

WIPO/GRTKF/IC/SS/GE/23/5 ORIGINAL: ENGLISH DATE: APRIL 16, 2024

Special Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

Geneva, September 4 to 8, 2023

REPORT

adopted by the Committee

- 1. Convened by the Director General of the World Intellectual Property Organization ("WIPO"), the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("the Committee" or "the IGC") held its Special Session in a hybrid format from September 4 to 8, 2023.
- 2. The following States were represented: Albania, Algeria, Angola, Argentina, Australia, Austria, Azerbaijan, Bahamas, Barbados, Bhutan, Bolivia (Plurinational State of), Brazil, Brunei Darussalam, Canada, Chile, China, Colombia, Cook Islands, Costa Rica, Côte D'Ivoire, Croatia, Cuba, Czech Republic, Democratic People's Republic of Korea, Denmark, Djibouti, Dominican Republic, Egypt, El Salvador, Ecuador, Ethiopia, Finland, France, Gambia, Germany, Ghana, Guatemala, Guyana, Hungary, India, Indonesia, Iran (Islamic Republic of), Iraq, Ireland, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Kyrgyzstan, Kuwait, Latvia, Lebanon, Lithuania, Malaysia, Malawi, Mexico, Morocco, Myanmar, Nicaragua, Niger, Nigeria, North Macedonia, Oman, Pakistan, Panama, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Republic of Korea, Romania, Russian Federation, Saudi Arabia, Senegal, Seychelles, Singapore, South Africa, Spain, Sri Lanka, Switzerland, Thailand, Trinidad and Tobago, Tunisia, Turkey, Uganda, Ukraine, United Arab Emirates, United Kingdom, United States of America, Venezuela (Bolivarian Republic of), Yemen, Zambia and Zimbabwe (94). The European Union ("the EU") and its Member States were also represented as a member of the Committee.
- 3. The Permanent Observer Mission of Palestine participated in the meeting in an observer capacity.
- 4. The following intergovernmental organizations ("IGOs") took part as observers: African Union (AU); Secretariat of the Convention on Biological Diversity (SCBD); South Centre (SC); United Nations Conference on Trade and Development (UNCTAD); and United Nations Educational, Scientific and Cultural Organization (UNESCO) (5).
- Representatives of the following non-governmental organizations ("NGOs") took part as observers: ADJMOR; Agencia Internacional de Prensa Indígena (AIPIN); Arts Law Centre of Australia; Assembly of First Nations; Association allemande pour la propriété industrielle et le droit d'auteur (GRUR); Association américaine du droit de la propriété intellectuelle (AIPLA); Association internationale pour la protection de la propriété intellectuelle (AIPPI); Call of the Earth (COE): Centre de documentation, de recherche et d'information des peuples autochtones (DoCip); Comisión Jurídica para el Autodesarrollo de los Pueblos Originarios Andinos (CAPAJ); CropLife International (CROPLIFE); Fédération internationale de l'industrie phonographique (IFPI)/International Federation of the Phonographic Industry (IFPI); Fédération internationale des conseils en propriété intellectuelle (FICPI); For Alternative Approaches to Addiction, Think & do tank (FAAAT); Foundation for Aboriginal and Islander Research Action (FAIRA); Fundación Empresas Indígenas; Health and Environment Program (HEP); Indian Council of South America (CISA); Indigenous Information Network (IIN); Innovation Insights; Institute for Intellectual Property and Social Justice (IIPSJ); Instituto Indígena Brasilero da Propriedade Intelectual (INBRAPI); Intellectual Property Owners Association (IPO); International Centre for Environmental Education and Community Development (ICENECDEV); International Federation of Pharmaceutical Manufacturers Associations (IFPMA); International Indian Treaty Council; International Trademark Association (INTA); Kanuri Development Association; Ka'uikiokapō; Knowledge Ecology International, Inc. (KEI); MALOCA Internationale; Mbororo Social Cultural Development Association (MBOSCUDA); Native American Rights Fund (NARF); New Zealand Institute of Patent Attorneys (Incorporated) (NZIPA); Pacific Islands Forum Secretariat; Rassemblement des africains conscients, intègres, nationalistes, engagés et solidaires association (RACINES); Red Mujeres Indígenas sobre Biodiversidad (RMIB); Russian Association of Indigenous Peoples of the North (RAIPON); Tebtebba Foundation - Indigenous Peoples' International Centre for Policy Research and

Education; Third World Network (TWN); Tulalip Tribes of Washington Governmental Affairs Department; and West Indian Tribal Society (40).

- 6. The list of participants is annexed to this report.
- 7. The Secretariat noted the interventions made, and the proceedings of the session were communicated and recorded on webcast. This report summarizes the discussions and provides the essence of interventions, without reflecting all the observations made in detail or necessarily following the chronological order of interventions.
- 8. Mr. Wend Wendland of WIPO was Secretary to the IGC Special Session.

AGENDA ITEM 1: OPENING OF THE SESSION

- 9. The IGC Chair, Ms. Lilyclaire Bellamy, opened the session and invited the Assistant Director General to make opening remarks.
- The Assistant Director General, Mr. Edward Kwakwa, delivered opening remarks on behalf of the Director General. In July 2022, the WIPO General Assembly made the decision to convene a Diplomatic Conference to conclude an International Legal Instrument relating to Intellectual Property, Genetic Resources, and Traditional Knowledge Associated with Genetic Resources ("Diplomatic Conference") in 2024. The WIPO General Assembly also decided that the IGC Special Session should further close any existing gaps to a sufficient level regarding document WIPO/GRTKF/IC/SS/GE/23/2. This document would constitute the basic proposal for the Diplomatic Conference. To prepare for the IGC Special Session, a series of informal regional meetings had been organized: the Group of Latin American and Caribbean Countries ("GRULAC") had met in Uruguay in April 2023; the Asia and the Pacific Group ("APG") had met in Indonesia in May 2023; the African Group had met in Algeria in June 2023; and the Central European and Baltic States Group ("CEBS Group") had met virtually in June 2023. In addition, a cross-regional technical meeting, funded by the China Funds in Trust, had been organized in Beijing, China, in July 2023. These meetings had successfully helped build a common understanding both within and among the regional groups on issues regarding the Text of a Draft International Legal Instrument Relating to Intellectual Property ("IP"), Genetic Resources ("GRs") and Traditional Knowledge Associated with Genetic Resources ("aTK"). The Secretariat thanked the Governments of Uruguay, Indonesia, Algeria, Poland and China for hosting and co-organizing each critical meeting. The negotiating text for this Special Session would constitute the substantive articles of the basic proposal for the Diplomatic Conference in 2024. The Preparatory Committee of the Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources ("Preparatory Committee"), meeting in the following week, would incorporate in the basic proposal any agreed revisions of the draft text decided upon during the IGC Special Session. The Special Session would mark the last opportunity to revise the draft text ahead of the Diplomatic Conference. He called for flexibility and pragmatism from all Member States. The importance of the Voluntary Fund was underscored, and he acknowledged the contributions that the representatives of Indigenous Peoples as well as local communities had made to the process and their specific wish to participate as directly and as effectively as possible. The Secretariat thanked the Governments of Australia, Germany and Mexico for their recent contributions to the WIPO Voluntary Fund, which had allowed four representatives of Indigenous Peoples as well as local communities to participate in this Session. The Voluntary Fund would be used to fund the participation of Indigenous Peoples as well as local communities in the Diplomatic Conference, and in the case of insufficient resources, through the budget allocated for the Diplomatic Conference. The Secretariat encouraged Member States to consult internally and identify ways in which to raise further contributions to the Voluntary Fund.

11. The Chair thanked the delegates, Group Coordinators, the three Vice-Chairs and the Secretariat. She also thanked the Governments of Uruguay, Indonesia, Algeria, Poland and China for hosting the regional and cross-regional meetings prior to the Special Session. She recalled that the session was organized in a hybrid format, and as in previous meetings, the session was on live webcast on the WIPO website, which helped to improve openness, transparency and inclusiveness. She recalled that in 2022, the WIPO General Assembly had decided that the Special Session should further close any existing gaps to a sufficient level regarding the document WIPO/GRTKF/IC/SS/GE/23/2 ("Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources"). That document would constitute the basic proposal for the Diplomatic Conference. The Preparatory Committee should incorporate in the basic proposal any further agreements of the Special Session. The basic proposal would be considered by the Diplomatic Conference. The Chair acknowledged the importance and value of indigenous representatives, as well as other key stakeholders such as representatives of industry and civil society.

AGENDA ITEM 2: ADOPTION OF THE AGENDA

Decision on Agenda Item 2:

- 12. The Chair submitted the draft agenda circulated as WIPO/GRTKF/IC/SS/GE/23/1 Prov. for adoption and it was adopted.
- 13. The Chair opened the floor for opening statements. [Note from the Secretariat: Many Delegations that took the floor for the first time congratulated and thanked the Chair, the Vice-Chairs and the Secretariat and expressed their gratitude for the preparation of the session. A few statements were tabled in writing only and these are available online at https://www.wipo.int/meetings/en/details.jsp?meeting_id=76648.]
- The Delegation of Ghana, speaking on behalf of the African Group, stated that Africa was home to diverse cultures, Indigenous Peoples as well as local communities, and unique ecosystems, and had long been a repository of TK and GRs. Those resources were invaluable to societies and played a vital role in global scientific and economic research, ecological sustainability, and national advancement. Those resources were also the heritage of its people, and the essence of African identity. Their appropriate utilization was important not only for the continent but also for the global community. The unregulated and unlawful historical access to use and exploit those resources should require urgent and effective attention. The conviction of the global imperative motivated the journey towards developing a comprehensive international instrument that safeguarded GRs and aTK. The Group acknowledged the progress made so far within the framework of the IGC. It commended the dedication and constructive contribution of all participating delegations. It also thanked WIPO for facilitating the regional meetings and the technical meeting in Beijing to hold informal discussions among regional groups. It expressed its gratitude to the Government of Algeria for hosting the African regional meeting and the Government of China for hosting the cross-regional meeting. It recalled that the mandate of the Special Session was to close any remaining gaps in the document to a sufficient level with a view to advancing toward the Diplomatic Conference. In that regard, the African Group called upon all Member States to show political flexibility in order to make tangible progress toward the Diplomatic Conference. The African Group reiterated its position that the future instrument should contain a mandatory disclosure requirement and ensure its mutual supportiveness with other relevant international instruments. It hoped that the engagement and deliberations at the Special Session would be guided by a commitment to equity and fairness, as the IGC

progressed towards attaining an instrument that rectified the historical and current imbalances in the exploitation of GRs and TK. It was essential that the benefits derived from those resources were distributed among all stakeholders, especially communities that had served and continued to serve as their custodians. While aiming to prevent the erroneous grant of patents, the instrument should ideally ensure that local committees had authority over their resources. Finally, it reaffirmed the readiness to engage constructively and its commitment to working collaboratively with all Member States to craft a fair, balanced and effective international instrument.

- 15. The Delegation of Switzerland, speaking on behalf of Group B, remained confident that the IGC would be able to make progress and put forward a report with a revised draft text to the Preparatory Committee. It expressed appreciation for the virtual expert groups and their contributions to expediting the work of the IGC. Considering the nature of the expert groups to provide neutral and technical analysis, the result of their discussions should be given due consideration in the discussions during the Special Session. The Special Session was the last IGC session to advance the discussion on the substantive issues in the draft text. It stressed the importance of applying an efficient and transparent working methodology to make full use of the time available. It showed its support for the establishment of ad hoc contact groups that would be open to all interested delegates. It wished that those ad hoc contact groups would negotiate the text with a view to finding consensus in the plenary and, if necessary, amending the draft text. At that stage of the negotiations, and given the brevity of the draft text, it would be crucial that the revisions of the draft instrument included the texts negotiated by Member States. It stressed the importance of organizing the revisions in an efficient manner. With respect to the role of facilitators, Group B expressed some concerns. It supported a transparent, inclusive, and Member State-driven methodology. It then highlighted a few substantive issues which were important to all Group B members. It was of utmost importance that the instrument set appropriate standards for disclosure at the international level, including floors and ceilings. The disclosure requirement should provide a useful and shared international standard and must be drafted as a transparency measure. This also meant that the content and the trigger for disclosure would need to be clear and reasonable for applicants. easily implementable by offices, and meaningful in a patent context. Any sanctions must be balanced and should consider practical implications for innovation, and any post-grant sanctions for noncompliance with the disclosure requirement should not provide a basis for revoking patents or otherwise interfering with the patent holder's rights. In negotiating the text of this instrument, the relationship of the instrument with other international agreements should be further considered. Group B looked forward to the continued and active participation of Indigenous Peoples as well as local communities, and other observers in the IGC. It acknowledged their valuable and essential contribution to the work of the IGC. In that regard, Group B expressed its gratitude to the Governments of Mexico, Australia and Germany for their contributions to the WIPO Voluntary Fund to enable the effective participation of indigenous representatives in the Special Session as well as the Preparatory Committee. It reiterated its continuous engagement in the work of the IGC to contribute constructively to a mutually beneficial result on the path to the Diplomatic Conference.
- 16. The Delegation of China thanked the Chair, Vice Chairs and Secretariat. It recalled the regional meetings and all the work that had been done to better prepare for the Diplomatic Conference. It also recalled the cross regional meeting in Beijing from July 25 to 27, 2023, where delegates had had an informal exchange on important issues related to GRs and aTK and thanked all participants in the Beijing meeting. It recalled that the Special Session would be the final opportunity for a focused discussion on the text before the Diplomatic Conference. Many issues remained, and there would be a need to further bridge differences in order to arrive at a solution that was acceptable to all parties. It reaffirmed its commitment to participating in the discussions in a positive, pragmatic and constructive manner. It suggested focusing on the provisions on disclosure requirements, sanctions, and exceptions and limitations. It reiterated

its willingness to actively exchange views with all parties on relevant issues. It called on all parties to work together during the Special Session and demonstrate flexibility in order to narrow gaps and forge consensus. It hoped that this session would make positive progress towards the conclusion of a meaningful international instrument for the proper protection of GRs, which would therefore lay a solid foundation for the convening of the Diplomatic Conference.

- The Delegation of Poland, speaking on behalf of the CEBS Group, looked forward to discussing the proposed provisions, and modalities of the working methodology for the session. It emphasized that the work should be based on Member State-driven principles, ensuring full transparency in the process of negotiations. The importance of involving Indigenous Peoples as well as local communities in the process was emphasized, and thanks were extended to the Governments of Australia, Germany and Mexico for their contributions to the WIPO Voluntary Fund. It also welcomed the recent agreement within the Program and Budget for 2024/2025, facilitating the participation of representatives of Indigenous Peoples as well as local communities in the work of the IGC and the Diplomatic Conference. It thanked the Government of China for organizing the informal cross-regional discussions on GRs and aTK, held in Beijing in July, which had been seen as a helpful contribution. It recalled a series of regional consultations held earlier in the year, including a consultation among the CEBS Member States organized by the Patent Office of the Republic of Poland, with the assistance of the WIPO IGC Secretariat on June 30, 2023. All those efforts had reflected greater determination to move the process toward reaching an agreement acceptable for all WIPO members. The Group thanked the work of the ad hoc expert groups which had met earlier in the year, and the report contained in document WIPO/GRTKF/IC/47/13 was acknowledged. It took positive note of the participation of the experts from the CEBS Group. The very basis of the negotiations related to GRs and aTK should be a balanced and flexible approach to solving the issues. CEBS Member States had thoroughly studied the documents and recalled the importance of an evidencebased approach when discussing the draft text. The Group expressed its commitment to engaging constructively during the discussions and achieving a mutually acceptable outcome.
- 18. The Delegation of Tajikistan, speaking on behalf of the Central Asian, Caucasus and Central European Countries ("CACEEC"), expected that, under the Chair's skilled guidance and leadership, Member States would find common ground on core issues. It recognized the IGC's work, in line with its mandate, leading to the Diplomatic Conference in 2024. CACEEC was ready to engage in negotiations, with a specific focus on unresolved issues and the consideration of options for a future instrument. It acknowledged the substantial agenda before the IGC and pledged its continuous engagement and commitment to contributing in a constructive manner to ensure the successful completion of the work.
- The Delegation of Iran (Islamic Republic of), speaking on behalf of APG, stated that, after many years of negotiations, the Special Session had come to a critical juncture to finalize an instrument on GRs and aTK. It acknowledged the progress made in narrowing gaps and building a common understanding on core issues related to GRs and aTK. It reminded all participants of the 2022 WIPO General Assembly's decision on convening a Diplomatic Conference. The Group looked forward to the convening of the Diplomatic Conference. It believed that the aim for the Special Session should be to exclusively address and close any existing gaps. It emphasized the need for an effective and flexible, yet inclusive, process as it had been the case in the previous IGC sessions. APG Member States had participated in the cross-regional meeting in Beijing and in the regional meeting in Bali to build a common understanding on issues concerning IP, GRs, and aTK with the goal of achieving a successful outcome at the Diplomatic Conference in 2024. It looked forward to further engagement with other Groups and moving the discussion forward. The draft text was viewed as a compromise solution to reach common ground and convergence of views and positions. As the negotiations were reaching their final stage, it believed that more flexibility and political will must be exercised by all Member States. It emphasized the importance of not letting differences prevent

delegations from reaching an agreement in order to increase the efficiency of the patent system and ensure the protection of GRs and aTK in a balanced and adequate manner. It hoped that, under the Chair's able guidance, the IGC could further expedite its work toward this common goal. It reiterated APG Member States' commitment to constructively engaging with all parties in advancing a mutually acceptable outcome.

- The Delegation of Venezuela (Bolivarian Republic of), speaking on behalf of GRULAC, noted that the IGC was in the final stages of a long process. It acknowledged the different working documents of the IGC, including the draft text. A clear working methodology had been seen as a reflection of the plurality of views which characterized the IGC process. It acknowledged the important contributions made by Indigenous Peoples, local communities and experts in the process. It emphasized the specific nature of the instrument, which was not meant to create new rights but to recognize the ancestral rights of Indigenous Peoples as well as local communities. It stressed the need for the political commitment of all parties to reach agreements that would ensure better IP governance, proper use of GRs and aTK, and fair access to them and their benefits worldwide. It outlined five guiding principles to guide the work: establishing an international legally binding instrument; ensuring that the instrument be mutually beneficial for all relevant stakeholders; establishing a mandatory disclosure requirement for GRs and aTK, including provisions for sanctions and remedies for noncompliance with the disclosure requirement; recognizing all beneficiaries in the agreement; and promoting equality in the global IP system for sustainable development and human rights. It expressed its commitment to the final phase of the process before the Diplomatic Conference and acknowledged the challenges in achieving consensus on a wide range of issues. A shared spirit of constructive dialogue would lead to an ambitious, balanced and effective outcome. GRULAC thanked the Governments of Mexico, Australia and Germany for their contributions to the Voluntary Fund.
- The Delegation of Indonesia, speaking on behalf of the Like-Minded Countries ("LMCs"), thanked the Secretariat for the convening of regional and cross-regional meetings and for the informal information session leading up to the session. It emphasized the significance of the work during the session, especially in light of the historic decision taken by the 2022 WIPO General Assembly, which had been seen as a resounding call to action. That call to action not only reflected a shared conviction but also signaled the need for an international instrument to protect GRs and aTK from misappropriation, aiming for a more equitable global IP landscape. The success in that endeavor had the potential to inspire similar efforts in different domains, highlighting the role of multilateralism in addressing global challenges, with WIPO playing a crucial role. It acknowledged the contributions of the Indigenous Caucus. The text discussed during the Special Session represented decades of compromises. With perhaps some minor amendments, LMCs believed that the draft text represented the best way forward. Any proposal deviating from the current text and further expanding gaps should be avoided. It emphasized the need for a legally binding instrument for the protection of GRs and aTK, while recognizing the diversity of interests. It reiterated that that could only be achieved through the establishment of a mandatory disclosure requirement, along with adequate sanctions and remedies for noncompliance. Such an instrument should be implemented in a mutually supportive manner with other relevant international agreements. Those elements constituted the core of the legal instrument. Regarding the working methodology, the IGC's objective should be to ensure the further closing of existing gaps, and an effective and inclusive process. Inclusivity would be properly featured in the process of the IGC. Expanding the Friend of the Chair mechanism to include more "Friends" was seen positively, as it could provide more balanced and comprehensive technical advice to the Chair and a more inclusive process, which had been a mainstay throughout the past IGC sessions. The Delegation emphasized the importance of the Special Session as the last attempt to further close gaps before the Diplomatic Conference. It underlined the need for delegations to exercise flexibility, good faith and political will, and expressed confidence in the successful leadership of the Chair.

