds for pre-grant opposition but also permits post-grant opposition."[170]

"The Indian grounds for post-grant opposition are broad enough to challenge novelty, inventive steps and the process of industrial application, best method, claims and disclosure of origin and even the use of indigenous or local knowledge."[171] Given this comparison, it is suggested that the existing Bangladeshi provision is not sufficient and should be amended to include more extensive pre-grant heads of objection as well as a process for post-grant opposition.

In taking such a legislative step it is further suggested "that the heads of objection should be as wide as possible so that the twin aims of ensuring access to medicine with the aim of promoting innovation within the pharmaceutical industry are not hampered."[172] During field studies in Bangladesh, a majority of the participants opined that the Indian example of pre-grant and post-grant opposition may need to be replicated in Bangladesh.[173] But, one participant argued that the local pharmaceutical industry and public health organizations in Bangladesh lack adequate expertise and resources to effectively exploit pre-grant and post-grant opposition; therefore, they should prepare themselves to use the proposed provision for pre-grant and post-grant opposition effectively.[174] Another participant also criticized that there is no accessible online information about ongoing patent applications in Bangladesh and that even a paper copy of DPDT's journal is not distributed regularly; therefore, interested parties will

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[167] Azam & Richardson, *supra* note 165, at 8.

[168] *Id.*

[169] *Id.*

[170] *Id.* at 8 n.31.

[171] *Id.*; *see also* Archana Shanker & Neeti Wilson, *The Patent Opposition System in India*, IAM MAGAZINE 14 (July 8, 2010), http://www.iam-magazine.com/issues/article.ashx?g=4ed76a24-e544-4547-a651-84c0542aecd1.

[172] Azam & Richardson, *supra* note 165, at 8–9.

[173] During interviews, this view was echoed by most of the officials of large, medium, and small pharmaceutical companies in Bangladesh and also supported by local IP academics and public health NGOs.

[174] Interview with IP academic at the University of Chittagong, in Chittagong, Bangl. (Mar. 5, 2012).

have extreme difficulties in collecting the required information to oppose any patent application or granted patent.[175] Therefore, simply having this provision may not be enough unless access to information regarding patent applications and granted patents is regularly updated and available for review by interested parties. One participant in the interview argued that this provision may open the flood gates to unnecessary opposition and may even frustrate investments in the pharmaceutical sector.[176]

The issue of how long a patent should last also needs consideration.

J. Duration of Patent Protection

Under section 14 of the PDA of Bangladesh, patent protection is available for sixteen years. The TRIPS Agreement requires that patent protection be available for twenty years. The Brazilian Industrial property law simply indicates that patent protection shall be for twenty years from the date of filing.[177] Indian Patent law extends the duration to twenty years subject to the patent legislation in India, and that duration is to be counted from the date of filing:

> Subject to the provisions of this Act, the term of every patent granted, after the commencement of the Patents (Amendment) Act, 2002, and the term of every patent which has not expired and has not ceased to have effect, on the date of such commencement, under this Act, shall be twenty years from the date of filing of the application for the patent.[178]

While the TRIPS Agreement limits the ability of Bangladesh to explicitly reduce a patent period, the legislative amendment should contain a qualification. To that extent, it is suggested that while amending the PDA to be TRIPS compliant, Bangladesh could include that the "duration of protection is subject to exceptions as included in this Act or to be included by any future amendments." Such an extension may provide the government with some freedom to act as times change and TRIPS compliance is assessed. It will also permit the government to act immediately in case of a health emergency or to act because of some other type of public interest. During the interview, some participants considered this kind of reservation to be useful to limit patent

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[175] *Id*.

[176] Interview with CEO of an MNPC operating in Bangladesh, in Dhaka, Bangl. (Mar. 7, 2012).

[177] Lei No. 9.279 art. 40, de 14 de maio de 1996, Diario Oficial Da Uniao [D.O.U.] de 15.05.1996. (Braz.), translated in Brazil: Industrial Property Law, 14/05/1996, No. 9.279, http://www.wipo.int/wipolex/en/details.jsp?id=515 (last visited Mar. 24, 2014) ("An invention patent shall remain in force for a period of 20 (twenty) years, and a utility model patent for a period of 15 (fifteen) years from the date of filing.").

[178] 2005 Patent (Amendment) Act, § 53(1), 2005 (India).

protection, if necessary, on public interest grounds.[179] However, one participant argued that limiting patent protection will discourage investment in the pharmaceutical sector; rather, he argued that twenty years is not sufficient to recover investment and that the duration should be extended to thirty years in the pharmaceutical sector.[180]

The United States and the European Union (as insisted and supported by their MNPCs), while negotiating bilateral investment agreements with the developing countries and the LDCs, including Bangladesh, insisted on the inclusion of extended periods for pharmaceutical patents beyond twenty years in order to compensate the originator of the drug for the time lost during the patent application and drug registration procedures.[181] The United States and the European Union considered this a legitimate right which must be granted in order to "compensate" its pharmaceutical companies for any "unreasonable" delays throughout the patent examination or the registration process.[182]

But "[t]he costs of patent term extension are grave."[183] For example, "a recent study in the Republic of Korea concluded that the extension of patent terms is likely to cost the Korean National Health Insurance Corporation . . . 504.5 billion won (US $529 million) for extending drug patents for three years and 722.5 billion won (US $757 million) if it has to agree to a four-year extension as proposed under [Free Trade Agreement] negotiations with the United States."[184]

The TRIPS Agreement "is clear regarding this term of protection. It does not specify that a member state is obliged to extend the patent protection term for any reason (including delays in registering drugs or issuing patents) beyond the term prescribed under Article 33."[185]

In this regard, the CIPIH Report stated that "[b]ilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce

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[179] From interview data (this has been supported by many large, medium, and small local pharmaceutical companies in Bangladesh).

[180] Interview with executive of a MNPC operating in Bangladesh, in Dhaka, Bangl. (Mar. 9, 2012).

[181] *See* Emily Jones, *Signing Away the Future: How Trade and Investment Agreements Between Rich and Poor Countries Undermine Development* (Oxfam Briefing Paper No. 101, March 2007), *available at* http://www.oxfam.org/sites/www.oxfam.org/files/Signing%20Away%20the%20Future.pdf.

[182] *Id.*

[183] El Said, *supra* note 85, at 145.

[184] *Id.*; *see also U.S. FTA May Cost Drug Industry $1.2 Billion: Gov't*, THE HANKYOREH (Oct. 17, 2006), http://english.hani.co.kr/arti/english_edition/e_business/165065.html.

[185] El Said, *supra* note 85, at 144; *see* INT'L CENTRE FOR TRADE AND SUSTAINABLE DEV., RESOURCE BOOK ON TRIPS AND DEVELOPMENT (2005). It should be noted that patent term extensions were proposed by the developed countries and rejected by the developing countries during the Uruguay Round.

access to medicines in developing countries."[186] Therefore, LDCs such as Bangladesh should not adopt patent term extension under the patent regime and should not agree in any future FTAs for patent terms beyond the TRIPS Agreement. Again, the government of Bangladesh needs to craft enforcement provisions in a way so as not to become a barrier to the production and supply of generic drugs.

K. Not to Adopt Overprotective Enforcement Provisions

LDCs such as Bangladesh should be aware that the TRIPS Agreement only sets minimum requirements with respect to enforcement of IPRs. However, there has been an increased focus on strengthening mechanisms for enforcement of IPRs far beyond what is required by the TRIPS agreement through so called "anti-counterfeiting" initiatives.[187] The developing countries and LDCs are increasingly under pressure to place criminal sanctions on a wide array of IPR violations, including patent infringement.[188] But placing criminal sanctions on

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[186] CIPIH REPORT, *supra* note 27, at 182.

[187] *See generally* GLOBAL COMM'N ON HIV AND THE LAW, REGIONAL ISSUES BRIEF: INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO MEDICINES 22 (Feb. 17, 2011), *available at* http://www.ippacificislands.org/health/IssuesBrief_IPR.pdf. For example:

> In 2008, Kenya enacted its Anti-Counterfeit Act, purportedly designed to address the problem of counterfeit goods, including substandard and spurious medicines. It attached harsh criminal sanctions related to counterfeiting. However, according to the definition of the Act safe, effective and legitimate generic medicines were also considered "counterfeit." By conflating the issues of safety, quality and efficacy, and the separate field of intellectual property, the Act potentially criminalized the manufacture, import, export, possession or sale of perfectly safe generic medicines. Kenya's Anti-Counterfeit Act was challenged before the High Court in July 2009 by three petitioners living with HIV on the basis that impinges on their constitutional right to health. The Court passed preliminary judgment in favour of petitioners on 23 April, 2010 and suspended powers of Anti-Counterfeit Agency to interfere with importation and distribution of generics pending ruling on the substance.

UNITED NATIONS DEV. PROGRAMME, GOOD PRACTICE GUIDE: IMPROVING ACCESS TO TREATMENT BY UTILIZING PUBLIC HEALTH FLEXIBILITIES IN THE WTO TRIPS AGREEMENT 47 (2010) [hereinafter GOOD PRACTICE GUIDE], *available at* http://content.undp.org/go/cms-service/stream/asset/?asset_id=3259443.

[188] *See generally* Ermias Biadgleng & Viviana Tellez, *The Changing Structure and Governance of Intellectual Property Enforcement* (S. Ctr. Research Paper No. 15, Jan. 2008), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1210622; Susan Sell, *The Global IP Upward Ratchet, Anti-Counterfeiting and Piracy Enforcement Efforts: The State of Play* (Am. Univ. Wash. Coll. L. Prog. Info. Justice & Intell. Prop., PIJIP Research Paper Series. No. 15, 2010), *available at* http://digitalcommons.wcl.american.edu/research/15/.

patent infringement (e.g., considering generic medicines "counterfeit"[189]) can restrict access to medicines and, therefore, "could have a chilling effect on generic manufacturers' willingness to enter the market with affordably priced generic medicines."[190]

On the other hand, "overbroad powers granted to customs officials, have already been used to hinder the legitimate trade of affordable generic medicines" under the pretext of counterfeiting and infringement.[191] For example, in 2009, Dutch authorities seized a shipment in transit of the generic drug Abacavir produced in India, purchased by UNITAID[192] and on its way to Africa, on grounds that the generic version of the medicine violated patent rights in Europe.[193]

The use of the term "counterfeit" medicines became further controversial when the WHO-IMPACT meeting in December2008 suggested that a medical product is counterfeit when there is a false representation in relation to its identity, history or source, its container, packaging or other labeling

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[189] *See generally* CARLOS CORREA, CENTRE FOR INTERDISCIPLINARY STUDIES ON INDUSTRIAL PROPERTY AND ECONOMICS, THE PUSH FOR STRONGER ENFORCEMENT RULES: IMPLICATIONS FOR DEVELOPING COUNTRIES (2007); Michael Blakeney, *International Proposals for the Criminal Enforcement of Intellectual Property Rights: International Concern with Counterfeiting and Piracy*, INTELL. PROP. Q. 1 (2009).

[190] UNITED NATIONS DEV. PROGRAMME, *supra* note 187, at 46.

[191] *Id.*; *see* Henning Grosse Ruse-Khan & Thomas Jaeger, *Policing Patents Worldwide? EC Border Measures Against Transiting Generic Drugs Under EC and WTO Intellectual Property Regimes*, 40 INT'L REV. INTELL. PROP. & COMPETITION L. 502 (2009); *see also* JENNIFER BRANT WITH ROHIT MALPANI, OXFAM INT'L, EYE ON THE BALL MEDICINE REGULATION—NOT IP ENFORCEMENT—CAN BEST DELIVER QUALITY MEDICINES (Feb. 2, 2011), *available at* http://www.oxfam.org/sites/www.oxfam.org/files/eye-on-the-ball-medicine-regulation-020211-en.pdf.

[192] UNITAID is the first global health organization that "uses innovative financing to increase funding for greater access to treatments and diagnostics for HIV/AIDS, malaria and tuberculosis in low-income countries." *About Unitaid*, UNITAID, http://www.unitaid.eu/en/who/about-unitaid (last visited Apr. 20, 2014). It is "[b]ased in Geneva and hosted by the World Health Organization, approximately half of UNITAID's finances come from a levy on air tickets." *Id.* It "was established in 2006 by the governments of Brazil, Chile, France, Norway and the United Kingdom as the 'International Drug Purchasing Facility.'" *Id.* It is now backed by an expanding north-south membership, including Cyprus, Korea, Luxembourg, Spain, Cameroon, Congo, Guinea, Madagascar, Mali, Mauritius and Niger along with philanthropic organization like the Bill & Melinda Gates Foundation. *Id.*

[193] *See* Frederick M. Abbott, *Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare*, 1 WORLD INTELL. PROP. ORG. J. 43, 47 (2009), *available at* http://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID1535521_code157668.pdf?abstractid=1535521&mirid=1.

information.[194] On the other hand, the 66th meeting of the WHO Regional Committee for South East Asia rejected the WHO-IMPACT definition of counterfeit drugs. Recognizing the need to separate IP issues from quality and safe medical products, the draft resolution urged member countries to refrain from IP enforcement that compromises access to medicines.[195] In this regard, the Indian Pharmaceutical Alliance (IPA) argues that the references to "history" and "source" in the WHO-IMPACT definition suggest patent infringement and that this might affect exports of generics (from India) because it wrongly leads the public to believe that generics are counterfeits.[196] Therefore, India requested the original WHO definition of counterfeit medicines be maintained:

> A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.[197]

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[194] IMPACT, SUMMARY REPORT FOR THIRD IMPACT GENERAL MEETING (Dec. 2–5, 2008), *available at* http://www.who.int/impact/resources/IMPACT thirdgeneralmeeting_report.pdf?ua=1.IMPACT (International Medical Products Anti-Counterfeiting Taskforce) is a global coalition of all stakeholders including NGOs, enforcement agencies, pharmaceutical manufacturers associations, and drug and regulatory authorities. More information is available at WORLD HEALTH ORG., http://www.who.int/impact/about/en/ (last visited Apr. 5, 2014).

[195] For details, see N. Lalitha, *Access to Indian Generic Drugs: Emerging Issues*, *in* INTELLECTUAL PROPERTY, PHARMACEUTICALS AND PUBLIC HEALTH: ACCESS TO DRUGS IN DEVELOPING COUNTRIES 225–52 (Kenneth C. Shadlen, S. Guennif & N. Lalitha, eds., 2011).

