TICFA and Intellectual Property Rights: Implications and Challenges for Subsistence Needs in Bangladesh

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Introduction

At the age of multilateral trading system, a least developed country (LDC)[1] like Bangladesh signs bilateral investment treaties (BIT) with other countries or organization keeping in mind its developmental needs and challenges in various sectors including public health, food security and so on.. To mitigate the developmental needs and address the challenges arising thereof, the country endeavours to develop a viable public health system and boosting agriculture by ensuring the due reward to the traditional farmers. At the same time, being a member of the World Trade Organization (WTO) it will have to comply with the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) once the transition period expires in 2021 or for pharmaceuticals in 2033 or after it graduates to the developing country status. Though, intellectual property rights (IPRs) owning developed countries reap the benefits of IPRs harmonization through the TRIPS, still flexibilities in the TRIPS offer policy space for developing and LDCs. During the transition period an LDC like Bangladesh requires to exploit the TRIPS flexibilities for establishing a viable legal and infrastructural base to combat the TRIPS after its compliance. When developing countries and LDCs are vocal in the multilateral forums like the WTO by upholding their concern for socio-economic needs, the developed countries have taken different strategies to ratchet-up IPRs protection beyond multilateral platforms. During the late years of the last century Bangladesh entered BITs with the United States (US) and the European Union (EU). Remarkably, those BIT's contained IPRs but did not explicitly refer to its specific IPRs obligations. However, at the dawn of the new century the US opted for a more comprehensive agreement namely the Trade and Investment Framework Agreement (TIFA) which during the course of negotiations was renamed as the Trade and Investment Co-operation Framework Agreement (TICFA)[2] contains a preambular paragraph on IPRs obligations.[3]

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[1] Out of 48 LDCs 34 are WTO Members and Bangladesh is one of them. <http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm> 5 December 2015.

[2] The United States-Bangladesh TICFA signed on 25 November 2013 and came into force on January 30, 2014. <http://www.ustr.gov/about-us/press-office/press-releases/2014/April/US-

While Bangladesh is in transition in respect of the TRIPS, the TICFA requires an immediate "effective and adequate protection and enforcement of intellectual property rights". The framework agreement holds the tone requiring Bangladesh to maximize IPRs protection. This tone is likely to pose challenges for Bangladesh in terms of limiting TRIPS flexibilities, affecting IPRs regime reform agenda and waiving Doha round privileges. The tone of the TICFA also holds the likelihood of giving birth to the Free Trade Agreements (FTAs) for further ratcheting up IPRs protection. As FTAs stand for other countries, they might contain clauses like Non-Violation Complaints (NVCs) with the effect of squeezing the policy space for Bangladesh. Such IPRs maximization as envisioned by the TICFA may have consequences on public health, food security, agro-biodiversity and growing industries like Information and Communication Technology (ICT).

This paper exclusively deals with intellectual property rights (IPRs) landscape of the TICFA. It relies on secondary sources and raises questions what the probable consequences the TICFA might bring in the area of intellectual property rights; how the TICFA might affect public health, food security and agro-biodiversity of Bangladesh; whether the TICFA might impact on the Doha Round privileges for Bangladesh in the area of IPRs; whether the TICFA bears any TRIPS-Plus obligation on its face; how the TICFA might affect the regime reform agenda of Bangladesh in the field of IPRs; how the TICFA might affect policy space of Bangladesh in IPRs.

The first part of the paper tends to identify the TRIPS-Plus effect of the TICFA on its face. The second part argues that the FTAs might follow the TICFA, since the latter is a framework agreement. The third part landscapes the likely TRIPS-Plus effects of FTAs that might follow the TICFA by citing US-FTAs with some other countries. The fourth part portraits the likely impact of the TICFA on the TRIPS option creating standards in different IPRs areas having stance on public health, food security and agro-biodiversity. The fifth part depicts the potential impact of the TICFA on the Doha Round privileges of Bangladesh as an LDC. The sixth part warns the potential adverse effects of the TICFA on the IPRs regime reform agenda of Bangladesh. The seventh part claims that "one-on-one" arrangement like the TICFA might affect the pro-active role of Bangladesh in the LDCs forum at the WTO. The final part argues that introduction of "non-violation" regime in the future FTAs likely to derive from the TICFA might seriously prejudice the IPRs policy space for Bangladesh. Most importantly it argues that, the inclusion of non-violation regime in the FTAs may give impetus to the claim of developed countries to withdraw the moratorium on non-violation complaints under the TRIPS.

Bangladesh-Hold-Inaugural-Trade-Investment-Cooperation-Forum-Agreement-Meetin> 14 May 2014.

[3] Discussion TIFA was first initiated in 2002.
<http://archive.thedailystar.net/beta2/news/ticfa-with-the-us/> 19 July 2014.

1. Express 'TRIPS Plus'[4] Effects of TICFA: Implications and Challenges for Bangladesh

The TICFA, in its IPRs clause in the preamble mandates "adequate and effective protection and enforcement of IPRs" by the parties. This type of vague expressions e.g. "adequate and effective protection" have also been used in several other TIFAs.[5] In various literatures[6] it has pointed out that these vague standards are not defined precisely under these bilateral arrangements, therefore, the effect of these provisions may not be felt initially but is most likely to be felt in relation to issues related to investment and FDI in the future. So the use of these vague expressions can be used by the IPRs maximalist USA to exert pressure on Bangladesh to maximize IPRs protection.[7]

Another striking fact is that, in the same clause of the preamble of the TICFA it has been mandated that the contracting parties must have to comply with the WTO TRIPS Agreement, the Berne Convention and "any other intellectual property rights related agreements *as applicable to the parties*" (emphasis added). One may argue that, the USTR may pressurize Bangladesh to incorporate IPRs standards from 'any international intellectual property rights related agreement' which contains TRIPS Plus by using this clause. But this is not a sound argument. It is interesting to note that, according to the second paragraph of the TICFA text "parties" means collectively both the parties and 'party' means an individual party. So, literal interpretation of this clause only refers to an international IPRs-related agreement to which both the US and Bangladesh are party.