- 22. The Delegation of the EU, speaking on behalf of the EU and its Member States, reiterated its view that any international instrument on GRs and aTK that would have an impact on the patent system should demonstrate a balanced and flexible approach. It had studied the text and would share its views on the preferred wording in the articles. It remained committed to engaging constructively during the session, as well as during the Preparatory Committee and the upcoming Diplomatic Conference.
- The representative of the Arts Law Centre, speaking on behalf of the Indigenous Caucus, noted that the period between 2022 to 2032 had been declared as the International Decade of Indigenous Languages. She emphasized that Indigenous Peoples required positive protection for GRs and aTK in accordance with their internationally recognized rights, as expressed in the UN Declaration on the Rights of Indigenous Peoples ("UNDRIP"). The IGC should consider those positive protections when determining the pace at which this instrument moves forward. That involved respecting the rights of Indigenous Peoples, particularly the requirement for free, prior and informed consent ("FPIC") when their GRs and aTK were impacted. The current text failed to recognize minimum standards in several key areas, which undermined the fundamental rights of Indigenous Peoples and disadvantaged them. She highlighted the responsibility of the Indigenous Caucus in advocating for the rights of 370 million Indigenous Peoples worldwide, who often resided in areas with significant biodiversity. A mere token acknowledgement of UNDRIP in the current text fell short of a true recognition of the rights of Indigenous Peoples. She called on Member States to respect their rights to full and effective participation and address Indigenous Peoples' concerns adequately in the Diplomatic Conference. She acknowledged the stage of negotiations and presented priorities to reconcile the interests of Indigenous Peoples and Member States. Those priorities included the principles that Contracting Parties should consult with Indigenous Peoples, the inclusion of the source or origin in disclosure requirements for GRs for transparency and legal certainty, and the confirmation that participating indigenous organizations would have the capacity to observe and intervene regarding the text during the Diplomatic Conference. The adoption of those reasonable considerations by Member States was fundamental to the legitimacy of the instrument. Without such reasonable accommodation, it would be untenable for the Indigenous Caucus to consider the instrument as reflecting a fair or reasonable effort in protecting, respecting and promoting the rights of Indigenous Peoples regarding their GRs and aTK. She expressed gratitude to Australia, Germany and Mexico for their contributions to the Voluntary Fund, enabling Indigenous Peoples as well as local communities to participate in the IGC process.

AGENDA ITEM 3: PARTICIPATION OF INDIGENOUS PEOPLES AND LOCAL COMMUNITIES

24. The Chair thanked the Governments of Australia, Mexico and Germany for their contributions to the Voluntary Fund, which facilitated the attendance of four representatives of Indigenous Peoples as well as local communities at the session. She mentioned the presence of a donation box outside the conference room and encouraged everyone to contribute, emphasizing that no amount was too small. The Chair also called upon Member States to consult internally and contribute to the fund. She stressed the importance of the fund to the credibility of the IGC, highlighting that the contribution and participation of Indigenous Peoples and local communities were essential and necessary to the process. The Voluntary Fund would be used to support the participation of Indigenous Peoples as well as local communities in the Diplomatic Conference 2024. In the event of insufficient funds, the budget allocated for the Diplomatic Conference would be utilized. The Chair drew attention to document GRTKF/IC/SS/GE/23/INF/3, which provided information on the current state of the Voluntary Fund. [Note from the Secretariat: The session then moved on to facilitating a presentation by the Indigenous Caucus, recognizing one of their members who passed away.]

Decisions on Agenda Item 3:

- 25. The Committee took note of document WIPO/GRTKF/IC/SS/GE/23/INF/3.
- 26. The Committee strongly encouraged and called upon members of the Committee and all interested public and private entities to contribute to the WIPO Voluntary Fund for Accredited Indigenous and Local Communities.

AGENDA ITEM 4: GENETIC RESOURCES

27. [Note from the Secretariat: This part of the session took place on September 4, 2023, after an informal consultation on the working methodology.] The Chair informed the IGC that an agreed position had been reached on the working methodology. The working methodology was flexible and dynamic, subject to change based on the progress made. The work on Agenda Item 4 would commence in plenary, focusing on comments on document WIPO/GRTKF/IC/SS/GE/23/2. The substantive articles of the draft text, which were the preamble and Articles 1 to 9, were the primary focus of the Special Session. The administrative and final provisions, as found in document GRATK/PM/2, would be addressed by the Preparatory Committee. Participants were encouraged to provide proposals on the draft administrative and final clauses during the Preparatory Committee. However, participants could refer to these clauses during the Special Session if they were relevant to the preamble and the substantive articles. The Chair reminded that the plenary remained the decision-making body, and the discussions would be recorded. Informals in a hybrid format could be established when appropriate. Informals aimed to narrow gaps and propose a compromise text to the plenary. The Chair outlined the modalities of informals, which included the appointment of a Vice-Chair to coordinate discussions, open participation and interpretation in six languages. The Chair explained that ad hoc contact group(s) could also be established when appropriate. The ad hoc contact group(s) would be chaired by a Vice-Chair, and meet in-person with English as the working language. Participants were reminded to maintain the informality of the informals and ad hoc contact group(s). In line with previous practice, the Chair invited Ms. Margo Bagley to be the Friend of the Chair, who would act as a technical advisor to the Chair. Throughout the week, the Chair would meet, as needed, with Group Coordinators, groups or individual participants to discuss and seek their advice. Taking into account the views, positions and proposals expressed, a revised version of WIPO/GRTKF/IC/SS/GE/23/2, Rev. 1, would be prepared and made available on Wednesday afternoon, September 6, 2023. The Chair expected it would contain a few changes which would close any existing gaps to a sufficient level. The Chair could establish, as appropriate, an ad hoc contact group(s)/informals on September 7, 2023, to further review Rev. 1. A further revised text, Rev. 2, would be prepared and made available on Friday morning, September 8, 2023. The Committee would review Rev. 2 and agree on any proposed changes to it on Friday, September 8, 2023. Any changes agreed upon by the Committee to document WIPO/GRTKF/IC/SS/GE/23/2 would be reported to and incorporated by the Preparatory Committee into the Basic Proposal for an International Legal Instrument relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources. Several information documents were prepared for this session, including WIPO/GRTKF/IC/SS/GE/23/INF/2, which provided a factual report on virtual activities mandated by IGC 43. The Secretariat issued an online survey and organized ad hoc virtual meetings of experts on possible disclosure requirements and on information systems of GRs. TK and TCEs. Member States and accredited observers had been invited to nominate

experts for the virtual meetings by submitting the name and full contact details of the nominee(s), as well as a curriculum vitae that demonstrated their area of expertise. The Secretariat had selected experts based on their expertise and experience, taking into account regional and gender balance. The virtual expert meetings on information systems had looked at the draft texts on TK, TCEs and GRs and made a textual proposal on Article 7 of the draft text. The virtual expert meetings on possible disclosure requirements had made textual proposals on Articles 2, 3, 6, 7 and 8 of the draft text. The Chair invited the Delegation of India to introduce document WIPO/GRTKF/IC/SS/GE/23/3 ("Draft Text Proposal from India to WIPO IGC for Modifications in the Draft Negotiating Text for International Instrument for Protection of Genetic Resources and Associated Traditional Knowledge").

The Delegation of India expressed its gratitude to the Secretariat for the excellent preparations, which had led to the Special Session. The Delegation provided a brief introduction to its proposal, as contained in WIPO/GRTKF/IC/SS/GE/23/3. It reiterated full support for the ongoing efforts of the IGC to make progress towards a substantive instrument for IP, GRs and aTK. The Delegation explained its proposal, which was drafted with a view to making minimal modifications to the text, while aiming to bring clarity. The Delegation proposed to refer to the term "IP" instead of restricting the scope of the instrument to patents in the preamble, acknowledging the limited nature of the substantive obligations. This proposition aimed to align with the view that the preamble should serve as an interpretive guide to the instrument's overarching purpose and philosophy. Within the draft text, the current scope of Article 9 allowed for potential future reviews of extending disclosure requirements under Article 3 to other forms of IP. However, it believed that, in the absence of a broad reference to the IP system in the preamble, the scope of the instrument could become restricted and inconsistent. It proposed to modify the objectives, in order to introduce measures for the protection of GRs and aTK, as opposed to merely enhancing the efficacy, transparency and quality of the patent system. The existing international and national patent systems had already provided for several measures and obligations which required a patent applicant to ensure sufficiency of disclosure in the application. The Delegation emphasized that the disclosure requirement was part of the rationale of patent law. Therefore, building upon the existing obligations of the patent regime, the instrument should create a clear disclosure obligation on a patent application in respect to GRs and aTK. Since the source of the knowledge or resource, on which the invention was based, was known or ought to be known to the applicant, disclosure of source should be established as a mandatory obligation. That would support the objectives of other international instruments for the protection of GRs and aTK, and would help good compliance with both national and international laws. The term "country of origin" currently used in Article 3 was ambiguous, as it was not clear whether it was a country where the material was obtained or originated from. The GRs obtained might also have different properties depending on the region from where they came from, even within the same country. Consequently, the Delegation proposed that the content of the disclosure should be adequately clear and not lead to different interpretations. The minimum standards of the content of disclosure must be established to advance the objective of the instrument. In respect to the trigger, the Delegation preferred the word "materially" over "directly based on", since the latter could possibly imply that the GR would have to be physically obtained for the disclosure. Certain qualifiers in the definition of "materially based on" had been proposed to be removed, in order to make the trigger of disclosure clear and consistent. The Delegation proposed to define the term "Traditional Knowledge associated with Genetic Resources". In the absence of such a definition, the instrument might fall short of establishing legal certainty required for patent applicants to fulfill disclosure obligations. One of the key principles guiding the work of the IGC had been to develop a clear understanding of the modalities of an international disclosure requirement system, which would enable policymakers to make informed decisions regarding the costs, risks and benefits of a disclosure requirement. The scenario where substantive element of the instrument remained undefined could create ambiguity for business and applicants. Hence, the Delegation proposed to define the term based on the existing

definitions, which had been under discussion in the IGC. It suggested modifications to Article 6, so as to clarify the level of obligation for each specific measure. The objective of those proposals were to provide a basis for discussions on key policy questions without prejudging the outcome of the discussions. The Delegation reiterated its commitment to facilitating progress and helping to close existing gaps to a reasonable level. It affirmed its readiness for further work on revisions to the draft text. It looked forward to discussing its proposals openly and welcomed queries and feedback from other delegations.

- 29. The Chair invited participants to make general comments on the preamble and Articles 1 to 9.
- 30. The Delegation of Switzerland, speaking on behalf of Group B, suggested revisiting the preamble at the conclusion of the week, after more progress was achieved on the substantive provisions.
- 31. The representative of MALOCA Internationale highlighted specific areas of concern in the text. The redlines included the need for the inclusion of the FPIC of Indigenous Peoples in Articles 4 and 8, and an additional objective in Article 1 to ensure the protection of GRs and aTK of Indigenous Peoples.
- 32. The Delegation of the EU, speaking on behalf of the EU and its Member States, expressed its support for the preamble and noted that it clearly limited the scope of the instrument to patents. A general remark was that throughout the text, acronyms should be spelled out. For example, "aTK" would read as "traditional knowledge associated with genetic resources".
- 33. The Delegation of Poland, speaking on behalf of the CEBS Group, expressed its lack of significant reservations regarding the preamble. It aligned itself with the statement made by the Delegation of EU, on behalf of the EU and its Member States, that the scope of the instrument should be limited to patents. It proposed to look at the preamble at the end of the session.
- 34. The representative of the Assembly of First Nations, speaking on behalf of the Indigenous Caucus, expressed a sentiment that a stronger language acknowledging and reaffirming the obligations outlined in UNDRIP should be incorporated into the document. He also noted that the current draft of the preamble was relatively weak in recognizing Indigenous Peoples. He expressed his interests in enhancing the inclusion of Indigenous Peoples and local communities in the draft text at a later stage.
- 35. The representative of MBOSCUDA reiterated the Indigenous Caucus' view that the current text was weak in recognizing the commitments made by the States within UNDRIP.
- 36. The Delegation of China believed that in addition to the patent system, it was also necessary to enhance the efficiency, transparency and the quality of trademarks and geographical indications. It believed that the scope of the instrument should be extended, at least in the preamble, to cover IP, rather than being limited to patents. It proposed that the text of the preamble should state "IP" or "IP system" instead of not "patents".
- 37. The Delegation of Canada believed that broadening the scope beyond patents to encompass all forms of IP would present challenges in interpreting the instrument and complicate the IGC's efforts to close existing gaps in the text. The Delegation pointed out that the articles had been drafted with a focus on the patent system, and extending those obligations to other types of IP, especially those that did not require application or registration, such as copyright, would raise questions about how disclosure mechanisms would work. It mentioned ongoing negotiations related to disclosure mechanisms in the context of the design law, and

expressed a desire not to prejudice those negotiations by introducing relevant obligations in the current instrument.

- 38. The Delegation Thailand expressed its support for the preamble text, which it found to be clear in outlining the main objective of the instrument to enhance the effectiveness, transparency and quality of the patent system and to prevent the erroneous granting of patents. Considering the proposal made by the Delegation of India, it noted the connection between Article 9 and the preamble, and expressed a willingness to support the replacement of "patent system" with "Intellectual Property system" in paragraph 3 of the preamble, if the proposal gained majority support.
- 39. The representative of the Assembly of First Nations, speaking on behalf of the Indigenous Caucus, suggested revising the first paragraph to "recognizing and reaffirming obligations set forth in the UN Declaration on the Rights of Indigenous Peoples and Member States" commitment to achieving the ends of UNDRIP". Regarding the second paragraph, similar to the position of the Delegation of India, he recommended broadening the scope of the preamble to encompass the IP system instead of solely focusing on the patent system. In the third paragraph, he highlighted the potential role of the IP system and suggested adding ", including preventing misappropriation" at the end.
- 40. The Delegation of the Republic of Korea acknowledged the substantial gap among Member States regarding the scope of the IP system. It referred to the decisions of the General Assembly, and stated that the scope of the instrument should be restricted to the patent system. The Delegation supported the current text.
- 41. The Delegation of Japan expressed its support for the proposal made by the Delegation of Switzerland, on behalf of Group B, regarding revisiting the preamble later in the week. The Delegation asserted that the term "IP system" or "IP" would not be suitable for use in the preamble or elsewhere in the text. The scope of instrument should be limited to the patent system not the IP system. It would be appropriate to maintain consistency in the language used for the objectives and content throughout the instrument.
- The Delegation of the United States of America stated that genuine differences existed among Member States regarding the potential impact of the disclosure requirement imposed by the instrument. It proposed to revise the fourth paragraph of the preamble to "Recognizing that an international disclosure requirement related to GRs and Associated TK in patent applications has benefits for providers and users of such resources and knowledge". The preamble should reflect a balance between transparency and the transaction costs of disclosure requirements. Consequently, it suggested replacing the phrase "mutually supportive", which described how the instrument related to other agreements, with "coherent" throughout the preamble and the rest of the instrument. The Delegation disagreed with the suggestion of the Delegation of India to expand the scope of the instrument beyond patents to encompass IP in general. The focus of the instrument was on patent disclosure requirements. Article 9 provided for a review over time and Article 15 addressed amendments to the instrument. Replacing "patent" with "IP" would go beyond the subject matter that had been discussed over time in the IGC and would prejudge outcomes of potential work under those clauses. It disagreed with the proposal on the inclusion of "misappropriation of GRs and aTK" in the preamble. The focus of the negotiation was on the patent disclosure requirement for GRs and aTK, not the creation of a sui generis regime for their protection. To that end, the preamble had already mentioned the importance of having a disclosure requirement that prevented patents from being granted erroneously for inventions that were not novel or inventive. In the fifth paragraph, it suggested replacing "and" with "should ensure coherence with" and deleting "should be mutually supportive" at the end.

- 43. The Delegation of the Russian Federation emphasized the importance of constructive dialogue to bring the various positions closer and reach consensus on the remaining unresolved issues of the document. It thanked the China National Intellectual Property Administration for hosting the Cross-Regional Technical Meeting on IP, GRs and aTK in Beijing and all participants of this event for their openness and readiness to engage in a constructive dialogue. Regarding the preamble, it supported the current wording with a view to reaching consensus. Regarding the proposal made by the Delegation of India, it had no objection to replacing "patent system" with "IP system". However, it expressed reservations about the proposal on adding "including preventing misappropriation" to the preamble, because this idea is included in the concept of "the potential role of the patent system in contributing to the protection of GRs and aTK" that is already in the preamble.
- 44. The Delegation of Egypt supported the proposal made by the Delegation of India, as the reference to "IP system" was more suitable. That proposal would facilitate the upcoming review process scheduled to take place four years after the entry into force of this instrument.
- 45. The representative of KEI proposed to replace the beginning of the sixth paragraph with "recognizing and reaffirming the role that the intellectual property system plays". This change would provide a more accurate description of the role of the IP system in promoting various benefits related to GRs and aTK.
- 46. The representative of HEP expressed her support for the well-drafted preamble. She emphasized the need to make progress and achieve maximum consensus on the preamble by focusing on the current text.
- 47. The Delegation of Mexico preferred the use of "intellectual property system" instead of "patent system". However, in order to benefit the negotiations, it also showed flexibility in supporting the current text. It proposed to include "and for the recognition of the relevance of these to Indigenous Peoples" in the first paragraph. In the second paragraph, it suggested adding "in consultation with Indigenous Peoples" after "offices to have access to appropriate and adequate information on GRs and aTK". In the third paragraph, it proposed to add "the protection of the collective rights of Indigenous Peoples and the need to ensure fair and equitable benefit sharing" at the end. Regarding the seventh paragraph, it proposed to include the Nagoya Protocol and to highlight the importance of international instruments on the rights of Indigenous Peoples. The Delegation introduced a new paragraph: "Recognizing the rights and interests of Indigenous Peoples to maintain control, protect, and develop intellectual property that they possess as part of their cultural heritage, including genetic resources and traditional knowledge associated with genetic resources".
- 48. The Delegation of Algeria supported the replacement of "patent system" with "intellectual property system" in the preamble, emphasizing the importance of ensuring consistency with the IGC's mandate. That would also allow for a potential extension of the scope of the instrument as provided for in Article 9. It also supported the proposal to revisit the preamble at the end of discussions.
- 49. The Delegation of Canada expressed its supports to the proposals made by the representative of the Assembly of First Nations, on behalf of the Indigenous Caucus, which aimed at amending the last paragraph of the preamble to read as follows: "Recognizing and reaffirming obligations set forth in the UNDRIP and Member States' commitment to achieving the ends of the UNDRIP".
- 50. The representative of TWN expressed his support for replacing "patent" with "intellectual property rights". He also emphasized the importance of mentioning the prevention of misappropriation in the text to ensure coherence.