[196] *See New Counterfeit Definition a Threat to Generics, Says India*, SCRIP INTELLIGENCE (May 30, 2008), http://www.scripintelligence.com/home/news/New-counterfeit-definition-a-threat-to-generics-says-India-56036.

[197] *See General Information on Counterfeit Medicines*, Medicines, WORLD HEALTH ORGANIZATION, http://www.who.int/medicines/services/counterfeit/overview/en/ (last visited Mar. 24, 2014).

However, the TRIPS Agreement does not require the criminalization of patent infringement, and it limits criminalization obligations to a limited class of wilful trademark counterfeiting and copyright piracy on a commercial scale.[198]

Neither Brazil nor India has adopted any overprotective enforcement mechanisms that could criminalize generic production and supply. Therefore, while instituting TRIPS-compliant enforcement obligations within domestic patent law and pharmaceutical regulations, the government of Bangladesh, rather than adopting overprotective provisions that would hamper supply of generic medicines, should focus on efforts to strengthen drug regulatory authorities, promote rational use and public awareness not to sell, buy, or distribute any fake or counterfeit medicines, and avoid not defining the counterfeiting of medicines so as to include patent infringement.

Apart from the above legislative options, the government of Bangladesh should consider some additional interventions to ensure access to medicines and to promote pharmaceutical innovation in the process of moving towards a TRIPS-compliant regime.

II. GOVERNMENT-INTERVENTION OPTIONS

Although the patenting of pharmaceuticals and consequent impact on pharmaceutical price is not the only issue affecting access, it is considered a significant barrier and one that is common to all developing countries, whatever their stage of development.[199] That is why, during the interviews in Bangladesh, most of the participants echoed that simply using the flexibilities available in the TRIPS Agreement when drafting national patent laws will not improve access to medicines in Bangladesh, especially when the country's economic development, health infrastructure, drug distribution, and drug availability is in disarray.[200] There is also fear that achievements made thus far through the local production

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[198] *See* TRIPS Agreement, *supra* note 2, art. 61. It states:

> Members shall provide for criminal procedures and penalties to be applied at least in cases of *wilful trademark counterfeiting or copyright piracy on a commercial scale*. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale.

Id. (emphasis added).

[199] *See Access to HIV/AIDS Treatment in Developing Countries*, INTERAGENCY COALITION ON AIDS AND DEVELOPMENT (Aug. 2001), http://www.icad-cisd.com.

[200] Interview with officials at the Directorate General for Drug Administration in Bangladesh and Public Health NGOs, in Dhaka, Bangl. (Mar. 12-15, 2012).

of pharmaceuticals will not continue if MNPCs and developed countries put pressure on Bangladesh to refrain from producing and exporting cheaper generic drugs that compete with the more expensive patented brands produced by the MNPCs.[201]

However, MNPCs and developed countries like the United States and the European Union are not yet pressuring Bangladesh for pharmaceutical patents. As an LDC, Bangladesh still can waive compliance with the pharmaceutical patents of the TRIPS Agreement. Additionally, Bangladesh is not a competitive threat yet because it is not a country that promises huge profits.[202] Some critics consider that, "[d]espite having 125 million people, the average wage, life expectancy, and literacy rates are among the lowest in the world," and its local pharmaceutical industry is incapable of making the raw materials for new drugs; hence, MNPCs are not interested in putting any pressure on Bangladesh.[203] In 1997, the U.S. Embassy in Bangladesh reported: "Intellectual property infringement is common, but is currently of relatively limited significance for US firms."[204] According to Oxfam, "[t]his attitude may change soon, as it has happened in other poor countries such as Ghana and Uganda, where multinational companies have already acted to stop them importing cheaper generic drugs, which compete with the more expensive patented brands of medicine."[205] Therefore, apart from reforming patent law, Bangladesh may need to consider some other alternative governmental-intervention options to ensure access to medicines.[206]

Supporting alternative measures apart from market-based instruments, Dr. Zafarullah Chowdhury remarked that:

> Medicines are one commodity you can't leave to market forces. The market is simply not competent. . . It makes for monopolies and cartels, not competition. And every drug is, by definition, essential. If you have a malfunctioning liver and only one drug can save your life, that to you is the most essential drug in the world. Allowing the global drug market to be controlled by foreign firms (with lengthy periods of patent control) is not going to help us.[207]

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[201] *See* OXFAM GB, MAKE VITAL MEDICINES AVAILABLE FOR POOR PEOPLE: BANGLADESH 5–6 (Feb. 8, 2001), *available at* http://oxfamilibrary.openrepository.com/oxfam/bitstream/10546/112437/1/bangaldesh-medicines-poor-080201-en.pdf.

[202] *See generally id.* at 8.

[203] *Id.* at 4.

[204] *Id.* at 5.

[205] *Id.*

[206] Email interview with a patent law academic in New Delhi, India (Mar. 11, 2012).

[207] OXFAM GB, *supra* note 201, at 6.

Dr. Chowdhury further added that "[l]ocal drug firms have no innovative technology, therefore when Bangladesh is bound to honour foreign patents on new drugs 'that could be our collapse.'"[208]

Another renowned public-health activist in Bangladesh, Farhad Mazahar, remarked that "[t]he impact [of pharmaceutical patents] on Bangladesh will be huge because most of our raw materials [for new and existing drugs] come from India. . . . Our companies are only pharmacies, really [not the pharmaceutical industry itself]."[209] Therefore, considering the delicate infrastructure of the public-health situation, the low level of access to medicines, and lack of innovation among the local pharmaceutical industries in Bangladesh, it is suggested that Bangladesh may adopt some alternative measures using the examples of Brazil, India, and South Africa, which are: (i) drug price control; (ii) national competition law; (iii) the introduction of the patent prize system; (iv) limiting data protection; (v) developing a patent pool on country specific diseases; (vi) avoiding TRIPS-plus requirements in any future bilateral investment agreements (BITs) or under Free Trade Agreements (FTAs) with the developed countries more particularly with the United States and the European Union; (vii) lobbying for the further extension of the transitional period for pharmaceutical patents; (viii) introducing process patents only for limited periods and adopting a utility model law; and (ix) instituting the Special Investment Protection Regime, an open source drug innovation, and the Social Business Model in the pharmaceutical sector.

A. Drug Price Control

Affordability of medicines by individual patients in the LDCs is an important factor influencing access to care and treatment.[210] However, control over the cost of medicines exists in one form or another in most countries. For example, in Australia, "new drugs with no advantage over existing products are offered at the same price."[211] "Where clinical trials show superiority, incremental cost effectiveness is assessed to determine whether a product

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[208] *Id.*

[209] *Id.*

[210] *See generally* DRUGS AND MONEY: PRICES, AFFORDABILITY AND COST CONTAINMENT (M.N.G. Dukes et al. eds., 7th ed. 2003), *available at* http://www.euro.who.int/__data/assets/pdf_file/0011/96446/e79122.pdf.

[211] Amit Sen Gupta, *Should Drug Prices Be Controlled?*, ECONOMIC TIMES (Aug. 6, 2002), http://articles.economictimes.indiatimes.com/2002-08-06/news/27340990_1_drug-prices-price-controls-drug-companies.

represents value for money at the price sought."[212] In the United Kingdom, the pharmaceutical price-regulation scheme (PPRS), a voluntary agreement between the United Kingdom's Department of Health and the Association of the British Pharmaceutical Industry exists so that companies negotiate profit rates from sales of drugs to the National Health Service (NHS).[213] In France, Italy, and Belgium, prices are set in relation to the relative cost and the contribution made to the national economy.[214]

In Bangladesh, there is no drug price-control mechanism under the existing Patent Act. However, the Drug Control Ordinance of 1982 provides for the fixing of prices by a committee appointed by the government.[215] The committee mostly deals with essential medicines, as listed by the DGDA in Bangladesh. Accordingly, no such listed drugs can be circulated without such pricing controls.[216]

This is a vital guarantee that the prices of pharmaceuticals, whether produced nationally or imported from the outside, will not increase without prior government authorization.[217] Further, it is within the government's purview to refuse the registration of any pharmaceuticals that are regarded as too expensive or unaffordable.[218]

In 1982, 150 pharmaceuticals were defined as essential pharmaceuticals[219] and any changes to prices were decided by the Drug Control Committee.

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[212] JAN SWASTHYA ABHIYAN, NAT'L COORDINATION COMM., ACCESS TO ESSENTIAL MEDICINES 37 (Feb. 2007), *available at* http://www.healthpolicy.cn/rdfx/jbywzd/gjjy2/yd/yjwx/201002/P020100227572014659949.pdf. *See generally* JON SUSSEX, KOONAL K SHAH & JIM BUTLER, CONSULTING REPORT 10/2: THE PUBLICLY FUNDED VACCINES MARKET IN AUSTRALIA (Oct. 2010).

[213] The PPRS regulates profits to a band of 17 to 21 % on historic capital or the initial capital used to begin the venture with a 25% variation on either side. Companies are free to set prices, provided the rate of return is within the band. If the profits are higher, the companies have to reduce profits the next year and if the profits are lower, they can raise their prices. For details, see KEVIN A HASSETT, PRICE CONTROLS AND THE EVOLUTION OF PHARMACEUTICAL MARKETS, COMM. ON INTELL. PROP. RIGHTS, INNOVATION AND PUBLIC HEALTH (July 22, 2004), *available at* http://www.who.int/intellectualproperty/news/en/Submission-Hassett.pdf.

[214] *See* Alan Maynard & Karen Bloor, *Dilemmas in Regulation of the Market for Pharmaceuticals*, 22 HEALTH AFFAIRS 31, 37 (May/June 2003).

[215] *See* Azam & Richardson, *supra* note 39.

[216] *See* ULRIKE POKORSKI DA CUNHA, STUDY ON THE VIABILITY OF HIGH QUALITY DRUGS MANUFACTURING IN BANGLADESH 7 (2007), *available at* http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/en-high-quality-drugs-bangladesh-2007.pdf.

[217] No drug can be introduced into the market without prior approval from the Drug Control Committee and price fixation by the Drug Price Committee as per Drugs (Control) Ordinance, 1982 § 9(2)), 1982 (Bangl.).

[218] Drugs (Control) Ordinance, 1982, § 6(1) (Bangl.).

[219] *See* DA CUNHA, *supra* note 216.

However, since 1993, the number of price-controlled pharmaceuticals has reduced to 117 primary health-care pharmaceuticals.[220] The Drug Control Ordinance 1982 has empowered the government to determine the maximum retail price (MRP) of 117 essential drug-chemical substances. The MRP is broken down into trade price (75.5%), wholesale commission (2.3%), retail commission (12.0%), and value-added tax (12.5%) for local products.[221] The breakdown for imported products is made into trade price (88.89%) and retail commission (11.11%).[222]

Non-essential drugs are priced through a system of indicative prices. The rule is applicable only in the case of locally-produced goods. A fixed percentage of mark-up is applied to the cost and freight price of finished goods to determine the MRP of imported finished goods. This is followed irrespective of whether they are essential or non-essential products. Therefore, for pharmaceuticals that do not fall into the controlled category, the manufacturer is able to set the price of the pharmaceutical. In principle, this does not mean that an exorbitant price can be set by a manufacturer, as the price must be approved (but not controlled) by the Drug Control Committee.[223] But in practice, the Committee accepts the pricing as offered by the manufacturers or importers if it is not within the list of essential medicines; no other stakeholders have a say in fixing the price.[224] Therefore, sometimes manufacturers or importers can fix higher prices if it is not within the essential medicines list in Bangladesh, and the Committee will not object or criticize the pricing.

The list needs to be updated from time to time, as in some cases the old listed medicines may not work and patients will need expensive new medicines that are often beyond price control. One such situation is found in multi-drug resistance, where the older drugs are not working and yet the patient is unable to buy the new expensive drugs. Dr. Zaman Khan explained the situation in Bangladesh:

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

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[220] Interview with an official at the DDA, in Dhaka, Bangl. (Feb. 26, 2012).

[221] THE WORLD BANK, BANGLADESH: DIAGNOSTIC TRADE INTEGRATION STUDY 162 (2013), *available at* http://www.mincom.gov.bd/doc/dtisvoleom03.pdf.

[222] *Id.*

[223] Drugs (Control) Ordinance, 1982, § 4(2) (Bangl.).

[224] Interview with a policy analyst of an international public health NGO, in Dhaka, Bangl. (Feb. 23, 2012).

> afford to buy medicines. Even the cheaper versions are often beyond them.[225]

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

> "We just want the best possible answers to treat all diseases. Simply, we must have the drugs here when they are available in developed countries. And they have to be affordable for poorer people to buy." People are often too poor to buy the correct drugs needed to cure an illness or cannot complete the full course of medicines, which in turn leads to more resistance.[226]

Public health activists and generic producers in Bangladesh raising concerns about the possible negative impact of TRIPS on the public health situation in Bangladesh say that "people of Bangladesh could be very seriously affected. It is an alarming and dismal picture."[227]

That is why most of the public-health NGOs and public-health experts in Bangladesh believe that the government of Bangladesh should establish a permanent price-control mechanism accessible to the general public and public-health groups to make the existing price-control mechanism more effective.[228] Any individual or public-health group should then be permitted to challenge or review the pricing of medicines on social or health grounds.[229] Another concern is that there are a number of pharmacies in the country that operate without a license and sell pharmaceuticals to customers without a prescription and at a higher price.[230]

The Committee should be given jurisdiction to deal with these issues, and the public-health interest groups should be able to access the Committee.[231] An example of such a body is the Canadian Patented Medicine Prices Review Board (PMPRB), established in 1987 under the Patent Act as an independent quasi-judicial tribunal, which limits the prices set by manufacturers for all patented medicines, new and existing, sold in Canada, under prescription or over the counter, to ensure pricing is not excessive.[232] As an independent quasi-judicial body, the PMPRB carries out its mandate independently of other organizations, such as Health Canada, which approves drugs for safety and efficacy, and public

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[225] OXFAM GB, *supra* note 201, at 4.

[226] *Id.*

[227] *Id.*

[228] Interview with public health NGOs and pharmaceutical researchers, in Dhaka, Bangl. (Mar. 12, 2012).

[229] *Id.*

[230] Interview with a public health activist, in Dhaka, Bangl. (Dec. 23, 2009).