Further, the TICFA in its preamble has referred to the 1986 US-Bangladesh Bilateral Investment Treaty[8] categorically providing that the TICFA 'is without prejudice to

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[4] Sell defines "TRIPs-Plus" as "provisions that either exceed the requirements of TRIPS or eliminate flexibilities in implementing TRIPS". Susan K Sell, 'TRIPS-Plus free trade agreements and access to medicines' (2007) 28(1) *Liverpool law review* 41-75; See also, Said, below note 4, 93-94

[5] The US-Yemen (2004), US-Sri Lanka (2002) and US-Thailand (2002) TIFAs, for example, uses the phrase "adequate and effective protection" of intellectual property rights

[6] Mohammed K L Said, *Public health related TRIPS-plus provisions in bilateral trade agreements: A Policy Guide for negotiators and implementers in the WHO Eastern Mediterranean Region* (World Health Organization and International Centre for Trade and Sustainable Development 2010) 97: See also El-Said. Mohammed. 'The Road from TRIPS-Minus, to TRIPS-Plus: Implications of IPRs for the Arab world' (2005) 8 *Journal of World Intellectual Property* 53-65.

[7] For Drahos 'The *wide-ranging terms* in which BITS are drafted are likely to give international investors grounds for arguments, which if successful, may well be TRIPS-plus in their effects' (emphasis added) ; See Peter Drahos, 'BITS and BIPs: Bilateralism in Intellectual Property' (2002) 4 *Journal of World Intellectual Property* 791, 795.

[8] The United States-Bangladesh Bilateral Investment Treaty 1986 signed 12 March 1986 (entered into force 25 July 1989) Treaty Doc. 99-23 Congress (hereinafter the US-Bangladesh BIT)

the rights and obligations of the Parties under the Bilateral Investment Treaty' i.e. the BIT has been given overriding effect. Mere reference to the 1986 BIT vitiates the argument that, the TICFA *ex facie* does not contain any 'TRIPS Plus' IPRs standard, for this type of BIT with mandate to protect the investment[9] of nationals of either party is considered to be 'TRIPS Plus'.[10] This follows that, in the future negotiations of FTAs in the 'TICFA-Forum' the US will claim TRIPS Plus IPRs standards (if needed) to protect its investors under the 1986 BIT, for the TICFA does not prejudice the protection of IPRs under the BIT. So, the TICFA along with the 1986 BIT requires Bangladesh to ratchet up IPRs regime to protect the US investments. The 1986 BIT, for instance, requires Bangladesh[11] to join to the UPOV[12] which is a TRIPS Plus move, since it limits options for Bangladesh to choose a *sui generis* PVP regime under Art.27.3.b of the TRIPS Agreement.

2. TICFA as a Platform for Negotiating Future FTAs

The Trade and Investment Cooperation Forum Agreement (TICFA) signed[13] between the US and Bangladesh is a bilateral trade agreement. It is the Bangladesh version of "Trade and Investment Forum Agreements" (TIFAs)[14]. Trade and

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[9] The BIT is to protect the rights of the investors and the definition of 'investment' in Article1 includes intellectual property. Drahos holds in respect of the US-Nicaragua BIT that, '[t]he Nicaraguan BIT, like other BITs, does not set specific standards of intellectual property. Instead, it protects the rights of investors who use intellectual property as a mode of investment. The BIT accomplishes this by including intellectual property in its definition of investment'. See Drahos, above n 7, 794.

[10] Mohammad Towhidul Islam, *TRIPS Agreement of the WTO: Implications and Challenges for Bangladesh* (CSP, New Castle upon Tyne, 2013) 76, 131. He holds that the 1986 BIT bears the risk of curtailing TRIPS flexibilities and imposing TRIPS Plus IPRs standards resulting in fatal impact on Public Health and Agriculture of Bangladesh.

[11] Mohammad Towhidul Islam, 'TRIPS Agreement and Plant Genetic Resources: Implications and Challenges for Food Security in Least Developed Countries like Bangladesh' (2011) 22(1) *Dhaka University Law Journal* 36.

[12] International Convention for the Protection of New Varieties of Plants (in short UPOV after its French acronym) was adopted on 2 December 1961, revised in 1978 and 1991.

[13] The United States-Bangladesh TICFA came into force on January 30, 2014. <http://www.ustr.gov/about-us/press-office/press-releases/2014/April/US-Bangladesh-Hold-Inaugural-Trade-Investment-Cooperation-Forum-Agreement-Meetin> 14 May 2014.

[14] Bhala defines TIFA as:

> [a] bilateral accord used by the United States, often as a precursor and pre-condition for a free-trade agreement (FTA). TIFAs are negotiated mainly with countries whose economies were once closed or isolated and are now beginning to open to international trade and investment. Also established by TIFAs are other joint working groups between the United States and its partner country to discuss how an FTA might proceed. These working groups address issues pertaining to trade and investment liberalization, including intellectual property protection, labour and the environment, small and medium size enterprises (SMEs), and trade capacity

Investment Framework Agreements (TIFAs) "provide strategic frameworks and principles for dialogue on trade and investment issues between the United States and the other parties to the TIFA"[15]. Despite the diversity of titles[16] the main purpose of TIFAs is to create "a forum for the United States and other governments to meet and discuss issues of mutual interest with the objective of improving cooperation and enhancing opportunities for trade and investment." Importantly, TIFAs lays down foundations to negotiate Free Trade Agreements (FTAs) between the parties.[17] So far IPRs protection is concerned, TIFAs generally do not contain any substantive provision[18] but only mandate in the preambles an effective and adequate protection. Mohammed Said[19] finds that, "in the area of intellectual property protection, these agreements occasionally include brief references to improving and enhancing intellectual property protection between member states." The US-Bangladesh TICFA in paragraph 8 articulates the IPRs protection clause:

> *Recognizing* the importance of providing adequate and effective protection and enforcement of intellectual property rights and adherence to intellectual property rights norms in accordance with the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights, the Berne Convention on the Protection of Literary and Artistic Works, and any other intellectual property rights-related international agreements as applicable between the Parties.

One of the functions[20] of the "TICFA-Forum"[21] is "to identify and work to remove impediments to trade and investment between the Parties"[22]. Absence of strong IPRs regime in Bangladesh as desired by the US may be construed as an impediment to trade and investment. The US, thus, in the future FTAs negotiation may bring the

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building. See Bhala R. *Dictionary of International Trade Law* (LexisNexis, Newark, New Jersey, 2008).