- 51. The Delegation of Iran (Islamic Republic of) supported the proposal made by the Delegation of India to broaden the scope of the instrument by replacing "patent system" with "intellectual property system".
- 52. The Delegation of Switzerland expressed its interests in revisiting the preamble once further progress had been made on the text. It expressed its interests in looking at the proposal made by the Indigenous Caucus regarding UNDRIP. With reference to the proposal made by the Delegation of the United States of America regarding the fourth paragraph, it believed that the paragraph could be further improved to read "recognizing the need for legal certainty and consistency with respect to disclosure requirements related to GRs and aTK in patent applications and, therefore, also recognizing that an international disclosure requirement has benefits for the patent system". The Delegation did not support the general reference to "IP" instead of "patent", but recognized that some room to include a more general reference to IP could be found.
- 53. The Delegation of the United Kingdom supported the proposal made by the Delegation of Switzerland, on behalf of Group B, to revisit the preamble later in the week to ensure legal certainty in the text. It stated that the suggestions on replacing "patent" with "IP" in the preamble would make the scope of the instrument unclear.
- 54. The Delegation of South Africa aligned itself with the comments made by the Delegations of Egypt and Algeria, and supported the proposal made by the Delegation of India.
- 55. The Delegation of Peru supported that the instrument focused on patents, taking into account the possibility of reviewing and continuing discussions for potential expansion through Article 9.
- 56. The Delegation of Nigeria supported revisiting the preamble at the end of the session in light of any significant progress made. It reminded that typically a preamble was regarded as legally non-binding. In the spirit of cooperation in finding convergence and closing some gaps, it suggested the deletion of "the promotion of" in the first paragraph. Regarding the second paragraph, it was important to think about "having access to appropriate information on GRs" not as patent systems, but as administration of the patent system. It suggested cleaning up the second paragraph, which might address some of the concerns raised by the Delegation of the United States of America. It supported a reformulation, consistent with the proposal made by the Indigenous Caucus and supported by the Delegation of Canada, to acknowledge both the UNDRIP and the Nagoya Protocol. Regarding the patent system versus the IP system, it was important to maintain coherence, so it supported the use of the word "coherence" in the fifth paragraph. However, noting that there were spillover effects on other aspects of IP, the Delegation would be interested in seeing the proposals for rewording before making a categorical decision, one way of the other.
- 57. The Delegation of France supported the statements made by the Delegation of Switzerland, on behalf of Group B, and the Delegation of the EU, on behalf of the EU and its Member States, emphasizing the importance of limiting the instrument to the patent system initially and considering the possibility of extending it to the IP system through the review clause in Article 9.
- 58. The Delegation of Pakistan supported widening the scope of the instrument to IP system, at least acknowledging a connection with the larger IP system in the preamble. It also supported the proposal to revisit the text of the preamble at the end of the discussion.

- 59. The Delegation of Venezuela (Bolivarian Republic of) emphasized the need to recognize Indigenous Peoples in the preamble of the instrument.
- 60. The Delegation of Germany supported to limit the scope of the instrument to patents instead of extending to IP in general.
- 61. The Delegation of Niger supported to refer to the IP system, rather than just the patent system, in the preamble, noting the potential expansion through Article 9. It also reminded all delegations that the preamble was not legally binding.
- 62. The Delegation of Bangladesh supported the proposal made by the Delegation of India on replacing "patent system" with "IP system" in order to broaden the scope of the instrument. It also proposed to keep the fifth paragraph unchanged.
- 63. The representative of INBRAPI emphasized the importance of the preamble, even though it might not be legally binding. She expressed her gratitude to the Delegation of Mexico for voicing the hopes and expectations of Indigenous Peoples in the negotiations.
- 64. The Delegation of Samoa supported to refer, in the preamble, to the "patent system" rather than the "IP system". It emphasized the importance of not widening the scope of the instrument at this point, which would be time consuming and take the IGC back. It suggested that any necessary changes to the preamble should be addressed during the review process.
- 65. The Delegation of Colombia supported to limit the reference in the preamble to the patent system to maintain consistency. It acknowledged the possibility of reviewing the scope of the instrument with other types of IP in the future.
- 66. The Delegation of Ecuador supported the statements made by the Delegations of Peru and Colombia. The Delegation intended to participate constructively, and supported the text as it was. However, it was flexible with respect to the proposal made by the Delegation of Indian on replacing "patent system" with "IP system" in the preamble.
- 67. The representative of MALOCA Internationale stated that his community in Colombia had a different understanding of the concepts of GRs and aTK, and did not necessarily recognize themselves in the concepts being discussed in the negotiations.
- 68. The Chair opened the floor for comment on Article 1.
- 69. The Delegation of Switzerland, speaking on behalf of Group B, stated that Article 1 was fine with respect to the objectives. Some members might have additional suggestions.
- 70. The Delegation of the EU, speaking on behalf of the EU and its Member States, supported the current text of the objectives outlined in Article 1. There was a need to include a definition of "traditional knowledge associated with genetic resources" in Article 2.
- 71. The representative of the MALOCA Internationale mentioned that one of the objectives should be to protect GRs and aTK of Indigenous Peoples. He emphasized that there should be no separation between GRs and TK. Nonetheless, he believed that if there was no explicit mention of the safeguarding of GRs and the TK of Indigenous Peoples, this would be deemed unacceptable, especially for the Indigenous Caucus.
- 72. The Delegation of Venezuela (Bolivarian Republic of), speaking on behalf of GRULAC, supported the current form of Article 1. It also expressed its openness and willingness to listen to any proposals from other delegations.

- 73. The Delegation of Poland, speaking on behalf of the CEBS Group, supported the statement made by the Delegation of the EU, on behalf of the EU and its Member States, in particular, the inclusion of the definitions of TK or aTK. It preferred a definition of aTK.
- 74. The Delegation of Iran (Islamic Republic of), speaking on behalf of APG, explained that the objectives of this instrument encompassed several key aspects. These included the prevention of the erroneous granting of patents, ensuring the effectiveness of the patent system, and the avoidance of undue burdens on applicants and patent offices. Furthermore, it noted that some APG Member States believed that one of the objectives was to prevent the unauthorized and uncompensated use of GRs, while others viewed it from a more practical standpoint. When it came to the objectives of the instrument, the majority of the APG Member States agreed with the stated positions. Additionally, it highlighted that certain Member States suggested including other IP systems and the effective protection against the misappropriation of GRs and aTK in the objectives.
- 75. The representative of the Assembly of First Nations, speaking on behalf of the Indigenous Caucus, reminded the IGC of the origins of the IGC, which was established to address gaps in the IP system with respect to Indigenous Peoples' rights. The purpose had been to consider mechanisms for safeguarding Indigenous Peoples' rights, and to facilitate control, development and dissemination of Indigenous Peoples' information and GRs. He also acknowledged the Indigenous Peoples' continued customary use, development and exchange of GRs with other tribal nations and communities. Therefore, the objectives of the instrument should go beyond merely enhancing the efficacy of the IP system itself. He generally agreed with the Delegation of India on the minimum standards for those objectives, one of which should be to contribute to the protection of GRs and aTK within the IP system. The Indigenous Caucus would draft and share a text later. The proposed approaches would involve discussions on elements, such as FPIC.
- 76. The Delegation of Japan supported the current wording of Article 1. Regarding the proposal made by the Delegation of India, which aimed to contribute to the protection of GRs and aTK within the IP system, the Delegation held a different perspective. It argued that the term "IP system" was inappropriate within this article. This instrument focused on disclosure requirements, and it was crucial to maintain consistency in both objectives and content throughout the instrument.
- 77. The Delegation of China supported the current version of Article 1. In addition, it expressed a willingness to remain flexible and open to improvements. Article 1 expressed the overall scope and purpose of the instrument effectively. Regarding the preamble, the Delegation pointed out the similarity between paragraph (a) and (b) of Article 1 with paragraphs 1 and 2 of the preamble. It reiterated its proposal to mention the "IP system" instead of "patent system" in order to make the instrument more comprehensive and inclusive.
- 78. The Delegation of India wished to withdraw some of its proposed wording for Article 1, as contained in WIPO/GRTKF/IC/SS/GE/23/3, which was "to contribute to the protection of GRs in the IP system". It suggested the new wording "to contribute to the protection of GRs in the patent system".
- 79. The Delegation of Mexico highlighted the importance of including a new paragraph that read as follows: "contribute to the protection of the collective rights of Indigenous Peoples, and GRs and aTK in the IP system". It proposed an addition to sub-paragraph (b), suggesting the inclusion of the sentence" of the Indigenous Peoples with the purpose to achieve access and benefit-sharing" at the end.

- 80. The Delegation of the Russian Federation supported the current wording of Article 1. The objectives were succinctly and clearly stated, and the article did not contain provisions that had been already covered by other international agreements or unrelated to the patent system. It emphasized that the term "enhancing the efficacy" should make it clear that a disclosure requirement implemented at the national level should be effective, practical and easily implementable, and not result in overly burdensome transaction costs. It had no objections to the proposal made by the Delegation of India regarding the use of the term "IP system". However, it pointed out some inconsistencies in the terms used. In the chapeau of Article 1, the Delegation of India proposed to use "IP system", though "patent system" had been proposed to be used in paragraphs (a) and (b). Regarding Article 1, the Delegation expressed its flexibility and indicated its readiness to engage further in discussions.
- 81. The Delegation of Ghana, speaking on behalf of the African Group, agreed with the wording of the first objective. It proposed to broaden the formulation of the second objective which would read as follows: "prevent patents from being granted erroneously for inventions that are not novel or inventive or are offensive with regards to GRs and aTK."
- 82. The Delegation of Egypt recalled the decisions of the 2022 General Assembly regarding the Diplomatic Conference. That decision had been built on two foundations: the Chair's Text and the contributions of Member States. Regarding Article 1, it proposed a slight modification of the text, namely "enhance the efficacy, transparency and quality of the patent system with regard to the protection of GRs and aTK".
- 83. The Delegation of Ecuador conveyed its support for the original text with reference to the patent system. It expressed flexibility, particularly in the context of Article 9, which provided room for expansion to other types of IP.
- 84. The Delegation of Samoa agreed with the sentiments previously expressed by the Delegation of Ecuador. It supported the current formulation of Article 1, which did not imply a lack of recognition for the need to protect TK, aTK and TCEs within IP systems in WIPO. It believed that altering the current formulation from "patent" to "IP" to encompass other IP regimes would not be advisable. Each type of IP regime had different requirements, and attempting to address them all within the current instrument would require a significant overhaul.
- 85. The Delegation of Australia supported the current text. It also indicated its willingness to support the proposal on adding the reference to the contribution to the protection of GRs and aTK to the chapeau, which was proposed by the Delegation of India. That would help reflect that the intent of the instrument was indeed to contribute to the protection of GRs and aTK. To the extent that the text aimed to improve the efficacy, transparency and quality of the patent system and prevent the erroneous grant of patents, it would be useful to include that proposal in the objectives.
- 86. The Delegation of the United States of America supported the statement made by the Delegation of Switzerland, on behalf of Group B. It endorsed the original language of the article, but expressed reservations about including language related to the protection of GRs and aTK. It expressed concerns that such inclusion might be interpreted as favoring *sui generis* exclusive rights for GRs and aTK. While the IGC's mandate referred to the protection of GRs and aTK, the mandate of the Diplomatic Conference on GRs and aTK differed in scope. It did not explicitly mention protection in that context.
- 87. The Delegation of Switzerland supported the current objectives. It made a couple of observations on the proposals from other delegations. Regarding the additional language that referred to contributing to the protection of GRs and aTK, that language could be considered as long as it remained focused on the patent system but not IP in general. It acknowledged that

the Delegation of India had also agreed to maintain this focus on the patent system. To enhance the clarity of the objectives, it proposed that that language could be moved to the end of the objectives, following paragraph (b), saying, "and thereby contributing to the protection of GRs and aTK within the patent system". Regarding the two main objectives, the first one was linked to the mandatory disclosure requirement, while the second one was linked with the article on information systems. The Delegation of Ghana, on behalf of the African Group, had proposed to amend the second objective by adding the term "offensive". It sought further clarification on how that term would be understood and linked to specific measures in the instrument, such as disclosure requirements and information systems. The Delegation expressed uncertainty about the intended goal of the term, and could not support its inclusion.

- 88. The Delegation of Ghana, speaking on behalf of the African Group, conveyed the decision of the African Group to withdraw its earlier proposal. It expressed its wish to keep the text in its current form.
- 89. The Delegation of the Republic of Korea supported the statement made by the Delegations of Japan and the United States of America. It disagreed with the proposal to expand the scope of the instrument.
- 90. The representative of CAPAJ expressed her gratitude for the support and facilities provided by the Chair and the Secretariat, which had allowed Indigenous Peoples to contribute to the discussions. She conveyed her sympathy for the positions taken by the Delegations of India and Mexico, the Delegation of Ghana, on behalf of the African Group, and the Delegation of Venezuela (Bolivarian Republic of), on behalf of GRULAC. She highlighted the importance of the concept of the progressive nature of rights, which had been incorporated into the instrument.
- 91. The Delegation of New Zealand indicated its support, in principle, for the suggestions put forward by the Indigenous Caucus and the Delegation of India. Those suggestions revolved around the need for the objectives to reflect the protection of TK and GRs. It suggested that discussions involving interested Member States and the Indigenous Caucus could serve as a means to bridge existing gaps.
- 92. The Delegation of the United Kingdom supported the statement made by the Delegation of Switzerland, on behalf of Group B, and affirmed its support for Article 1 as currently drafted.
- 93. The Delegation of Canada supported Article 1 as it was currently drafted.
- 94. The representative of HEP emphasized the importance of not spending excessive time on this article due to the limited time available for discussions.
- 95. The Delegation of Saudi Arabia supported the wording of Article 1.
- 96. The representative of IIPSJ mentioned that it was the Amazon Day. She urged all Member States and participants to consider that when drafting their proposals. She emphasized the importance of thinking about the work and lives of their ancestors and finding solutions to the longstanding issues being discussed. She underscored the urgency of reaching a consensus to protect not only the interests of Indigenous Peoples living in the Amazon but also for the benefit of all mankind.
- 97. The Delegation of Ghana supported the textual proposal made by the Delegation of Egypt, which had been supported by the Delegations of New Zealand and Australia. Its support was based on the belief that the proposal built upon the idea referred in the third paragraph of the preamble. The idea related to the potential role of the patent system in contributing to the

protection of GRs and aTK. It would be useful to further develop the idea by explicitly including the protection of GRs and aTK as part of the objectives.

- 98. The representative of MBOSCUDA conveyed the desire of the Indigenous Caucus to include a new paragraph: "ensuring the consistency with UNDRIP, particularly concerning the application of the principle of FPIC".
- 99. The representative of the Assembly of First Nations proposed to modify the text in the chapeau as follows: "the objectives of the instrument are to contribute to the protection of GRs and aTK within the patent and IP system". He supported the proposal made by the representative of MBOSCUDA and suggested adding "the sharing of benefits with Indigenous Peoples and local communities" in Article 1(b). He thanked the Delegation of Mexico for its proposals.
- 100. The Delegation of Lebanon highlighted the importance of the article on objectives. It stressed that the overarching objective should be to guarantee the protection for GRs and aTK. It emphasized that the objective should not be focusing on patents. It drew attention to the need for clear definitions of terms, in particular, aTK and GRs. The current Article 2 lacked clear definitions for those two crucial terms. Regarding Article 1(b), the Delegation wondered whether the prevention of patents from being granted erroneously pertained to future patents granted or it also applied to patents that had already been granted and enjoyed effective protection.
- 101. The representative of the MALOCA Internationale underlined the importance of including in Article 1 a reference to the protection of GRs and aTK.
- 102. The Delegation of Bangladesh noted that the objectives could have been more reflective of promoting users' compliance with national access and benefit-sharing ("ABS") principles, in line with the CBD and the Nagoya Protocol. However, in the pursuit of achieving common ground to facilitate progress in the negotiations, it supported the text with the proposal made by the Delegation of India.
- 103. The representative of TWN emphasized the importance of recognizing the true objective of the instrument, which he believed was closely related to the protection of GRs and aTK within the patent system. He expressed the significance of the proposal made by the Delegation of India in that context. Article 1(b) currently conveyed the idea that the objective was to prevent patents from being granted erroneously for inventions that lacked novelty or inventiveness with regard to GRs and aTK. That conveyed the message that TK and aTK were patentable, but in many jurisdictions, TK was outside the patent regime and required separate protection. The patent system had a responsibility to prevent misappropriation and enhance the implementation of ABS mechanisms. The representative believed that the current objectives were very narrow and did not fully address the real issues. The logic behind the disclosure regime aimed to prevent erroneous granting of patents, which were not only related to the novelty or inventive step, but also related to ex-ante recognition of TK being patentable. That could compromise the efficiency of the system if not properly recognized. Additionally, the demand for equitable benefit-sharing was a crucial factor that needed to be recognized in the instrument. Failure to acknowledge that fact would mean turning a blind eye to the real issue at hand.
- 104. The Delegation of Brazil supported Article 1 as it was, but it did not oppose to any language that introduced the importance of protecting GRs and aTK.
- 105. The Delegation of the Philippines aligned itself with the statement made by the Delegation of Iran (Islamic Republic of), on behalf of APG. It supported the draft text of Article 1. However, it also believed that the text could potentially be enhanced to cover other areas of IP that were

relevant to GRs and aTK in the future. It suggested that such enhancements could be included in the preamble, as had been suggested by some delegations.

- 106. The Chair opened the floor for discussions on Article 3.
- 107. The Delegation of Switzerland, speaking on behalf of Group B, emphasized that the disclosure requirement should be drafted as a transparency measure. It stressed that the content and trigger of disclosure would need to be clear and reasonable for applicants, easily implementable by offices and meaningful in a patent context. Regarding the trigger, Group B agreed with the recommendation by the virtual expert group, which suggested using the term "materially and directly based" in Articles 3.1 and 3.2, in combination with the definition contained in Article 2. That trigger appropriately reflected the need for a close causal link between GRs and the invention. It also supported the recommendation made by the virtual expert group regarding the use of the term "the country of origin from which the GRs were obtained".
- 108. The Delegation of Iran (Islamic Republic of), speaking on behalf of APG, stated that the majority of APG Member States wished for an effective mandatory disclosure requirement that would protect GRs and aTK against misappropriation, in accordance with national circumstances. It supported the current formulation of Article 3.
- 109. The representative of the MALOCA Internationale emphasized her desire to see the inclusion of the FPIC of Indigenous Peoples in Article 3, to prevent possible misappropriation. She noted that the rights of Indigenous Peoples had already been internationally recognized, and in some cases, it had been shown that local communities needed to be involved, and that consultations were required. She did not want to merely include those internationally recognized rights but wanted to ensure their practical implementation. She reminded the IGC that WIPO had an obligation to respect international standards.
- 110. With a view to reaching consensus, the Delegation of the Russian Federation had no objections to the current wording of Article 3. It emphasized the importance of the Chair's clarifications that the trigger and the content should be workable in practice and reflect various circumstances where GRs and aTK could be sourced. Any disclosure requirement should not lead to obligations on patent applicants that could not be fulfilled or that could only be fulfilled with unreasonable time and effort and that would, therefore, hinder innovations based on GRs and aTK. Furthermore, it generally did not object to the proposals put forward by the Delegation of India regarding Article 3 and indicated its readiness to engage further in discussions on this article.
- 111. The Delegation of Ghana, speaking on behalf of the African Group, supported the establishment of an effective mandatory disclosure requirement. The requirement should serve to protect GRs and aTK. In principle, it supported the current formulation of Article 3.1 as drafted. A pragmatic consideration was that patent offices might not always be equipped to verify the authenticity of disclosure of sources or origin in patent applications. It emphasized that any additional rules for patent or IP offices should be matters for national laws or regulations.
- 112. The Delegation of Canada aligned itself with the statement mad by the Delegation of Switzerland, on behalf of Group B. It supported the addition of "from which the GRs were obtained" to Article 3.1(a) proposed by the virtual expert group, as it would more closely align the GRs provision of 3.1(a) with the aTK provision in Article 3.2(a). The proposed amendments clarified that the obligation was to disclose the particular country from which the relevant GRs were obtained, rather than every possible country where the GRs might be located. Practically speaking, it would be challenging for any patent applicant to know all the countries where the

GRs existed in *in situ* conditions. However, it was more likely that the applicant would know from which country the specific samples of the GR had been obtained. The Delegation believed that making that change would reduce the administrative burden on patent applicants while still identifying the source of the GRs.