[231] *Id.*

[232] *See About PMPRB*, PATENTED MEDICINE PRICES REVIEW BOARD, http://www.pmprb-cepmb.gc.ca/english/View.asp?x=1433 (last visited Mar. 20, 2014).

drug plans, which approve the listing of drugs on their respective formularies for reimbursement purposes.[233]

The PMPRB has a dual role of regulating and reporting.[234] Its regulatory role is to protect consumers and contribute to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive.[235] Its reporting role contributes to informed decisions and policy-making by reporting on pharmaceutical trends and on the R&D spending by pharmaceutical patentees.[236] This Board is unique in the sense that it was set up exclusively to monitor the prices of patented drugs. Besides, the Board also analyzes the therapeutic contribution of patented pharmaceuticals, and it documents pharmaceutical R&D investment in Canada. A similar mechanism should be considered by Bangladesh as it moves towards a TRIPS-compliant patent regime.

However, it is interesting to note here that, aside from some small pharmaceutical companies, both the leading local pharmaceutical industries in Bangladesh and the MNPCs operating in Bangladesh oppose the price-control mechanism.[237] One participant during the interview argued that "some companies are trying to seize the market with the low price low quality products which may become a real threat for public health."[238] This was also supported by another participant claiming that price control may encourage cheap drugs and may, in a way, encourage low quality counterfeited pharmaceuticals.[239] The CEO of one small pharmaceutical company argued that that the "withdrawal of price control will become a threat for access to medicines and for their (small pharmaceutical companies) survival" as well.[240] He further added that "it is better to have price control to encourage local competition and ensure

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[233] *Id.*

[234] *Id.*

[235] *Id.*

[236] *Id.*

[237] The survey indicated that 50% of pharmaceutical companies operating in Bangladesh strongly agreed with the withdrawal of price control and 27% of pharmaceutical companies also agreed with the withdrawal (this represents all multinational, large, and medium-sized companies that participated in the survey). Conversely, 18% strongly disagreed and 5% disagreed with the proposition (all of them small pharmaceutical companies).

[238] Interview with an official of a large local pharmaceutical company, in Dhaka, Bangl. (Mar. 13, 2012).

[239] This view of large pharmaceutical companies was also supported by an official of a medium-sized local pharmaceutical company during the interview, in Dhaka, Bangl. (Mar. 13, 2012).

[240] Interview with the CEO of a local pharmaceutical company, in Dhaka, Bangl. (Dec. 28, 2009).

affordability of pharmaceuticals for the local people."[241] The Bangladesh Association of Pharmaceutical Industries made no comment about this, as it considered this an issue of contention both from legal and political perspectives and agreed that in their organization there is a conflict of opinions among the members.[242] Yet, public-health NGOs and IP academics in Bangladesh support a broadening of the role of price control and believe any attempt to withdraw price control will be a disaster.[243] One official at the DPDT in Bangladesh argued that "reality shows that even the Government is not able to control price effectively with the present ordinance. So the non-existence of price control would definitely lead towards the real disaster in terms of access to drugs."[244] He further added that "in the absence of it, the price of drugs would be sky-high, which would ultimately lead towards the real obstacle in order to access to drugs."[245]

In India, there is a National Pharmaceutical Pricing Authority (NPPA) which was established under the Drugs (Prices Control) Order, 1995[246] and entrusted to fix or revise the prices of controlled bulk drugs and formulations (bulk drugs are price-controlled like the essential medicines list in Bangladesh) and to enforce prices and availability of medicines in India. It has also been empowered with the task of recovering amounts overcharged by manufacturers for controlled drugs from the consumers, and it also monitors the prices of decontrolled drugs in order to keep them at reasonable levels. But, drug-control mechanisms in India are also considered ineffective, as explained by the taskforce popularly known as Dr. Pronab Sen Task Force, which was formed by the government of India to evaluate the drug-control mechanisms in India.[247] The taskforce argued that "no price regulatory mechanism can be effective unless there is a credible threat of price controls being imposed and enforced. However, it is also felt that often the present price control system is inappropriate, inadequate, cumbersome, and time consuming."[248]

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[241] *Id.* (confirming the notion of small pharmaceutical companies supporting price control measure because the benefits consider their low production range that is limited to certain products only).

[242] Interview with an official of BAPI, in Dhaka, Bangl. (Jan. 23, 2009).

[243] Interview with IP academics and public health activists, in Dhaka, Bangl. (Mar. 14, 2012).

[244] Interview with a deputy registrar at the Department of Patents, Designs and Trademarks, in Dhaka, Bangl. (Jan. 22, 2009).

[245] *Id.*

[246] Drugs (Prices Control) Order, 1995, Gazette of India, section III(2) (Jan. 6, 1995), *available at* http://nppaindia.nic.in/drug_price95/txt1.html.

[247] *See generally* RECOMMENDATIONS OF THE TASK FORCE CONSTITUTED UNDER THE CHAIRMANSHIP OF DR. PRONEB SEN TO EXPLORE ISSUES OTHER THAN PRICE CONTROL TO MAKE AVAILABLE LIFE-SAVING DRUGS AT REASONABLE PRICES (2005), *available at* http://www.drugscontrol.org/f_recom2005.pdf.

[248] *Id.* at ¶ 1.1.

The taskforce further recommended that "[p]rice controls should be imposed not on the basis of turnover, but on the 'essentiality' of the drug and on strategic considerations regarding the impact of price control on the therapeutic class. This must be a dynamic process."[249] "The ceiling prices of controlled drugs should normally not be based on cost of production, but on readily monitorable market-based benchmarks."[250] Some other recommendations of the taskforce which may also be relevant for Bangladesh are as follows:

- A process of active promotion of generic drugs should be put in place, including mandatory debranding for selected drugs.
- All public health facilities should be required to prescribe and dispense only generic drugs, except in cases where no generic alternative exists.
- In the case of proprietary drugs, particularly anti-HIV/AIDS and Cancer drugs, the government should actively pursue access programmes in collaboration with drug companies with differential pricing and alternative packaging, if necessary.
- Public Sector Enterprises (PSEs) involved in the manufacture of drugs should be revived where possible and used as key strategic interventions for addressing both price and availability issues. Arrangements may need to be made to ensure their continuing viability.
- Fiscal incentives should be provided on a long-term assured basis to research and development activities in drugs.[251]

One public health activist remarked that the government of Bangladesh should also appoint a taskforce to review its drug control mechanism and that it would benefit immensely from the Indian taskforce report suggestion to restructure the existing drug-control mechanism.[252] However, another participant remarked that the Canadian approach is free from the problems identified by the Indian taskforce, and, therefore, an agency like in Canada—empowered with the recommendations made by the Dr. Pronob Sen Task Force particularly regarding promotion of generic drugs and revival of public sector enterprise such as essential drugs limited (governmental pharmaceutical manufacturing facility in Bangladesh)—may help Bangladesh to develop a unique mechanism to maintain access to medicines, to assess the R&D investment in the pharmaceutical sector, and to feed information back to the government on such matters as incentives

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[249] *Id.* at ¶ 1.2.

[250] *Id.* at ¶ 1.5.

[251] DEP'T OF CHEMICALS & PETROCHEMICALS TASK FORCE, TASK FORCE TO EXPLORE OPTIONS OTHER THAN PRICE CONTROL FOR ACHIEVING THE OBJECTIVE OF MAKING AVAILABLE LIFE-SAVING DRUGS AT REASONABLE PRICES 53–54 (Sept. 20, 2005), *available at* http://pharmaceuticals.gov.in/drpronabreport.pdf (India).

[252] Interview with a public health activist and policy analyst working with a public health-based international NGO, in Dhaka, Bangl. (Feb. 11, 2012).

like tax exemption and other policy measures.[253] Some researchers such as A. K. Monawar Uddin Ahmad stated that "the withdrawal of price controls of many pharmaceutical products did not lead to any rise in the price level . . . [and] the MRP of some finished formulations [actually] reduced due to competitive bulk drug pricing."[254]

However, price control also has some built-in limitations or problems, such as it could disrupt the balance between supply and demand in the market. If prices are held below natural levels, resources such as talent and investor capital leave an industry to seek a better return elsewhere.[255] Therefore, there will be less discovery and innovation and fewer new drugs will become available to consumers.[256] Although supply and demand shift constantly based on the price of raw materials, production costs, and local needs, the government price will change only after a lengthy political and bureaucratic process. That is why the government price will effectively never be an equilibrium price, which means that the government price will be either too high or too low.[257] Price control also could affect openness of competition and the availability of alternatives; hence, it would tend to discourage rapid entry of generic medicines.[258]

In the context of Bangladesh, one important element that needs serious consideration is that the majority of drug costs are privately paid for in the absence of an effective health insurance system that provides access and availability to all.[259] Price regulation in most of the countries oriented towards the determination of prices involve a government purchasing the medicines for delivery through the public health system or fixing the reimbursement rates against insurance claims, but rarely fixing prices prevailing in the open

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[253] Interview with an IP lawyer working as an in-house legal counsel and regulatory affairs adviser at a local pharmaceutical company, in Dhaka, Bangl. (Feb. 13, 2012).

[254] A.K. Monaw-war Uddin Ahmad, *Competition, Regulation and the Role of the State: The Case of Bangladesh*, 53 J. ASIATIC SOC'Y OF BANGL. 199, 211 (2008).

[255] Fiona M. Scott Morton, *The Problems of Price Controls*, REGULATION 50 (2001), *available at* http://object.cato.org/sites/cato.org/files/serials/files/regulation/2001/4/morton.pdf.

[256] *Id.*

[257] *Id.* at 53.

[258] *See* Patricia Danzon & Michael Furakawa, *Prices and Availability of Pharmaceuticals*, 27 HEALTH AFF. 221, 225 (2005).

[259] *See generally* Wendy J Werner, *Micro-insurance in Bangladesh: Risk Protection for the Poor?*, 27 J. HEALTH POPULATION & NUTRITION 563 (2009), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2928102/pdf/jhpn0027-0563.pdf.

market.[260] Leading large and medium pharmaceutical companies are now more interested in exporting to other countries rather than supplying the local market due to low profits from price-controlled products.[261] Again, MNPCs operating in Bangladesh are not interested in supplying products in the local market that are under price control and have low profit margins.[262] In the absence of production by the MNPCs and of inadequate supply from leading local companies, small pharmaceutical companies with inadequate quality control are trying to seize the gap. Unless the price control mechanism works efficiently and timely with proper information about the market and relevant products, excessive price control in the long run will not give optimal results for public health in Bangladesh; rather, it could create a market for low-quality cheaper products. Considering the limitations of price control, competition law may be an additional instrument for Bangladesh.

B. National Competition Law

While implementing the TRIPS Agreement, members can prevent the abuse of IPRs and control anti-competitive practices either by integrating competition rules into the national IP law or by framing a separate competition law to prevent abusive monopoly practices or the abuse of a dominant position.[263] Article 8.2 of the TRIPS Agreement permits WTO members to adopt "[a]ppropriate measures . . . to prevent the abuse of intellectual property rights" . . . or . . . practices which unreasonably restrain trade or adversely affect the international transfer of technology," whereas Article 40 of the TRIPS Agreement recognizes the possible link between intellectual property laws and competition policy.[264] Therefore, the use of competition law and policy could

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[260] For example, in the United Kingdom, "public health and insurance takes care of 83.4 percent of the spending on medicine, and in Germany, it is 78.5 percent." S. Narayan, *Some Approaches to Pricing Controls for Patented Drugs in India*, 41 ISAS INSIGHTS 1, 2 (Dec. 1, 2008), *available at* http://mercury.ethz.ch/serviceengine/Files/ISN/94707/ipublicationdocument_singledocument/f8515305-e6a3-4b13-9ba4-27d9ba38b937/en/42.pdf.

[261] Interview with patent lawyers and pharmaceutical researchers, in Dhaka, Bangl. (Mar. 14, 2012).

[262] Interview with public health activists, in Dhaka, Bangl. (Mar. 16, 2012). All activists supported the notion that MNPC's operating in Bangladesh are not interested in supplying products in the local market that are under price control and have low profit margins.

[263] SISLU F. MUSUNGU ET AL., UTILIZING TRIPS FLEXIBILITIES FOR PUBLIC HEALTH PROTECTION THROUGH SOUTH–SOUTH REGIONAL FRAMEWORK 19–20 (2004), *available at* http://www.iprsonline.org/resources/docs/trips-health-southcentre2004.pdf.

[264] TRIPS Agreement, *supra* note 2, art. 8.2; *see id.* art. 30; Thomas Cottier & Ingo Meitinger, *The TRIPS Agreement Without a Competition Agreement?* 4 (Fondazione Eni Enrico Mattei Working Paper No. 65-99, 1998).

provide developing countries with several advantages including:[265] (a) countries will have flexibilities under the TRIPS Agreement to use a competition framework appropriate to their socioeconomic condition; (b) countries will have the freedom to define what constitutes anti-competitive behavior; (c) competition law and policy is well suited for implementation by an independent competition authority vested with extensive investigative powers; and (d) competition law and policy has already been used successfully by South Africa to reduce the price of essential medicines.

A World Bank study emphasizing the importance of developing and institutionalizing appropriate competition policy by the developing countries and LDCs stated:

> Unless developing countries rapidly establish adequate competition frameworks and regulatory institutions that also address monopoly abuse of [intellectual property rights], it is possible that increasing [intellectual property right] protection could result in welfare losses from monopoly behavior.[266]

Therefore, the government of Bangladesh should consider using the national competition law in a way to prevent the abuse of monopoly pricing during the post-TRIPS patent regime. Brazil introduced new competition law in December 2010,[267] whereas India enacted a competition law in 2002.[268] However, India and Brazil have yet to effectively use competition law or policy for the pharmaceutical sector, whereas South Africa has already successfully

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[265] Tenu Avafia et al., *The Ability of Select Sub-Saharan Africa Countries to Utilize TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries* 2–4 (tralac Working Paper, No. 12/2006, Aug. 2006), *available at* http://www.section27.org.za/wp-content/uploads/2010/10/Avafia-Berger-and-Hartzenberg.pdf.

[266] THE WORLD BANK, WORLD DEVELOPMENT REPORT: BUILDING INSTITUTIONS FOR MARKETS 147 (2002), *available at* http://www.ctc-health.org.cn/file/2009083127.pdf.

[267] In Brazil, a competition law, Law No. 8,884/94, was replaced by an updated Competition Act, Law No. 12,529/11, which went into force on May 29, 2012. Ana Paula Martinez, *Abuse of Dominance: The Third Wave of Brazil's Antitrust Enforcement?*, 9 COMPETITION L. INT'L 169, 170 (2013). Article 1 of the Brazilian competition law states that the statute's objective is to set "out antitrust measures in keeping with such constitutional principles as free enterprise and open competition, the social role of property, consumer protection, and restraint of abuses of economic power." Federal Law No. 8,884 of June 11, 1994 (Braz.).