[15] Office of the United States Trade Representative <http://www.ustr.gov/trade-agreements/trade-investment-framework-agreements> 23 May 2014.

[16] For example, The TIFA of the US with the South African Customs Union is titled as Trade, Investment, and Development Agreement (TIDCA)

[17] See Said, above n 6, 47. The US-WAEMU and US-South Africa TIFAs, for example, in articles 8 and 3 respectively , provides discretion to the parties to enter into further "Agreements" for the sake of trade and investment during the course of consultation and cooperation

[18] The US-Yemen (2004), US-Sri Lanka (2002) and US-Thailand (2002) TIFAs, for example, refers to IPRs protection in their respective preambles and they do not contain substantive IPRs protection clause.

[19] Said, above n 6, 48.

[20] Articles 3 and 4 of the TICFA has laid down the functions of TICFA-Forum

[21] Article 2 of the TICFA establishes the US-Bangladesh Forum on Trade and Investment (shortly, the TICFA-Forum).

[22] Article 3.3 of the TICFA.

IPRs protection as an issue. For example, IPRs protection was an issue in the 'TICFA Forum' in its first meeting held on April 28, 2014.[23]

3. Implied 'TRIPS Plus' Impact of TICFA: Implications and Challenges for Bangladesh

Even if Bangladesh claims that the TICFA, on its face, does not have any 'TRIPS Plus' impact, yet the US can pressurize Bangladesh to adopt TRIPS Plus IPRs standards within the TRIPS framework in two ways. Firstly, the TRIPs Agreement confers on its members the discretion to implement "more extensive protection"[24] than is conferred by TRIPS standards[25]and the US may allure or pressurize Bangladesh[26] to compromise with the TRIPS 'minimum standards'[27] . Secondly, the

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[23] <http://www.ustr.gov/about-us/press-office/press-releases/2014/April/US- Bangladesh-Hold-Inaugural-Trade-Investment-Cooperation-Forum-Agreement-Meetin> 14 May 2014.

[24] UNCTAD holds that, "...despite the flexibilities it grants - the TRIPS Agreement itself leaves open, favours or maybe even induces higher standards of protection. For example, in article 1 paragraph 1, the TRIPS Agreement itself allows WTO members to provide for "more extensive protection" than is required by the agreement..." See UNCTAD, *Intellectual Property in the World Trade Organization Turning it into Developing Countries' Real Property,*14, UNCTAD/DITC/TNCD/2006/8).

[25] See Drahos, above n 7, 792.

[26] As to how the US uses this room in TRIPS Shaded aptly puts: "TRIPS permits countries to exceed TRIPs standards and the US has been pressuring them to do so. It has offered countries WTO Plus market access in exchange for TRIPs-Plus policies". See Shadlen, Ken, 'Policy Space for Development in the WTO and Beyond: the case of Intellectual Property Rights' (Tufts University, Global Development and Environment Institute, Working Paper No. 05-06, 2005) 11 <http://ase.tufts.edu/gdae>. The US may also apply the "Special 301" sanction against its trading partners who do not have satisfactory level of IPRs protection regime. The sanction may be in the form of withdrawal of benefits or impositions of higher tariffs. Bello and Holmer succinctly points out : 'the Special 301 provisions of the 1988 Trade Act require the Office of the U.S. Trade Representative (the "USTR") 7 to identify annually "priority foreign countries" (1) whose failure to protect intellectual property is the most onerous and has the greatest adverse impact on U.S. products; and (2) that are not entering into good faith negotiations or making significant progress in negotiations (multilateral and bilateral) to provide adequate and effective protection of intellectual property rights. Such identification normally triggers an investigation of such country's intellectual property practices, which may lead to retaliation against such country if it refuses to reform its practices satisfactorily'. See for a details account Judith H Bello and Allan F Holmer, 'Update: Special 301' (1990-1991) 14 *Fordham International Law Journal* 874, 874-875; see also Islam, above n 7, 41-42. However, Carvalho argues that, putting pressure to adopt higher IPRs standards as means of sanction for any non-WTO matters is not allowed under Art.1.1 of the TRIPS Agreement. See Carvalho, below n 27, 61.

[27] de Carvalho succinctly puts that, "[t]he second sentence of Article1.1...makes it clear that the TRIPS Agreement : a) is a minimum standards Agreement and that b) it aims at harmonizing the national laws of WTO Members, yet without making them uniform". See de Carvalho, Nuno Pires, *The TRIPS Regime of Patent Rights* (2nd Edition, Kluwer Law International, 2005) 60.

US on the table of the TICFA in future FTAs negotiations may render Bangladesh to compromise with the "option creating standards"[28] due to the TRIPS.

4. Potential impacts of TICFA on "TRIPS Option Creating Standards": implications and Challenges for Bangladesh

"TRIPS option creating standards" otherwise known as TRIPS flexibilities allows members to qualify the operation of some standards and to choose among standards.[29] Standards that allow members to qualify the operation of some standards include determining patentability criteria under article 27.1, excluding some subject-matter from patentability under art.27(2) and 27(3), to choose a sui generis regime Plant Varieties Protection (PVP) regime under article 27.3.b, to determine the exhaustion regime under article 6, to define what constitutes national emergency to issue compulsory license under article 31, to determine the exceptions to patent rights under article 30 and 31 and framing a regime to combat anti-competitive practices under article 40. Again, Said[30] has broadly categorized 'TRIPS flexibilities' as flexibilities relating to implementation[31], flexibilities relating to substantive standards of protection[32], flexibilities related to enforcement[33] and flexibilities outside the scope of the TRIPS[34] but having bearing on IPRs.

Potential Impact of TICFA on Public Health Related TRIPS Flexibilities: Implications and Challenges for Bangladesh

The Free Trade Agreements (FTAs) likely to be negotiated in the "TICFA-Forum" will require Bangladesh to ratchet up IPRs regime and exclude Public Health Related flexibilities[35] in the TRIPS which will affect public health. Islam[36] points out

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[28] Drahos has identified three types of "option creating standards" in the TRIPS i.e. which allows the members to qualify the operation of some standards, to choose among standards and to choose when to adopt standards. See Drahos, above n 7, 792

[29] Ibid.

[30] Said, above n 6, 90.