- 113. The representative of the Assembly of First Nations noted that, while the disclosure requirement mainly applied to state parties, some materials might be obtained through agreements with Indigenous Peoples or acquired from Indigenous lands. Considering this, he proposed an amendment to Article 3.1(a): "the country of origin of the GRs and Indigenous Peoples or local communities from which the GR originated". Regarding Article 3.2, he suggested that it could be made more concise by deleting Article 3.2(b) and amending Article 3.2(a) as follows: "where the claimed invention in a patent application is materially/directly based on aTK, each Contracting Party shall require the applicant to disclose the Indigenous Peoples or local communities for which the aTK originated". Additionally, he recommended inserting a new 3.3(b) that would read: "each Contracting Party should also require the applicant, when Article 3.2 applies, to make a declaration that the aTK has been acquired in accordance with national law, with Indigenous Peoples' customary laws and protocols and international instruments, and the applicant should provide notice of the filing of the patent application to the Indigenous Peoples or local community concerned".
- 114. The representative of HEP supported the current wording of Article 3, particularly with respect to the disclosure requirement. She emphasized the importance of ensuring that the source of GRs was disclosed. The current wording was satisfactory in that regard. She also stressed the need to avoid redundancy in the instrument and highlighted the significance of having provisions that made it easier for Indigenous Peoples and local communities to benefit from the instrument. In Cameroon, there were local communities that were not Indigenous Peoples.
- 115. The Delegation of Uganda agreed with the statement made by the Delegation of Ghana, on behalf of the African Group, and emphasized the need for a mandatory disclosure requirement.
- 116. The Delegation of Mexico believed there was no need to include words such as "directly" or "materially" in Article 3. because the importance was that the invention per se was based on the GRs in question. It suggested the following revisions for Article 3.1(a): "the source of the GRs, in situ and/or ex situ, the country of origin, including the land territory and natural resources of Indigenous Peoples who own the GRs". This would provide a link between the GRs and Indigenous Peoples. Regarding Article 3.1(b), even in the case that the applicant did not have the information mentioned in Article 3.1(a), it suggested the following wording: "should provide all the information necessary to determine the traceability of the GRs". Though the applicant might not have the precise information, there needed to be a traceability of the GR in question. Regarding Article 3.2(a), it suggested the following modification: "the Indigenous Peoples or local communities from whom the aTK has been obtained". For Article 3.3, it suggested to include geographical sources in the declaration. It wished to add to Article 3.4 "in accordance with national legislation". Regarding Article 3.5, it proposed to add the wording at the end of the sentence "when the verification is possible, it would be carried out in accordance with national legislation". For Article 3.6, it believed that making the information disclosed available should only take place after the agreement had been reached.
- 117. The Delegation of Thailand aligned itself with the statement made by the Delegation of Iran (Islamic Republic of), on behalf of APG. It supported the fundamental principles embodied in Article 3, which centered around the application of a mandatory disclosure requirement. It agreed with the text, which triggered the obligation to disclose the actual source of GRs and aTK where they were obtained. However, it noted that it would also make sense for applicants

to provide not only the country of origin but also the more specific location of the GR, which would enhance transparency in the patent application process. It provided an example from the agricultural sector where inventions based on multiple generations of breeding came from numerous sources from various jurisdictions. Regarding Articles 3.1 and 3.2, the Delegation identified an ambiguity concerning the use of the terms "materially and directly". It wished to await further debate on that matter. It agreed with the wording of Article 3.4 that allowed policy space for Contracting Parties to shape the legal basis for the disclosure requirement within the patent application process. It suggested that further clarification might be necessary in practice to delineate how inventors' or patent applicants' actions would be monitored or regulated through the disclosure requirement, especially concerning the actual use of GRs or TK. It implied that specific policy development within the IP offices of Contracting Parties would be essential to provide clarity on how to certify the basis of FPIC and legitimacy of access to GRs and TK.

- 118. The Delegation of the United Kingdom emphasized the importance of ensuring a high level of legal certainty for officers and applicants, which met the objectives of the instrument. The former Chair's Notes to the text stated that the instrument had intended to provide a causal link between the invention and GRs and aTK. The Delegation identified the need for further clarifications regarding that causal link to ensure legal certainty regarding what would trigger the disclosure requirement and how far along the research chain the requirement would extend. To address those concerns, it supported the condition that the invention should be "materially and directly based on" the GRs and aTK. It proposed that the GRs and aTK must have been "necessary for and material to the claimed invention", rather than merely incidental to its development. This position aligned with suggestions made by the virtual expert group. It suggested clarifying in the chapeau of Article 3.1 that it was the GRs identified in the claim to the patent that triggered the disclosure requirement. To implement that, it proposed adding the phrase "which are identified in the claims of the patent" in the chapeau of Article 3.1 after the term "GRs". It suggested that Article 3.1(a) should specify that the country of the GRs should be the one from which the inventor and applicant obtained the GRs. It questioned the use of the term "minimum information" required in Articles 3.1 and 3.2, as the term had not been introduced previously. It advocated for greater legal clarity by referring to "the information" required by Articles 3.1 and 3.2" instead of using the term "minimum information".
- 119. The Delegation of Poland, speaking on behalf of the CEBS Group, emphasized the importance of disclosure requirements within the instrument. It appreciated the concept for the trigger that depended on the close connection between the invention and GRs and aTK used in the invention. It supported the requirement that the claimed invention should be based on the specific properties of GRs and/or aTK. It could accept the proposals from the virtual expert group. Specifically, it highlighted the need to remove parentheses from the phrase "materially/directly based on". It suggested amending the language of content to "the country of origin from which the GRs were obtained" to ensure that applicants should indicate the country possessing the GRs *in situ* conditions and from which the GRs were obtained.
- 120. The Delegation of Niger aligned itself with the statement made by the Delegation of Ghana, on behalf of the African Group. It underscored the importance of Article 3 in the instrument. While the text was not entirely perfect, it was crucial to minimize existing disagreements.
- 121. The Delegation of Japan supported the statement made by the Delegation of Switzerland, on behalf of Group B, and the statement made by the Delegation of the United Kingdom. To provide legal certainty for applicants, it was necessary for IP offices to establish a clear and transparent relationship between the claimed inventions and GRs or aTK when the IP office required the disclosure of GRs and/or aTK. To achieve that, it emphasized the importance of a comprehensive understanding for patent applicants of what triggered the disclosure

requirements under the instrument. Specifically, it supported the proposal put forth by the virtual expert group, which included the terms "materially and directly based on". The Delegation also supported the suggested amendment to Article 3.1(a), which aimed to clarify "the country of origin from which the GRs were obtained". It opposed the proposal to require evidence of ABS, such as FPIC and mutually agreed terms. The Delegation made a clear distinction between this instrument and existing agreements such as CBD, Nagoya Protocol and other related regimes.

- 122. The Delegation of Singapore aligned itself with the APG positions delivered in the statement made by the Delegation of Iran (Islamic Republic of), on behalf of APG. It supported the existing formulation of Article 3 of the Chair's text. It indicated its openness to considering the suggestions made by many Member States regarding the use of "materially and directly" and "country of origin from which the GRs were obtained". These would enhance legal certainty for both patent applicants and patent offices. It emphasized the necessity of Article 3.3 to ensure the functionality and feasibility of the disclosure requirement for applicants. It underscored that Article 3.3 should be applied in full and equal measure to both the disclosure requirements of GRs and aTK.
- 123. The representative of the Tebtebba Foundation supported the statements made by the Delegation of Mexico and other parties advocating for going beyond the disclosure of the country of origin of GRs in Article 3.1. He emphasized the importance of transparency and legal certainty, noting that those principles should be applied not only to patent applicants but also to Indigenous Peoples and local communities. The issue of verifying the source of GRs had been agreed upon globally upon the entry into force of the CBD in 1993. Furthermore, UNDRIP, since 1997, had required the verification of the source of aTK and GRs, including the FPIC of Indigenous Peoples. Although some considered that requirement aspirational, he stressed the importance of giving meaning to such aspirations. The Nagoya Protocol, ratified by certain parties since 2014, mandated FPIC for access to aTK and GRs. He emphasized the need for alignment with other agreements and aspirations. He expressed confusion about resistance to the idea that one did not have to show they had valid acquisition of GRs. If there was not a permissive regime that allowed countries to set those requirements, there would be increasing divergence from the CBD, the Nagoya Protocol and UNDRIP. He believed "materially and directly" was narrow and preferred using only "materially". Article 8 could be undermined without a permissive regime. Patent offices might currently lack the capacity to assess those issues but the presence of mechanisms like the ABS Clearing-House Mechanism under the Nagoya Protocol could make the information more accessible. He was opposed to Article 3.5. which categorically ruled out any requirements related to those matters, aligning with the statement made by the Delegation of Mexico.
- 124. The Delegation of Brazil proposed to replace "materially/directly based on" with "that arises from the utilization of" in Articles 3.1 and 3.2. The Delegation explained its proposal that the term "materially/directly based on" lacked substantive meaning in multilateral agreements related to GRs and aTK. The term "utilization" had already been used in many multilateral agreements such as the Nagoya Protocol and the International Treaty on Plant Genetic Resources for Food and Agriculture, as well as in the recently adopted Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas beyond National Jurisdiction ("BBNJ Treaty"). Using consistent terminology across international agreements enhanced the support and understanding of the objectives of the instrument. Furthermore, "utilization" was a term widely accepted and applied in the context of IP rights. That change would still ensure that the disclosure of GRs and aTK maintained the causal link with the invention, which was a key aspect of the disclosure requirement. The term "utilization" would also encompass digital sequence information ("DSI"), which was crucial in modern biotechnology.

- 125. The representative of INBRAPI pointed out that the discussion on disclosure requirements had been ongoing for 23 years and highlighted the significance of those requirements in providing legal security, certainty and transparency. GRs were found both *in situ* and *ex situ* and there had been instances where FPIC was not appropriately sought. She emphasized the importance of supporting Indigenous Peoples in that regard. She echoed the points made by representatives of the Tebtebba Foundation and the Assembly of First Nations regarding the need to protect the interests and rights of Indigenous Peoples and local communities concerning GRs and TK. TK and GRs were intertwined and could not be separated in their context. She supported to include a reference to FPIC in the text, as in the Nagoya Protocol. Indigenous Peoples and local communities should benefit from the use of their GRs and aTK.
- 126. The representative of NARF aligned her position with the previous statements made by the representatives of the Assembly of First Nations and the Tebtebba Foundation. She supported the removal of the entire Article 3.3, which presented a significant opportunity for patent applicants to evade the disclosure requirement. She emphasized that it was highly unusual for an applicant not to know at least the source of the GRs and aTK. However, if Article 3.3 was to be retained, the declaration of lack of knowledge should include an affirmation that reasonable due diligence had been exercised to ascertain the information. Article 3.3 would read: "In cases where none of the information in Articles 3.1 or 3.2 is known to the applicant, each Contracting Party shall require the applicant to make a declaration to that effect, including an affirmation that reasonable due diligence has been exercised to obtain the information".
- 127. The representative of the Tulalip Tribes supported the proposals made by the representatives of the Assembly of First Nations and NARF regarding Articles 3.1 and 3.3. Additionally, he offered an alternative textual proposal for Article 3.3: "In cases where none of the information in Articles 3.1 and/or 3.2 is known to the applicant, acting with due diligence, each Contracting Party should make a declaration to that effect".
- 128. The Delegation of Egypt aligned itself with the statement made by the Delegation of Ghana, on behalf of the African Group. It proposed to replace Article 3.3 with "where applicable and in accordance with national law, the applicant shall disclose information concerning ABS requirements and the FPIC".
- 129. The Delegation of China recognized the importance of incorporating aTK into the instrument for the protection of GRs. It emphasized the need to consider variations in national legislations to ensure effective implementation. Regarding Article 21, the Delegation asked if Member States could make reservations on disclosure requirements of TK related to GRs. It suggested that the definitions of GRs and aTK could be clarified in national legislation. It suggested using "materially" as the trigger for the disclosure requirement, noting its broader and more targeted scope. It also called for further clarification of the term "materially". It proposed expanding the scope of providers of TK to include other holders, together with Indigenous Peoples and local communities, to accommodate diverse national contexts. The Delegation emphasized that applicants must possess knowledge of the direct source of the GRs they were using and should be obligated to disclose that information, otherwise the disclosure requirement would not be as effective as it should be. It suggested that an applicant's lack of information regarding the country of origin should not exempt them from an explanation.
- 130. The Delegation of India supported that disclosure obligations should not impose additional costs or burdens on applicants and should be straightforward to comply with and be enforced by patent authorities. It proposed to give priority to disclosing the source of GRs and TK over the country of origin, as the source was typically known to the applicant. The disclosure of the country of origin should only apply if it had already been known, to prevent additional transaction costs and burden on applicants. It endorsed the proposals from other delegations

that clarified the singular country from which materials were obtained, rather than originated, as GRs obtained from the same country might vary in properties depending on the region. Disclosing the source would provide clarity on the content of disclosure. Regarding the trigger, it preferred a broader "materially based on" trigger, recognizing the balance between the interests of GR and aTK owners and the obligations on patent applicants. It suggested a broader definition of "materially based on" in Article 2 to define the scope of the trigger. Regarding the mandatory nature of disclosure, it proposed that the disclosure of GRs should be mandatory to ensure maximum transparency, with the possibility to make a declaration. However, it acknowledged scenarios where applicants might be unaware that their knowledge was based on TK, and it suggested allowing declarations. It proposed a minor change in Article 3.4 to define a specific time period for modifications to patent applications, to subsequently disclose if the applicant was not aware of the information at the time of filing. This would prevent open-ended processes, and provide certainty to applicants and patent offices.

- 131. The Delegation of Ghana aligned itself with the statement made by the Delegation of Ghana, on behalf of the African Group. It emphasized the importance of keeping the word "or" between "materially" and "directly", which gave Member States a choice. The term "directly based" was contentious because it implied physical access to GRs by applicants. That interpretation was considered overly restrictive. To address that concern, the term "materially based" was preferred. Combining both terms using the word "and" would imply maintaining both interpretations and removing flexibility concerning the term "materially".
- 132. The Delegation of Canada supported the statements made by the Delegations of the United Kingdom, Japan and Switzerland, on behalf of Group B. It supported amendments proposed by the virtual expert group on possible disclosure requirements, which included a group of experts representing diverse regions with a balanced view. Those amendments included changing the trigger to "materially and directly based on". It agreed with the explanation provided in the report on the virtual expert group that "materially and directly based on" meant that the GRs and/or aTK must be necessary for and material to the claimed invention. The claimed invention should depend on the specific properties of the GRs and/or insights from the aTK. It believed that that definition of the trigger would clarify the scope of the disclosure obligation, enhance transparency and predictability for patent applicants, and ultimately contribute to the objective of improving the efficacy, transparency and quality of the patent system. Article 3.4 addressed the obligation of patent offices to provide an opportunity for applicants to rectify any failures to include the minimum information referred to in Articles 3.1 and 3.2 or correct any disclosures that were erroneous or incorrect. The Delegation noted that the current text did not accommodate situations where patent right holders might need to rectify a failure to provide the requisite information post-grant. It emphasized that permitting an applicant or patent right holder to rectify a failure in meeting formality requirements was not just a matter of administrative convenience but also ensured fairness in the patent system. Some failures to meet a formality requirement might occur due to unforeseeable circumstances or honest errors. Denying an opportunity to rectify such failures post-grant could be overly harsh and impede innovation and investment in research and development. It noted other international patent-related instruments that offered avenues for rectification and correction when certain formality requirements were not met and might require proper notice to be served, ensuring a balance between rigorous patent protection and the practicalities of human and systemic error. Regarding Article 3.4, the Delegation referred to the proposal made by the Delegation of India concerning a prescribed period to rectify a failure to include the minimum information referred to in Articles 3.1 and 3.2. That prescribed period would be acceptable as long as it was tied to a proper notice with a reasonable amount of time to respond, reflecting that the notice should be granted pre-grant or post-grant as the case might be. It proposed to add "and patent right holders" after the term "patent applicant" in Article 3.4.

- 133. The Delegation of Switzerland supported the statement made by the Delegation of Switzerland, on behalf of Group B. The carefully drafted Article 3 considered the interests of patent holders and patent offices. It believed that minor changes could further enhance legal certainty while maintaining the transparency objective. It suggested incorporating the recommendations from the virtual expert group, including adding the term "Indigenous Peoples and local communities" to the definition of the source of GRs. It expressed concern that some proposals from some participants seemed to deviate from the initial transparency objective of the disclosure requirement. It could not support some proposals related to traceability, which was compliance with FPIC or ABS legislations. The Delegation addressed Article 3.4 and its relationship with Article 6.2, where there was also a right to rectify. It was better to address the right to rectify in Article 6.2. It thanked the Delegation of India for its proposal to include a reasonable time period for rectification. Regarding Article 3.6, it suggested using the phrase "to make the information specified in this Article available" instead of "to make the information disclosed available". It understood that to be a minimum requirement and the information wanted would be the minimum information.
- 134. The Delegation of Oman underscored the importance of disclosing the source of GRs and aTK. It highlighted the importance of achieving a balance between the rights of applicants and Indigenous Peoples. It supported the proposals made by the Delegation of India to apply the instrument to IP law in a broader sense.
- 135. The Delegation of Samoa stated that the disclosure requirement was merely a part of the formal examination process and should not have an impact on the validity of the patent if a failure to disclose was rectified within acceptable time frames. Assessing whether an invention was materially or directly based on GRs or aTK should be part of the substantive examination. It noted the challenge of determining whether the application was materially or directly based on GRs and/or aTK during formality examinations, especially when the responsibility fell on the applicant or inventor, who might have a biased perspective in the absence of effective sanctions. The Delegation preferred a simple reference to the country of origin or source if an invention was based on GRs or aTK to discharge the duty of an inventor or patent applicants. It acknowledged the ongoing discussion of country of origin versus source, and its potential impact on any payable royalties from such patents, as the source could be a scientific book rather than Indigenous Peoples or local communities. In the interest of consensus and achieving a favorable outcome for the Diplomatic Conference, the Delegation accepted the current compromise in light of Article 9, aligning itself with the position of APG.
- 136. The Delegation of Guatemala expressed the importance of clarity and precision in Article 3. In Article 3.1, it suggested removing the word "claimed" to broaden its scope and deleting the terms "materially/directly", because the disclosure requirement should apply to all inventions. In Article 3.2, it proposed to remove the word "claimed" and delete the terms "materially/directly". It supported the drafting of subparagraphs (a) and (b). It suggested the deletion of both Articles 3.3 and 3.5. It emphasized the need to consider that the international instrument, when approved, would have to be considered in the context of other international treaties and conventions, such as the Vienna Convention on the Law of Treaties and those related to the human rights of Indigenous Peoples.
- 137. The Delegation of Lebanon highlighted the importance of the disclosure requirement, emphasizing that Member States and Indigenous Peoples would need to disclose the GRs and aTK. Regarding Article 3.1, it preferred the phrase "materially or directly based on GRs" when describing the claimed invention in the patent application. It suggested the deletion of the entire Article 3.4, as it might inadvertently shift responsibility to applicants and Indigenous Peoples for any errors made.

- 138. The Delegation of Australia acknowledged that the text aimed to be a minimum standard that could be widely agreed. Making many changes would be challenging at this stage. In relation to Article 3.1(a), it agreed with the use of the phrase "from which the GRs were obtained". The focus should be on what the patent applicant possessed and what information was available to them, without imposing additional burdens. It expressed flexibility regarding the order of subparagraphs (a) and (b) for clarity. Concerning Article 3.2(a), it suggested potential additional wording to clarify that the Indigenous Peoples or local communities who provided the aTK should be named. Regarding Article 3.3, it recognized the utility of allowing patent applicants to declare their lack of information, but expressed the need to avoid creating a potential loophole. It expressed willingness to explore language that could enhance clarity in that regard.
- 139. The Delegation of the United States of America aligned itself with the statement made by the Delegation of Switzerland, on behalf of Group B, along with statements made by the Delegations of Canada, Japan, the United Kingdom and Poland, on behalf of the CEBS Group. It endorsed the recommendations of the virtual expert group to use "materially and directly based on" as the trigger for the disclosure requirement. It supported replacing "of the GRs" in Article 3.1(a) with "from which the GRs were obtained" to create symmetry with Article 3.2(a). The Delegation stressed the need for a precise trigger with a clear causal connection between the claimed invention and GRs and aTK to balance the transparency and transactional costs of the instrument effectively. Without that clarity, the users of the patent system will struggle with compliance and the resulting legal uncertainty could undermine innovation. It indicated it could accept the proposal made by the Delegation of India to make the applicant's declaration in Article 3.3 optional to reduce transaction costs for patent applicants. For legal certainty, Article 3.3 should clarify that rectification should apply to the information required, not minimum information. It disagreed with the proposal made by the Delegation of India to broaden the scope of the required disclosure, emphasizing that a targeted disclosure struck a balance between transparency and transactional costs. The Delegation also disagreed with the stated justification that the applicant would always be aware of the source of the GRs and aTK. For Article 3.3, it suggested replacing the word "each" with "a", and replacing the word "shall" with "may". It proposed to amend Article 3.4 to clarify that both patent applicants and patent holders had the opportunity to rectify errors or omissions and that the opportunity was reasonable to ensure that applicants and holders would have sufficient due process in their efforts to rectify. It also disagreed with the proposal made by the Delegation of India regarding Article 3.4 to make it more difficult for parties to rectify omitted or erroneous information, as it undermined the objectives of transparency and patent quality. Regarding Article 3.4, it proposed the following wording: "Offices shall provide guidance to patent applicants on how to meet the disclosure requirement as well as a reasonable opportunity for patent applicants and patent holders to rectify a failure to include the information required by paragraphs 3.1 and 3.2 or correct any disclosures that are erroneous or incorrect".
- 140. The Delegation of Nigeria aligned itself with the statement made by the Delegation of Ghana, on behalf of the African Group. It considered Article 3 carefully balanced, emphasizing the need to keep interventions minimal to advance the discussion. Regarding Article 3.1, the Delegation believed there was no necessity to include the suggested addition "which are identified in the patent application". The phrase "claimed invention" had encompassed that suggested inclusion. It supported the insertion of "due diligence requirements" in Article 3.3, as proposed by the Indigenous Caucus. It highlighted the importance of compromise regarding "materially and directly based". It found the definition, along with notes associated with Article 3, crucial. It aligned with the Delegations of India and Switzerland in advocating for a specified time period in Article 3.4, asserting that an open-ended opportunity to rectify would undermine the seriousness of the article. It concurred with the observation of the Delegations of Switzerland and Australia that the article had undergone thorough revisions with the virtual expert group. The Delegation wished to minimize modifications. It emphasized the significance

of the accompanying notes in Article 3 and suggested that they be carried forward to the Diplomatic Conference.