[268] In India, the Competition Act was enacted in 2002 to replace the Monopolies and Restrictive Trade Practices (MRTP) Act, 1969. Terry Calvani & Karen Alderman, *Bric in the International Merger Review Edifice*, 43 CORNELL INT'L L.J. 73, 74 n.3 (2010). It established the Competition Commission of India to "eliminate practices having adverse effect on competition, to promote and sustain competition, protect the interests of consumers and ensure freedom of trade carried on by other participants" in markets. Vinod Dhall, *Competition Law in India*, 21-SPG ANTITRUST 73, 73 (2007).

implemented and tested its competition law in the pharmaceutical sector, and, therefore, South African competition law appears to have a viable role to play in reducing the price of medicines.[269] Therefore, the model of South African competition law should be adapted to suit Bangladesh's unique national circumstances.

In South Africa, the Medicines and Related Substances Control Amendment Act[270] created ground for using competition law to ensure access to medicines in case of excessive pricing and abuse of a dominant position. This Act was enacted in response to the HIV/AIDS crisis that the country had been facing and in response to the lack of access to pharmaceuticals due to cost. Section 15C, considered controversial by the MNPCs, reads:

> Section 15C - Measures to ensure supply of more affordable medicines
>
> The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may -
>
> (a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act 57 of 1978) determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;
> (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported.[271]

The above provision authorizes the South African government to determine to what extent a specific drug patent will apply. This provision was a

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[269] *See generally* Carina Smit, The Rationale for Competition Policy: A South African Perspective (2005), *available at* http://ri.search.yahoo.com/_ylt=A0LEViuCLa9Td0AAP8UPxQt.;_ylu=X3oDMTByMG04Z2o2BHNlYwNzcgRwb3MDMQRjb2xvA2JmMQR2dGlkAw--/RV=2/RE=1404018178/RO=10/RU=http%3a%2f%2fwww.econex.co.za%2findex.php%3foption%3dcom_docman%26task%3ddoc_download%26gid%3d9%26Itemid%3d60/RK=0/RS=NdgxNzag2LVbPCuMZOSFbG1.BJU-.

[270] Medicines and Related Substances Control Amendment Act 90 of 1997 (S. Afr.), *available at* http://www.afma.co.za/imgs/New%20AFMA%20links/AFMA%20Website/ACT%20101%20of%201965%20-%20MEDICINES%20AND%20RELATED%20SUBSTANCES%20CONTROL%20ACT/ACT%20101%20of%201965%20-%20Amendment.pdf.

[271] *Id.* at § 15C.

direct challenge to the pharmaceutical industry.[272] Such an enactment demonstrates that in becoming TRIPS compliant, a nation may avail itself of some latitude within the flexibilities allowed under the TRIPS Agreement; particularly, in pursuance of the imperative of public welfare.

The South African Competition Commission has already applied competition law successfully in the pharmaceutical sector to deal with restrictive practices and abuse of a dominant position. In *Hazel Tau and Others vs. GlaxoSmithKline and Boehringer Ingelheim*, the prices set by these two companies were considered an obstacle to access to antiretroviral medicines.[273] The Competition Commission ruled that they had violated the Competition Act, 1998 by "1. Den[ying]a competitor access to an essential facility[,] 2. Excessive pricing[,] and 3. Engag[ing] in an exclusionary act," whereas the pharmaceutical companies were merely exercising the exclusive right they were granted through their patent as in many other countries.[274] Yet, the Commissioner stated:

> Our investigation revealed that each of the firms has refused to license their patents to generic manufacturers in return for a reasonable royalty. We believe that this is feasible and that consumers will benefit from cheaper generic versions of the drugs concerned. We further believe that granting licenses would provide for competition between firms and their generic competitors. We will request the Tribunal to make an order authorising any person to exploit the patents to market generic versions of

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[272] According to *Court Case Between 39 Pharmaceutical Firms and The South African Government*, CPTECH, http://www.cptech.org/ip/health/sa/pharma-v-sa.html (last visited Apr. 5, 2014):

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

[273] *See Competition Commission Finds Pharmaceutical Firms in Contravention of the Competition Act*, CPTECH (Oct. 16, 2003), http://www.cptech.org/ip/health/sa/cc10162003.html (last visited Apr. 24, 2014).

[274] *Id.*

> the respondents' patented medicines or fixed dose combinations that require these patents, in return for the payment of a reasonable royalty.[275]

Even though the two companies denounced the complaint as unfounded, they compromised with the Commission and granted voluntary licenses to produce a generic version of their patented pharmaceuticals. Since this case, there has been huge success in South Africa toward providing access to pharmaceuticals for anti-HIV and AIDS.[276]

The government of Bangladesh enacted Competition Act, 2012 in June, 2012.[277] According to one study, "A draft bill for such a law was first proposed in 1996; however, it took sixteen years to finally come to fruition."[278] The progress of the bill was delayed: "the political will to implement a competition law is limited, and there [was] some opposition from business groups."[279] Indeed, competition problems are potentially more serious in a country such as Bangladesh, which has "a weaker private sector, where one or a few dominant firms can take control" and abuse their dominant position.[280] The media coverage suggests that "Bangladesh may suffer from significant competition problems, with substantial costs to consumers" and to the public-health sector of Bangladesh, more particularly.[281]

The government of Bangladesh should use the competition law given that its objective should be the welfare of its population. Despite the enactment of the competition law back in 2012, it has yet to be implemented as the Ministry of Commerce in Bangladesh has not adopted rules required to enforce it.[282] However, when considering some weaknesses within South African competition law, it is suggested that in any future Bangladeshi competition law, "to increase its effectiveness as a tool for reducing prices of essential medicines," any

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[275] Rachel Roumet, *Access to Patented Anti-HIV/AIDS Medicine: The South African Experience*, 3 EUR. INTELL. PROP. REV.137, 141 (2010) (quoting *South African Competition Finds GSK and BI Responsible for 'Excessive Pricing' and 'Abuse of Market Position*, HIV Treatment Bulletin, at 10, Dec. 2003/Jan. 2004, *available at* i-base.info/htb/files/2010/03/htb4-10dec03.pdf.

[276] *Id.*

[277] RAFIA AFRIN WITH DANIEL SABET, WILL BANGLADESH'S NEW COMPETITION LAW PROVE EFFECTIVE? 1 (July 2012), *available at* http://www.ulab.edu.bd/CES/documents/Competition_law_07-12.pdf.

[278] *Id.*

[279] KAREN ELLIS ET AL., ASSESSING THE ECONOMIC IMPACT OF COMPETITION: FINDINGS FROM BANGLADESH v (2010), *available at* http://www.odi.org.uk/sites/odi.org.uk/files/odi-assets/publications-opinion-files/6058.pdf.

[280] *Id.* at 2.

[281] *Id.*

[282] Shakhawat Hossain, *No enforcement of Laws on Food Adulteration, Children, Fair Trade*, NEW AGE (May 19, 2014 1:14 AM), http://newagebd.net/12634/no-enforcement-of-laws-on-food-adulteration-children-fair-trade/#sthash.IMYI3DvK.dpuf (last visited June 30, 2014).

competition commission should be empowered with the authority to issue compulsory licenses, to recommend fixed royalty rates and also to expressly allow for the export of products produced under compulsory licenses in order to maintain sustainable investment.[283] In addition, LDCs such as Bangladesh may also stipulate in national competition law that compulsory licensing could be granted in cases of anticompetitive behavior such as in the case of the patent holder's unilateral refusal to grant a license (refusal to deal).[284] Competition law could also be applied in the case of obtaining pharmaceutical patents in an unjustified and fraudulent manner.[285] Again, the issues of "poor quality" and "frivolous" patents and regulatory practices such as marketing approval and data exclusivity can also be controlled under competition law.[286]

During an interview, the participant argued that use of competition law would be a viable tool for Bangladesh to prevent excessive pricing and to allow generic production of particular pharmaceutical products if there is any abuse of dominant position as it would be extremely difficult for Bangladesh to allow a compulsory license under the patent law due to political pressure from the developed countries.[287] In contrast, another participant argued that even use of competition law may not be so easy as it may also face political pressure and the competition authority should also have enough expertise and resources to guide its reasoning.[288]

Another alternative government-intervention mechanism is a prize system.

C. Introduction of Patent Prize System

The use of patent prizes as an alternative to patents as proposed by some scholars such as Joseph E. Stiglitz could address the lack of incentive for problems such as disease in developing countries and would provide

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[283] Avafia et al., *supra* note 265, at 6.

[284] *See* Carlos M. Correa, *Intellectual Property and Competition Law: Exploring of Some Issues of Relevance to Developing Countries* 8–12, 20–22 (Int'l Centre for Trade and Sustainable Dev., Issue Paper No. 21, Oct. 2007), *available at* http://ictsd.org/i/publications/11376/?view=document.

[285] *See id.* at 13–19. In fact, these patents should never have been granted in the first place. Lack of proper resources, expertise, and proper examination in the LDCs may allow for such fraudulent registrations. In these situations, competition law plays an important role.

[286] *See id.* at 13–16.

[287] Interview with an IP academic at University of Chittagong, in Chittagong, Bangl. (Jan. 18, 2012).

[288] Interview with a public health activist, in Dhaka, Bangl. (Jan. 23, 2012).

immediately affordable pricing for products still under patent protection.[289] In a prize system, "[i]nstead of authorizing drug developers to exclude competitors, the government would pay successful developers," and, therefore, "[o]ther firms, including generic drug manufacturers, would be free to make and sell the drugs in question."[290] It is also stated that, in some studies, many drug companies spend much of the money earned through patents on marketing and advertising as opposed to researching for the new drugs.[291]

However, "[t]he controversy between a patent and prize systems [sic] reaches as far back as the nineteenth century" where "commentators proposed 'bonuses'[be] granted to inventors by the government, professional associations financed by private industries, intergovernmental agencies, or an international association funded by private industries" internationally.[292] Michael Polanvyi trumpeted the idea of prizes as a means of patent reform back in 1944 stating that "[i]n order that inventions may be used freely by all, we must relieve inventors of the necessity of earning their rewards commercially and must grant them instead the right to be rewarded from the public purse."[293] However, these suggestions did not garner much support.

The Royal Academy of Science in Paris had a prize system that "served as a model for scientific societies in other countries during the eighteenth and nineteenth centuries. The lack of a central authority or specific policy for prize distribution" made the prize system contentious and, some claimed, corrupt.[294] "Academy members were at odds when trying to determine which fields should receive general prizes," and "[s]uch disputes were only partly resolved by commissions represented by multiple disciplines. At the same time, prizes were

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[289] *See* Joseph E. Stiglitz, *Scrooge and Intellectual Property Rights*, 333 BRITISH MED. J. 1279 –80 (2006); *see also* Joseph E. Stiglitz & Arjun Jayadev, *Medicine for Tomorrow: Some Alternative Proposals to Promote Socially Beneficial Research and Development in Pharmaceuticals*, 7 J. GENERIC MEDS., 217–26 (2010).

[290] William W. Fisher & Talha Syed, *A Prize System as a Partial Solution to the Health Crisis in the Developing World*, *in* INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES 182 (Thomas Pogge et al. eds., 2010).

[291] *See generally* Mayer Brezis, *Big Pharma and Health Care: Unsolvable Conflict of Interests Between Private Enterprise and Public Health*, 45 ISRAEL J. PSYCHIATRY & RELATED SCI. 83 (2008), *available at* http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=0CDEQFjAB&url=http%3A%2F%2Fpublichealth.doctorsonly.co.il%2Fwp-content%2Fuploads%2F2011%2F12%2F2008_2_3.pdf&ei=tcpaU6HqKOibygGWgIGADQ&usg=AFQjCNEMADdtvGdLYfBgHEf6vNfUNfAzJg&sig2=WHkdek0mZKGiZN2vtwhjmw.

[292] Marlynn Wei, *Should Prizes Replace Patents? A Critique of the Medical Innovation Prize Act of 2005*, 13 B.U. J. SCI. & TECH. L. 25, 28–29 (2007).

[293] Michael Polanvyi, Patent Reform, 11 REV. ECON. STUD. 61, 65 (1944) (emphasis omitted).

[294] Wei, *supra* note 292, at 29 (footnote omitted).

becoming increasingly a matter solely of money, not honor."[295] The "ultimate question of whether the costs outweigh the benefits of a prize system over a patent system remains open" and is one that "can only be answered empirically."[296] There are few studies that have focused on the economic effects of prizes,[297] and there is no consensus on how prize systems should be designed.[298]

Nevertheless, a prize system may be designed to encourage local pharmaceutical companies and MNPCs to invest in R&D for the diseases most prevalent in Bangladesh. A prize system is justified on the grounds that granting patents stimulates a monopoly rather than the R&D necessary to deal with particular problems of a country without resources such as Bangladesh, or of inventing something where there is no hope of a huge profit.[299] Further, it is criticized that "the patent system and other exclusive rights contribute to high drug prices, global health inequities, limited access to potentially life-saving medicines and medical technologies, and the production of drugs that have little incremental therapeutic value."[300] In a system that rewards patent owners, pharmaceutical companies will target only affluent patients who can pay more or significantly higher prices that cover the cost of research, development, and marketing; therefore, "pharmaceutical companies have little incentive to invest in R&D for low-return . . . neglected diseases, or other 'non-profitable' diseases."[301] The World Health Organization "estimates approximately ten million lives could have been saved with access to existing medicines and

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[295] *Id.*

[296] *Id.* at 31.

[297] *See generally* Lee N. Davis, Should We Consider Alternative Incentives for Basic Research? Patents vs. Prizes (2002) (unpublished manuscript), *available at* www.druid.dk/conferences/summer2002/Papers/DAVIS.pdf.

[298] Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV.115, 121 (2003).

[299] *See generally* Davis, *supra* note 297.

[300] Wei, *supra* note 292, at 26 (footnote omitted). Many authors have criticized the growing numbers of "me-too" drugs on the market, products that duplicate the therapeutic value of already existing drugs. *See* Aidan Hollis, An Efficient Reward System for Pharmaceutical Innovation 6 (June 10, 2004) (unpublished manuscript), *available at* http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCgQFjAA&url=http%3A%2F%2Fwww.who.int%2Fintellectualproperty%2Fnews%2FSubmission-Hollis6-Oct.pdf&ei=_NtaU6e8LeeCyAGmr4DYDQ&usg=AFQjCNG-8dN4dHWIGNvPtp9YIl-bmeuEDQ&sig2=ZlShHqeLTATOwf1gDOB8sA; Youngme E. Moon & Kerry Herman, *Marketing Antidepressants: Prozac and Paxil* (Harvard Business School Case 502-055, Oct. 2005). For an argument favorable toward "me-too" drugs for creating competition, see Thomas H. Lee, *"Me-too" Products: Friend or Foe?*, 350 NEW ENG. J. MED. 211 (Jan. 15, 2004).

