

Supplementary Submission to the High Level Panel (HLP) on Access to Medicines Third World Network (TWN)

Introduction

The objective of this supplementary submission is to clarify certain issues that came up during TWN's deposition before the HLP on 16th March 2016 in Johannesburg. In addition, it also addresses two general issues i.e. the approach of the HLP to the issue of access to medicines and the nature of recommendations.

Approach and Scope of Recommendations

TWN proposes that the HLP should approach the issue of access to medical products with an open mind and to come out with the best recommendations which can ensure access to medicines without much financial and human resources implications. While making such recommendations the HLP should not be constrained about the political feasibility of the implementation of its recommendations. The political feasibility is a secondary issue, which cannot be judged *ex ante*. Any such *ex ante* assessment is essentially an exercise of speculation and prejudices what actions can and cannot be undertaken. Further, political feasibility is not constant and subject to change depending on various other dynamics. Therefore, the HLP should be ambitious in its approach and examine whether the international trade and intellectual property (IP) regime poses policy space constraints for United Nations Member States to take measures to ensure access and availability of affordable medicines in a sustainable manner.

Intellectual Property Rights

The HLP needs to specifically focus on the constraints posed by the international IP regime to ensure access to new medical products. The current IP regime, especially the TRIPS product patent regime and free trade agreements, eliminates/delays the generic competition. The strategy to use the TRIPS flexibilities to address concerns on access to medicines is not working efficiently and suffers from structural constraints. Therefore changes in the international IP regime are important to address the down stream access to IP protected medical products.

The origin of the HLP goes back to the recommendation of the Global Commission on HIV and the Law. The Commission recommended: "*The UN Secretary-General must convene a neutral, high-level body to review and assess proposals and recommend a new intellectual property regime for pharmaceutical products. Such a regime should be consistent with international human rights law and public health requirements, while safeguarding the justifiable rights of inventors.*" Therefore, it is important for the HLP to examine the full potential of the feasibility of existing strategies i.e. to make full use of the flexibilities to

address and overcome the IP constraints to ensure access to IP protected medical products, especially regarding patent and data exclusivity.

Further, the Commission on Intellectual Property Rights (CIPR) and the Commission on Intellectual Property, Innovation and Public Health (CIPIH) also recommended the use of the TRIPS flexibilities. Based on the recommendations of CIPIH, the World Health Organization adopted a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA). Therefore it is important for the HLP to examine the feasibilities as well as constraints in using the strategies such as use of the flexibilities to address access to medical product with patent or data exclusivity protection.

As mentioned above, while making recommendations on the international IP regime, the HLP should not be constrained over whether an amendment to the TRIPS Agreement would be acceptable to WTO Member States.

TWN Proposal

TWN proposes that non-exclusive licenses be given to generic manufacturers to produce new medical products to market in developing countries, and that this is not limited to the generic manufacturers of developing countries alone. All generic manufacturers are to be allowed manufacture and market new medical products by paying a royalty to other originator companies.

This proposal is made in the context of experiences of developing countries during the last 20 years to use the TRIPS flexibilities. The constraints of using TRIPS flexibilities warrant a quick response. Therefore TWN proposes that permission be provided to generic manufacturers to produce new medicines against fixed royalty rates, as an interim measure to address the grave access to medicines situation in developing countries. After the necessary amendment to the international IP regime the same mechanism can be extended even to developed countries.

Even though the HLP's mandate is not restricted only to developing countries, the HLP should nevertheless keep the principle of special and differential treatment at the forefront while making recommendations.

Policy Incoherence

There is a policy incoherence between the international IP regime and international human rights regime. The only strategy or approach to address this incoherence till date is the use of TRIPS flexibilities. However, the experiences of 20 years show that this strategy is not working due to various reasons including the political pressure and it incapacitates majority of UN Member States to fulfil their human rights obligations. This shows that there is policy incoherence between the international human rights law and the international obligation contains in the TRIPS Agreement. Therefore HLP should address whether the current IP regime as well as trade regime incapacitate UN Member States from

fulfilling their human rights obligations. Further, HLP also needs to examine whether the international human rights obligations such a right to health and right to science has peremptory norm status (jus cogens) .

Similarly there is a policy incoherence between Sustainable Development Goal 3 and IP obligations under Free Trade Agreements (FTAs). One of the means of implementation on of SDG 3 states: *“Support the research and development of vaccines and medicines for the communicable and noncommunicable 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 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”*. However many developing countries who have undertaken TRIPS Plus obligations cannot fully use the TRIPS flexibilities. Thus the TRIPS plus obligations are clearly incoherent with means of implementation on SDG 3. Therefore, HLP needs to make recommendation to address the policy incoherence emanating form FTAs and bilateral investment treaties.