



STATEMENT

WIPO Diplomatic Conference on Genetic Resources and Associated Traditional Knowledge

13 MAY 2024, GENEVA – IFPMA and our members support predictable access to genetic resources that can be the starting point for biopharmaceutical research and development. We are concerned that the outcome of this Diplomatic Conference could detrimentally affect innovators' continued ability to research, develop, and manufacture products related to genetic resources.

Despite over 20 years of negotiations, fundamental elements such as objectives, scope, and definitions remain unclear. There has been no substantial evidence or assessments to justify the need for this instrument. We believe those advocating for it should demonstrate the benefits observed in their national systems.

The objective of this instrument seems to be compliance with Access and Benefit-Sharing (ABS) legislations. However, some of the disclosure proposals would reduce the use of genetic resources, stifle innovation, and eliminate benefit-sharing.

As users of the patent system, our member companies struggle to see the merit in a new international patent disclosure requirement. We firmly believe the proposed instrument will not enhance the efficacy, transparency, or quality of the patent system, nor will it prevent the granting of erroneous patents. The proposed disclosure requirement does not aid IP offices in assessing patentability criteria such as novelty, industrial application, and non-obviousness.

The negotiating text conflates patentability with the proposed disclosure requirement, which undermines the patent system. Patents that meet patentability criteria could be refused or revoked due to issues with the new disclosure requirement, which are administrative and separate from patentability. This poses a disproportionate risk to valid patents.

We recognize that around 30 countries have patent disclosure requirements in their legislation. However, significant discrepancies exist among these systems. Some countries implement this as a simple formality, imposing limited burden on patent applicants and offices. However, others have systems that create substantial administrative burdens and delays, disincentivizing innovation involving genetic resources. We are aware of some examples where patent applications were abandoned due to legal uncertainties and lengthy delays, illustrating the negative impact of stringent disclosure requirements.

Furthermore, the proposed instrument does not promote consistency, international harmonization, or simplification for applicants. It leaves much discretion to signatory states for national implementation and could apply retroactively. The broad wording of the new disclosure requirement adds further legal uncertainty, as it could encompass evidence of prior informed consent and mutually agreed terms, unrelated to the patent system, in many countries.

We continue to believe that the costs of a new patent disclosure requirement outweigh any undemonstrated benefits. Nonetheless, we are willing to work constructively with delegations to find an outcome at this Diplomatic Conference that does not undermine innovation.