- 141. The Delegation of the Republic of Korea supported the wording of the trigger as expressed by the Delegations of the United States of America, Japan, the United Kingdom, Canada and Switzerland, on behalf of Group B. Regarding Articles 3.1 and 3.2, it noted discussions from a recent meeting with domestic stakeholders who voiced strong concerns about acquiring information, such as the source or the country of origin of the GRs from providers, such as intermediaries. It highlighted that the provision, as it currently stood, might place an excessive burden on applicants and potentially discourage them from using the patent system. It disagreed with the proposal regarding Articles 3.1 and 3.2 to request applicants to provide both information.
- 142. The Delegation of the EU, speaking on behalf of the EU and its Member States, supported the use of the term "materially and directly based on" as trigger for the disclosure requirement, which was a proposal put forth by the virtual expert group and various delegations. It also supported the change to Article 3.1(a), which emphasized the "country of origin from which the GRs were obtained". That addition was seen as valuable in clarifying the source of the GRs, particularly in situations where multiple countries had the same GRs in *in situ* conditions. The applicant should indicate only one country from which the GRs were actually obtained. It suggested that more discussions were needed concerning Article 3.4 as to the possible ways guidance could be given by the Offices. It expressed a willingness to actively participate in further discussions on that issue. The Delegation agreed on the current wording of Articles 3.3, 3.5 and 3.6.
- 143. The representative of TWN emphasized that the term "materially and directly based on" depended on its definition. It was crucial to use terms with shared understandings to reduce ambiguity and increase transparency. "Utilization" was a commonly understood term, which might be preferable to "materially or directly based on". Patents might not always explicitly claim or refer to GRs, even though they were essential for the invention. He gave examples, such as vaccine patents, where the virus GRs were crucial, yet the patents might not claim the virus *per se.* He stressed the importance of disclosing such utilization. In Article 3.1, the term "country of origin from which the GRs were obtained" should be used. The burden should be on the applicant to state at least the source from which the GRs were obtained. That change would simplify disclosure and reduce transactional costs. He expressed dissatisfaction with the explanation notes for Article 3.5. He found the explanation notes unconvincing, and highlighted the importance of considering the statement made by the Delegation of Mexico. He suggested that Member States should be allowed the policy space to verify information, especially at the national level, to ensure effective implementation. In the absence of such verification, sanctions and remedies would be problematic.
- 144. The Delegation of Israel supported the statement made by the Delegation of Switzerland, on behalf of Group B. It supported the recommendations made by the virtual expert group, specifically in relation to Articles 3.1 and 3.2, where the patent application was "materially and directly based on" GRs and aTK.
- 145. The Delegation of Pakistan supported the statement made by the Delegation of Iran (Islamic Republic of), on behalf of APG. In principle, it supported to retain the current formulation of Article 3. It remained open to minimal modifications with a spirit of constructive engagement. It sought clarity on the formulation proposed by the Delegation of Switzerland, on behalf of Group B, in Article 3.1(a), regarding "the country of origin from which the GRs were obtained". It wondered how that formulation would be interpreted, because it might imply that GRs could be categorized as being obtained from a country where they did not exist *in situ* conditions. It was flexible regarding the inclusion of the formulation "source of GRs" as

proposed by the Delegation of India. It expressed its openness to either using "materially/directly" or retaining "materially" in relation to the content of disclosure.

- 146. The Delegation of the Cook Islands suggested the use of the term "materially based on" for the sake of clarity and legal certainty. It emphasized that any use of TK must be protected. It expressed its flexibility with using a term that captured the use of aTK.
- 147. The Delegation of Colombia supported the statements made by the Delegations of Bolivia (Plurinational State of), Ecuador and Peru, and expressed its concern about the term "claimed" in Articles 3.1 and 3.2 and in the definition included in Article 2. It preferred its deletion to avoid misinterpretation. It suggested including references and examples of particular applications in a way that helped patent applicants understand how to carry out the invention, especially regarding claimed products or procedures related to access to GRs. It recommended the deletion of the terms "materially/directly" and proposed alternative wording such as "invention based/developed/used" without using "materially" or "directly". It emphasized the importance of linking GRs to the country of origin, as any other proposal might unfortunately lead to the granting of exclusive rights without acknowledging the origin or authorization of the country of origin. Additionally, it suggested adopting an appropriate definition of "country of origin" as "the country possessing GRs in situ, including those also found ex situ". The Delegation suggested including a definition of the source of GRs: "any source for ex situ conservation from which the applicant has received GRs, for example a gene bank, a research center or the international system of treaties on phytosanitary resources for agriculture, or any other existing ex situ collection or depository of GRs".
- 148. The Delegation of Uruguay did not disagree with the current wording of Article 3, but emphasized the need for flexibility to consider the important concerns raised by other delegations, as mentioned in the preceding statements. It highlighted the importance of retaining Article 3.5, because such verification should not necessarily be carried out by IP offices, as it could impose excessive financial and human resource burdens. It supported to retain Articles 3.5 and 3.6 in its current wording, emphasizing the fundamental importance of transparency. Transparency was crucial for building trust and confidence, and any changes to that article might hinder the creation of a positive atmosphere during the Diplomatic Conference.
- 149. The Delegation of New Zealand supported the drafting proposal put forth by the representative of the Tulalip Tribes concerning due diligence in Article 3.3. That approach was seen as an effective means to establish a fair and equitable environment for patent applicants. It was essential not to penalize those who engaged with Indigenous Peoples or took steps to acknowledge the country of origin. The Delegation reaffirmed its commitment to the current wording of Article 3.1(a). It supported any drafting that enhanced the ability to trace GRs back to their country of origin.
- 150. The Delegation of Malaysia supported Article 3 as outlined in the draft text. It endorsed the use of "materially or directly". However, it held a different perspective on Article 3.1(a). It believed that requiring applicants to specify the exact area of origin for GRs other than the country would impose an additional burden. It supported the disclosure obligation to be limited to the country of origin. Regarding Article 3.5, the Delegation believed that it should be the responsibility of the patent office to verify the authenticity of the disclosure. It supported Article 3.6, emphasizing the importance of public disclosure in the patent system.
- 151. The representative of the MALOCA Internationale emphasized the importance of FPIC, which was recognized in UNDRIP and enshrined in the constitutional documents of several countries. The customary laws of Indigenous Peoples had also been recognized. He considered the non-inclusion of those concepts in the text as a redline. He appreciated the clarification made regarding the reference to the country of origin in Article 3.1. He wondered

about the consensus requirement for making additions or modifications to the text, and suggested exploring alternative procedures if consensus could not be reached.

- 152. The Delegation of Vanuatu expressed its support for the current formulation of Article 3, though it remained flexible to any modifications.
- 153. The Delegation of Bangladesh supported the statement made by the Delegation of Iran (Islamic Republic of), on behalf of APG. It preferred the current text, but indicated its openness to minor modifications. It supported to replace "materially/directly" with the term "utilization" or "utilize", as proposed by the Delegation of Brazil. It supported the proposal made by the Delegation of India to add a timeframe in Article 3.4. Regarding the trigger for disclosure requirement, it believed that the minimum requirement should be in alignment with Article 2(c) of the Nagoya Protocol.
- 154. The Delegation of Italy noted a contradiction in the text between Article 3.5 and the last part of Article 3.4. It pointed out that in Article 3.5, there was no obligation to verify the authenticity of the disclosure. It was impossible for offices to provide patent applications to rectify a failure or correct any disclosures that were erroneous or incorrect. It suggested a solution, which involved deleting "or correct any disclosures that are erroneous or incorrect" from Article 3.4.
- 155. The Delegation of Kenya supported the statement made by the Delegation of Ghana, on behalf of the African Group. Many African countries had already had implemented similar provisions in their national laws. It supported the explanatory notes, which provided clarity on the article.
- 156. The Delegation of Morocco emphasized the importance of the disclosure requirement. It supported the statement made by the Delegation of Ghana, on behalf of the African Group, especially regarding terminology. It suggested that, in the spirit of good faith and given the uncertainty of the information required in Articles 3.1 and 3.2, there should be an obligation to disclose everything, and it leaned towards favoring an obligation as per Article 3.3. It expressed a willingness to make minimal amendments to the article to achieve consensus.
- 157. The Delegation of Bolivia (Plurinational State of) acknowledged the importance of protecting the rights of Indigenous Peoples and taking into account their aspirations throughout the process. It supported the disclosure requirement but had some reservations regarding Articles 3.5 and 3.6. It stressed the importance of ensuring that the disclosure of origin provided legal security to Indigenous Peoples.
- 158. The Delegation of Chile supported the current wording of Article 3. It specifically agreed with the statement made by the Delegation of Uruguay regarding Articles 3.5 and 3.6.
- 159. The representative of HEP supported to move forward based on the current wording of Article 3.
- 160. The Chair recalled that the Special Session was the first opportunity to examine the text. All articles needed to be discussed in plenary before moving on the more detailed discussions in smaller groups. She urged participants to make concise and focused comments during the plenary session. The Chair opened the floor for comments on Article 6.
- 161. The Delegation of Switzerland, speaking on behalf of Group B, emphasized the need for clear language within Article 6 to provide a maximum standard. While it was essential to impose sanctions for willful non-compliance with Article 3, revoking a patent or similar measures that impacted patent holders' established rights could have severe repercussions on innovation.

As an alternative, it supported sanctions that would not infringe patent holders' rights, ensuring a more balanced approach.

- 162. The Delegation of Ghana, speaking on behalf of the African Group, believed that revocation should be included in cases of fraudulent intent. However, in the interest of advancing the text, it also expressed willingness to support the current formulation of the text.
- 163. The Delegation of Iran (Islamic Republic of), speaking on behalf of APG, stated that the majority of APG Member States supported the current draft of Article 6, as the current draft provided sufficient flexibility to ensure the enforceability of the disclosure requirement. However, some Members believed that there should be more clarity, particularly in relation to Article 6.5. This included defining who would be considered parties in a dispute and specifying the required dispute mechanisms. While APG generally favored a flexible and less prescriptive approach, it recognized that there were various aspects of the article that required further discussion.
- 164. The Delegation of the United States of America aligned itself with the statement made by the Delegation of Switzerland, on behalf of Group B. In Article 6.1, it indicated it could accept the proposal made by the Delegation of India only if patent applicants and holders have a reasonable opportunity to rectify non-compliance with Article 3, both pre-grant and post-grant. Regarding Article 6.2, it disagreed with the Delegation of India's proposed language that denied rectification opportunities after patent issuance. It suggested that that approach should be broadened to apply to both applicants and patent holders both pre-grant and post-grant. Applicants and patent right holders should have a reasonable opportunity to rectify a failure to comply with Article 3 within a prescribed time period. The proposal made by the Delegation of India would undermine the patent quality aims of the instrument that benefited GR and aTK holders. In Article 6.2, it emphasized that rectification should not only cover omissions but also corrections of erroneous information. In Article 6.3, it stressed the importance of setting a ceiling on penalties for failure to comply with Article 3, which would be of utmost importance to ensuring legal clarity and consistency required for the innovation system. Article 6.3 should unequivocally forbid the use of revocation, cancellation, denial or loss of patent rights or any other measures that adversely impacted patent rights for failure to comply with Article 3. It expressed concerns about the proposal made by the Delegation of India that omitted such assurances, as that could undermine the entire bioscience ecosystem, including seed investment transfer rights and scaling of innovations. The Delegation proposed that Article 6.3 should not be subject to any other provision, and Article 6.4 on post-grant sanctions or remedies should be subject to Article 6.3. Regarding Article 6.4, it favored the voluntary approach in the text, contrary to the proposal made by the Delegation of India, which mandated post-grant sanctions or remedies. In Article 6.5, it suggested deleting the "all parties concerned" as it was vague and broad. It clarified that dispute resolution mechanisms existed to facilitate solutions to disputes arising from noncompliance with Article 3. It proposed to add a new Article 6.6. Decisions on sanctions and remedies under Article 6 should be subject to independent review. such as judicial review. In terms of specific edits, it suggested deleting "the" before "information required in Article 3" in Article 6.1. It proposed to replace "an applicant" with "applicants and patent rights holders", insert "reasonable notice and" before "opportunity", replace "include" with "provide", delete "minimum", replace "detailed" with "required", and insert "including correction of erroneous information previously provided" in Article 6.2. In Article 6.3, it proposed the following language: "No Contracting Party shall deny, cancel, revoke or render unenforceable a patent, or take any other measures that adversely impact a patent holder's rights, on the basis of an applicant's failure to comply with a disclosure requirement directed to GRs and Associated TK". Article 6.4 would read "Subject to Article 6.3, each Contracting Party may provide for post grant sanctions or remedies where there has been fraudulent intent, in regard to noncompliance with the disclosure requirement in Article 3 of this instrument, in accordance with its national law." Article 6.5 would read "Without prejudice to non-compliance as a result of a fraudulent

intention as addressed under Article 6.4, Contracting Parties shall put in place adequate dispute mechanisms that allow for timely and mutually satisfactory solutions to disputes arising from compliance with the obligation set forth in Article 3."

It proposed new Article 6.6: "Any decision relating to sanctions or remedies shall be subject to judicial review or other independent review by a distinct higher Authority in that Contracting Party."

- 165. The representative of TWN commented on Articles 6.3 and 6.4. He highlighted a concern related to the current draft, where the possibility of revoking patents was limited to cases of fraudulent intent, as stated in Article 6.4. Proving fraudulent intent could be challenging, and make it difficult to apply sanctions effectively. This limitation went against the remedies available in many jurisdictions, where wrongful disclosure or failure to disclose could lead to patent revocation. The proposal would compel countries to change their domestic laws to align with the instrument. He concluded by asserting that the existing policies should not be eliminated through Article 6.3.
- 166. The Delegation of Niger aligned itself with the statement made by the Delegation of Ghana, on behalf of the African Group. Article 6 enjoyed broad support among various groups. It emphasized that the revocation of a patent, as outlined in the article, was considered as a last resort. Regional legislation, particularly in Africa, had already included provisions for patent revocation. The Delegation welcomed the article and believed it contributed to bringing positions closer.
- 167. The Delegation of the Russian Federation conveyed its support for the current wording of Article 6. The text aligned with the logic commonly found in international documents, particularly generalization and flexibility. It highlighted that Article 6 offered flexibility to potential Contracting Parties, allowing them to determine what appropriate measures should be taken to address the transaction costs for IP offices, as well as provides legal certainty for patent applicants. It had no fundamental objections to the proposals presented by the Delegation of India.
- 168. The Delegation of Brazil wished to delete the current Articles 6.3, 6.4 and 6.5. It suggested a new 6.3: "In case that the rectification mentioned in Article 6.2 is not successful, Contracting Parties shall implement the sanctions and/or remedies provided for in its national law". It proposed a new Article 6.4: "Contracting Parties may put in place adequate dispute mechanisms that allow all parties concerned to reach timely and mutually satisfactory solutions in accordance with its national law". For Article 6.5, it suggested that "Procedures concerning the enforcement of this instrument shall be fair and equitable. They shall not be unnecessarily complicated or costly or entail unreasonable time limits or unwarranted delays". The Delegation explained that the proposed amendment to Article 6.3 aimed at resolving conflicts with some national legislations that allowed for revocation. It believed that their proposals aligned with the instrument's objective of enhancing transparency and efficiency of the patent system, avoiding legal conflicts, and reducing transaction costs. Its proposed Article 6.5 copied Article 41.2 of the TRIPS Agreement, to ensure that the application of sanctions did not create a burden for implementation of the instrument. It highlighted the importance of setting minimum standards while allowing signatories flexibility in adopting stronger protection or adequate enforcement measures as per their national practices.
- 169. The Delegation of Venezuela (Bolivarian Republic of), speaking on behalf of the GRULAC, conveyed its positive response to the proposal presented by the Delegation of Brazil, and reaffirmed its commitment to collaborate towards achieving a consensus.
- 170. The Delegation of Egypt aligned itself with the statement made by the Delegation of Ghana, on behalf of the African Group. Article 6 should be very brief, acknowledging the

diverse legal systems among Member States. Consequently, Article 6 should primarily emphasize the establishment of administrative and legal sanctions to address violations of the rights as reflected in the instrument. It stressed the importance of leaving specific details for national law. Regarding revocation, the Delegation underscored its significance in cases of fraud only. It suggested deferring further discussions on dispute resolution mechanisms to the review process.

- 171. The Delegation of China commended the text for its ability to accommodate various legislations and practices from different countries. It acknowledged that the text offered guidance for dealing with patent applications that violated the disclosure requirement, and allowing room for countries to adapt their approaches in accordance with their domestic laws. Articles 6.3, 6.4 and 6.5 that were related to detailed provision on sanctions could be further simplified and clarified, particularly when addressing situations involving fraudulent intent. It noted that the existing text effectively reflected the instrument's objectives.
- 172. The Delegation of Canada emphasized that both patent applicants and patent right holders should be offered the opportunity to rectify a failure to include the minimum required information before Contracting Parties resorted to imposing sanctions or directing remedies. Therefore, it proposed to amend Article 6.2: "Each Contracting Party shall provide an applicant or a patent right holder with an effective notice of a failure to include the information detailed in Article 3 and a reasonable opportunity to rectify the failure before implementing sanctions or directing remedies".
- 173. The Delegation of Switzerland aligned itself with the statement made by the Delegation of Switzerland, on behalf of Group B. It emphasized the importance of establishing a clear maximum standard for post-grant sanctions. There could be various approaches to achieving such a standard. Its preferred approach would be to amend Article 6.1 to align with the proposal made by the Delegation of India, emphasizing that there should be pre-grant and post-grant sanctions. The Delegation saw that as setting the minimum standard for both pre-grant and post-grant sanctions. It believed that Article 6.2 should be read together with Article 3.4, where there was an opportunity in the pre-grant situation to rectify a failure. It wished to see a better difference between the opportunity to rectify a failure in the pre-grant situation and in the post-grant situation. In the pre-grant situation, the right to rectify should not iust be for a failure but also for the correction of erroneous or incorrect disclosures within a reasonable timeframe. In the post-grant situation, the opportunity to rectify should be limited to unintentional errors. With reference to the proposal made by the Delegation of India, the Delegation agreed that while pre-grant sanctions were crucial, there should also be an opportunity for rectifying unintentional failures post-grant. Regarding Article 6.3, it was open to the proposal put forward by the Delegation of the United States of America. The Delegation proposed to delete Article 6.4, as there were very different legal concepts around fraud and fraudulent intent. It believed that, with a clear minimum standard in Article 6.1 and a clear maximum standard in Article 6.2, it would be sufficient not to address the specific situation of fraud.
- 174. The Delegation of Japan aligned itself with the statement made by the Delegation of Switzerland, on behalf of Group B, and supported the statements made by the Delegations of the United States of America and Canada. It believed it was overly harsh to revoke a patent due to the failure to disclose the origin or source of the GR and/or aTK, especially as that information was not directly linked with the patentability of the invention. In addition to the possibility to rectify the failure to include necessary information, the instrument should also provide opportunities to correct erroneous information both pre-grant and post-grant.
- 175. The Delegation of the Republic of Korea aligned itself with the statement by the Delegation of the United States of America. The primary aim of Article 6 was to facilitate a

disclosure for the patent system through sanctions and remedies. The purpose of the discussions on GRs and aTK was to enhance the transparency and efficiency of the patent system by adopting a disclosure requirement. It raised concerns regarding the proposed changes to Articles 6.1 and 6.2, that placed an excessive burden on Contracting Parties by requiring them to prepare both pre-grant and post-grant measures. The Delegation preferred Article 6.1 of the original draft.

