



statement

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Agenda item 18: Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)

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Mr. Chairman,

The International Federation of Pharmaceutical Manufactures and Associations would like to take this opportunity to express the position of the research based pharmaceutical industry, with regard to negotiations on an international instrument relating to intellectual property aiming to ensure the balanced and effective protection of genetic resources (GRs), traditional knowledge (TK) and traditional cultural expressions (TCEs).

The IGC discussions started in 2000 when there were no user country Access and Benefit Sharing (ABS) compliance regulatory frameworks in place. This has fundamentally changed in 2014 when Nagoya Protocol entered into force.

We are of the view that for a very simple reason the IGC should not be endeavoring to develop a new international access and benefit-sharing monitoring and compliance system (ABS), as one already exist.

IFPMA supports the objectives of the Convention on Biological Diversity (CBD) and the Nagoya Protocol and has in the last two decades actively contributed to discussions on the development of the Protocol and its translation into national and international legislation.

We firmly believe that the achievements of the CBD and Nagoya Protocol should not be replicated at the IGC and the objectives of the CBD and Nagoya related to facilitation of access to genetic resources and the fair and equitable sharing of the benefits should not be pursued through the patent system as this would lead to many unintended consequences. Let me enumerate just a few:

- The principles introduced by disclosure requirements that are unclear in terminology, scope and applicability, especially if linked to patent validity, would create legal and commercial uncertainty which would have a negative impact on investment. Reducing investment and discouraging R&D activities utilizing GRs would be directly contrary to the objectives of the CBD;
- The Nagoya Protocol requires countries to implement an effective ABS compliance system to prevent misappropriation of GR, but does not mention a disclosure obligation as a possible compliance mechanism;
- Potential disclosure requirement would not achieve the objectives of combating "misappropriation" or compliance with access-benefit-sharing systems or monitoring the use of genetic resources. For example, a disclosure requirement would do nothing to assist in monitoring any use of genetic resources that does not involve patenting;
- Checking and monitoring the disclosure requirement would be in the hands of patent offices, that neither have the capacity, mandate or knowledge to perform such tasks and would be exposed to additional burden;
- Patent law or examination is not the right means to control requirements about origin of genetic resources used in developing new products. Moreover, the TRIPS Agreement



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prohibits such additional conditions on patentability. In addition, the proposed requirements are specifically targeted to biotechnology and other life sciences using genetic resources and, therefore, would not be consistent with the principle in the TRIPS Agreement that patents be made available without discrimination based on the field of technology.

Contrary to the issue of misappropriation of GRs, the issue that the IGC and the patent system can reasonably address in our mind is the erroneous grant of patents. This can be done through improved databases which ensure the access to appropriate information for patent offices and guidelines for the examination of patent applications directed to genetic resources and or traditional knowledge.

We hope that this Committee will in the next biennium take into account the existence of the ABS framework put into place through the adoption of the Nagoya Protocol and consider above-mentioned suggestions.

Thank you.