INNOVATION COUNCIL

Innovator Perspectives on the IGC Negotiating Text
Start of the Diplomatic Conference – May 2024

Proposed International Legal Instrument relating to Intellectual Property, Genetic Resources and Traditional Knowledge associated with Genetic Resources: Concerns with the Negotiating Text

Definitions: Key terms and definitions remain ambiguous. For instance, the language for the trigger for applying the PDR has not been agreed. Its present wording appears to cover derivatives and DSI, which should be excluded based on the review clause. Similarly, there is no definition of traditional knowledge associated with genetic resources in the text, and human genetic resources are only excluded from the instrument's scope through a footnote.

Retroactivity: Currently, the text only excludes the retroactive application of the future instrument (in relation to patent applications filed before ratification/accession by a Contracting Party) subject to existing retroactivity provisions in national laws. Moreover, retroactivity in relation to genetic resources accessed prior to the instrument entering into force is not excluded at all. The timing of the instrument's application is essential for legal certainty.

Patentability Criteria: PDRs potentially inject additional requirements into the patent system that go beyond the internationally accepted criteria of novelty, non-obviousness, and utility. Patents on inventions that meet patentability criteria should not be refused due to issues with the PDR. Likewise, patents should not be invalidated, revoked, or held unenforceable due to issues with the PDR. Nor should they be transferred to a third party or subject to a compulsory license on this basis. Taking the patent owner's rights away in any form would be a disproportionate response, given the PDR is purely administrative, aimed at transparency.

Unknown Origin: Patent applicants must be offered the option to simply state they do not know the origin or source of the GR or associated TK. It is not always possible to know with certainty where GR and associated TK were obtained, in light of vast compound libraries built over many years, the proliferation of databases, and the reality that modern R&D programs involve interaction with many different genetic resources.

ABS Requirements: The language of the PDR must be clear and narrow. The PDR must not require patent applicants to show evidence of prior informed consent and mutually agreed terms for access and benefit sharing (ABS), in addition to information about the origin and source of the GR and associated TK. Such requirements are already proscribed in the Convention on Biological Diversity/Nagoya Protocol; they are distinct from a patent-related transparency requirement set forth in a new WIPO instrument.

Fraudulent Intent: This concept, along with the sanctions deemed to result from it, should be removed from the text. The concept differs across jurisdictions and, in some countries, doesn't exist.

Correcting Disclosures: There must be fair procedures by which patent applicants can remedy a PDR deemed insufficient or lacking. Allowing correction of mistakes in relation to administrative matters allows for fairness and due process.

Scope and DSI: The text should expressly confirm that digital sequence information (DSI) is excluded from the instrument. DSI provide the foundation for how companies interact with hundreds, sometimes thousands, of genetic resources in modern R&D programs. Inclusion of DSI in this instrument is not feasible.