**WHO Statement to WIPO Standing Committee on the Law of Patents, 19th Session**

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- as part of a presentation by WHO-WIPO-WTO on their joint study: “PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE”

Honorable Chair of the 19th Session of the Standing Committee on the Law of Patents, respected national delegates, Ladies and Gentleman;

It is my great pleasure and honor to have this opportunity to present WHO’s perspective with regard to a joint study by WHO, WIPO and WTO on promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade – a study which our Director General, Dr Margaret Chan termed as “…a big report with a noble mission” in her speech at the launch of the study on 5th February at WTO along with the DGs of WIPO and WTO.

She called it *noble* because the central core of this work is aimed at improving the access to medicines and related technologies as part of health service provision especially to those who continue to suffer and die for want of these public health goods. This joint study is a testament that WHO is not alone in pursuing this goal and despite different mandates of WIPO and WTO we are united as members of the United Nations System in this cause. You have heard how these three organizations have come together, and I must add here, urged by their Members and led by their respective leadership, to forge a tri-lateral cooperation which is a unique example of inter-agency collaboration at multilateral level for shared objective of assisting governments and benefitting people in their quest for accessible health care through functional health systems as their fundamental human right.

Member states of WHO have provided a repeated mandate to its Director General to work on issues related with access to medicines in relation with intellectual property protection. The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property which our Member States adopted in 2008 also guide us to collaborate with other competent international organizations in providing technical assistance to Member States. This trilateral cooperation is partly a product of this guidance and mandate by our Member States.

Honorable delegates; from public health point of view this study has first of all treated medical innovation as an important dimension of access. The phenomenon of globalization is affecting disease epidemiology and resulting in redistribution of burden of disease. To address these challenges new medical technology tools are needed to be developed and existing interventions needs to be re-tooled and their access needs to be ensured. Development of heat stable medicines and vaccines; reformulation of existing medicines in new fixed-dose combinations for better supply and compliance including better paediatric formulations; medical devices for the aging populations across the world; safer and effective medicines for neglected tropical diseases are examples where medical innovation is urgently needed and once developed these technologies need to be delivered to those who need them the most. The study hence brings together innovation and access as two sides of the same coin.

WHO has been involved in promoting access to medicines and health technologies by addressing its multifarious but traditional determinants that lie within the purview of health sector i.e. selection of essential medicines and priority health technologies; affordable prices; adequate financing and procurement and supply systems. This study however brings together a plethora of other policy determinants which are at the cross-roads of law and economics i.e. intellectual property and trade and cover areas such as, competition policy; tariffs; intellectual property protection law; pricing policies; traditional knowledge and its management; innovative financing mechanisms – and most importantly it focuses on the interplay of these policy arenas and what kind of opportunities and challenges these intersections can present to the policy makers. It illustrates these intersections with practical examples and with the help of empirical evidence which is much more available than when these discussions started in 1996 at World Health Assembly, the very next year of creation of WTO.

The study presents evolving burden of disease and health risks as a basis to set priorities for medical innovation and access. Globally, for example, non-communicable diseases are projected to account for over three quarters of all deaths by 2030 and uni-polar depressive disorders are going to be number one cause with highest percentage for disability adjusted life years. These considerations, the study argues, should guide innovation and access efforts now and for the future.

Regulation of health technologies is another area which study presents both in the context of innovation i.e. clinical trials, and access i.e. assurance of quality, safety and efficacy of medicines and health technologies for their production through compliance to good manufacturing practices, for market authorization and for their supply through public and private channels. The importance of robust regulation through institutional development of reliable national regulatory authorities and importance of regulatory harmonization is emphasized throughout the study. The challenges of regulatory pathways for biotechnology products and bio-similars are amply described.

The study also present for the first time tariff data on pharmaceutical products and highlights an interesting fact i.e. whereas most industrialized countries have removed tariffs on pharmaceuticals not all developing countries have done the same. This is paradoxical to a parallel desire to improve access to medicines. In countries where majority of medicines are imported and out-of-pocket expenditures to buy health care are high i.e. up to 70%, subjecting essential medicines to tariffs and taxes result in prices high enough to be unaffordable to poor people. The study raises such policy issues also to draw the attention of policy makers.

I would like to highlight one major issue that WHO has been trying to grapple with for about a decade now i.e. when markets fail to provide incentives for development of medical technologies required in developing countries especially for neglected diseases then how to encourage such R&D. The study present this work in WHO by highlighting the need for development of alternative mechanisms for financing and incentivizing such essential R&D. This is where innovative financing and new ways of working for ensuring needed R&D are described.

Of course a big part of the study deals with intellectual property protection issues and how different multilateral, plurilateral but also regional and bilateral trade agreements affect innovation and access. Challenges posed by difficulties in accessing relevant patent information; ever-greening trends in patent management; sometimes poor quality of patent applications accepted by national patent offices and cumulative effect of all these on public health in terms of inefficient procurement and delays in availability of generic medicines are also discussed.

In a nutshell, there are two central messages of this study. One, in a complex policy world of 21st century when universal health coverage is becoming a passionately pursued goal and people’s expectations and demands are rising for high quality accessible health care the supply side has to readjust itself in terms of innovation and delivery of health care including health technologies and in order to make it possible the policy makers have no choice but to be better informed, evidenced based and affirmative in action and for this they have to deal with many policy domains to strike coherent policy solutions to respond to challenging situations. And the second message of the study is that through technical cooperation among themselves, WHO, WIPO and WTO can assist national policy makers by providing technical assistance for development of balanced and coherent policies for need based medical innovation and reliable access. This study is a reflection of this commitment by the three organization and provides a backdrop for their future cooperation and provision of technical assistance in these areas.

I thank you Mr Chairman for this opportunity.