[301] Wei, *supra* note 292, at 26. Only 10% of the world's expenditure on R&D is spent on targeting 90% of the disease burden. *Id.* at 26 n.5 (citing Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1042–57 (2005).

vaccines. The deadweight loss of monopoly pricing of drugs is anywhere between $3 billion to $30 billion annually for the U.S. drug market alone.[302] In this context, a prize system has three underlying goals: (i) to provide incentives for R&D in new, significantly better medicines; (ii) to enhance access to medicines; and (iii) to focus more resources on non-profitable diseases such as neglected diseases.[303]

Considering potential benefits and limitations, Bangladesh could introduce a prize system while maintaining the patent system initially rather than preventing patents altogether. The prize system should have as its principle queries: (1) the number of patients benefited by the invention/innovation; (2) "the incremental therapeutic benefits of the innovation; (3) the degree to which the innovation addresses healthcare needs, including global infectious diseases, orphan illnesses, and neglected diseases affecting the poor in developing countries; and (4) '[t]he improved efficiency of manufacturing processes for drugs.'"[304]

During World Health Assembly 60.30:

> The governments of Bolivia, Suriname and Bangladesh present[ed] for discussion a proposal concerning the possible use of prizes as a new incentive mechanism for innovation in new cancer treatments and vaccines that would separate rewards to innovation from the price of the products. . . .
>
> This proposal is based on an earlier proposal presented by the governments of Barbados & Bolivia in April 2008 during the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property.[305]

As mentioned in the proposal, "[a]ccess to new cancer treatments and vaccines in developing countries is limited, due to several factors including, but not limited to: poor medical infrastructure; inadequate screening; and the high costs

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[302] Wei, *supra* note 292, at 26–27 (footnotes omitted).

[303] *Id*. at 28 (footnotes omitted).

[304] *Id*. at 34; *see also* Fisher & Syed, *supra* note 290.

[305] PROPOSAL BY BOLIVIA, SURINAME AND BANGLADESH: PRIZES AS A REWARD MECHANISM FOR NEW CANCER TREATMENTS AND VACCINES IN DEVELOPING COUNTRIES 1 (Apr. 15, 2009) [hereinafter PROPOSAL], *available at* http://www.who.int/phi/Bangladesh_Bolivia_Suriname_CancerPrize.pdf. The proposal stated:

> According to the WHO, of the more than 8 million persons who died from cancer in 2008, 5.7 million, or 71 percent, lived in developing countries. Cancer is a leading cause of death worldwide. According to the WHO, the percentage of total deaths attributed to cancer is expected to decline in developed countries, but to increase in all developing country regions.

Id. (emphasis omitted); *see also* Krista L. Cox, *The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines Through Voluntary Licenses*, 4 HASTINGS SCI. & TECH. L.J. 291 (2012).

of oncology equipment, services and medicines."[306] It also mentioned that "[h]igh prices for new cancer drugs and vaccines either discourage use completely, or place enormous burdens on the healthcare budgets of developing countries. Treatments for several new cancer drugs exceed [U.S.] $50,000 per completed course."[307]

However, this was not a proposal for a global prize fund; rather, it suggested that "national governments in developing countries introduce a new system of rewarding the development of new medicines and vaccines for cancer."[308] Specifically, it proposes "that developing countries de-monopolize the entire sector of medicines and vaccines for cancer, and permit free entry by generic suppliers."[309] The proposal further states that "[i]n return for ending the monopoly, developing country governments would offer to provide a domestic system of rewards for developers of new medicines and vaccines for cancer that is based on a fixed percentage of the national budget for cancer treatments."[310]

It was argued that such a proposal is consistent with the TRIPS Agreement as developing countries "can eliminate the exclusive rights to use patented inventions, in cases where patent owners receive remuneration or compensation."[311] However, there has been no outcome from this proposal. Again, "[o]n February 24, 2005, some 162 leading medical researchers, NGOs, parliamentarians, government officials, and other stakeholders submitted a letter to the [WHO] asking that it evaluate a proposal for a new global treaty to support medical R&D."[312] The letter proposed "to deal with higher drug prices for consumers in developed and developing countries by introducing a Medical R&D Treaty Framework that could ultimately replace existing or planned trade agreements that focus on patents or drug prices."[313]

According to a paper by Andrew Farlow:

> In late 2005 Kenya formally submitted a resolution to the WHO's Executive Board (WHO EB) asking for the creation of a working group of member states to consider the [Medical R&D treaty (MRDT)]. In January 2006 Brazil co-sponsored the resolution. Subsequently, the WHO EB

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[306] PROPOSAL, *supra* note 305, at 2.
[307] *Id*.
[308] *Id.*
[309] *Id*.
[310] *Id*. (emphasis omitted).
[311] *Id*. at 3; *see also* TRIPS Agreement, *supra* note 2, arts. 30, 31, 44.
[312] *Proposal for Treaty on Medical Research and Development* (Feb. 2005), CPTECH, http://www.cptech.org/workingdrafts/rndtreaty.html (last visited April 5, 2014).
[313] *Id.*

> approved a heavily bracketed version of a draft resolution. That draft was debated at the World Health Assembly (WHA) in late May 2006.[314]

The MRDT would require all countries—rich and poor—to pledge to spend a fixed percent of their Gross Domestic Product (GDP) on medical R&D.[315] The WHO Consultative Expert Working Group (CEWG) report also proposed the creation of a new binding agreement to provide billions of dollars annually for R&D to address the special health care needs of poor persons living in developing countries, and to introduce new approaches to funding R&D that included open innovation models, the delinkage of R&D costs from product prices and technology transfer and capacity building in developing countries.[316] However, the CEWG report also stated that "[w]e see a convention not as a replacement for the existing intellectual property rights system, but as a supplementary instrument where the current system does not function."[317]

"Although the sponsors believe that a treaty on MRDT would considerably 'transform the landscape of biomedical innovation to incorporate needs-driven health research and development,' several developed country members, primarily the U.S. and the EU, said that the WHO was not an appropriate forum for discussing the treaty."[318] Finally the WHO negotiations on MRDT ended without any concrete action, and, instead, the WHO deferred the issues until 2016 by deciding to convene another open-ended meeting of Member States prior to the 69th WHA in May 2016 to assess progress and continue discussions on the remaining issues in relation to monitoring,

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[314] Andrew Farlow, A Global Medical Research and Development Treaty: An Answer to Global Health Needs? 12 (2007) (IPN Working Paper on Intellectual Property, Innovation and Health), *available at* http://www.andrewfarlow.com/global_medical_research_treaty.pdf; *see* WHO, [GLOBAL FRAMEWORK ON] ESSENTIAL HEALTH RESEARCH AND DEVELOPMENT, *in* EXECUTIVE BOARD, 117TH SESSION, RESOLUTIONS, DECISIONS, AND ANNEXES 20 (Jan. 27, 2006), *available at* http://apps.who.int/gb/ebwha/pdf_files/EB117-REC1/B117_REC1-en.pdf.

[315] Ryan Abbot, *Potential Elements of the WHO Global R&D Treaty: Tailoring Solutions for Disparate Contexts*, INTELLECTUAL PROPERTY WATCH (Jan. 29, 2013), http://www.ip-watch.org/2013/01/29/potential-elements-of-the-who-global-rd-treaty-tailoring-solutions-for-disparate-contexts/.

[316] *Id.*

[317] *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination*, WORLD HEALTH ORGANIZATION (Apr. 5, 2012), http://www.who.int/phi/CEWG_Report_5_April_2012.pdf.

[318] *WHO Tackles Intellectual Property, R&D Treaty*, BRIDGES WEEKLY TRADE NEWS DIGEST 1, 3 (May 27, 2009), *available at* http://www.ictsd.org/sites/default/files/review/bridgesweekly/bridgesweekly13-19.pdf.

coordination and financing for health R&D.[319] Public health groups like Knowledge Ecology International criticized the outcome by saying that:

> A treaty on R&D financing would have not have cost the United States any money, while creating obligations on other countries to pay more for global health R&D projects. The only reason for blocking this initiative was to protect the existing drug development business model. The existing model benefits big pharma the most, and exploits consumers and marginalizes the poor.[320]

On the basis that there is no international scheme, Bangladesh would try a country-specific prize fund based on the most preventable diseases in Bangladesh. During surveys of the pharmaceutical companies in Bangladesh, none of them showed any interest in the prize system. However, pharmaceutical researchers and public health NGOs termed this as a viable option during interviews.[321]

Limiting data protection could also be a policy position in need of consideration by the government of Bangladesh.

D. Limit Data Protection

Pharmaceutical companies are required to submit test and clinical data relating to safety and efficacy to national health authorities to get marketing approval for any newly-developed pharmaceuticals.[322] The data exclusivity provisions "refer to a practice whereby, for a fixed period of time, national drug regulatory authorities prevent and block the registration files of an originator to be used to register a therapeutically equivalent generic version of that medicine without obtaining the consent of the patent holder unless the generic manufacturer actually conducts the clinical trials again."[323]

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[319] *See* James Love, *WHO Negotiators Propose Putting Off R&D Treaty Discussions Until 2016*, KNOWLEDGE ECOLOGY INTERNATIONAL (Nov. 28, 2012, 8:22 PM), http://keionline.org/node/1612.

[320] *Id.*

[321] Based on the interview responses from pharmaceutical academics and researchers.

[322] Carlos M. Correa, *Protecting Test Data for Pharmaceutical and Agrochemical Products Under Free Trade Agreements*, IPRSONLINE, http://www.iprsonline.org/unctadictsd/bellagio/docs/Correa_Bellagio4.pdf.

[323] "Data exclusivity was first introduced in 1987 in a number of European countries to compensate for insufficient product patent protection. However, product patents for twenty years are now available in all 27 EU member states. The rules on data exclusivity have been changed in the EU pharmaceutical laws adopted in 2004." MOHAMMED EL SAID, PUBLIC HEALTH RELATED TRIPS-PLUS PROVISIONS IN BILATERAL TRADE AGREEMENTS: A POLICY GUIDE FOR NEGOTIATORS AND IMPLEMENTERS IN THE WHO EASTERN MEDITERRANEAN REGION 186 n.15 (World Health Org. & Int'l Ctr. for Trade & Sustainable Dev., 2010), *available at* http://applications.emro.who.int/dsaf/dsa1081.pdf.

Supporters of data exclusivity provisions consider it important to compensate for inordinate delays in granting patents and also to recover investment and research costs for the innovators. On the other hand, generic companies believe:

> Data exclusivity has nothing to do with protecting research data. Long after the data exclusivity period has expired, the originator documentation remains protected by copyright laws and other legal provisions. Data exclusivity merely extends the originator company's market monopoly over a product by not allowing the authorities to process an application for marketing authorisation.[324]

Therefore, "[d]ata exclusivity can be a barrier to generic entry irrespective of whether the drug was patented, or if the patent period has expired."[325]

In India, when generic companies apply for approval of a pharmaceutical, they are not required to conduct their own studies and submit independent data.[326] Rather, companies can rely on the safety and efficacy data submitted by the innovator company to get marketing approval for their products.[327]

Article 39.3[328] of the TRIPS Agreement is being interpreted by some multinational companies and some developed countries, particularly in the United States, "to mean that WTO member countries are required to grant data exclusivity for a specified period of time."[329] Yet, in tracing the history and the

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[324] *Data Exclusivity*, EUROPEAN GENETIC MEDICINES ASSOCIATION, http://198.170.119.137/gen-dataex.htm (last visited Mar. 14, 2014).

[325] INTEGRATING REPORT, *supra* note 28, at 62.

[326] Animesh Sharma, *Data Exclusivity with Regard to Clinical Data*, 3 INDIAN J. L. & TECH. 82, 96–97 (2007), *available at* http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CDMQFjAA&url=http%3A%2F%2Fwww.ijlt.in%2Farchive%2Fvolume3%2FSharma%2520-%2520Data%2520Exclusivity%2520with%2520regard%2520to%2520Clinical%2520Data%2520%5B3%2520Indian%2520J.%2520L.%2520%26%2520Tech.%252082%5D.pdf&ei=4ixcU-HwEIL4yQH_wYDgAg&usg=AFQjCNHBhgliAokiwM2bWu0ZZf96wThMaA.

[327] *Id.* at 84.

[328] Article 39.3 of the TRIPS Agreement states:

> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

TRIPS Agreement, *supra* note 2, art. 39.3.

[329] Sudip Chaudhuri, *TRIPS and Changes in Pharmaceutical Patent Regime in India* 19 (Indian Institute of Management Calcutta, Working Paper No. 535, Jan. 2005).

text of Article 39, scholars "have concluded that the protection need not be in the form of data exclusivity."[330]

If data exclusivity "were the intention then the terms 'exclusive rights' would have been used as in Article 70.9" of the TRIPS Agreement.[331] Article 39.3 of the TRIPS Agreement "requires countries to protect data against 'unfair commercial use.'"[332] Additionally, "countries have the discretion to [protect data] not through data exclusivity but by proscribing situations where a competitor obtains the results of testing data through fraud, breach of confidence or other 'dishonest' practices and derive a commercial advantage."[333] Thus, "[p]rotection is not necessary if regulatory authorities do not require the submission of such data for marketing approval or if the data are already public."[334] Protection should only be required for new chemical entities so that each country can have considerable freedom "in defining what is 'new,' and may exclude the different formulations based on the same chemicals."[335]

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

> Given the negative impact on public health and access to medicines of providing for data exclusivity, it is important that developing countries try to avoid it. If unable to avoid data exclusivity, countries should limit the duration of data exclusivity as well as its scope (e.g., only for new chemical entities, and only for undisclosed data). Countries should also consider creating exemption mechanisms by which they can exempt products from data exclusivity provisions if necessary.[336]

Moreover, the CIPIH Report also reaffirms this under Recommendation 4.20, which states:

> Developing countries need to decide in the light of their own circumstances, what provisions, consistent with the TRIPS agreement, would benefit public health, weighing the positive effects against the negative effects. A public health justification should be required for data protection rules going beyond what is required by the TRIPS agreement. There is unlikely to be such a justification in markets with a limited ability

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[330] *Id.*
[331] *Id.*
[332] *Id.*; *see* TRIPS Agreement, *supra* note 2, art. 39.3.
[333] Chaudhuri, *supra* note 329, at 19.
[334] *Id.*
[335] *Id.* at 20.
[336] WORLD HEALTH ORG., INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO MEDICINES: A SOUTH-EAST ASIA PERSPECTIVE ON GLOBAL ISSUES 28 (2008), *available at* http://apps.searo.who.int/pds_docs/B3468.pdf.

