Re: Concerns with statements expressed by the World Intellectual Property Organization (WIPO) relating to the United Nations Secretary-General's High-Level Panel on Access to Medicines (HLP)

11 February 2016

Dear Dr. Francis Gurry,

We are writing to express concern with the positions articulated by representatives of WIPO at mission briefings of the United Nations Secretary-General's High-Level Panel on Access to Medicines (HLP) in Geneva on 1 February 2016 and in New York on 4 February 2016.

Background

In November 2015, the United Nations Secretary-General Ban Ki-moon convened the High-Level Panel on Access to Medicines with the objective of reviewing and assessing "proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."[1]

On 1 February 2016, at the mission briefing in Geneva, Thomas Bombelles (Head, Global Health, WIPO), expressed the following reservation with respect to the mandate of the HLP,

> *While WIPO is pleased to be included in the Secretary-General's initiative, we are sensitive to the prima facie assumption in the HLP's mandate that there is a policy incoherence between using intellectual property laws and regulations to encourage innovation and the imperative of delivering medicines and other health services to those in need.*

On 4 February 2016, at the mission briefing in New York, Lucinda Longcroft (Head of New York Office, WIPO) reiterated the same message,

> *"WIPO is sensitive to any assumption in the HLP mandate that there is a policy incoherence between using IP laws and regulations to encourage innovation and the imperative of delivering medicine and health services to those in need."*

At the mission briefings, WIPO noted that "coherence exists in the recognition that without productive innovation, there is nothing to have access to".

[1] http://www.unsgaccessmeds.org/the-process/, Accessed 9 February 2016

In addition, your representatives in Geneva and New York employed the trope “adding light not heat” in describing WIPO’s role in publishing the 2013 trilateral study - Promoting Access to Medical Technologies and Innovation along with the World Health Organization (WHO) and the World Trade Organization (WTO).

Policy Incoherence - Is WIPO operating in a vacuum?

In the context of the UN HLP’s mandate to remedy the “policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies”, it is remarkable - and profoundly disturbing - that in 2016 - WIPO would express reservations that the International Bureau remained “sensitive to any assumption in the HLP mandate” that there is a policy incoherence between international human rights law and trade rules.

The remarks made by the representatives of WIPO are based on erroneous assumptions. They imply that IP protection - especially patents and the grant of monopolies- are the critical mechanism to support product development, and that tradeoffs between innovation and access are both necessary and acceptable. However, while under the current system patents play a role in innovation, the costs are high, and equating patent protection with innovation both overstates the importance of patent monopolies and ignores the possibilities of reforms that eliminate the trade-offs between innovation and access. Further, the views expressed by WIPO representatives that patents as a tool for incentivizing R&D investments ignores well known evidence regarding the market failure in the funding of basic science, unbiased comparative clinical trials, neglected diseases, antibiotics, rare diseases, and global health threats such as Ebola, unwanted rationing of medicines, excessive prices and unequal access, further illustrate the limitation of the patent system as an instrument for incentivizing R&D investment.

It would be worth recalling that in April 2001, the policy incoherence of international trade rules with the right to health precipitated the African Group to request the WTO to hold a special session of the WTO TRIPS Council to clarify the relationship between intellectual property rules and access to medicines. This paved the way for the seminal Doha Declaration on the TRIPS Agreement and Public Health. In its request, the African Group observed,

> *As the recent upsurge of public feelings and even public outrage over AIDS medicines had shown, there was at the moment a crisis of public perception about the intellectual property system and about the role of the TRIPS Agreement, which was leading to a crisis of legitimacy for the TRIPS Agreement. Whilst this storm was raging outside the WTO, and legitimately so, Members inside the WTO could not shut their eyes and ears.*[2]

[2] IP/C/M/30, World Trade Organization, *MINUTES OF MEETING Held in the Centre William Rappard from 2 to 5 April 2001,* 1 June 2001.

In a bid to remedy the policy incoherence of trade rules and the right to health, in May 2011, the African Group and the Development Agenda Group submitted a joint proposal (SCP/16/7) for an SCP Work Program on Patents and Health:

> *The WHO Global Strategy and Plan of Action (GSPOA) on Public Health, Innovation and Intellectual Property adopted in 2008 states that while international IP agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries, they may face obstacles in the use of flexibilities. Thus, there is a need to address this problem and remove obstacles faced by developing countries in making full use of the public health related flexibilities. The GSPOA also states that IPRs should not prevent Member States from taking measures to protect public health, and that international negotiations on issues relating to IPRs and health should be coherent in their approaches to the promotion of public health.*
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> *In order to protect public health, the flexibilities and safeguards contained and allowed by the TRIPS Agreement would need to be incorporated in the national legislation. There is equally the need to ensure that international commitments, including regional and bilateral arrangements, do not restrict these flexibilities and safeguards. Moreover, these safeguards and flexibilities have to be workable in practice, particularly with respect to ensuring access to medicine.*[3]

In the context of 15 years of discussions at WHO, WTO and WIPO on the relationship between international human rights law, trade rules and public health, it is baffling that WIPO, in 2016, would argue that it is

> *"sensitive to the prima facie assumption in the HLP's mandate that there is a policy incoherence between using intellectual property laws and regulations to encourage innovation and the imperative of delivering medicines and other health services to those in need."*

Are the views expressed by WIPO officials (at the mission briefings in Geneva and New York) a reflection of the WIPO secretariat's official position? If so, how does this comport with the WIPO Development Agenda adopted by the WIPO General Assembly in 2007 and the robust (and unresolved) discussions on patents and health in WIPO's Standing Committee on the Law of Patents (SCP)?

We respectfully ask you to clarify the International Bureau's views on this matter, in relation to the work of the United Nations Secretary-General's High-Level Panel on Access to Medicines.

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[3] http://www.wipo.int/edocs/mdocs/scp/en/scp_16/scp_16_7.pdf, SCP/16/7, Proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group, 18 May 2011.

Sincerely,

Organizations

TWN

Third World Network