- 176. The representative of HEP acknowledged that there was some ambiguity surrounding the issue of sanctions in Article 6. However, she firmly believed that both Articles 6.1 and 6.2 should remain unchanged. She wondered whether an "independent review system" was relevant to WIPO's work. She emphasized the complexity of the matter and the need for a clearer understanding of who would oversee sanctions and the nature of the independent system. She pointed out that patent offices, while responsible for granting patents, were not immune to errors, and determining good faith or bad faith in patent applications could be challenging.
- 177. The representative of KEI highlighted a practice in the United States of America related to contractors that received Federal funding. In that practice, contractors were obligated to disclose inventions that came out of that funding to the government, which should be reported in the patent application as well. There existed a remedy for cases of non-disclosure, wherein the government of the United States of America had the right to claim ownership of the patented invention if the inventor failed to disclose the government had rights in the past. He found it intriguing that amidst discussions about potential remedies for non-disclosure, the United States of America already had a remedy in place where the government could assume ownership of the invention.
- 178. The Delegation of the United Kingdom supported the statement made by the Delegation of Switzerland, on behalf of Group B. It emphasized the importance of establishing a framework within the instrument that encompassed both minimum standards and maximum harmonized obligations, which created a harmonized standard for disclosure requirement systems and rationalized the currently disparate existing national systems. Balanced sanctions were deemed a vital component. It endorsed the intent of the text to exclude revocation or any measures that could adversely affect the patent holder's rights. That would ensure that incentives to innovation were maintained and that there would be no chilling effect of the use of patent systems globally. In that regard, it aligned itself with the proposed changes presented by the Delegations of the United States of America and Canada. Those proposed changes were seen as contributing to a clearer and more balanced understanding of the obligations and rights of applicants concerning sanctions.
- 179. The Delegation of Nigeria aligned itself with the statement made by the Delegation of Ghana, on behalf of the African Group. Regarding Article 6, it recognized the substantial time and effort that had been invested in deliberations. The article was viewed as a balanced and well-reasoned approach to encompassing sanctions and remedies. The Delegation conveyed a hesitancy towards any further drafting, redrafting, or attempts to dilute the intention of the article. It found surprising that certain delegations aimed to eliminate references to fraud or fraudulent intent in Article 6.4. It drew attention to Article 10.1 of the Patent Law Treaty, which comprehensively addressed the issue of fraudulent intent in patent applications. It emphasized the importance of minimal intervention in altering the article on sanctions and remedies. Although the Delegation believed that the text should remain unchanged, it expressed its openness to engaging with other delegations who had proposed some redrafting.
- 180. The Delegation of India explained that it had proposed to set minimum standards for sanctions and remedies. It emphasized the potential benefits of applying uniform minimum standards across all articles. However, it believed that that setting minimum standards for

disclosure and maximum standards for sanctions would not guarantee the instrument's objective of enhancing effectiveness of the patent system regarding GRs and aTK. The Delegation asserted that sanctions and remedies should be left to national laws without imposing a maximum standard. It drew from its national experience, where a provision for revocation in case of non-disclosure had existed for many years but no patents had been revoked on those grounds. That provision was seen as an effective deterrent to non-disclosure. In Article 6.1, the Delegation proposed that measures available for sanctions and remedies should be for both pre-grant and post-grant of a patent. In Article 6.2, before a patent was granted, the applicant should be provided an opportunity to correct or add missing information. Article 6.3 provided an option for Contracting Parties to use revocation. Given the understanding of fraudulent intent as a ground for revocation, it recommended incorporating revocation in Article 6.4. It proposed an inclusive approach in Article 6.5, offering parties flexibility to adopt dispute resolution mechanisms, recognizing that not all jurisdictions might be prepared for such mechanisms.

- 181. The Delegation of Mexico proposed the following amendment to Article 6.1: "Each Contracting Party shall establish legal, administrative, and/or policy measures pre- and post-grant". It suggested including at the end "Contracting Parties should endeavor to establish such measures together with Indigenous Peoples, in accordance with their relevant national legislation". In Article 6.2, it believed there should be a possibility to rectifying the failure to disclose. For Article 6.3, the Delegation proposed to provide parties with the option, in accordance with national legislation, to revoke or render unenforceable patents. The proposed revision read: "Subject to Article 6.4, Contracting Parties are not obliged to revoke or render unenforceable a patent solely on the basis of an applicant's failure to disclose the information specified in Article 3 of this instrument". The Delegation suggested that Article 6.4 should specifically mention revocation and it proposed the following wording: "Each Contracting Party may provide for post-grant sanctions or remedies, including revocation, where voluntarily or with fraudulent intent, the applicant has omitted the information required in Article 3 of this instrument, in accordance with its national law". In Article 6.5, it suggested adding "including Indigenous Peoples" after "allow all parties concerned" to recognize Indigenous Peoples as stakeholders in that context.
- 182. The Delegation of Samoa explained that fraudulent intent with regard to the disclosure requirement in Article 3 was a serious behavior that could trigger criminal provisions and would likely deprive local communities and Indigenous Peoples of payable royalties. A failure to disclose information could make the work of patent examiners difficult and might lead to erroneous granting of patents. The Delegation argued that a patent right was a personal property right that should not be protected under the law in the case of unethical or dishonest behavior. It aligned itself with the APG's position on Article 6 and supported the revocation of a patent that was materialized under fraudulent intention, but only as a last resort.
- 183. The Delegation of the EU, speaking on behalf of the EU and its Member States, emphasized the importance of having a clear and precise framework for sanctions. It proposed amendments to enhance clarity. It appreciated the fact that Article 6.3 aimed at a ceiling, that there would be no revocation for sanctions for non-compliance with disclosure obligations. It was concerned that the current wording of Articles 6.3 and 6.4 together would not safeguard such a ceiling. It believed that the term "fraudulent intent" lacked clarity since there was no common understanding of the term. In Article 6.1, it suggested adding "both before and after the granting of a patent" before "to address" to ensure that sanctions could apply in both pre-grant and post-grant situations. It believed that Article 6.4 should be deleted, as Contracting Parties could apply post-grant sanctions under Article 6.1 anyway. It supported the removal of the term "solely" in Article 6.3. Regarding Article 6.2, it supported the inclusion of a prescribed time period. In Article 6.5, it sought clarification on what was meant by "adequate dispute mechanisms" and who would be parties to such mechanisms. It supported the

independent judicial review related to sanctions and remedies and supported the proposal to a new Article 6.6 to that effect.

- 184. The Delegation of Poland, speaking on behalf of the CEBS Group, aligned itself with the position presented by the Delegation of the EU, on behalf of the EU and its Member States.
- 185. The Delegation of Nepal supported the proposals made by the Delegation of India.
- 186. The Chair opened the floor for comments on Article 7.
- 187. The Delegation of Switzerland, speaking on behalf of Group B, supported the inclusion of an article on information systems, and indicated that Group B members might have specific comments and suggestions to improve the text.
- 188. The Delegation of Ghana, speaking on behalf of the African Group, proposed to amend the title of Article 7 to "Information Systems in Relation to the Disclosure Requirement". While the African Group expressed its flexibility, it highlighted that access to information systems by foreign IP offices should be subject to authorization by states. It suggested deleting Article 7.3, as it could prejudge the future work of the Assembly and Contracting Parties.
- 189. The Delegation of the EU, speaking on behalf of the EU and its Member States, supported the current wording.
- 190. The Delegation of Venezuela (Bolivarian Republic of), speaking on behalf of GRULAC, supported the position presented by the Delegation of Ghana, on behalf of the African Group.
- 191. The Delegation of Poland, speaking on behalf of the CEBS Group, supported the position presented by the Delegation of the EU, on behalf of the EU and its Member States. It agreed with the creation of an information system which was considered complementary to the disclosure requirement.
- 192. The Delegation of the United Kingdom emphasized the importance of information systems in preventing the erroneous granting of patents, and supported the establishment of databases as outlined in Article 7.
- 193. The Delegation of Iran (Islamic Republic of), speaking on behalf of APG, expressed general agreement with the proposed text for Article 7. It emphasized the importance of establishing information systems, including databases for GRs and TK, in consultation with relevant stakeholders, particularly Indigenous Peoples and local communities through voluntary and transparent mechanisms. Some Member States within APG shared specific views and concerns, including the need for reframing Article 7.3 to make it less prescriptive and allow for wider policy space for national authorities. They also asked for clarification regarding whether the establishment of the database would be compulsory and regarding the term "regional information system". It highlighted the importance of considering ongoing developments and discussions regarding the protection of the rights of Indigenous Peoples and local communities, the defensive protection role of establishing databases, and improving the draft to integrate Articles 7.1 and 7.2.
- 194. The Delegation of Mexico proposed to amend Article 7.1 as follows: "Contracting Parties may establish information systems, such as databases of GRs and aTK, in coordination and consultation with Indigenous Peoples and the relevant stakeholders, taking into account their national circumstances under the expressed approval of the legitimate owners".

- 195. The Delegation of Venezuela (Bolivarian Republic of) supported the proposal made by the Delegation of Mexico regarding Article 7.1. It suggested that at the end of Article 7.1, it should mention the FPIC of Indigenous Peoples. Additionally, it noted that September 5 was the International Day of Indigenous Women, which had been established in 1983 in Bolivia.
- 196. The Delegation of the Republic of Korea supported the current form of the article.
- 197. The Delegation of Japan supported Article 7. It emphasized the importance of high-quality databases for patent examiners and offices. It disagreed with modifying the title to include the term "disclosure requirements". The Delegation believed that information systems should contribute to prior art searches beyond disclosure requirements. It supported the modification of the wording of Article 7.1, proposed by the virtual expert group.
- 198. The Delegation of the Russian Federation supported the current wording of Article 7. The proposed measures establishing information systems would significantly improve the quality of patent examinations by reducing the number of erroneously granted patents.
- 199. The Delegation of Argentina supported the amendment proposed by the Delegation of Mexico.
- 200. The Delegation of the United States of America supported the statements made by the Delegation of Switzerland, on behalf of Group B, and the Delegations of Japan and the Republic of Korea. It supported the original wording of Article 7 with the exception of the amendment proposed by the Delegation of Japan.
- 201. The Delegation of Egypt supported the statement made by the Delegation of Ghana, on behalf of the African Group. It insisted that information systems should remain optional. It proposed to delete Article 7.3.
- 202. The Delegation of Nigeria support the statement made by the Delegation of Ghana, on behalf of the African Group, and the statement made by the Delegation of Egypt. It supported to include "in relation to the disclosure requirement" in the title of Article 7. It emphasized the connection between information systems, prior art and disclosure requirements. It expressed its concerns about Article 7.3, considering it overly detailed and intrusive.
- 203. The Delegation of South Africa supported the statements made by the Delegations of Egypt and Nigeria.
- 204. The Delegation of Namibia supported the statement made by the Delegation of Ghana, on behalf of the African Group. It emphasized the complementary nature of the information systems in supporting disclosure requirements.
- 205. The representative of the Tebtebba Foundation aligned itself with the statement made by the Delegation of Ghana, on behalf of the African Group, and the statement made by the Delegation of Nigeria. He expressed his concerns about introducing the term "defensive protection". He emphasized the need for further discussion on that matter, as it could have implications for the TK instrument.
- 206. The Delegation of Niger supported the statement made by the Delegation of Ghana, on behalf of the African Group, which had been endorsed by several African countries. It emphasized that the provision should not be binding or obligatory.
- 207. The representative of INBRAPI supported the proposal made by the Delegations of Mexico, Venezuela (Bolivarian Republic of) and Argentina on Article 7. She emphasized the

importance of establishing defensive protection databases in consultation and coordination with Indigenous Peoples, with their FPIC.

- 208. The Delegation of Thailand aligned itself with the position of the APG, which supported the current text. It emphasized that the establishment of information systems should support disclosure requirements without affecting the protection of secret TK. The Delegation raised some questions and uncertainties about how those information systems and databases would function in practice, including what information they would contain, whether they would be related to the genetic sequence data, whether they would be publicly accessible, and how data utilization would require FPIC or mutually agreed terms. The Delegation supported the integration of working groups to develop interoperability standards and guidelines to safeguard and develop the WIPO Portal, as mentioned in Article 7.3.
- 209. The Delegation of Kenya supported the sentiments expressed by the Delegation of Ghana, on behalf of the African Group. Article 7.3 should be deleted as it was seen as overly intrusive.
- 210. The Delegation of Uganda aligned itself with the statement made by the Delegation of Ghana, on behalf of the African Group, and supported by other African countries. Article 7 would be a complementary measure and each Member State might choose whether or not to use it.
- 211. The representative of the MALOCA Internationale understood that databases were useful for verifying novelty in the patent system. However, when it came to the Amazon, it was challenging, if not impossible, to place all traditional GRs into a database. He wondered how such databases could be protected from artificial intelligence ("Al") or super Al. Regarding Article 7.1, he supported the inclusion of consultations with Indigenous Peoples. He underscored the importance of FPIC, which was included in UNDRIP.
- 212. The Delegation of Switzerland expressed its desire to retain the current title of Article 7, noting that the suggested change would limit the article. It addressed aspects related to both national databases and potential undisclosed elements. It acknowledged the importance of correctly identifying the origin of GRs for patent examiners, which would be facilitated by utilizing databases. Information systems had their potential to streamline the implementation of disclosure requirements. The Delegation clarified its position on not deleting Article 7.3. Instead, it was open to simplifying the language while specifically preserving Article 7.3(d), which aimed to establish the international dimension of the information system. It proposed to add to Article 7.3 an additional function which read: "share information specified in Article 3 among all Contracting Parties to this instrument". Although the details were not fully developed, the concept around the international information system would potentially simplify the implementation of national disclosure requirements, provided that Contracting Parties were willing to share information with each other. That approach, if adopted, would benefit both patent holders and examiners.
- 213. The representative of KEI expressed appreciation for the voluntary nature of information systems. His concerns regarding the implementation were mitigated by the voluntary aspect. He underlined that room for considerations related to the sensitive nature of data and the future role of AI were presented in Article 7. The World Health Organization adopted in 2019 transparency measures in the markets for medicines and health products, specifically referring to WHA 72. He proposed the possibility of including voluntary sharing of economic data resulting from those systems in the list of matters to consider. He highlighted the need for greater transparency and accessibility in the implementation of GRs and TK systems in various countries.

- 214. The Delegation of India supported the current form of Articles 7.1 and 7.2. It aligned itself with the APG's position. It indicated its willingness to consider modifications to the text in Article 7.3, as proposed by certain delegations. Drawing from its national experience, the Delegation highlighted the value of information systems as a complementary measure. It shared the reliability of its national database which had been acknowledged by its national patent office and with 15 other international patent offices which had engaged in partnerships. That experience led the Delegation to support the idea of information systems as a complementary measure.
- 215. The representative of the Tulalip Tribes aligned himself with the statement made by the Delegation of Mexico and other delegations regarding Article 7.1, regarding the inclusion of "Indigenous Peoples and local communities".
- 216. The Delegation of Samoa aligned itself with the APG's position. It stressed the importance of obtaining the FPIC of Indigenous Peoples and local communities before their GRs or aTK was shared in any information system. That requirement applied regardless of whether the GRs or aTK were related to local or foreign GRs or aTK. It supported information systems only for the purpose of determining disclosure requirements and substantive examinations. It emphasized the need to address any unauthorized access by patent examiners to those systems, in line with the standards set forth in Article 7.3. It expressed discomfort with the idea of transferring control of the database of Samoa's GRs and aTK to another entity. It suggested that Article 7.3 could be implemented by WIPO, which would initially build national independent databases before providing an international option.
- 217. The representative of HEP believed that information systems could play a crucial role in improving the lives of local communities in the future. She acknowledged the existence of online databases and repositories within WIPO, containing information on TK and TCEs. She also mentioned the presence of various organizations that collected and stored data, some of which was made public available while others remained restricted. She supported the initiative and hoped that all Contracting Parties would recognize the availability of resources that could be utilized. Regarding Article 7.1, there had already been a wealth of existing information that had been disclosed, and there was no need for Contracting Parties to hasten the process further or make it unnecessarily complicated. She underscored the importance of addressing the plight of people who had suffered from the misuse of their TK over many years.
- 218. The Delegation of INBRAPI took the floor, as there had been an interpretation issue in her previous statement. She had been working closely with Indigenous Peoples in Brazil. She had been actively engaged in discussions and forums related to IP rights. Her statement aimed to address concerns related to databases, focusing particularly on defensive protection. She stressed the importance of positive protection measures to ensure that the rights of Indigenous Peoples were adequately safeguarded throughout the process. She acknowledged and thanked the Delegation of Samoa for its support in that regard.
- 219. The Delegation of Nigeria expressed its concerns regarding Article 7. It acknowledged the utility of information systems in helping examiners to determine the validity of patents. However, it pointed out that the article did not address the legal implications of those databases. The Delegation emphasized the importance of avoiding extensive revisions to Article 7, which was considered peripheral to the goals of the instrument. Regarding Articles 7.1 and 7.2, it advocated for obtaining the permission of Indigenous Peoples and local communities for the establishment of databases, aiming to preserve the integrity of GRs and indigenous communities. It urged for a balance between information systems and the obligation to respect the custodians of those resources. The article delved into the administrative capacities of patent offices and Member States. It raised issues with constitutional implications, integrity and cybersecurity. It raised concerns about potential cybersecurity attacks on databases containing

GRs and aTK and the resulting IP consequences. The Delegation raised questions about the criteria for examiner to access to the database. It suggested that Article 7 be reviewed for consensus before being further explored, given its unusual and far-reaching nature.

- 220. The Delegation of Lebanon indicated that the information system should be mandatory rather than optional. It stressed its significance in determining the rights related to GRs and believed that information systems played an essential role in ensuring effective disclosure requirements. The Delegation supported to remove Article 7.3.
- 221. The representative of TWN shared his concerns regarding Article 7. He acknowledged that the article might be useful for certain countries in the context of patent examination, but could also be a threat to bio-piracy. He sought clarification regarding safeguards and wondered what they were meant to protect against. He believed that those safeguards were intended to address the misappropriation of GRs and aTK. That, in turn, reflected that the instrument's purpose extended beyond achieving transparency and efficiency, but addressed the issue of misappropriation.
- 222. The Delegation of New Zealand supported the statements made by the representative of the MALOCA Internationale and the Delegation of Mexico regarding Article 7.1, regarding the inclusion of "Indigenous Peoples and local communities". It emphasized the importance of including Indigenous Peoples in the development of information systems.
- 223. The Delegation of China noted that information systems, while protecting GRs and preventing incorrect authorizations, could not replace the disclosure requirement. It believed that information systems should be conserved as a secondary measure. It took note of the discussions about Article 7.3.
- 224. The Delegation of Oman supported the current wording of Article 7 except Article 7.3.
- 225. The representative of KEI suggested the IGC looking at the database provision in the BBNJ Treaty.
- 226. The representative of INBRAPI supported the statements made by the Delegations of Venezuela (Bolivarian Republic of), Samoa and Nigeria. She emphasized the importance of having guidelines for safeguarding information systems containing GRs and aTK. Regarding Article 7.3(c), she noted that those information systems on TK should not be freely and publicly available, nor should they be considered in the public domain. She stressed the need for minimum safeguards, ensuring transparency and securing the FPIC of Indigenous Peoples, and recognizing that they were the depositaries and primary source of the TK that was secret and sacred. Those safeguards would not only enable transparency and access to TK information, but also foster trust between Indigenous Peoples and IP offices and address concerns related to patent applications.
- 227. The Chair opened the floor for discussion on Article 9.
- 228. The representative of TWN expressed the importance of having a review article in the instrument, especially to address emerging challenges and issues related to the implementation or enforcement of provisions. He raised a concern regarding the omission of addressing DSI derived from GRs. While the instrument excluded DSI from its scope, it was suggested that the issue could be addressed under Article 9 during the review, which was scheduled four years after entry into force. DSI was a reality, and many GR transfers current occurred through DSI rather than in a physical form. The review process could be lengthy, noting the example of the TRIPS Agreement, which took about 20 years to reach a reasonable conclusion. He expressed his concern that the treaty had left out an important issue, namely the misappropriation of GRs.