> to pay and little innovative capacity. Thus, developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS.[337]

During the surveys in Bangladesh, all but one of the participants argued that Bangladesh should not give any test data protection.[338] They also stated that it would be beneficial to follow the Indian approach so as to allow generic competition.[339] One participant argued that granting test data protection over clinical and pre-clinical trial data could restrict entry of generic medicines as local pharmaceutical companies in Bangladesh lacks financial and technical resources to conduct original clinical trial.[340] However, one MNPC remarked in the survey that "test data protection may encourage foreign direct investment and technology transfer in Bangladesh."[341]

As an LDC, Bangladesh is still enjoying the Doha waiver for pharmaceutical patents; therefore, currently, there is no test-data protection system in Bangladesh, and Bangladesh should maintain that position so as to help local generic producers. However, Bangladesh should work towards creating a patent pool in cooperation with other countries and private organizations.

E. Patent Pool on Country Specific Diseases

A patent pool is an agreement between two or more patent owners to license one or more of their patents to one another or third parties, whether they are transferred directly by the patentee to license or through any medium, such as a joint venture, set up specifically to administer the patent pool.[342] Therefore, a patent pool is a mechanism through which various patents held by different entities such as companies, universities, and research institutions are made available to others for production or further development.[343] The patent holders receive royalties for the use of the patent not from the user directly, but from the

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[337] CIPIH REPORT, *supra* note 27, at 126.

[338] In the survey, all the local (large, medium, and small) pharmaceutical companies supported the Indian position while one MNPC supported test data protection and other MNPCs did not disclose their position on the issue.

[339] *Id.*

[340] Interview with an academic at the University of Dhaka, in Dhaka, Bangl. (Mar. 13, 2009) (discussing the pharmaceutical technology).

[341] From survey response by one MNPC, in Dhaka, Bangl. (Jan. 22, 2009).

[342] *See* Steven C. Carlson, *Patent Pools and the Antitrust Dilemma*, 16 YALE J. ON REG. 359, 367–68 (1999).

[343] *See* Robert P. Merges, *Institutions for Intellectual Property Exchange: The Case of Patent Pools*, *in* INTELLECTUAL PRODUCTS: NOVEL CLAIMS TO PROTECTION AND THEIR BOUNDARIES (Rochelle Dreyfuss, ed., 2001).

pool management.[344] Patent pools are increasingly seen as a useful tool in tackling barriers to access to medicines in developing countries through the sharing of knowledge and technologies.[345]

The rationale for creating a patent pool is that it helps to lower the price of pharmaceuticals, and it enhances innovation by considering particular local health needs.[346] Further, "[a] patent pool that licenses patents in several countries can ensure that generic manufacturers operate in efficient economies of scale" and can ensure enhanced capacity to manage legal issues as **t**he multitude of patents, potential claims of infringement, variance of national laws, complexity of international treaties and national patent laws and "complicated rules for the export of medical technologies under compulsory licenses present barriers for the expanded use of generic medicines."[347] Patent-pool managers "have the expertise and capacity to manage issues that arise on behalf of governments, donors, public health agencies, patent owners and generic manufacturers."[348] It is also worth noting that collective management of the patent pool "will help [establish] global 'best practice' norms for licensing on such issues as quality control, remuneration, open competition, etc."[349]

The World Health Assembly of the WHO discussed patent pools back in 2008 and later in the Consultative Expert Working Group Report, and considered it a feasible mechanism to accelerate the availability of low-cost newer medicines in developing countries.[350] However, the possibility of creating a medicines patent pool (MPP) was first proposed to UNITAID in 2006 by Knowledge Ecology International (KEI) and Médecins Sans Frontières, following a proposal by KEI at the International AIDS Conference in 2002.[351] Then UNITAID played an instrumental role in the creation of the MPP and decided to explore the possibility of establishing a MPP in July 2008. Finally, UNITAID decided in December 2009 to create and fund a patent pool focusing on increasing access to HIV medicines in developing countries, which became a reality in July 2010. It has also been endorsed by the WHO, the U.N. High Level

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[344] Manisha Singh Nair, *Rationality of a Patent Pool*, IP FRONTLINE (Apr. 3, 2009), http://www.ipfrontline.com/depts/article.asp?id=22735&deptid=6.

[345] *Id.*

[346] *Id.*

[347] KNOWLEDGE ECOLOGY INTERNATIONAL, IGWG SUBMISSION ON COLLECTIVE MANAGEMENT OF INTELLECTUAL PROPERTY -- THE USE OF PATENT POOLS TO EXPAND ACCESS TO NEEDED MEDICAL TECHNOLOGIES 3 (Sept. 30, 2007), *available at* http://www.who.int/phi/public_hearings/second/contributions_section2/Section2_Manon Ress-PatentPool.pdf.

[348] *Id.*

[349] *Id.*

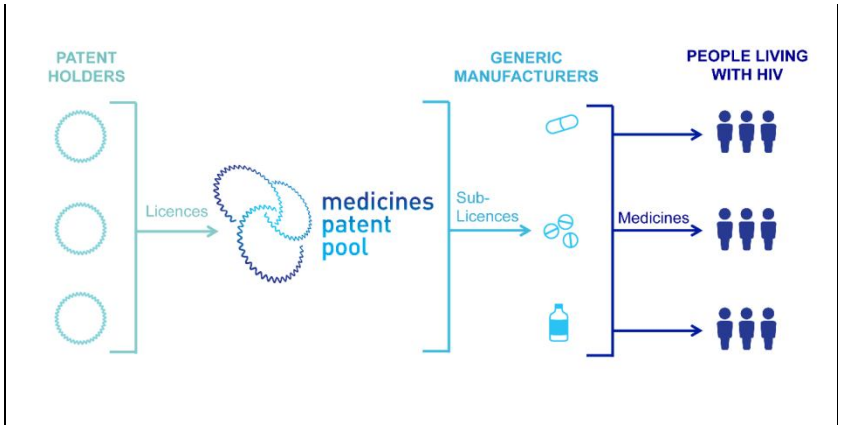
[350] David de Ferranti, *Can Patent Pools Get More AIDS Drugs to Patients?*, HUFFINGTON POST (Apr. 9, 2012), http://www.huffingtonpost.com/david-de-ferranti/aids-drugs_b_1404218.html.

[351] *Id.*

Meeting on AIDS, and the Group of 8 as a promising approach to improve access to HIV medicines.

The MPP negotiates with the patent holders to license to the MPP.[352] This means that the patent holder allows other producers to manufacture and sell low-cost, quality versions of the patented medicine in developing countries, or develop adapted formulations under certain terms and conditions. The MPP seeks licenses that push the status quo in the direction of greater access to medicines—covering more countries and containing public-health oriented terms and conditions—with the ultimate aim of ensuring all people living with HIV in developing countries can access the treatment they need at affordable prices.

Once the license is signed with the original patent holder, the MPP proceeds to make sub-licenses with the low cost generic manufacturers and other entities. The manufacturer is then free to develop, produce and sell the medicine in the agreed countries under strict quality assurance. It is stated that "[t]he MPP will particularly ease the development and production of fixed-dose combination drugs (FDCs) that have proven to simplify treatment for people living with HIV and facilitate treatment scale-up in developing countries, and medicines suited for the specific needs of children."[353] In this way, more people can be treated with the same amount of money, which is crucial in a climate of increasing needs and funding challenges. "Patent holders can get a small royalty on the sales of the medicines, and people living with HIV get access to affordable, adapted treatment they need at prices they can afford."[354] Figure 1 depicts the working procedure of MPP.



[352] For details about the working procedure of the MPP, see *About the MPP*, MEDICINES PATENT POOL, http://www.medicinespatentpool.org/about/ (last visited Mar. 15, 2014).
[353] *Id.*
[354] *Id.*

Figure 1 Working Procedure of MPP[355]

In analyzing the importance of the MPP, it was remarked in the Huffington Post:

> As of today, the history of the MPP is still being written. It will be important to see over the coming year whether this patent pool will become large enough to effectively accelerate the production of low-cost generic versions of new AIDS drugs and the creation of the fixed-dose combination. Millions of patients in countries around the world will be affected by what happens.[356]

Bangladesh could consider a patent-pool structure for prevalent diseases in Bangladesh jointly in consultation with other countries having necessity of such pharmaceuticals. This could be accomplished by using Articles 66.2[357] and 67[358] of the TRIPS Agreement to seek technical and financial cooperation from developed countries for developing a patent pool for the specific prevalent diseases in Bangladesh. During the surveys, none of the pharmaceutical companies expressed any interest in the patent pool. However, during the interview some participants argued that this option may be useful for

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[355] *How It Works*, MEDICINES PATENT POOL, http://www.medicinespatentpool.org/wp-content/uploads/how-it-works-diagram.png (last visited Mar. 24, 2014).

[356] deFerranti, *supra* note 350.

[357] Article 66.2 of the TRIPS Agreement provides that "Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base." TRIPS Agreement, *supra* note 2, art. 66.2. "This article puts an *obligation* on developed Member countries to provide incentives to enterprises and institutions. However, the precise nature of the incentives is not established; only their end is spelled out: to enable LDC members 'to create a sound and viable technological base.'" Carlos Correa, *Intellectual Property in LDCs: Strategies for Enhancing Technology Transfer and Dissemination* 3, 18 (UNCTAD The Least Developed Countries Report 2007, Background Paper No. 4, 2007), *available at* http://unctad.org/Sections/ldc_dir/docs/ldcr2007_Correa_en.pdf.

[358] "Article 67 of the TRIPS Agreement sets out developed countries' commitments on technical cooperation. This Article provides that developed country members must provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country members to facilitate TRIPs implementation. Such assistance can include assistance in drafting laws and regulations to protect IPRs as well as the establishment or reinforcement of domestic enforcement agencies." Farhana Yamin, *Globalisation and the International Governance of Modern Biotechnology:* IPRs, Biotechnology and Food Security, Foundation for International Environmental Law and Development 25, *available at* http://www.sristi.org/mdpipr2004/other_readings/OR%2042.pdf.

Bangladesh to gain technological and financial assistance from developed countries on country-specific diseases.[359]

Further, Bangladesh should also avoid entering any agreements that limit flexibilities allowed under the TRIPS Agreement or that could impose any TRIPS-plus obligations.

F. Not to Agree on Any BITs or FTAs Eroding TRIPS Flexibilities or Imposing TRIPS-Plus Obligations

The ability of LDCs like Bangladesh to utilize the flexibilities of the TRIPS Agreement "is being slowly eroded away through various bilateral and regional negotiations with developed countries."[360] High-income and industrialized countries—more particularly the United States and the European Union—put pressure on developing countries and LDCs to introduce TRIPS-plus provisions, e.g., commitments beyond those specified by TRIPS and those providing more extensive protection than TRIPS.[361] "TRIPS-plus provisions are introduced through bilateral agreements, such as free trade agreements (FTAs) and investment treaties."[362] Between 2001 and 2010, "72 FTAs with intellectual property clauses have been announced to the WTO. Of specific concern are the FTAs between developed countries and markets, most notably the United States and the European Union with low and middle income countries" because extensive patent provision in the FTAs restricts utilization of TRIPS flexibilities and hence present barriers to access of essential pharmaceuticals.[363] More recently serious concerns have been raised regarding The Trans-Pacific Partnership Agreement (TPP)[364] and Anti-Counterfeiting Trade Agreement

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[359] During interviews, this was supported by IP academics, pharmaceutical researchers and public health activists working in national and international NGOs having involvement in the public-health sector in Bangladesh.

[360] GOOD PRACTICE GUIDE, *supra* note 187, at 49 (citing Miguel Ernesto Cortes Gamba, *Intellectual Property in the FTA: Impacts on Pharmaceutical Spending and Access to Medicines in Colombia*, IFARMA 37 (Oct. 2006), *available at* http://www.ifarma.org/web/wp-content/uploads/2009/02/tlc_colombia_ingles1.pdf).

[361] Peter Drahos, *BITS and BIPS: Bilateralism in Intellectual Property* 4 J. WORLD INTELL. PROP. 791, 800–01 (2001), *available at* https://www.anu.edu.au/fellows/pdrahos/articles/pdfs/2001bitsandbips.pdf.

[362] GOOD PRACTICE GUIDE, *supra* note 187, at 49; Drahos, *supra* note 361, at 802.

[363] GLOBAL COMM'N ON HIV AND THE LAW, *supra* note 187, at 25; *see also* GOOD PRACTICE GUIDE, *supra* note 187; *see also* Susan K. Sell, *TRIPS-Plus Free Trade Agreements and Access to Medicines*, 28 LIVERPOOL L. REV. 41 (2007).

[364] The Trans-Pacific Partnership Agreement (TPP) is originally based on an agreement originally concluded in 2005 between Brunei, Chile, New Zealand, and Singapore and now also negotiated between Australia, Malaysia, Peru, the United States, and Vietnam. *See* Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP*, 18 J. INTELL. PROP. L. 447, 454–61 (2011).

(ACTA)[365] due to the inclusion of TRIPS-plus patent provisions which may have serious impacts on public health. LDCs like Bangladesh should be aware of the various TRIPS-plus provisions that can have a negative impact on the use of TRIPS Agreement flexibilities and subsequently on access to affordable medicines. Below are some of the most common TRIPS-plus provisions related to public health and access to medicines:

- Waiving the LDC exception as allowed under the TRIPS agreement[366]
- Defining "innovation" for the purposes of determining patent protection to include minor "me-too" molecular variations
- Restricting patent oppositions
- Extending patent terms beyond 20 years for delayed marketing approval
- Limiting parallel imports of patented drugs
- Restricting grounds for compulsory licensing
- Imposing "data exclusivity" rules
- Linking patent systems to drug regulatory systems[367]

These TRIPS-plus provisions, if adopted by any developing countries and LDCs, will outweigh the benefits of the TRIPS flexibilities for the country concerned and will have severe consequences on access to medicines.[368] The pressure to adopt more extensive protection than required by the TRIPS

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[365] The Anti-Counterfeiting Trade Agreement (ACTA) is a multinational treaty, which aims to establish an international intellectual property framework targeting primarily counterfeit goods, generic medicines and copyright infringement on the Internet, and would create a new governing body outside existing forums, such as the World Trade Organization, the World Intellectual Property Organization, or the United Nations. It has yet to come into effect. ACTA has been criticized by Doctors Without Borders for endangering access to medicines in developing countries. *See A Blank Cheque for Abuse: ACTA and Its Impact on Access to Medicines*, MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN (Feb. 17, 2012), *available at* http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/Access_Briefing_ACTABlankCheque_ENG_2012.pdf.

