Mr Chair,

I am speaking on behalf of the EU and its Member States. The EU and its Member States would like to thank the WIPO Secretariat for preparing a draft reference document on the exception to patent rights regarding acts for obtaining regulatory approval from authorities in document SCP/27/3. We have read the document with great interest. We are also very grateful for today’s presentation.

We wish to highlight the broad information and resource base from which the document has benefited. As noted in the introduction, the primary source of information for the preparation of the reference document was information collected through the SCP activities. As such, it is a good example of making use of this information and the work that has been conducted by the SCP in the past.

The reference document covers the list of issues which the Committee decided to address at its last session. In particular, it provides for a description of the regulatory review exception, an overview of its objectives and goals, national/regional implementation, challenges faced by member States in implementing the exception, and results of the national/regional implementation. However, we note that compared to the agreed list of issues, the element of “the multilateral legal framework of the regulatory review exception” has been added by the Secretariat. Considering its relevance to the topic at hand, we consider the overview provided of the WTO Dispute Settlement Panel Report regarding the Canada – Patent Protection of Pharmaceutical Products case justified.

It was interesting to learn that the exception is found in the applicable laws of more than 65 countries and that different approaches are taken in implementing this exception in the national level as regards to various important elements of its implementation, such as the source of law, beneficiaries,
products and acts covered by the exception, as well as the conditions of taking advantage of the exception.

We are particularly interested in the part dealing with results of implementation of the exception in national/regional laws. On the one hand it appears that some Member States reported positive effects on the timeliness of regulatory registration and entry of generic versions of medicines into the market. On the other hand, the impact of the exception on competition between originator and generic products and reduction of price of the originator products remains unclear.

As to the challenges faced by Member States in implementation of the exception, it appears that these challenges are mostly related to uncertainty about the scope of the exception in the national laws and lack of awareness about this exception among potential users. We note that such challenges could be addressed by relevant and carefully targeted awareness raising and training activities.

Based on the draft reference document, there does not appear to be a specific need for normative work on the international level concerning the regulatory review exception at this stage.

At SCP 26 it was decided that preparation of the draft reference document covering the exception regarding acts for obtaining regulatory approval from authorities would be a first step of the work of the SCP in analysing the specific exceptions and limitations to patent rights in conjunction with patent protection. We are ready to further discuss the value of this exercise and whether it should be repeated for other exceptions and limitations. In general, the EU and its Member States are supportive of initiatives which truly contribute to our knowledge and understanding of the topic of exceptions and limitations, including those which have the potential of addressing development issues.

We would like to take this opportunity to emphasise again the utmost importance of striking an appropriate balance between work on exceptions and limitations to patent rights and on the legal standards used to determine whether an invention is patentable, such as novelty, inventive step, and industrial applicability. These two topics are closely interlinked, therefore, a holistic approach should be taken in order to find an appropriate balance between the interests of rights holders and the general public.

We look forward to hearing the views of other participants on the draft reference document and a constructive discussion on this agenda item.

Thank you.

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