[31] Examples of the category flexibilities include leeway to define concepts related to patentability such as novelty, new inventions and inventiveness, the TRIPS transition period.

[32] Examples of the category flexibilities include choosing the exhaustion regime, using exceptions to patentability and trademarks protection, choosing sui generis PVP regime, defining regime against anti-competitive practices.

[33] Examples of the category flexibilities include the right and discretion to establish their own national legal and judicial systems to implement and enforce the intellectual property standards of protection.

[34] For example, Traditional Knowledge (TK), folklore, biodiversity, farmers right, data exclusivity.

[35] Musungu and Oh has identified following public health related flexibilities in the TRIPS: (1) transition periods; (2) compulsory licensing; (3) public, non-commercial use of patents; (4) parallel importation; (5) exceptions from patentability; and (6) limits on data protection. See for details Sisule F. Musungu and Cecilia Oh, *'The Use of Flexibilities in*

that, highly restrictive regulatory regime due to the TICFA will result in the discontinuation of the current practice of reverse -engineering drugs and supplying them at cheaper rates disregarding their patents. Rahman[37] maintains, the "TRIPS Plus" regimes are likely to make Bangladesh compromise the access of its poor people to essential medicines. These predictions are confirmed by the experience of FTAs signed between the US and other countries.[38] "TRIPS Plus" scenarios take place in the area of public health include patent term extensions, patentability of second uses (otherwise known as ever greening of patents), determination patentability criteria as per the US maximalist standards, limiting grounds for issuing compulsory licensing, prohibiting parallel importation through introducing national exhaustion regime, rendering the early work exception available only after the patent term expires and providing for data exclusivity rendering the generic producers to push up the prices of essential medicines.[39]

Potential Impact of TICFA on Agriculture Related TRIPS Flexibilities: Implications and Challenges for Bangladesh

Article 27.3.b of the TRIPS Agreement categorically provides that WTO Members may exclude from patentability whole plants, plant varieties (provided an alternative system of protection is provided), parts of plants and essentially biological processes for their reproduction.[40] An alternative system for the protection of plant varieties must be either by patents or by an effective *sui generis* system or by any combination thereof.[41] The term "sui generis" for PVP left enormous scope for

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TRIPS by Developing Countries: Can They Promote Access to Medicines?' (South Centre, 2006) xvi.

[36] Islam, above n 10, 173.

[37] Rahman, Mustafizur, 'Globalization, Developed Country Policies and Market Access: Insights from Bangladesh Experience' in Robert Picciotto and Rachel Weaving (eds.) *Impact of Rich Countries' Policies on Poor Countries : Towards a Level Playing Field in Development Cooperation* (2004) 67, 91, cited in Islam, above n 10, 174.

[38] On the impact of Preferential Trading Agreements (PTAs) on Public Health, See generally Roffe, Pedro, and Christoph Spennemann, 'The impact of FTAs on public health policies and TRIPS flexibilities' (2006) 1(1) *International Journal of Intellectual Property Management* 75-93. See also Said, above n 6, 94-98; Lindstrom, Beatrice, 'Scaling back TRIPS-plus: An analysis of intellectual property provisions in trade agreements and implications for Asia and the Pacific' (2009) 42 *New York University Journal of Law and Policy* 917.

[39] See Roffe, P. and Spennemann, above n 36, 80-85. Sell points out that:

> Particular provisions in these bilateral and regional trade agreements include: (1) data exclusivity provisions; (2) prohibitions of parallel importation; (3) linkage between drug registration and patent protection; (4) highly restrictive conditions for issuing compulsory licenses; (5) expanded subject matter requirements; and (6) patent term extensions. All of these provisions have been crafted by the brand-name pharmaceutical industry and serve to reduce the availability of affordable drugs.

[40] See de Carvalho, above n 27, 217.

[41] *TRIPS Agreement* Article 27.3.b.

interpretation and like all WTO members Bangladesh has freedom to design its own PVP framework as per its own needs and particularities.[42] Bangladesh can, for example, grant exceptions to the exclusive rights of breeders with respect to the propagating materials of new varieties in order to enable farmers to save, reuse, exchange and sell seeds.[43] A *sui generis* PVP framework can also recognize farmers as breeders additional and protect traditional agrarian practices.[44] In the context of Agriculture-prone Bangladesh, Islam holds that, the PVP regime of Bangladesh while strengthening Plant Breeders Rights (PBRs) should also make provision recognizing farmers as breeders, farmers' right to preserve the traditional farming practices, farmers' contribution to innovation by selecting and maintain of seeds and farmers' right to access to benefit sharing (ABS).[45]

The TICFA being a platform for negotiating Free Trade Agreements (FTAs) bears the high risk of imposing "TRIPS Plus" IPRs standards in the field of Plant Varieties Protection (PVP). For example, the FTAs of the US with Bahrain, Morocco, Jordan, Singapore and Chile provide patent protection for plants either expressly or impliedly.[46] As experience shows, the US may require Bangladesh in the future FTAs likely to due at the TICFA to protect GM varieties[47] and to join the UPOV.[48]

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[42] Carolyn Deere, *The Implementation Game: the TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (OUP, 2009) 86. Islam puts succinctly: 'use of the term sui generis gives them[Members] discretion to determine the type and design of plant protection regime...which enables [them] to promote innovation plant breeding while preserving national objectives like protecting biodiversity, traditional farming and food security'. See Islam above n 9, 52. Narasimhan holds that the term 'sui generis' was used for "[t]he purpose of developing a PVP law may be interpreted to mean a customized law that a country establishes according to its biodiversity and agricultural concerns". See Narasimhan S Mullapudi, *Towards a Balanced 'Sui Generis' Plant Variety Regime: Guidelines to Establish a National PVP Law and an Understanding of TRIPS-plus Aspects of Plant Rights* (2008) 21. For Singh "the option of sui generis under TRIPS Agreement provides sufficient flexibility for countries to design a system that best fits their circumstances and meets their goals and objectives". See Harbir Singh, 'Plant variety protection and food security: Lessons for developing countries' (2007) 12 *Journal of Intellectual Property Rights* 391-399.

[43] Ibid.

[44] Anitha Ramanna and Melinda Smale, 'Rights and Access to Plant Genetic Resources Under India's New Law' (2004) 22(4) *Development Policy Review* 423, cited in Islam, above n 8, 70

[45] Islam, above n 10, 52.