[366] LDCs may need to adopt TRIPS-compliant national law including pharmaceutical patents despite the fact that they are entitled to a transition period until January 1, 2016 to fully implement patent protection for pharmaceuticals—and as per decision of June 2013, have exemption until July 1, 2021 for general TRIPS obligations (which was July 1, 2013 earlier) and possibly have a separate extension for pharmaceutical patents even beyond 2021.

[367] *See* Gaelle P. Krikorian & Dorota M. Szymkowiak, *Intellectual Property Rights in the Making: The Evolution of Intellectual Property Provisions in US Free Trade Agreements and Access to Medicine*, 10 J. INTELL. PROP. L. 388 (2007); *see also* GOOD PRACTICE GUIDE, *supra* note 187.

[368] *Trading Away Health: How the U.S.'s Intellectual Property Demands for the Trans-Pacific Partnership Agreement Threaten Access to Medicines*, MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN 12 (Aug. 2012), *available at* http://aids2012.msf.org/wp-content/uploads/2012/07/TPP-Issue-Brief-IAC-July2012.pdf.

Agreement has also led to the debate over the floor versus ceiling in an international IP regime.

Annette Kur and Henning Grosse Ruse-Khan argue that advancing the concept of a ceiling for the TRIPS Agreement would protect flexibilities under the TRIPS Agreement from encroachment by "IP maximalists."[369]

> [T]he concept of maximum rights or 'ceiling rules' which provide for a binding maximum amount of IP protection that WTO Members can offer in their national laws . . .[to] maintain a balanced approach towards IP protection, and to protect members states' autonomy in preserving public policy goals vis-à-vis pressure exerted against them in bilateral trade negotiations.[370]

According to them, TRIPS Art. 1:1 provides that:

> [M]ore extensive protection may only be granted "provided that such protection does not contravene the provisions of this Agreement." In spite of that, the general perception in international IP regulation so far has been that above the prescribed minimum standards there is no ceiling or limit other than the sky.[371]

On the other hand, J.H. Reichman stated that with the mandates, the TRIPS Agreement established a floor for global IP norms.[372] Reichman contends that "states must accord to the nationals of other member states those international minimum standards of intellectual property protection that are comprised within 'the treatment provided for in this Agreement.'"[373] The U.S. government and its industry lobbyists argue that the TRIPS Agreement should not only be preserved as the "floor" for global standards, but that more attempts need to be taken to strengthen the TRIPS Agreement and other agreements to upgrade legal systems and enforcement mechanisms in the field of IP.[374]

To date, there is no debate at the WTO or other international bodies regarding the introduction of ceiling or maximum protection restriction or any proposal in support of it from the developing countries or the LDCs. In the

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[369] *See* Annette Kur & Henning Grosse Ruse-Khan, *Enough is Enough: The Notion of Binding Ceilings in International Intellectual Property Protection* 44 (Max Planck Institute for Intellectual Property, Competition & Tax Law, Research Paper Series No. 09-01, Dec. 8, 2008), *available at* http://ssrn.com/abstract=1326429.

[370] *Id.* at 1.

[371] *Id.*

[372] *See generally* J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement*, 29 INT'L L. 345 (1995).

[373] *Id.* at 351.

[374] *See* GLOBAL INTELLECTUAL PROPERTY CENTER, TRIPS: FLOOR VERSUS CEILING*?* 4 (Jan. 26, 2010), *available at* http://www.theglobalipcenter.com/sites/default/files/reports/documents/TRIPS_FloorVsCeiling_WP_1_10_2.pdf.

absence of any maximum limit, a country could frame its IP law based on its comparative advantage in a specific (R&D-based) area of innovation or imitation. Additionally, considering the importance of other societal values and public goods beyond those of commercial interest as well as the country's stage of development, LDCs and developing countries may need distinct types of ceilings. Any international binding regime on the ceiling, at least if placed within the WTO, could potentially open the door for further complex legal disputes under the WTO dispute settlement body and could further jeopardize the process of ongoing policy space for access to medicines and other developmental goals in the LDCs.

Therefore, LDCs such as Bangladesh need not adopt any ceiling on IPRs at the national level, but instead can keep the space open to strengthen IPRs in future if local industry matures and engages in innovation. Rather, Bangladesh should try to avoid any TRIPS-plus obligations in free trade and investment agreements with the United States, the European Union, or with any other developed countries, and it may need to be aware of and try to mitigate TRIPS-plus obligations in various bilateral and regional free trade or investment agreements.[375] While avoiding TRIPS-plus obligations will allow LDCs like Bangladesh the freedom to utilize TRIPS flexibilities, LDCs including Bangladesh could also lobby for further extension of the TRIPS waiver periods in general and with pharmaceutical patent waivers in particular.

G. Lobby for the Extension of the Transition Period for Pharmaceutical Patents

Considering the vulnerable condition of LDCs due to their socioeconomic conditions and weak public-health infrastructures, the introduction of pharmaceutical patents will make LDCs more marginalized in terms of coping with the prevailing situation. Bangladesh, in cooperation with other LDCs, should consider lobbying for further extension of the transitional period for pharmaceutical patents beyond 2016 (now beyond 2021 after the new extension

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[375] Since 2003, Bangladesh has been negotiating a Trade and Investment Framework Agreement (TIFA) with the United States to include provisions on IP. It was finalized to ratify in 2009 and revised further in 2012, but ratification was postponed by the government of Bangladesh in consideration of possible negative campaigns in the upcoming election. There is an assumption that proposed TIFA text could impose TRIPS-plus obligations on Bangladesh. While request for disclosure of draft TIFA text for the sake of avoiding controversies, an official of the U.S. mission in Dhaka said Washington was not in a position to make the draft public before signing of the agreement. "There are other drafts of TIFA and this one is similar to that," said the U.S. official. *See* Khawaza Main Uddin, *Govt Inching Closer Towards Signing TIFA with US*, BUSINESS INFO BANGLADESH (Nov. 7, 2009), https://web.archive.org/web/20101120054050/http://bizbangladesh.com/business-news-2758.php (accessed by searching for bizbangladesh.com/business-news-2758.php in the Internet Archive index).

decision on June 2013) so that it will have more time to develop its infrastructure and its local pharmaceutical industry to deal with public-health problems in a post-TRIPS setting. The Prime Minster of Bangladesh has argued that it is necessary for LDCs like Bangladesh to receive another fifteen-year extension based upon their weak infrastructure, vulnerable health conditions, and the nascent stage of their pharmaceutical industries.[376] During her deliberation to the Sixty-fourth World Health Assembly (May 17, 2011), the Prime Minister of Bangladesh, Sheikh Hasina, reiterated that the flexibilities accorded within the existing IP regime, in particular the patent waiver for LDCs for pharmaceuticals, must be extended further.[377]

In this respect, Bangladesh could argue that the socioeconomic situation, low level of development, and health and technical infrastructure for which the transitional period was granted are still prevalent in LDCs; therefore, the graduation to a pharmaceutical patent regime will have a huge negative impact on Bangladesh.[378] Unless there is considerable progress in the social and economic development of the LDCs, growth of health infrastructure, and an increase in the accessibility and availability of medicines, Bangladesh should argue for the continuation of the waiver for pharmaceutical patents under the principle of special and differential treatment for the derogation from commitment.[379]

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[376] Sheikh Hasina, Prime Minister of Bangladesh, Speech to the Sixty-fourth World Health Assembly (May 17, 2011), (transcript available at http://www.who.int/mediacentre/events/2011/wha64/sheikh_hasina_speech_20110517/en/index.html).

[377] *Id.*

[378] To continue the transitional period until graduation to a higher level of social and economic development and, hence,an ideal situation for the introduction of pharmaceutical patents case by case or under a country-driven approach with recourse to the WTO, Special and Differential Treatment may be sought. *See* Thomas Cottier, *From Progressive Liberalization to Progressive Regulation in WTO Law*, 9 J. INT'L ECON. L. 779, 414–19 (2006).

[379] Special and differential treatment (S&D) is a set of GATT provisions (GATT 1947, Article XVIII) that exempts developing countries from the same strict trade rules and disciplines of more industrialized countries. For example, in the Uruguay Round Agreement on Agriculture, LDCs are exempt from any reduction commitments and developing countries are given longer time periods to phase in export subsidy and tariff reductions than the more industrialized countries. Using this principle, exemption from introducing pharmaceutical patents may also be extended as long as problems of access to pharmaceuticals and a low level of social and economic development persists in the particular developing countries and LDCs. *See, e.g.*, Javier Lopez Gonzalez et al., *TRIPS and Special & Differential Treatment – Revisiting the Case for Derogations in Applying Patent Protection for Pharmaceuticals in Developing Countries* 17–34 (NCCR Trade Regulation, Working Paper No. 2011/37 May 2011), *available at* http://www.wti.org/fileadmin/user_upload/nccr-trade.ch/wp6/publications/wp_2011_37.pdf.

On November 11, 2011, on behalf of the LDC group, the delegation of Bangladesh to the WTO submitted to the TRIPS Council an elements paper on the extension of the TRIPS transition period for LDCs, which mentioned that LDCs are facing serious economic, financial, and administrative constraints on their efforts to bring their domestic legal systems into conformity with the TRIPS Agreement.[380] This request was made to extend the transitional period for implementing the TRIPS Agreement, which was scheduled to expire on July 1, 2013.

Accordingly, the TRIPS Council decision on June 11, 2013 extended not only general TRIPS obligations but also obligations to introduce TRIPS pharmaceutical patents until July 1, 2021. However, LDC members of the WTO could make separate requests to extend the pharmaceutical patent waiver even further. Ellen 't Hoen, former director of the Medicines Patent Pool and former head of the Médicins Sans Frontières' Campaign for Access to Essential Medicines, remarked that:

> *LDCs [could] also ask for an extension for pharmaceuticals and data protection closer to the 2016 deadline, they could ask for a longer deadline than 2021 for pharmaceuticals, for example, until they have 'graduated' to developing country status, which is what they tried to do for the entire TRIPS agreement.*[381]

Most of the survey participants in Bangladesh argued that the government of Bangladesh along with other LDCs should lobby for a further extension for pharmaceutical patents until 2030 or until graduation from LDC category by a particular LDC.[382] The MNPCs that participated in the surveys argued that a further extension of the waiver for pharmaceutical patents will not benefit Bangladesh and, rather, will hamper the technological development and further investment in the sector.[383] In contrast, during the interview, one participant argued that the local pharmaceutical sector in Bangladesh has yet to have

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[380] WTO COUNCIL FOR TRIPS, ELEMENTS PAPER ON THE EXTENSION OF THE TRANSITION PERIOD UNDER ARTICLE 66.1 OF THE TRIPS AGREEMENT, IP/C/W/566 (Nov. 11, 2011), *available at* http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=6&ved=0CEkQFjAF&url=http%3A%2F%2Fwww.ip-watch.org%2Fweblog%2Fwp-content%2Fuploads%2F2011%2F11%2FWTO-doc-W566.doc&ei=lv9cU-33OKqdyQG_w4HgBg&usg=AFQjCNEEQe_k107vA2PV-_j20i4_tkeNjg&sig2=0K0XkqPW_WKUWGzmnXcsTg&bvm=bv.65397613,d.aWc.

[381] Catherine Saez, *What Does WTO Extension For LDCs To Enforce IP Mean For Pharmaceuticals?*, INTELLECTUAL PROPERTY WATCH (Aug. 2, 2013, 11:45 AM), http://www.ip-watch.org/2013/08/02/what-does-wto-extension-for-ldcs-to-enforce-ip-mean-for-pharmaceuticals/ (emphasis added) (quoting Ellen **'**t Hoen).

[382] This position was supported by all the large, medium, and small local pharmaceutical companies in Bangladesh that participated in the survey.

[383] During the survey, this position was supported by all the MNPCs operating in Bangladesh.

enough R&D to compete with the MNPCs; therefore, further extension will help them to engage in R&D and prepare themselves for a transition to a pharmaceutical patent regime.[384] Further, one expert in the DPDT of Bangladesh commented that considering technical and infrastructural limitations in the DPDT, it would be better to have a transition period until 2030 for the introduction of pharmaceutical patents.[385] Therefore, Bangladesh should lobby for a further extension of pharmaceutical patents considering its present stage of technological capability and infrastructural development.

However, a simple extension of transitional periods without any concrete steps to promote the advancement of the pharmaceutical industry would be useless. Therefore, LDCs such as Bangladesh should use the transitional periods as part of a national strategy aimed at encouraging pharmaceutical production and investment in R&D based industry for progression towards innovation and TRIPS compliance. One such strategy is to introduce process patent and utility model law to encourage weak- or low-level national innovation and, consequently, promote technological learning and progression on basic research.

H. Provision for Process Patent During Transitional Period and Adoption of a Utility Model Law

Before adoption of the TRIPS Agreement, many countries provided only process—but not product—patents because process patents would still allow for the manufacture of patented products using a different process or method. This has particularly enabled manufacturers in certain countries such as India to make and become global suppliers of generic versions of patented.[386]

Despite having a long tradition of drug manufacturing, India's then applicable patent law (Patent Act of 1911) placed constraints on India's ability to use the full potential of its local industry. By introducing only process patents along with other supporting industrial policies, India was able to dislodge the MNPCs from their position of dominance and turn India into a major pharmaceutical-producing nation. As stated by Sudip Chaudhuri:

> A number of factors have contributed to the emergence of India as a major pharmaceutical producing nation. Among these are:
>
> - A tradition of development of process-technology by indigenous enterprises;
> - the externalities associated with the setting up of two major public enterprises;
> - the close association between manufacturers and government laboratories; and

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[384] Interview with an expert at the Directorate of Drug Administration in Bangladesh, in Dhaka, Bangl. (Jan. 12, 2012).

[385] Interview with a deputy registrar at the Department of Patents, Designs and Trademarks, in Dhaka, Bangl. (Jan. 22, 2012).

[386] *See* World Health Org., *supra* note 98, at 238.

