Submission by the Centre for WTO Studies, Indian Institute of Foreign Trade to the United Nation's High Level panel on Access to Medicines

A. Rationale of the submission

The conclusion of the Agreement on Trade Related Intellectual Property Rights (TRIPS) in 1995 brought in its wake a complete overhaul in the level of protection required to be provided by the members to the Agreement. At the same time, it allowed countries the policy space to adapt to the minimum norms set while crafting a legal framework that reflected their level of development and addressed public policy concerns on technology transfer, protection of public health and other sectors of vital importance. This flexibility or policy space is now being sought to be curtailed through Regional/Free Trade Agreements. Most IPR chapters in bilateral FTA/RTAs[1] do this by:

a) Seeking compliance with Multilateral Agreements that post date the TRIPS- thereby opening the member States of the bilateral/regional arrangement to provide protection beyond TRIPS (thus raising the minimum standards set by the latter). Equally important is the fact that compliance with hitherto independent Agreements can then be enforced through the dispute settlement mechanism of the concerned bilateral or regional trading agreements.

b) Address areas where the TRIPS Agreement was silent with a view to reduce flexibility. This has been seen in the way provisions relating to patentability criteria and protection of undisclosed information are being developed. The objective of this exercise is to reduce the flexibility available to countries to define these terms and implement the provisions in a manner that best suits their condition.

c) Enhance enforcement by delineating what action could be taken by judicial authorities; seeking criminal enforcement for actions that were until now only amenable to civil procedures such as trade secret theft; and by seeking statutory

[1] Text of the Trans-Pacific Partnership Agreement on https://ustr.gov/trade-agreements/.../trans-pacific-partnership/tpp-full-text; Leaked text of India EU FTA on Knowledge Ecology International. http://keionline.org/node/1681

damages for all offenses and possibility to impose exemplary damages.[2] Border measures are another very critical area where 'in transit' measures, ex-officio action and border enforcement for all rights including patents and designs are sought.[3] FTAs/RTAs seek to remove the safeguards and checks and balances so sacrosanct in the TRIPS provisions.

These agreements are seeking to curb the flexibility and reduce the ability of member States to address concerns. While this can impact an economy in many ways it substantively affects drug prices and access to medicines. An Oxfam study[4] on the impact of US Jordan FTA indicates that intellectual property rules adopted led to a delay in the entry of generic competition and access to medicines was seriously jeopardized with prices increasing considerably. Similarly other research studies bring out the inappropriateness of developed countries negotiating TRIPS Plus provisions in FTAs[5] and the impact this has on access to medicines.

B. Model to Address this Policy Incoherence

Four international human rights treaties and declarations collectively known as "International Bills of Human Rights' namely the: The United Nations Charter, Universal Declaration of Human Rights (UDHRs), International Covenant on Civil & Political Rights (ICCPRs), International Covenant on Economic, Social and Cultural Rights (ICESCRs) have provisions on ensuring health for all and on access to medicines.

[2] Transpacific Partnership Agreement

[3] Leaked India EU Bilateral Trade and Investment Agreement

[4] All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines, Oxfam Briefing Paper, March 2007

[5] The High Price of "Free" Trade: U.S. Trade Agreements and Access to Medicines Ruth Lopert and Deborah Gleeson in the Journal of Law, Medicine and Ethics (Vol 41, Issue 1, Pages 199-223, Spring 2013), B. Kiliç and P. Maybarduk, "Comparative Analysis of the United States' TPFTA Intellectual Property Proposal and Vietnamese Law," Public Citizen, 2011, available at (last visited February 19, 2013); B. Kiliç and P. Maybarduk, "Comparative Analysis of the United States' TPFTA Intellectual Property Proposal and Malaysian Law," Public Citizen, September 2011 (Updated December 2011), available at (last visited February 19, 2013); Public Citizen, "Comparative Analysis of the U.S. Intellectual Property Proposal and Peruvian Law, 2011," available at (last visited February 19, 2013); B.Kiliç and P. Maybarduk, "Comparative Analysis of the United States' TPPA Intellectual Property Proposal and Chilean Law," Public Citizen, April 2012, available at (last visited February 19, 2013).

UN Working Group on Access to Medicines identified six barriers to access to medicines in resource-poor countries (MDG Gap Task Force, 2008). One of the barriers was the Trade Related Intellectual Property Rights (TRIPS). With TRIPS Plus nature of FTAs/RTAs, the policy incoherence between trade and access to medicines and health and therefore human rights has become severe.