[46] Deere, above n 42, 338.

[47] Genetically Modified Organisms (GMOs) may have an adverse impact on ecosystem and human health and thus patenting of GMO varieties can be excluded under Art 27(2) of the TRIPS. On adverse impact of GMOs on ecosystem and human health see, for example, Laressa L Wolfenbarger, and Paul R Phifer, 'The ecological risks and benefits of genetically engineered plants' (2000) 290(5499) *Science* 2088-2093. The WTO observes: "With respect to GMOs, countries may exclude from patentability plants and animals as well as essentially biological processes for the production of plants and animals".

Higher IPRs standards in the PVP regime like the UPOV (1991) may have serious implications for Bangladesh in terms of sustained agricultural growth and food security.[49]

5. TICFA as a Road to "Doha- minus": Implications and Challenges for Bangladesh

As an LDC, Bangladesh has been provided with some privileges at the Doha Ministerial Round under the WTO TRIPS Agreement. These include extension of transition period[50] and special provisions addressing public health crises[51]. The special Doha regime has provided Bangladesh to invoke TRIPS objectives while complying with it, to choose a regime of exhaustion as per its own needs, to determine the grounds of issuing compulsory licenses, freedom to define what constitutes national emergency or case of extreme urgency and finally freedom to take the benefits of "Waiver Decision"[52]. The "Waiver Decision" has created

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_<http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c8s1p1_e.htm>16 16 May 2014.

[48] Article 4 of the US-Jordan and article 16 of the US-Singapore FTA respectively require Jordan and Singapore to join the UPOV, 1991. Singh concludes by analysis several US and EU FTAs that, "higher emphasis on plant variety protection [through UPOV] indicate that the *sui generis* option available under TRIPS is gradually being reduced to UPOV style legislation by the developed countries in their attempt to harmonize the IP laws worldwide". Harbir Singh, 'Plant variety protection and food security: Lessons for developing countries' (2007) 12 *Journal of Intellectual Property Rights* 391-399.

[49] Fred Magdoff and Brian Tokar, 'Agriculture and Food in Crisis: An Overview' (2009) 61(3) *Monthly Review*, cited in Islam, above n 10, 114; see also Singh, above n 48, 394.

[50] Initial transition period for the LDCs was for ten year since the date of application of the TRIPS Agreement. In the Doha Round three transition periods have been granted to the LDCs, two of them are plenary i.e. applicable to all TRIPS provisions and the other one was granted only in respect of pharmaceutical products. The plenary transition period extensions were granted on 29 November 2005 and on11 June 2013 respectively. The TRIPS compliance deadline the LDCs is on 1 July 2021 in pursuance of the TRIPS Council Decision of 11 June 2013. The special transition period for pharmaceuticals, granted in pursuance of Paragraph 7 of the Doha Declaration on TRIPS and Public Health, will expire on 1 January 2016. See generally, Arno Hold, and Bryan Christopher Mercurio, 'After the second extension of the transition period for LDCs: How can the WTO gradually integrate the poorest countries into TRIPS?' (2013). See also, UNDP/UNAIDS Issue Brief on TRIPS transition period extension for least-developed countries, 2013 <http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2013/JC2474_TRIPS-transition-period-extensions_en.pdf> 18 May 2014; also visit <http://www.wto.org/english/tratop_e/trips_e/ldc_e.htm> 18 May 2014.

[51] The provisions concerning "public health" have been provided in the Doha Declaration on the TRIPS and Public Health, the General Council Decision of August 30, 2003 (also known as waiver decision) implementing Paragraph 6 of the Doha Declaration .

[52] Islam succinctly puts the effect of waiver decision:

> "[t]he Decision provides a waiver for an exporter's obligation as provided in art.31 (f) to supply predominantly to the domestic market. It enables any

opportunity for Bangladesh to export generic medicines.[53] A notable change that have been made in the Doha regime in the 11 June 2013 extension is that, now the LDCs can roll back from their existing level of IPR regime. There is a North-South controversy as to whether the 11 June 2013 extension applies to pharmaceuticals and agro-chemicals.[54] If "rollback clause"[55] is not construed to apply to pharmaceuticals, the "paragraph 6 system" would be paralyzed, for many WTO members like Bangladesh not having national regime in line with para.6 system.[56] The "non-rollback clause" also has serious public health implications for the Members who has not incorporated international exhaustion regime (parallel import) in their extant IPRs regime.[57] The US claims that, the Doha Declaration is only a political declaration and not legally binding.[58] Against this backdrop, it is not unlikely that, the US may "strong arm" Bangladesh[59] to invoke a "Doha-minus" formula in

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country having manufacturing capacity to issue a compulsory license to produce generic drugs for export to countries that have insufficient or no manufacturing capacity...the exporting country, not the importing country, must pay compensation". See Islam, above n 10, 156

[53] See Mohammad Towhidul Islam, 'TRIPS transition for Pharmaceutical Patents' <http://www.thedailystar.net/op-ed/trips-transition-for-pharmaceutical-patents-24100> 20 May, 2014; see also IP-Watch, 'WTO States Agreement on TRIPS and Public Health on Eve of Ministerial' 6 December, <http://www.ip-watch.org> 23 May 2014.

[54] *Catherine Saez, What Does WTO Extension For LDCs To Enforce IP Mean For Pharmaceuticals. <http://www.ip-watch.org/2013/08/02/what-does-wto-extension-for-ldcs-to-enforce-ip-mean-for-pharmaceuticals/> 23 May 2014.*

[55] Paragraph 5 of the TRIPS Council decision of 29 November, 2005 provided that, '[l]east-developed country Members will ensure that any changes in their laws, regulations and practice made during the ...transition period do not result in a lesser degree of consistency with the provisions of the TRIPS Agreement". Decision of the Council for TRIPS of 29 November 2005, 30 November 2005(IP/C/40)

[56] Frederick M Abbott, 'Technical Note: The LDC TRIPS Transition Extension and the Question of Rollback' (2013) 15 *Policy Brief*

[57] Ibid. legally speaking, the non-rollback clause renders the entire architect of TRIPS flexibilities meaningless for the countries that do not have incorporated them in their IPRs regime. Ashen Habib Leon, 'The relevancy of 'rollback clause' for LDCs IPRs regime' <http://www.thedailystar.net/law-and-our-rights/the-relevancy-of-rollback-clause-for-ldcs-iprs-regime-18122> 6 December 2015.