- 229. The Delegation of Ghana, speaking on behalf of the African Group, recognized the potential value in linking Article 9 with Article 11. It supported the current form of Article 9.
- 230. The Delegation of the Russian Federation emphasized the importance of Article 9, which had been repeatedly noted by many delegations and discussed during this meeting. It did not object to the current wording. However, it highlighted the need to consider the correlation between Article 9 "Review" and Article 15 "Revision", which would be considered during the Preparatory Committee. It suggested to discuss the need to have both articles in the final document and the possibility of merging those articles. The Delegation emphasized its willingness to adopt a flexible approach to these issues and expressed its openness to dialogue.
- 231. The Delegation of Niger supported the statement made by the Delegation of Ghana, on behalf of the African Group. It emphasized the significance of the provision, which had the potential to extend the disclosure requirement to various types of IP. It noted the importance of including derivatives and DSI, especially concerning new and emerging technologies. The provision would not diminish the disclosure requirement. Instead, it would broaden its scope beyond patents.
- 232. The Delegation of the United States of America expressed its concerns regarding the potential implications of Article 9. It stressed that the wording of the article could weaken incentives for innovation by creating legal uncertainty, increasing compliance costs, and causing difficulties for patent system users, particularly those in the biosciences in terms of attracting investments and planning for costs associated with patent development. To guard those concerns, the Delegation proposed several edits to Article 9. It recommended adding a commitment to report on the scope and content of the instrument with inclusive participation by all WIPO Member States. Moreover, it suggested the removal of text identifying outstanding issues to address during a future review, as it believed that such language was premature and unnecessary. It proposed to delete Article 16 which addressed the modification of the instrument. That article would allow the Assembly to amend the instrument without requiring a Diplomatic Conference. Those proposed changes aimed to address the concerns of stakeholders who relied on predictable and reliable patent systems for their innovative work, particularly in the biosciences field. It proposed to insert "and report on" after "commit to a review of", and add "with inclusive participation by WIPO Member States" after "contents of the instrument". It also proposed to delete "addressing issues such as the possible extension of the disclosure requirement in Article 3 to other areas of intellectual property and to derivatives and addressing other issues arising from new and emerging technologies that are relevant for the application of this instrument".
- 233. The Delegation of Japan fully supported the proposal made by the Delegation of the United States of America, particularly the deletion of the language from "addressing issues" to "the application of this instrument". It endorsed the idea of replacing "Contracting Parties" with "Member States". The Delegation, as one of the largest applicants in the world, expressed that the outcome of discussions under Article 9 would have a significant impact on its domestic innovation activities. It emphasized that modifying the article was essential because it was impossible to anticipate the potential expansion of the instrument's scope, given the lack of agreement among Member States at the current time.
- 234. The Delegation of Iran (Islamic Republic of), speaking on behalf of APG, supported Article 9 in its current form. There had been some discussions regarding the relationship between Article 11 and Article 14, which APG had planned to address during the Preparatory Committee.

- 235. The Delegation of Canada supported the provision of the instrument, but opposed the reference to specific topics that the review should address. The review clause should be general and non-prescriptive to avoid limiting possible topics and prevent the provision from becoming outdated within the lifetime of the instrument. It proposed to amend the text as follows: "The Contracting Parties commit to a review of the scope and the contents of this instrument no later than four years after the entry into force of this instrument."
- 236. The Delegation of Lebanon pointed out that despite the instrument's intent to provide full protection for GRs and aTK, the wording of Article 9 revealed areas where such protection might not be granted, potentially leading to conflicts.
- 237. The Delegation of Samoa highlighted the importance of Article 9. It noted that the current text, focusing only on patent law, should be extended to other IP systems under Article 9. The Delegation aligned itself with the statement made by the Delegation of Iran (Islamic Republic of), on behalf of APG.
- 238. The Delegation of Egypt fully supported the statement made by the Delegation of Ghana, on behalf of the African Group.
- 239. The Delegation of India fully aligned itself with the statement made by the Delegation of Iran (Islamic Republic of), on behalf of APG, in supporting a mandatory review under Article 9, for potential extension to relevant IP systems and in respect to future technological developments.
- 240. The Delegation of Germany emphasized the importance of Article 9 and proposed extending the review period from four years to eight years.
- 241. The Delegation of the Republic of Korea supported the statements made by the Delegations of the United States of America and Japan regarding the potential negative impact of the article on innovation.
- 242. The Delegation of China supported the current text of Article 9 and emphasized its importance in the instrument. It noted that such review articles were customary in international agreements to address unforeseen changes and challenges.
- 243. The Delegation of the United Kingdom considered Article 9 to be unusual in a WIPO treaty, even though it would support its inclusion. It emphasized the importance of ensuring that the review text was appropriate and did not prejudge outcomes. It might be premature to identify specific areas for review before agreeing on the substantive provisions of the text.
- 244. The Delegation of Mexico stated that the content of Article 9 should depend on the scope of the instrument, specifically whether it covered patents or other forms of IP. It suggested that, given the fast pace of technological advancements, the review timeframe should be set at three years after entry into force. The review should address aspects not currently included in the instrument, such as the application of the disclosure requirement to derivatives and addressing relevant emerging technology-related issues.
- 245. The representative of INBRAPI believed that the review should consider expanding the disclosure requirement under Article 3 to encompass other aspects of IP, derivatives and other related matters. The review process should ensure the full and effective participation of Indigenous Peoples and align with other relevant international instruments.
- 246. The Delegation of Bangladesh supported the article in its current form.

- 247. The representative of HEP emphasized the necessity of having a review article. She considered the four-year period for review to be appropriate.
- 248. The Delegation of Malaysia supported the current form of Article 9, and the statement made by the Delegation of Iran (Islamic Republic of), on behalf of APG.
- 249. The representative of the Tebtebba Foundation emphasized the critical nature of Article 9, especially given the unique *sui generis* framework being created. Emerging technologies like DSI and AI were evolving quickly. He viewed the listed issues as indicative rather than obligatory, providing flexibility for review discussions. He expressed his concern about the proposed eight-year review period, given the rapid developments in technologies related to GRs and aTK. He endorsed the proposal made by the representative of INBRAPI to include Indigenous Peoples and local communities in the review process.
- 250. The Delegation of Colombia supported the statement made by the Delegation of Mexico. It expressed its interest in and support for the position that the disclosure requirement could also apply to derivatives.
- 251. The Delegation of Pakistan aligned itself with the statement made by the Delegation of Iran (Islamic Republic of), on behalf of the APG. It supported the inclusion of Article 9, which called for a mandatory review, in its current formulation.
- 252. The Delegation of Mozambique agreed with the content of Article 9, especially the proposed four-year period for review.
- 253. The Delegation of Switzerland expressed its concerns regarding the timescale, which might affect the participation of Member States. It emphasized that the process of ratifying such an instrument, including amending national laws, typically took several years. The Delegation suggested considering a more realistic timeframe, such as no sooner than four years, to provide adequate time to work on the current instrument for ratification.
- 254. The Delegation of Venezuela (Bolivarian Republic of), speaking on behalf of GRULAC, believed that the review should be the responsibility of the Contracting Parties.
- 255. The Delegation of Peru supported the statement made by the Delegation of Venezuela (Bolivarian Republic of), on behalf of GRULAC. It believed that while it was essential to address specific issues in the article, they could be revisited at a later stage depending on the progress of the negotiations.
- 256. The Delegation of Ecuador supported Article 9, emphasizing its importance in addressing historical issues within the scope of the instrument. It supported to initiate the review mechanism as soon as possible.
- 257. The Delegation of the EU, speaking on behalf of the EU and its Member States, emphasized the need for a longer timeframe for the implementation of the instrument. It proposed the inclusion of the phrase "no later than eight years after the entry into force of the instrument" to allow for the necessary time for incorporation into national law and the gathering of substantial experience. The Delegation also proposed a new Article 9, which would read as follows: "The Contracting Parties commit to a review of the scope and contents of this Instrument and the issues arising from new and emerging technologies, that are relevant for the application of the Instrument, no later than eight years after the entry into force of this Instrument".
- 258. The Chair opened the floor for comments on Article 8.

- 259. The Delegation of Switzerland, speaking on behalf of Group B, supported the recommendation of the virtual expert group regarding the removal of the footnote.
- 260. The Delegation of Ghana, speaking on behalf of the African Group, supported the removal of Footnote 8.
- 261. The Delegation of Argentina stated that the footnote should be part of a separate declaration.
- 262. The Delegation of the EU, speaking on behalf of the EU and its Member States, remained flexible and was open to considering suggestions from other delegations regarding Article 8.
- 263. The Delegation of Poland, speaking on behalf of the CEBS Group, expressed a preference for deleting the footnote. It also indicated that it would have additional comments on Article 9 later.
- 264. The Delegation of the United States of America supported the statement made by the Delegation of Switzerland, on behalf of Group B. It emphasized the critical importance of legal certainty for the effectiveness of the instrument. It suggested clarifying that nothing in the instrument should derogate from or modify any obligations Contracting Parties had to each other under other instruments or agreements. It proposed the deletion of Footnote 8. The Delegation proposed to replace "mutually supportive" with "coherent", and insert the following phrase: "Nothing in this instrument shall derogate from or modify any obligations that Contracting Parties have to each other under any other international agreement."
- 265. The Delegation of Iran (Islamic Republic of), speaking on behalf of APG, expressed its general agreement with and flexibility toward the proposed Article 8. While some APG Member States suggested the possibility of having a footnote with an indicative list of relevant international agreements to complement Article 8, others had concerns about that footnote and believed that it could limit the scope of Article 8 and potentially lead to confusion.
- 266. The Delegation of India supported the wording of Article 8. It suggested adding a footnote to explicitly mention certain agreements such as the CBD, the Nagoya Protocol, and the International Treaty on Plant Genetic Resources for Food and Agriculture. That was intended to clarify the kinds of instruments relevant to the instrument and ensure that the capacity of the parties to fulfill their obligations under those agreements would not be restricted due to the implementation of this instrument.
- 267. The Delegation of Colombia expressed its strong interest in retaining the footnote in Article 8.
- 268. The Delegation of Mexico suggested modifying the wording of the article as follows: "This instrument shall be implemented in a mutually supportive manner with other international agreements relevant to this Instrument, including those in the areas of human rights, environmental rights and cultural rights, in particular the United Nations Declaration on the Rights of Indigenous Peoples". That change aimed to explicitly mention the areas that could relate to the application of the instrument.
- 269. The Delegation of Japan supported the statement made by the Delegation of Switzerland, on behalf of Group B, regarding the deletion of the footnote. It also supported the proposed amendments made by the Delegation of the United States of America, which did not prejudge ongoing discussions on other international instruments.

- 270. The Delegation of the United Kingdom supported the statement made by the Delegation of Switzerland, on behalf of Group B. It addressed the need to implement Article 8 in a coherent and consistent manner with other international agreements, without prejudicing their implementation, causing conflicts, or modifying their provisions. It also supported the suggestions made by the Delegation of the United States of America.
- 271. The Delegation of the Republic of Korea supported the statement and the proposed wording presented by the Delegations of the United States of America and Japan regarding Article 8, as it believed that the text allowed obligations of other international agreements to be unduly changed by this instrument without the agreement of Member States. It emphasized that if disclosure requirements were integrated into the system, it might have placed additional burdens on parties that chose not to be a member of the instrument. Consequently, the Delegation asserted that the issue of the Patent Cooperation Treaty ("PCT") should be discussed at its own Union. As a result, it endorsed the proposal made by the Delegation of the United States of America to amend the language of Article 8 and delete the footnote.
- 272. The representative of the Tebtebba Foundation presented specific language in the spirit of compromise, which read: "This instrument should be implemented in a mutually supportive and coherent manner with other international agreements relevant to this instrument, including UNDRIP". He addressed concerns expressed by some delegations regarding the impact of this clause on the IP system. He emphasized the focus of the discussions pertained to GRs and aTK. He underlined that it did not encompass the IP system as a whole. Instead, it concentrated on the areas where the IP system intersected with GRs and aTK. It should not be perceived as a potential threat to other aspects of the IP system, except in those specific domains related to GRs and aTK. He urged for a compromise on this matter, emphasizing that it was not as critical as some had portrayed it to be.
- 273. The Delegation of China supported the notion that the current text should be in harmony with other pertinent international agreements. Regarding Article 8, it believed that the international instruments referenced in the note should not exclusively focus on the PCT. It pointed out that there was no consensus on the list of relevant agreements outlined in the note. As such, it maintained an open stance toward further discussions on that matter.
- 274. The Delegation of Lebanon supported the concept of aligning the text with other international agreements to promote mutual benefits. It suggested replacing "in a mutually supportive manner" with "in coherence with". The proposal aimed to ensure consistency with other international agreements.
- 275. The Delegation Canada preferred the phrase "in a coherent manner" instead of "mutually supportive manner". The rationale behind that modification was to avoid related instruments needing to be amended to support the implementation of the new instrument, thereby preventing potential legal uncertainty. It also aligned with interventions calling for the inclusion of UNDRIP, specifically by adjusting the text to refer to other instruments, including the UNDRIP.
- 276. The representative of the MALOCA Internationale indicated that a decision had been reached among the Indigenous Caucus. He proposed the following: "in a mutually supportive manner with other international agreements relevant to this instrument, in particular UNDRIP", which echoed the proposal made by the Delegation of Mexico.
- 277. The Delegation of the Russian Federation did not object to the current wording of Article 8. Regarding the proposal made by the Delegation of India, it pointed out that the inclusion of the note was non-binding given that the list of proposed of international agreements remains open in any case.

- 278. The Delegation of Nigeria disagreed with the proposed use of "mutually supportive" in the text, noting that it did not impose any obligations and could not lead to the alteration of existing treaties. The Delegation indicated its inclination to support the proposal which combined "mutually supportive" and "coherent" as a compromise.
- 279. The Delegation of the Cook Islands aligned itself with the position of APG. It supported the terms "mutually supportive" and "coherent". It also supported the inclusion of a footnote proposed by the Delegation of India, which highlighted the existing international frameworks. In Article 7, the Delegation of the Cook Islands emphasized the importance of databases considering the national circumstances of Contracting Parties, ensuring permission and consent from TK holders, and supporting the decision for national level approval for database access as put forward by the Delegation of Ghana, on behalf of the African Group, and the Delegation of Samoa. It expressed the need for minimum standards and suitable protective mechanisms for TK within such databases, while raising concerns about the prescriptive nature of Article 7.3. It underlined the importance of maintaining Article 9 and the crucial role of Indigenous Peoples and local communities in the scope and application of the instrument, and the need for their full participation in any review process.
- 280. The representative of MBOSCUDA supported the statement made by the representative of the Tebtebba Foundation.
- 281. The Delegation of Israel supported the statement made by the Delegation of Switzerland, on behalf of Group B, and the statements made by the Delegations of Japan and the United States of America. It requested the removal of Footnote 8 and favored the replacement of "mutually supportive" with "coherent". It emphasized that using a more inclusive term like "coherent" would create a broader foundation for agreement, especially considering that not all Member States were signatories to all relevant treaties.
- 282. The Delegation of Egypt expressed its concerns regarding the impact of the article on the PCT, particularly in the international phase. It argued that a footnote would not sufficiently address that issue. It also proposed adding a phrase at the end of the article: "taking into account the objectives and purpose of this instrument".
- 283. The Delegation of Samoa expressed its views on the connection between the PCT and national processes. It believed that any amendments from this instrument related to disclosures in the patent registration process might automatically impact the PCT process. It also raised concerns about the specific mention of other international agreements outside of WIPO in the footnote, as it could affect membership of a resulting agreement. There was no need for a footnote in that regard. It aligned itself with the position of APG to support Article 8 in its current formulation.
- 284. The representative of TWN wished to refer to the CBD, the Nagoya Protocol and the International Treaty on Plant Genetic Resources for Food and Agriculture. It drew attention to the 2003 proposal by the Delegation of Switzerland, which aimed at incorporating the disclosure requirement in the PCT.
- 285. The Delegation of Nepal supported the statements made by the Delegation of India and the Delegation of Iran (Islamic Republic of), on behalf of APG.
- 286. The Delegation of New Zealand supported the proposal made by the Delegation of Canada and others to include the reference to UNDRIP in Article 8.

- 287. The Delegation of Venezuela (Bolivarian Republic of) expressed its desire to include the rights of Indigenous Peoples in Article 8.
- 288. The Chair opened the floor for discussion on Article 4.
- 289. The Delegation of Ghana, speaking on behalf of the African Group, proposed to revise Article 4 as follows: "In complying with the obligations set forth in Article 3, Contracting Parties may, in consultation with Indigenous Peoples and local communities, in special cases, adopt justifiable exceptions and limitations necessary to protect the public interest. Provided such justifiable exceptions and limitations do not unduly prejudice the implementation of this instrument or its mutual supportiveness with other relevant instruments."
- 290. The Delegation of the EU, speaking on behalf of the EU and its Member States, believed that exceptions and limitations should narrow the scope of the disclosure obligations. It suggested the following: "In complying with the obligations set forth in Article 3, Contracting Parties may in special cases narrow the scope of the disclosure obligations by adopting justifiable exceptions and limitations necessary to protect the public interest, provided such justifiable exceptions and limitations do not unduly prejudice the implementation of this instrument or its mutual supportiveness with other instruments."
- 291. The Delegation of Switzerland, speaking on behalf of Group B, emphasized the need for further discussions on how to draft an article on exceptions and limitations, particularly to ensure it provided legal certainty without conflicting with the objectives of the instrument. It expressed the importance of considering the implications Article 4 might have on the minimum and maximum standards in the instrument.
- 292. The Delegation of Poland, speaking on behalf of the CEBS Group, found the language in the article unclear, and emphasized the need to clarify the scope of the requirements. It also aligned with the proposed language presented by the Delegation of the EU, on behalf of the EU and its Member States.
- 293. The Delegation of Canada supported the inclusion of a limited but flexible exceptions and limitations provision, which would allow Contracting Parties to address circumstances where disclosure might not be appropriate or could conflict with other obligations. However, the Delegation did not support the last clause, which reads "or mutual supportiveness with other instruments". It believed that prohibiting exceptions and limitations that might prejudice other unidentified instruments would add too much uncertainty to the provision, as all Contracting Parties might be signatories to those other instruments. It believed that parties should not be limited in their implementation of this instrument by referring to other instruments. As a solution, the Delegation of Canada proposed to delete the words "mutual supportiveness with other instruments".
- 294. The representative of the Assembly of First Nations, speaking on behalf of the Indigenous Caucus, proposed to add a sentence at the very end of the article, which read ", and must be developed in conjunction with the Indigenous Peoples and/or local communities concerned".
- 295. The Delegation of Venezuela (Bolivarian Republic of), speaking on behalf of GRULAC, stated that the majority of members of GRULAC believed that Article 4 should be deleted.
- 296. The Delegation of Switzerland aligned itself with the statement made by the Delegation of Switzerland, on behalf of Group B. It believed that incorporating a general article on exceptions and limitations in this instrument might not be the most suitable approach. Article 4 in its current form appeared to draw inspiration from instruments that had established new IP rights, which might not be entirely relevant to this instrument. The current instrument primarily aimed to

enhance transparency for the source or origin, rather than creating new patent or IP rights. The Delegation suggested a more precise and specific approach by defining exceptions and limitations applicable to the scope of the instrument, both mandatory and optional ones. It specifically emphasized that such provisions should not extend to human GRs. It preferred a more precise drafting of Article 4, so that the first line referred to Articles 3.1 and 3.2 and not Article 3 in its entirety. It believed that that would create legal certainty in the application of the instrument. It suggested the following language to replace the first phrase of Article 4 until the first comma: "In complying with the obligations set forth in Articles 3.1 and 3.2". Additionally, it recommended that Contracting Parties should have the option to decide whether to apply the disclosure requirements to non-parties. That flexibility could potentially serve as an incentive for countries to ratify the instrument, as members would only be sure that others would apply the disclosure requirements for GRs and aTK if they became a party to the instrument. It proposed to add the following sentence as Article 4.2: "Contracting Parties may choose not to impose the obligations set forth in Articles 3.1 and 3.2 in relation to GRs and aTK obtained from non-parties to this instrument."