- the patent and industrial policies since the 1970s[387]

Because Bangladesh still follows the Patent Act of 1911 (which was followed by India until 1970) the country should follow India's footsteps by introducing process patents and encouraging the local pharmaceutical industry to invest in R&D. They could also work in cooperation with local research institutions and Universities.

In addition to process patents, the government of Bangladesh could introduce a utility model law. This could play a very important role in promoting inventive and innovative activity not only in the pharmaceutical sector but also emerging local industries in the fields of information technology, textile manufacturing, telecommunications, and biotechnology. In Bangladesh, there are many small- and medium-sized enterprises (SMEs) including some pharmaceutical companies with inventive ideas; however, they often do not file patent applications due to the high cost of acquiring a patent, bureaucratic hurdles, long delays in acquiring a patent, and lack of confidence in their ability to satisfy high patentability requirements.

However, surveys show most of the local pharmaceutical companies believe that a simple system that could grant protection quickly would help them to quickly grow and further innovate.[388] Again, bureaucratic delays and expensive filings can be avoided if a simple system can be put into place. Such a system with a broad scope could help in overcoming the lack of incentives for inventions excluded from patent protection.[389] It is important to require relative novelty as opposed to absolute novelty for a utility model and also decrease the amount of time it takes to review and grant patents, possibly five years. Adopting relative novelty will ensure that the innovators get utility model protection quickly by way of simple examination even if the patent application contains only weak innovation—such as if there is at least one difference between the invention and the prior art.

Therefore, a utility model law along with the introduction of process patents should play an important role in filling the gap in law for promoting local, albeit weak inventions while also encouraging them to further research and innovation. However, it would be better for Bangladesh to introduce process patents under the existing patent law and adopt a separate law on utility models to encourage local innovation as local industries have yet to attain adequate

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[387] SUDIP CHAUDHURI, THE WTO AND INDIA'S PHARMACEUTICAL INDUSTRY 20 (2005). *See generally* Sudip Chaudhuri, TRIPS and Changes in Pharmaceutical Patent Regime in India (Indian Institute of Management 25–30 (Calcutta, Working Paper No 535, Jan. 2005), *available at* http://cdrwww.who.int/hiv/amds/IDA_India-Patent-amendments-Sudip.pdf.

[388] Based on the survey data of local large, medium, and small pharmaceutical companies in Bangladesh. However, MNPCs made no comments on this.

[389] *See* UMA SUTHERSANEN, UTILITY MODELS AND INNOVATION IN DEVELOPING COUNTRIES 5–7 (Feb. 2006), *available at* http://unctad.org/en/Docs/iteipc20066_en.pdf.

technical capacities and lack financial resources for basic research and, hence, for product patents as well. In addition to the process patent and utility model, the government of Bangladesh could also consider introducing special investment protection measures for the pharmaceutical industry to promote further investment, joint venture, technology transfer, and basic research in the pharmaceutical sector of Bangladesh.

I. Special Investment Protection Regime, Open Drug Innovation Model and Promotion of "Social Business" Model in the Pharmaceutical Sector

"There is a lack of new medicines for the 'neglected diseases'—those that primarily affect populations with little purchasing power, and therefore offer an insufficient incentive for industry to invest in R&D."[390] That is why developing countries and LDCs should devise a special investment regime to encourage investment in research related to country-specific neglected diseases and also could encourage local research institutions to join an open drug innovation model in the absence of huge financial resources for basic research.Shamnad Basheer proposed a comprehensive investment-protection regime based on the compensatory liability model, which will grant comprehensive market exclusivity for new drugs against free riders until such time as the investment in the discovery and development of that drug is recouped and considering that it could be more preferable to a patent regime.[391] He further recommended a reimbursement model, in which the costs of drug discovery and development can be reimbursed through public funding and prizes.[392] Unlike patents and data exclusivity for uniform periods of protection, the proposed regime will reward a rate of return on investment dependent inter alia on the health value of the drug.[393]

However, Basheer stated that his proposed investment protection regime is better suited to fostering cures for developed country diseases prevalent in the United States and the European Union.[394] Considering the huge cost for basic research and drug development and minimal financial resources of consumers in LDCs like Bangladesh, this kind of investment regime could be of little help to generate investment in the LDC-specific diseases.

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[390] Suerie Moon et al., *Innovation and Access to Medicines for Neglected Populations: Could a Treaty Address a Broken Pharmaceutical R&D System?*, 9 PLOS MED 1, 1 (2012).

[391] *See* Shamnad Basheer, *The Invention of an Investment Incentive for Pharmaceutical Innovation*, 15 J. WORLD INTELL. PROP. 305, 305 (2012), *available at* http://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID2203440_code339749.pdf?abstractid=2203440&mirid=1.

[392] *Id.* at 46–48.

[393] *Id.*

[394] *Id.* at 309.

Most of the developing countries and LDCs such as Bangladesh have clearly different pharmaceutical demands than developed countries. "The diseases of the poor attract very little R&D efforts by the large pharmaceutical industry, since they are not promising income generators. R&D is driven by market considerations. R&D targeting diseases found in developing countries is marginal."[395]

Despite the lack of patent protection for pharmaceuticals in Bangladesh until the patent waiver periods for LDCs expire, the government of Bangladesh could introduce a special investment-protection regime to encourage investment and technology transfer in the pharmaceutical sector by providing "exclusive marketing rights" for the same duration as patent. The government also could provide tax incentives for a certain period of time. In this regard, Bangladesh could set two preconditions for getting special investment protection: first, investment and/or technology transfer in an area of neglected diseases or diseases prevalent in Bangladesh and second, any drugs produced under the investment or by way of technology transfer, if intended to offer in the local market must satisfy requirements for licensing and market authorization by the DGDA in Bangladesh.[396]

The government of Bangladesh could also encourage local research institutions and pharmaceutical companies to engage themselves in the development of a new open source drug innovation model and to participate in

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[395] Carlos Correa, *TRIPS and R&D Incentives in the Pharmaceutical Sector* 19 (Comm'n on Macroeconomics and Health, Working Paper No.WG2:11, Nov. 2011), *available at* http://library.cphs.chula.ac.th/Ebooks/HealthCareFinancing/WorkingPaper_WG2/WG2_11.pdf.

[396] *See generally* WORLD HEALTH ORGANIZATION, GLOBALIZATION AND ACCESS TO DRUGS, HEALTH ECONOMICS AND DRUG SERIES 007 (Jan. 1999), *available at* http://apps.who.int/medicinedocs/pdf/whozip35e/whozip35e.pdf.

existing open source drug discovery models.[397] Open source drug discovery models are based on the idea that sharing medical information and international collaboration among scientists will advance medical research and, ultimately, will help patients all over the world suffering from neglected diseases.[398] As an example, Bangladesh could follow the Indian Open Source Drug Discovery (OSDD) project to encourage research on the prevalent diseases in Bangladesh. The Indian OSDD project is a collaborative online platform where contributors can collectively discover new therapies for neglected diseases, which initially focused on tuberculosis (TB) research. It was started in 2008 based on the $12 million in funding provided by the Indian Government along with a commitment to invest $35 million total towards the project. Therefore, the government of Bangladesh could provide some initial funding and encourage local research institutions and pharmaceutical companies to form collaborative drug innovation projects on country-specific diseases and later seek financial and technical cooperation from international organizations such as WHO, UNIDO, MNPCs, and transnational research institutions and funding from philanthropic organizations such as the Bill & Melinda Gates Foundation. Other open source initiatives in the pharmaceutical sector such as the Tropical Diseases

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[397] Open source "is a way of sharing data, expertise, and resources to increase collaboration, transparency, and cumulative public knowledge. It has been used in the software field since its infancy half a century ago, and tried in the bio-pharma field over the last decade." HASSAN MASUM & RACHELLE HARRIS, OPEN SOURCE FOR NEGLECTED DISEASES: CHALLENGES AND OPPORTUNITIES, CENTER FOR GLOBAL HEALTH R&D POLICY ASSESSMENT 3 (Feb. 22, 2011), *available at* http://healthresearchpolicy.org/sites/healthresearchpolicy.org/files/assessments/files/OS_for_NTDs_Consultation%20Draft.pdf. Additionally, a number of open source initiatives have started in the medical field such as India's Council of Scientific and Industrial Research, which is working on open source drug discovery to develop drugs for the treatment of drug-resistant tuberculosis. *See* COUNCIL OF SCIENTIFIC AND INDUS. RESEARCH, NMITLI ACHIEVEMENTS, *available at* http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0CEAQFjAB&url=http%3A%2F%2Fwww.csir.res.in%2FExternal%2FHeads%2Fcollaborations%2Fsa%2520old%2520new.pdf&ei=CcFOU7TLO9WsyASRpIL4Dg&usg=AFQjCNEkReHeI7eLQEjp046ICqlgNqcKtQ&sig2=HSlB_lx2j3rZ60LDaCSxNw. "In the long run, it may help minimize duplication of effort, and create a 'commons' of knowledge and data from which future innovation can grow." MASUM & HARRIS, *supra* note 397, at 3.

[398] *See* Stephen M. Maurer et al., *Finding Cures for Tropical Diseases: Is Open Source an Answer?*, 1 PLOS MED. 183 (2004).

Initiative,[399] TDR Targets,[400] Collaborative Drug Discovery[401] and The Lilly TB Drug Discovery Initiative[402] could also be examined by LDCs to gain an understanding of their working procedures and then used to develop more effective open source drug innovation projects targeting the health needs of the LDCs.

Furthermore, LDCs such as Bangladesh could devise a different strategy to encourage multinationals to invest in Bangladesh's pharmaceutical sector under the "social business model"[403] as part of their social corporate responsibility and humanitarian goals to help ensure that newly patented drugs that are necessary but not produced by the Bangladeshi pharmaceutical companies are available at affordable prices. This could be done either in cooperation with local research institutions or through a joint venture with local

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[399] "The Tropical Diseases Initiative (TDI) modeled itself explicitly on open source approaches as early as 2004 and produced a set of potential drug targets from pathogen genomes that have been released under a Creative Commons license for further work." Hassan Masum & Rachelle Harris, *Open Source for Neglected Diseases: Magic Bullet or Mirage?*, RESULTS FOR DEVELOPMENT INSTITUTE 7 (2011), *available at* http://r4d.org/sites/resultsfordevelopment.org/files/Open%20Source%20for%20Neglected%20Diseases.pdf.

[400] "TDR Targets is a WHO/TDR database that facilitates prioritization of potential drug targets across tropical disease areas." *Id.* It "brings together information on genomics, structural data, inhibitors and targets, and druggability." *Id.*

[401] Collaborative Drug Discovery is a California-based company, which "has created a platform for selective sharing of collaborative drug discovery data." *Id.* at 6. "It allows preclinical biological and chemical drug discovery data to be securely stored, shared, analyzed, and collaborated upon through a web interface." *Id.*

[402] The Lilly TB Drug Discovery Initiative is a not-for-profit public-private partnership headquartered in Seattle, Washington, with a mission to accelerate early-stage drug discovery and help identify the tuberculosis drugs of the future. It has opened access to its drug discovery expertise and scientific resources—such as its proprietary library of 500,000 compounds and innovative chemistry research tools—to be applied to the search for new drugs to fight tuberculosis. *See About the Initiative*, THE LILLY TB DRUG DISCOVERY INITIATIVE, http://www.tbdrugdiscovery.org/aboutinitiative.html (last visited Mar. 17, 2014).

[403] A social business is a non-loss, non-dividend company designed to address a social objective. MUHAMMAD YUNUS, BUILDING SOCIAL BUSINESS: THE NEW KIND OF CAPITALISM THAT SERVES HUMANITY'S MOST PRESSING NEEDS 1 (2010). In this type of business organization, profits are used in a manner in which they may expand the company's reach and improve the product or service to a greater extent than a traditional for-profit corporation, which is the reason why the investors receive no dividends or extra payments apart from their initial investment. *See* MUHAMMAD YUNUS, CREATING A WORLD WITHOUT POVERTY: SOCIAL BUSINESS AND THE FUTURE OF CAPITALISM 23–25 (2007). The main organizations promoting and incubating social businesses are the Yunus Centre in Bangladesh and the Grameen Creative Lab in Germany. *See* MUHAMMAD YUNUS, BUILDING SOCIAL BUSINESS: THE NEW KIND OF CAPITALISM THAT SERVES HUMANITY'S MOST PRESSING NEEDS 154–58 (2010).

pharmaceutical companies. The government of Bangladesh could provide "special exclusive marketing rights" for pharmaceuticals produced under a social business regime for a certain period of time in consultation with DGDA and prospective investors. In deciding to grant this exclusivity, LDCs can consider factors such as the nature of the investment, the necessity of the medication, and the local demand, and the exclusivity can be conditioned on the requirement that they maintain an adequate supply of the drug at an affordable price.

CONCLUSION

This Article examined the possible options for legislative changes and governmental interventions in developing countries and LDCs such as Bangladesh in comparison to the options used in Brazil, India, and South Africa, and it explained some of the drawbacks and limitations of existing patent laws. Considering the limitations of patent law, this Article explored possible governmental intervention options such as drug price control, national competition law, patent prizes, patent pools, process utility patents, investment protection regimes, and social business models that can be used to facilitate access to medicines.

This Article, among others, also explored the option of lobbying to extend the transitional periods for the introduction of pharmaceutical patents and recommended that developing countries and LDCs reject BITS/FTAs that contain TRIPS-plus provisions that result in the erosion of TRIPS flexibilities. However, a country cannot gain substantial benefits from the extended transitional periods or TRIPS flexibilities unless it has attained a certain level of technological capacity and has developed a strong generic pharmaceutical industry.[404] Even a compulsory licensing mechanism will be of little use without the technological capability to produce generic pharmaceuticals and a well-developed local pharmaceutical industry.[405] Hence, the creation of sound competitive market structures through competition law and enforcement could be more effective in enhancing both access to medical technology and fostering innovation in the pharmaceutical sector.[406] It can serve as a corrective tool if IPRs hinder competition and create a potential barrier to innovation and access.[407] Again, while adopting a TRIPS-compliant patent law, LDCs need to

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[404] *See* Bryan Mercurio, *Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines*, 5 NW. U. J. INT'L HUM. RTS. 1, 40 (2006).

[405] *Id.*

[406] WORLD HEALTH ORGANIZATION, PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE 53 (2012), *available at* http://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.

[407] *Id.* at 14.

ensure that their IP protection regimes do not run counter to their public health policies and that they are consistent with and supportive of such policies.