[58] Text: USTR Fact Sheet Summarizing Results from WTO Doha Meeting, Nov. 15, 2001, <http://www.usembassy.it/file200 11 1/alia/al 111516.htm> 6 December 2015. But, Gathii claims that Doha Declaration is binding from customary international law perspective, for this declaration was adopted unanimously. See Gathii, James Thuo, 'The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties' (2001) 15 *Harvard Journal of Law and Technology* 291.

[59] Sell puts that : " *Asymmetrical power relations* continue to shape intellectual property policy, reducing the amount of leeway that poorer and/or weaker states have in devising regulatory approaches that are most suitable for their individual needs and stages of development" (emphasis added). See Sell, above n 4, 41.

negotiating potential FTAs likely to due at the TICFA. Some snapshots of a "Doha-minus" landscape have been taken below.

"Doha-minus" by Introducing "Data Exclusivity"

In art 15.10 of the US-CAFTA FTA, for example, articulates a fixed term data exclusivity, which would disentitle the CAFTA countries to use the "Paragraph 6 System", for the System can be used as an exception to patent rights not as an exception to data exclusivity right. According to Abbott, 'even if a license is granted to a generic producer/importer, the patent owner will be able to prevent marketing of the equivalent medicine (because it will not consent or acquiesce to marketing).The generic product cannot be put on the market on regulatory grounds, regardless of the grant of license with respect to the patent.'[60]

Doha minus by introducing Patents for "new uses of known substances"

The TRIPS Agreement is silent as to whether patents should be granted for "new uses of known substances", leaving countries with flexibility to decide the question.[61] The Parties confirm that patents shall be available for any new uses or methods of using a known product, including new uses of a known product for the treatment of humans and animals. The U.S.-Morocco FTA, for example, in Article 15.9(2) provides that the Parties "confirm that patents shall be available for any new uses or methods of using a known product, including new uses of a known product for the treatment of humans and animals". In Art.14.8 (2), the U.S.-Bahrain FTA also articulates same type of provision. This practice of patenting "new uses of known substances" violates the Doha Declaration on TRIPS and public health, inasmuch it construes the TRIPS in such a way which renders medicine inaccessible and jeopardizes public health.[62]

Doha minus by way of Extending Patent Terms

The cardinal mandate of the Doha Declaration as said earlier is to make medicine accessible for all and to protect public health. A careful survey of some US FTAs reveals that, they tend to extend the TRIPS minimum patent term, by one way or the other, in the name of adjustment against the period that is required for regulatory approval of patent.[63]

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[60] Frederick M Abbott, 'The Doha Declaration on the TRIPS Agreement and public health and the contradictory trend in bilateral and regional free trade agreements' (*Quaker United Nations Office (Geneva)(QUNO), Occasional Paper* 14 2004).

[61] Since art.27.1 of the TRIPS Agreement does not define "novelty", it is up to the Members to define what constitute "novelty". They may well exclude "new uses of known substance" from the definition of novelty. Article 1.1 of the TRIPS has also mandated this leeway. See de Carvalho, above n 27, 64.

[62] One of the mandate of the Doha Declaration on the TRIPS and Public Health as stated in Art.4 is "that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

[63] See the U.S.-Bahrain FTA, Art.14.8 (6); CAFTA, Art.15.9 (6); U.S.-Chile FTA, Art.17.9 (6); U.S.-Morocco FTA, Art.15.9 (7); U.S.-Singapore FTA, Art. 16.7(7) (8). As regards

Excluding provision for parallel import

The Doha Declaration in article 5(d) categorically declares the freedom of the Members to choose a exhaustion regime. By mandating national exhaustion regimes or otherwise giving the patent holder exclusive right as to prevent importation of the patented product the FTAs are Doha-minus by eliminating a TRIPs-compliant opportunity to access more affordable patented drugs.[64] Article 15.9(4) of the U.S.-Morocco FTA, for example, provides that, "Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory".

Limiting the Grounds of Compulsory Licensing

Article 5(b) of the Doha Declaration on the TRIPS and Public Health gives liberty to the Members to determine the grounds for issuing compulsory licenses. Article 4.20 of the US-Jordan FTA restricts the grounds for issuing compulsory licenses. The Singaporean and Australian FTAs provide that if a Party uses a compulsory licence in the case of a national emergency, the Party "may not require the patent owner to provide undisclosed information or technical know-how related to a patented invention that has been authorised for use". [65]This is an attempt to paralyze the "para.6 system" in the name of "data exclusivity".[66]

Data exclusivity negates the Doha Mandate of "Access to Medicine"

Article 39.3 of the TRIPS Agreement requires members to provide protection against "unfair commercial use" of confidential information with respect to "new chemical entities" submitted during the regulatory review process. The provisions in the FTAs establish strict "marketing exclusivity" periods following approval based on submitted data (initially five years), do away with the limitation to "new chemical entities," and do not allow exceptions for fair or noncommercial uses, such as use by government authorities in public health systems.[67]

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patent term extension Correa puts succinctly: "[t]he possibility of such extension creates uncertainty for generic producers and, when effected, will have obvious consequences on public health: it will delay the introduction of competing products with the ensuing loss of consumer welfare and increased barriers to access to medicines, especially by the poor." See Carlos María Correa, 'Implications of bilateral free trade agreements on access to medicines' (2006) 84(5) *Bulletin of the World Health Organization* 399-404.

[64] Sell, above 4.

[65] Art.16.7.6 of the Singapore-US FTA, Art.19.9.7 Australia-US FTA.

[66] Jean-Frédéric Morin, 'Tripping up TRIPS debates IP and health in bilateral agreements' (2006) 1(1) *International Journal of Intellectual Property Management* 37, 47.

[67] Frederick M Abbott, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health' (2005) 99(2) *American Journal of International Law* 317, 350. Abbott reached in this conclusion by analyzing the U.S.-Australia FTA, Art. 17.10(1); U.S.-Bahrain FTA, Art. 14.9(1); CAFTA, Art. 15.10(1); U.S.-Chile FTA, Art. 17.10(1); U.S.-Morocco FTA, Art. 15.10(1); U.S.-Singapore FTA, Art. 16.8(1). Correa elsewhere pointed out that, "data exclusivity" is not contemplated under article39.3 of the TRIPS. See Correa, above n 63.