The question is what role can the UN play in this discourse when this is largely being negotiated between nation states with presumably some understanding of the impact TRIP Plus provisions are likely to have. However, it is important to keep in mind that the UN has the responsibility to ensure policy coherence between human right issues connected with access to medicines and trade in case the latter impinges upon the former in an adverse manner. The intervention being suggested is at the policy level to seek preservation of TRIPS flexibilities, mandating WHO and WIPO to create capacities among countries to examine TRIPS Plus issues and to understand their implications and interventions to bring in greater accountability of arbitration bodies.

C. Mechanism for Implementation

The model being suggested is more at the policy level and has three legs:

a. Foremost among all is a UN Resolution on the need to preserve TRIPS flexibility while negotiating RTAs/FTAs. The resolution should ideally identify the policy spaces available to countries under the TRIPS Agreement and the impact on access to medicines of giving up these flexibilities or adopting a tighter regime. The resolution should not be just limited to use of compulsory license.

b. UN Specialized agencies such as the World Health Organization (WHO) and the World Intellectual Property Organization (WIPO) must work more intensively towards preserving TRIPS Flexibilities while advising LDCs on the amendments required to their law. The impact of going beyond TRIPS or accepting TRIPS Plus commitments must also be clearly brought out in their policy documents used for

dissemination among developing countries and LDCs. Capacities need to be build among developing countries and LDCs on this issue.

c. Unlike under the TRIPS Agreement, disputes arising from the FTAs/RTAs go through opaque arbitration mechanisms which have no appeal. It is important that the UN set down guiding principles for the arbitrators on the manner in which provisions of FTAs and their compliance should be interpreted especially when it comes to access to medicine issues, public health matters or a decisions concerning sectors of vital importance to the said economy. The principles should clearly bring out the due weightage that needs to be given to policy concerns, public health measures taken by Governments and broader national interest when examining such cases.

d. From the UN, there should be a call for reforming the private arbitration bodies with a view to enhance transparency, address conflict of interest and build greater consistency in decisions while also seeking a mechanism for appeal.

D. Manner in which the Suggestion impacts Innovation, Public health, Human Rights and Trade

i) Impact on Innovation

TRIPS Agreement was negotiated with the objective of promoting technological innovation, enabling transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge. The RTAs/FTAs are bringing about a paradigm shift by disincentivizing path breaking medical research and development of technologies.[6]

The above proposal seeks to ensure that the TRIPS Agreement is complied with in letter and spirit and the flexibilities under the Agreement are utilised to model regimes that address the ground realities of the respective countries. This in turn will impact innovation and dissemination of technologies in a positive manner.

[6] Chandni Raina, "TPP's all about the health of Big Pharma", Financial Express 10th February 2016

ii) Impact on Access to Medicines and Public Health

The steps suggested will strengthen the hands of the developing countries and LDCs in preserving TRIPS flexibilities in RTAs/FTAs. The mandate to WHO and WIPO will build capacities among the developing countries and LDCs to duly take into account the impact IPR provisions in trading agreements can have on their ability to address public health problems. It is also important to inform the developing countries and LDCs that bilateral agreement involving TRIPS Plus provisions are likely to create uncertainty and lead to fragmentation of the market making it difficult for generic competition to enter.[7]

Guidance to arbitration bodies from the UN that public health measures and broader national interest are perfectly legitimate and cannot be overlooked will be important to at least place issues in perspective while deciding cases brought up by private companies against a State.

iii) Impact on Human rights

The model seeks to protect and nurture innovation while creating capacities among countries to examine the impact of their decisions, improve the understanding among the arbitrators on matters that concern public interest and create public opinion on TRIPS Plus issues. It would therefore impact the Sustainable Development Goal No. 3 on promoting health for all positively. The proposal will directly impact three targets set to be achieved by 2030 - ie-

- Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the

[7] ibid

full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all

- To end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases
- To reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being

while also impacting the others indirectly.

iv) Impact on Trade

The TRIPS Agreement was negotiated to reduce distortions and impediments in international trade while promoting effective and adequate protection of intellectual property rights. It was to ensure that measures and procedures to enforce intellectual property rights do not themselves become a barrier to legitimate trade. The bilateral trade agreements are seeking to tighten this framework to the advantage of the innovators and therefore create a misbalance between the users and creators of intellectual property. TRIPS Plus measures in bilateral trading arrangements will lead to uncertainty and evergreening of protection which in turn will impact competition and trade adversely. It is important that the balance be realigned to promote trade.