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Statements on behalf of the EU

WIPO Standing Committee on Law of Patents
25th session - Patents and Health

World Intellectual Property Organization Standing Committee on Law of Patents - 25th session Patents and Health 14 December 2016 EU Opening Statement
Madam Chair,

The European Union and its Member States take note of the contribution provided by the Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, and of the subsequent message of the Secretary-General, which encourages all stakeholders to chart a way forward in appropriate fora to ensure access to medicines and health technologies for all who need them, wherever they are.

The work conducted by the Panel started from an assumption that there was a "policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health". As the European Commission already indicated in its written contribution to the Panel, it does not share this assumption.

The European Union and its Member States share the Report's acknowledgement that there are many reasons "why people do not get the healthcare they need, ranging from: under-resourced health systems, a lack of sufficiently qualified and skilled healthcare workers, inequalities between and within countries, exclusion, stigma, discrimination and exclusive marketing rights". Another important problem are the global medicines shortages and stock-outs.

This is why in its written contribution to the Panel, the European Commission encouraged it to adopt a holistic approach to the problem of access to medicines that could result in a valuable contribution to the wider debate.

However, due to its limited mandate, the High-Level Panel has focused its proposals exclusively on
addressing an alleged conflict between a research and development model that (partially) relies on intellectual property rights and the possibility of providing affordable medicines. In doing so, it has missed an opportunity to advance more balanced, comprehensive and workable solutions to the problem of access to health. The European Union and its Member States would also highlight that no conclusions could be reached with the support by all Members of the Panel, as demonstrated by the dissenting opinions attached to this report.

The European Union and its Member States are committed to increasing access to affordable medicines and to find solutions to the world's pressing public health challenges and inequities. In line with the 2010 Communication and Council Conclusions on 'the EU role in Global Health', the EU pursues a rights-based approach to health. Strengthening all areas of a health system, including through the availability of qualified health workers, the provision of affordable medicines and the adequate financing of the sector, is central to moving towards universal health coverage with quality health services accessible and affordable for all. The quality and integrity of the pharmaceutical distribution chain is also essential to improving public health.

The challenge is to strike the right balance between the need to promote and finance the research of new and better medicines for all, ensuring that medicines are accessible and affordable to those in need, while guaranteeing the sustainability of health systems. We believe that these goals are not contradictory and must be pursued jointly.

The current innovation model, including the role of trade related to IP, has delivered consistent progress in global public health, leading to key new and improved treatments as well as much extended life expectancy, both in developed and least developed countries. This model already integrates a variety of tools such as incentives for innovation based on intellectual property, on public and private financing and awards or on public research. Such variety is necessary to address situations where there is a functioning market and those where there could be market failures.

The Report underplays the fact that the development of new drugs requires significant investment and long-term research, coupled with clinical trials and regulatory approval procedures. The exclusive right conferred by a patent is an important incentive for innovator pharmaceutical companies to make the necessary investments into that research and development. Without incentivizing the innovator pharmaceutical companies to invest in research, the sustainable development goal of ensuring healthy lives and promoting well-being for all, including achieving universal health coverage, would be severely undermined.

Several of the issues covered in the report's recommendations are addressed in EU legislation, EU & Commission policies and actions, including at multilateral level. To name a few examples: the Commission is a major funder of research and innovation for poverty-related and neglected diseases and for new antibiotics. At the WHO, the EU and its Member States support the implementation of the WHO global strategy and plan of action on public health, innovation and intellectual property, including the development of the Global Observatory on Health Research and Development. In the area of trade, the EU ensures that its free trade agreements are consistent with the Doha Declaration and it has supported the extension of the drug patent exemption for least-developed countries. As
part of its health policy, the EU adopted new legislation to ensure that all clinical trials to be conducted in the EU will be registered in a publicly accessible EU database (Regulation EU No 536/2014).

However, several other recommendations are not in line with the EU rules and practices and thus cannot be supported. This is, in particular, the case for the proposals to revise the paragraph 6 decision or the TRIPS Agreement on these matters, the recommendations in relation to INN and standard international common names for biological products, and the proposal to create additional structures at UN level on the issue of health technology innovation and access.

Any future activities at the UN level in this area should be conducted on the basis of a much broader understanding of the complex issues involved.

Thank you.