"Doha minus" by Denying Regulatory Use Exception to Patents

The United States links patents to the marketing approval process, precluding a country from approving a product with effect prior to the expiration of the patent term, without the "consent or acquiescence" of the patent holder.[68] The terms of the FTAs[69] applicable to pharmaceutical products, patents, and related regulatory matters raise a substantial number of concerns about the introduction of generic, off-patent products onto the market in the countries agreeing to these provisions, including the United States. These provisions may substantially reinforce the advantages of originators, even as to off-patent products, reducing the availability of alternatives and increasing prices, which undermines the Doha regime's mandate of accessible medicine for all.

6. Potential Impact of TICFA on IPRs "Regime Reform" Agenda in Bangladesh: Will the TICFA Translate "Doha-minus" in Bangladesh's IPRs Regime?

The TICFA is signed at a very crucial point of time, when Bangladesh has taken a legislative reform agenda in hand. Bangladesh is on process to draft a new patent legislation replacing the century-old Patent Act of 1911. The 1911 Act has been characterized as outmoded to serve the interest of Bangladesh in line with the Doha regime's sensation to public health and access to medicine for all, inasmuch it allows patent for any product or process.[70] The draft patent laws have been made several times,[71] the draft of 2013 being the latest. The draft of 2013, for example, have introduced the notion of international exhaustion[72] (allowing parallel import), incorporated the WTO General Council "waiver decision" of 2003[73], introduced higher threshold[74] of "inventive step" for patentability, prohibited patenting of product or process relating to agriculture and horticulture,[75] introduced wider

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[68] Abbott, Ibid. 351.

[69] See U.S.-Australia FTA, Art. 17.10(5); U.S.-Bahrain FTA, Art. 14.9(4); CAFTA, Art. 15.10(2); U.S.-Chile FTA, Art. 17.10(2); U.S.-Morocco FTA, Art. 15.10(4); U.S.-Singapore FTA, Art. 16.8(4).

[70] Section 2(8) of the Patent and Designs Act, 1911 defines an invention as "any manner of new manufacture and includes an improvement and an alleged invention". This definition is very wide and may be used to justify "ever-greening of patents" and patents "for new uses of known substances". These practices render the medicine inaccessible for people.

[71] Islam, above n 10, 169-170

[72] Art.31 of the Draft Patent Act, 2013 (Bangladesh)

[73] Art.30 of the Draft Patent Act, 2013.This provision allows Bangladesh to export generics in other LDCs with insufficient or no manufacturing capacities.

[74] Section 2(g) and 4 of the Draft requires that a patentable invention must have technical advancement; advanced efficacy and quality over its prior art and it must not be frivolous.

[75] Section 4(1)(k).

grounds for issuing compulsory licenses[76]. This new proposed regime has successfully translated the Doha mandate of protection of public health protection and access to medicine for all. Given the experience of "Doha minus" strategy[77] of the US in bilateral arrangements, one may entertain legitimate concerns as to whether this Draft Act would be passed or thrown away in the face of aggressive "Doha-minus" policy of the US.

There is also an ongoing enterprise to enact laws for protection of plant varieties, farmers' rights, traditional knowledge and biodiversity. Along with the PBRs, the Draft Plant Varieties Act, 2007 (Bangladesh) also provides protection of extant or community variety meaning farmers' variety or a landrace.[78] The Draft Act categorically prohibits protection of terminator seeds and of the GMOs without Environmental Impact Assessment (EIA).[79]As a party to the CBD and the ITPGRFA, Bangladesh has drafted the Biodiversity and Community Knowledge Protection Act (draft Biodiversity Act) containing access to PGRs and equitable benefit sharing. We have seen earlier that the US FTAs either require its counterpart to join the UPOV or to grant patents in plant varieties.[80] So, it is very likely that in the future FTAs negotiations at the "TICFA Forum" the US may require Bangladesh to grant plant patents or to follow the UPOV *in verbatim* while framing its PVP regime. This type of move may require Bangladesh to compromise some pro-public initiatives i.e. provisions excluding terminator seeds, GMOs from protection and provisions to protect biodiversity and traditional knowledge. Remarkably, under the EC-Bangladesh FTA (2001) Bangladesh is required to follow the UPOV (1991) in framing PVP regime.[81]

7. Potential Impact of TICFA on Bangladesh's standing in the LDCs Group at the WTO: Compromising Group Interest at the cost of Individual Interest

Bangladesh is one of the leading members in the LDCs group at the WTO. It has been very vocal to protect the LDCs interest in the Doha Round negotiations in different areas including the intellectual property rights. As the coordinator of the

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[76] Section 14, inspired by the Doha Declaration, has introduced wide grounds for issuing compulsory licenses like public interest, especially, national security, health, economy, nutrition. Under the section compulsory licenses may also be granted to prevent anti-competitive practices.

[77] A picture of Doha-minus strategy in FTAs has been in the previous part.

[78] See Islam, above n 10, 88.

[79] Ibid, 91.

[80] See above n 42, 46.

[81] Sarita Brault, 'PVP Flexibilities available to WTO Members: Country Profiles Related to Implementation of TRIPS Article 27.3(b)' (QUNO, January 2014) <http://s3.amazonaws.com/academia.edu.documents/33406692/PVP_flexibilities_available_to_WTO_Members_3libre.pdf?AWSAccessKeyId=AKIAJ56TQJRTWSMTNPEA&Expires=1400503494&Signature=gBL5wvdYoK8Qe%2FN6DyhJ%2FnWjpLc%3D> 5 December 2015.

LDC Group in 2003, 2007 and again in 2011, Bangladesh has ably advanced the interest of LDCs within the WTO.[82] Bangladesh has worked a lot on behalf of the LDCs group to translate WTO flexibilities for the world's poorest nations into trade and development outcomes.[83] Move of Bangladesh at the WTO on behalf of the LDCs has secured the interest of the LDCs. From IPRs perspective, the Doha Declaration on TRIPS and Public Health, transition period for pharmaceutical patents till 2033 and the 11 June 2013 extension of the transition period for LDCs till 2021 have been great success for the LDCs at the Doha Ministerial. On the contrary, these decisions have gone against the interest of the developed countries like the USA, who are opting for stronger IPRs protection worldwide to save their investment and trade. In the "TICFA-Forum" the USTR may pressurize Bangladesh to become silent in the LDCs Group, since Article 4 of the TICFA requires Bangladesh to refrain from taking any move which adversely affects the trade and investment interest of the US and *vice versa*.[84]

8. TICFA as a Platform for Negotiating "Non-Violation" Regime in the future FTAs: Implications and Challenges for Bangladesh

TICFA being a framework agreement[85] might be followed by FTAs. Recent US FTAs[86] contain non-violation complaint[87] clause in respect of various obligations

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[82] Pascal Lamy, "The WTO is your partner in achieving your development goals" (2012). < http://www.wto.org/english/news_e/sppl_e/sppl223_e.htm> 5 December 2015.

[83] Ibid.

[84] Khan aptly summarizes the potential impact of TICFA on Bangladesh's position in the LDCs Group at the WTO:

> Bangladesh has been one of the most influential and vocal WTO members in multilateral trade negotiations in upholding the interests of the LDCs. In many cases Bangladesh has operated as a leader on behalf of the LDCs at the WTO. However, by signing this bilateral forum agreement Bangladesh has weakened is position in this arena. For it has incurred an expectation that it will not harm the trade and economic interests of the US and its allies, thus undermining its capacity and will to stand up for the interests of other LDCs; and especially important development at a time when many of these countries – having already signed bilateral framework/forum agreements – have now started to feel the pinch of one-on-one approach based trade negotiations with the USA. See, Mohammad Tamizuddin Khan, 'TICFA, political economy of US bilateralism and Bangladesh' <http://www.bilaterals.org/?ticfa-political-economy-of-us> 19 May 2014.

[85] See above n 14.

[86] US FTAs with Oman 20.2(c); Morocco 20.2(c); Chile 22.2(c); CAFTA 20.2(c); Bahrain 19.2 (c)

[87] Non-Violation Complaint (NVC) is a GATT-WTO remedy which permits a WTO Members to challenge another's measure on the basis not of a failure to comply with an agreed obligation, but rather where the attainment of the Agreement's objectives is being impeded, or where a benefit under the Agreement is being "nullified or impaired", due to "the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement..." (Article XXIII of GATT 1994). On NVC see, generally, Robert W Staiger, and Alan O Sykes, 'Non-Violations' (2013) *Journal of*

including IPRs. Since NVCs jurisprudence developed under the GATT 1947 was mainly related to tariff concessions, the developing countries (albeit the LDCs) claim that NVCs are ill-suited to IPRs.[88] Developing countries and the LDCs argue that NVCs jurisprudence being imprecise, unpredictable and incoherent is ill suited to rule based WTO system, nay the TRIPS.[89] Developing countries and LDCs further argue that NVCs might frustrate the TRIPS flexibilities and the object and purpose of the TRIPS.[90] One may argue that, even if the FTAs likely to follow from TICFA bear no TRIPS-Plus provisions in IPRs chapter, Bangladesh might face the challenge to invoke TRIPS flexibilities due to the inherent open-endedness and ambiguity inherent in NVCs system. Currently, NVCs under the TRIPS have been foreclosed under a moratorium.[91] Apparently this moratorium does not affect a NVC system in vogue in the bilateral arrangements like FTAs having autonomous dispute settlement systems. Another intriguing issue is that, developed countries, who want the moratorium to be withdrawn, may argue that non-violation complaints in respect of IPRs have become customary international law citing numerous FTAs provisions.[92]

Conclusion

The wave of the US politics of FTAs has reached in Bangladesh by means of the TICFA. The bedrock of this politics is "TRIPS is the floor, not the ceiling". This paper has shown that, how this aggressive policy of maximization of IPRs has created serious challenges to the US trading partners in terms of jeopardizing public

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International Economic Law. For an analysis of non-violation complaint under TRIPS, see, summary note of the WTO secretariat vide IP/C/W/349/Rev.2, <http://www.wto.org/english/tratop_e/trips_e/ta_docs_e/6_ipcw349rev2_e.pdf> 5 December 2015; See also Matthew Stilwell, and Elizabeth Tuerk, *Non-Violation Complaints and the TRIPS Agreement: Some Considerations for WTO Members* (South Centre, 2000).

[88] See communication from developing countries to the TRIPS Council vide IP/C/W/385.

[89] Ibid. see also Sung-Joon Cho, 'GATT Non-Violation Issues in the WTO Framework: Are They the Achilles' Heel of the Dispute Settlement Process' (1998) 39 *Harvard International Law Journal* 311.

[90] Ibid. See also, Frederick M Abbott, 'Non-violation nullification or impairment causes of action under the TRIPS Agreement and the Fifth Ministerial Conference: A warning and reminder' (*Quaker United Nations Office (Geneva) (QUNO), Occasional Paper* 11 (2003).

[91] 9th WTO Ministerial Conference, Bali, 2013, Briefing note: 'Non-violation' in intellectual property—up for a decision in Bali,

Visit http://www.wto.org/english/thewto_e/minist_e/mc9_e/brief_nonviolation_e.htm (accessed on 19 July 2014)

[92] On the formation of customary international law see, generally, the *North Sea Continental Shelf cases,* ICJ Rep.1969, 1. Pertinently, the ICJ in this case held that on the formation of customary international law, practice of the most important countries i.e. most interested States in the relevant field. Since developed country FTAs are generally entered into with developing and least developed countries, the stand of the latter countries in the WTO on moratorium issue may be overawed.

health, food security and agricultural biodiversity. This paper has also showed that, how the US FTAs have flouted the letter and spirit of the Doha regime combating public health crises. The TICFA, as a fertile ground of potential US-Bangladesh FTAs, has also been characterized as a "TRIPS-Plus" and "Doha-minus" enterprise. This note has tried to landscape the potential impact of the TICFA on Bangladesh in the areas of public health, pharmaceutical industry, Agriculture and the ongoing regime reform agenda. Bangladesh should think twice before negotiating FTAs with a major player of international trade so that it can retain TRIPS flexibilities and privileges of Doha regime.