297. The Delegation of Australia demonstrated a degree of flexibility regarding the inclusion of this article in the instrument, recognizing that there might be some ambiguity in identifying the precise scenarios in which exceptions or limitations would be necessary within the context of a transparency-focused article. Nonetheless, it indicated its willingness to consider modifications if it held importance for other participants. It concurred with the proposal made by the Delegation of Switzerland to enhance clarity by specifying the reference to Articles 3.1 and 3.2. It also supported the proposal made by the Delegation of Canada to eliminate the phrase "mutual supportiveness with other instruments", as that aspect had already been addressed in the relevant article concerning international agreements. Furthermore, the Delegation recommended incorporating a language that highlighted the importance of consulting with Indigenous Peoples and local communities, if any exceptions were to be included in the implementation of the instrument. However, it underscored the need for flexibility in accommodating diverse national circumstances and approaches to the instrument.

298. The Delegation of the United States of America aligned itself with the statements made by the Delegation of Switzerland, on behalf of Group B, and the Delegation of Canada. It proposed a new paragraph that identified a non-exclusive list of specific types of GRs and aTK that would not be covered under this instrument. It recommended the exclusion of human GRs and DSI, in accordance with its treatment under the CBD and the Nagoya Protocol. Another exception it proposed was a public interest exception applied to GRs and aTK required to protect life or to prevent severe environmental degradation. The Delegation emphasized the critical need for the instrument to establish clear boundaries regarding the disclosure requirement, both what it included and what it excluded. It argued that without such clarity, those navigating the patent system would face compliance challenges. The Delegation reiterated its objection to the phrase "mutual supportiveness", asserting that it did not align with the instrument's balance between transparency and transaction cost within the patent system. It contended that that term failed to recognize the unique aspects of the patent system, innovation and the associated trade-offs, especially concerning non-IP agreements related to GRs and aTK. In light of those concerns, it expressed its willingness to accept the proposal made by the Delegation of Canada to remove the language pertaining to mutual supportiveness. It suggested restructuring the original text into three paragraphs, specifying different obligations and exceptions within each. The original paragraph would be relabeled to Article 4.1. It proposed new Articles 4.2 and 4.3: "4.2 Contracting Parties shall not impose the obligation set forth in Article 3 in relation to a claimed invention in a patent application that is materially and directly based on: (a) human genetic resources, including human pathogens; (b) DSI; or (c) GRs and aTK necessary to protect human, animal or plant life or health, including public health, or to avoid serious prejudice to the environment. 4.3 Contracting Parties may choose not to impose the obligation set forth in

Article 3 in relation to GRs or aTK obtained from a WIPO Member State that is not a party to this instrument."

- 299. The Delegation of Niger supported the statement made by the Delegation of Ghana, on behalf of the African Group. It disagreed with the proposals put forward by the Delegation of the United States of America concerning the exclusion of DSI. It mentioned that in the article on review, several aspects should be reviewed, including the possibility of extending the coverage to derivatives and DSI.
- 300. The Delegation of the Russian Federation supported the current version of Article 4. It acknowledged that the article was formulated with adequate flexibility and balance, providing Member States with the necessary freedom and latitude. It indicated its willingness to engage in discussions regarding the potential inclusion of a specific list of exceptions and limitations.
- 301. The Delegation of Egypt fully supported for the statement made by the Delegation of Ghana, on behalf of the African Group. In addition to the amendment suggested by the African Group regarding the need for consultation with Indigenous Peoples and local communities, it suggested adding "and all other beneficiaries as defined by national law".
- 302. The Delegation of Samoa believed that exceptions and limitations in any IP regime were to ensure flexibility in utilizing IP protected works without the need for the right holder's consent. It gave an example from copyright laws where there were exceptions allowing for educational use or scientific research, thus striking a balance between IP holders' rights and public interest. The Delegation pointed out that the purpose of Article 4 was unclear. If the intent was to introduce exceptions and limitations to the rights of Indigenous Peoples and local communities, following the three-step tests, as seen in other IP agreements, might be beneficial. It expressed the need for consultations with Indigenous Peoples and local communities.
- 303. The Delegation of China believed that exceptions and limitations in an instrument were necessary. The current text allowed for flexibility within national legislations. It also emphasized the need to establish appropriate exceptions and limitations based on the real situation of GRs and TK. It proposed that exceptions and limitations should be strictly limited to ensuring efficient protection of GRs and TK. It stressed the importance of considering the protection of the public interest when establishing exceptions and limitations. Its specific proposals for improving Article 4 included referencing the TRIPS Agreement and its provisions related to exceptions and limitations on granting of patents (Article 30) and other holders (Article 31). It suggested adding grounds for exceptions and limitations that accounted for public interest, national emergencies, or other circumstances of extreme urgency. Additionally, it recommended avoiding conflicts with the normal exploitation of GRs and TK by Indigenous Peoples, local communities and other beneficiaries who owned GRs and TK, and preventing undue prejudice to the legitimate interests of the related holders.
- 304. The Delegation of the United Kingdom supported the statement made by the Delegation of Switzerland, on behalf of Group B. It emphasized that the inclusion of exceptions and limitations in Article 4 served a valuable purpose. Exceptions and limitations helped address situations that fell outside the scope of the instrument, and provide clarity to both applicants and offices regarding when disclosure was required. Furthermore, it noted that exceptions and limitations were important when public policy concerns took precedence. The Delegation supported the statements made by the Delegations of Canada, Switzerland, and the United States of America.
- 305. The representative of the Tebtebba Foundation supported the language pertaining to consultations with Indigenous Peoples and local communities, but raised concerns about the current version of the text. He found the text highly problematic, particularly considering the

limited time available to conclude the work before the Diplomatic Conference. He provided an example. Climate change, which was a global crisis, had not been caused by Indigenous Peoples. He emphasized the critical importance of biodiversity and how Indigenous Peoples contributed significantly to its preservation. He referred to a report from the Intergovernmental Panel on Biodiversity and Ecosystem Services, which indicated that Indigenous Peoples played a substantial role in supporting 40% of the world biodiversity. He was concerned about the proposal put forth by the Delegation of the United States of America, as he believed that Indigenous Peoples could be harmed by climate change and biodiversity loss. He expressed his reservations about using the notion of public interest as suggested by the Delegation of the United States of America, when it was the same governments responsible for the environmental degradation. He recommended avoiding extensive lists, and suggested that if the public interest needed to be limited, it should be done sparingly and concisely.

- 306. The Delegation of Nigeria supported the statement made by the Delegation of Ghana, on behalf of the African Group. It emphasized the importance of adhering to the mandate of the General Assembly, which aimed to bridge gaps and prevent further escalation of issues. The Delegation conveyed a sense of responsibility and expressed satisfaction with Article 4, given the amendment mentioned earlier, which emphasized the importance of consulting with Indigenous Peoples and local communities. It noted the considerable progress made in the negotiation history of the article. It believed, in line with the Delegation of Samoa, that discussing exceptions and limitations should be avoided. It emphasized the significance of maintaining a consistent approach and avoiding actions that might contradict the progress achieved.
- 307. The Delegation of Japan supported the statements made by the Delegation of Switzerland, on behalf of Group B, and the Delegations of Canada, the United States of America, and the United Kingdom. It acknowledged the importance of granting each Member State a certain degree of policy space for exceptions and limitations. It emphasized the need to ensure legal certainty and consistency within the instrument to facilitate a streamlined process for patent applicants. It suggested the inclusion of a list specifying certain types of explicit exceptions, such as human GRs and DSI, as proposed by the Delegation of the United States of America. Furthermore, it supported the deletion of the final segment of the article concerning the mutual supportiveness with other instruments, echoing the proposal made by the Delegation of Canada.
- 308. The representative of TWN emphasized the importance of carefully considering the implications of adding an exceptions list, noting that the proposed list might inadvertently allow many related materials to evade disclosure. He drew attention to the fact that while exceptions related to protecting human, animal and plant health were derived from the TRIPS Agreement, the addition of an exceptions list could potentially lead to various related materials being exempt from disclosure requirements. He stressed the need for cautious and meticulous consideration when incorporating any exceptions and limitations on disclosure.
- 309. The representative of KEI shared his extensive experience in IP negotiations, particularly about exceptions and limitations. He indicated that Article 4, as currently drafted, appeared to be appropriate and satisfactory for achieving the objectives of the agreement. The list proposed by the Delegation of the United States of America might not be necessary given the flexibility of the existing draft. He highlighted the importance of understanding how exception clauses function in the context of IP rights, noting that the three-step test in various copyright agreements and the TRIPS Agreement should not be directly transposed into a disclosure requirement. He emphasized the complexity of exceptions within various agreements. For examples, in the Berne Convention and the TRIPS Agreement, exceptions were not limited to one or two articles but were distributed throughout the agreements. He believed that Article 4 provided ample means to address the issue at hand, emphasizing that the focus should be on

disclosure rather than on delineating an exhaustive list of items that would not require disclosure.

- 310. The Delegation of New Zealand supported the intervention made by the Delegation of Nigeria.
- 311. The Delegation of Switzerland believed that only minimal changes were needed for Article 4. It supported the proposals put forward by the Delegations of the United States of America and Japan, particularly the suggestion to clarify that the disclosure requirement would not be applicable to human GRs and DSI.
- 312. The Delegation of Israel supported the statement made by the Delegation of Switzerland, on behalf of Group B, regarding Article 4. It emphasized the importance of broad and openended exceptions and limitations to facilitate the flexible application of the instrument across various Member States. It underscored the role of this article as a key balancing mechanism, advocating for its flexibility to bridge gaps among Member States.
- 313. The Delegation of the Republic of Korea expressed its alignment with the proposals made by the Delegations of the United States of America, Canada, and Japan, regarding Article 4. It referred to the Article 27.2 of the TRIPS Agreement, which allowed the parties to exclude the protection of human and plant life or health from the patentability inventions.
- 314. The Chair opened the floor for comments on Article 5.
- 315. The Delegation of Ghana, speaking on behalf of the African Group, supported Article 5 in its current form.
- 316. The Delegation of Switzerland, speaking on behalf of Group B, believed the principle of non-retroactivity was crucial, and supported its inclusion in the provision. It indicated that members of Group B might offer more specific perspectives on drafting the provision.
- 317. The Delegation of Venezuela (Bolivarian Republic of), speaking on behalf of GRULAC, expressed its acceptance of Article 5 in its current form.
- 318. The Delegation of the EU, speaking on behalf of the EU and its Member States, indicated that the text only covered one important aspect of non-retroactivity for the instrument. On top of non-retroactivity for the time of the filing of a patent application, there should also be non-retroactivity related to the access to a GR or aTK. Only GRs and aTK that had been accessed after the entry into force of the treaty should be covered.
- 319. The Delegation of Iran (Islamic Republic of), speaking on behalf of APG, acknowledged its support for Article 5, while expressing the need for technical clarity on its implementation or application, especially in cases where a Contracting Party had pre-existing national regulations. Despite this, most APG Member States indicated their agreement with Article 5 in its current form.
- 320. The Delegation of Canada supported the statement made by the Delegation of Switzerland, on behalf of Group B. It emphasized that Article 5 was critical to ensure the flexibility and stability of the patent system. Understanding that the intent of the provision was to ensure a reasonable transition mechanism for applicants and IP offices and recognizing the right to priority enshrined in the Paris Convention, the Delegation proposed the addition of the term "or a priority date if claimed" after the words "filing date". Alternatively, it suggested the inclusion of a clarifying footnote to indicate that the filing date encompassed the priority date, if claimed. That proposal aimed to prevent the creation of new disclosure requirements for

subsequently filed applications when they had not been necessary for the original application filing.

- 321. The Delegation of Niger supported the statement made by the Delegation of Ghana, on behalf of the African Group. It highlighted that Article 5 was in alignment with the regulations outlined in the Vienna Convention on the Law of Treaties.
- 322. The Delegation of Poland, speaking on behalf of the CEBS Group, affirmed the significance of non-retroactivity provisions. It concurred with the rationale put forward by the Delegation of the EU, on behalf of the EU and its Member States. It supported Article 5 in its existing form.
- 323. The Delegation of India affirmed its support for the article in its current form.
- 324. The Delegation of Switzerland supported the statement made by the Delegation of Switzerland, on behalf of Group B. It emphasized the importance of maintaining the principle of non-retroactivity in the legal instrument. It showed interest in further exploring the proposal made by the Delegation of the EU, on behalf of the EU and its Member States, to apply the principle of non-retroactivity to GRs and aTK obtained before the entry into force of the instrument by the respective party. It recognized the rationale behind that proposal and noted that the knowledge of the source of GRs and aTK on the part of the applicant or inventor could not always be guaranteed, especially as given the ongoing lack of agreement concerning Article 3.3 of the instrument. The Delegation noted that Article 5 was subject to the prior national laws of Contracting Parties and such a broad reference to national laws could lead to confusion and increase ambiguity. It suggested replacing "laws" with "disclosure requirements relating to GRs and aTK".
- 325. The Delegation of Lebanon proposed a modification to Article 5, which read: "Contracting Parties shall not impose the obligations of the instrument in relation to patents which have been granted prior to that Contracting Party's ratification". Additionally, concerning Article 4, it proposed the addition of the phrase "provided justifiable exceptions and limitations do not unduly prejudice and the implementation of this instrument, nor the rights of Indigenous Peoples and local communities".
- 326. The Delegation of the Russian Federation supported the text of Article 5. It emphasized that the provisions of Article 5 bring legal clarity to the document.
- 327. The Delegation of the United States of America echoed its support for the statement made by the Delegation of Switzerland, on behalf of Group B. It emphasized the paramount importance of legal certainty to ensure the effectiveness of the instrument. Proposals were put forth to enhance clarity and minimize the disclosure burdens introduced by the instrument, thereby mitigating downstream costs and promoting innovation. The Delegation recommended certain amendments to Article 5, clarifying the applicability of the non-retroactivity clause to: "(1) patent applications not just filed but those with priority dates prior to a party's ratification or accession; and (2) applications that are materially and directly based on GRs or aTK obtained prior to a party's ratification or accession". The latter would be regardless of the patent application's priority date. It believed that the predictability introduced by those changes would help facilitate the compliance transition for patent applicants. Importantly, the changes would not affect pre-existing disclosure requirements. It suggested replacing "obligations of this instrument" with "obligations set forth in Article 3". It proposed to replace "which have been filed" with "with priority dates or patent applications that are materially and directly based on GRs or aTK that have been obtained". It also suggested replacing "laws" with "disclosure requirements relating to GRs and aTK".

- 328. The Delegation of China expressed its support for the current form of Article 5, emphasizing its balanced, rational and clear nature.
- 329. The Delegation of Ghana expressed its concerns over proposed modifications that could potentially create unintended consequences, specifically languages that the disclosure requirement would not apply to GRs or aTK obtained prior to that party's accession to the instrument. That type of language could permanently shield GRs or aTK from the instrument's scope, noting of potential misuse and abuse of the provision. It reiterated its reluctance to support any new language in the provision, emphasizing the importance of preserving the intended scope and purpose of Article 5.
- 330. The Delegation of the United Kingdom believed the article contributed to legal certainty by clarifying that the instrument did not apply to patents at all stages of their processing before a Contracting Party's ratification or accession. It proposed the inclusion of language to cover patents granted before a Contracting Party's ratification or accession, as some jurisdictions might recognize patents granted in a different jurisdiction but had no application stage. It suggested the following phrase "all patents that have been granted". Furthermore, it believed that GRs or aTK that had already been obtained prior to a Contracting Party's ratification or accession should also be covered by Article 5. It supported the textual suggestions put forward by the Delegations of the EU, on behalf of the EU and its Member States, Switzerland, the United States of America, and Canada.
- 331. The Delegation of Australia supported the article while acknowledging the need for clarity. It backed the proposals from the Delegation of Canada regarding priority dates and from the Delegation of Switzerland concerning national disclosure requirements. However, it also raised concerns regarding the addition of concepts such as accessing or obtaining GRs and aTK in the article. It highlighted the potential for adding uncertainty due to the lack of clear records regarding the timing of access or acquisition, which could complicate the implementation process. As a result, it declined to support those particular proposals at the present stage.
- 332. The Delegation of Samoa aligned itself with the position of APG and supported the comments made by the Delegation of Ghana. It emphasized that the article set a clear cut-off point for patent applications that had been filed before a Contracting Party's ratification or accession to the instrument. That cut-off point implied that future patent applications, including those pertaining to GRs and aTK in libraries, should not fall under the protection of Article 5. The Delegation acknowledged that the provision would not impact patents granted before ratification or accession. Its focus was on understanding the implications for the development of derivative patents derived from those excluded from Article 5. The Delegation wondered how the phrase "subject to national laws that existed prior to such ratification or accession" would apply to its specific national context.
- 333. The Delegation of Peru aligned itself with the statement made by the Delegation of Venezuela (Bolivarian Republic of), on behalf of GRULAC. It supported the current drafting of the article. It emphasized that the instrument was primarily focused on the disclosure requirement during the filing of an application and did not encompass the modalities of access. It would not support expanding the scope of non-retroactivity to include access to GRs and aTK, as it could introduce complexities in proving the moment of access, thus undermining the objective of ensuring certainty and predictability.
- 334. The Delegation of Italy wondered whether the ratification or accession date would be the dates considered for the principle of non-retroactivity, which was deemed crucial alongside other main articles of the text. It emphasized that the ratification and accession to instruments typically did not precisely align with the entry into force date. It suggested taking into account the possibility of retaining the reference to accession to the instrument but then subjecting it to

national laws that existed prior to such entry into force. It believed that reiterating ratification or accession might inadvertently trigger a material retroactivity in many cases.

- 335. The Delegation of Japan supported the statements made by the Delegation of Switzerland, on behalf of Group B, and the Delegations of Canada, the United States of America, and the United Kingdom. It emphasized the importance of non-retroactivity to ensure legal stability for applicants, who filed patent applications at the jurisdiction where the instrument was effective. The Delegation underscored the significance of not impeding the motivation of innovators who had acquired GRs or aTK without anticipating this instrument. To address that concern, it supported the proposal made by the Delegation of the United States of America, advocating for the extension of non-retroactivity to GRs or aTK obtained prior to ratification or accession to this instrument by the respective party. It supported the proposal aimed at encompassing patent applications with priority claims and granted patents covered by the article.
- 336. The Delegation of Egypt supported the statement made by the Delegation of Ghana, on behalf of the African Group.
- 337. The representative of CAPAJ acknowledged the statements made by the representative of the Assembly of First Nations and the Delegation of Egypt, emphasizing the need for the inclusion of Indigenous Peoples and local communities in Article 4. Additionally, she supported the suggestion made by the Delegation of Switzerland to engage in further deliberations on the drafting of Article 4.
- 338. The Delegation of Nigeria supported the statement made by the Delegation of Ghana, on behalf of the African Group. The target for non-retroactivity would be patents processed and existing pre-accession and pre-ratification in any domestic legal regime. It highlighted the importance of avoiding any inadvertent rush for the acquisition of GRs and aTK, and emphasized the importance of negotiating in good faith and preserving Indigenous knowledge, which had been part of the heritage of Indigenous Peoples since the precolonial era.
- 339. The Delegation of the Republic of Korea underscored the importance of ensuring stability in patent rights and predictability in the context of the instrument. It aligned itself with the positions of the Delegations of the United States of America, Japan, and Switzerland, on behalf of Group B.
- 340. The representative of the Tebtebba Foundation supported the positions articulated by the Delegation of Ghana, on behalf of the African Group, and the Delegations of Nigeria and Egypt. The non-retroactivity provision should solely apply to patents in process prior to the accession to the instrument, and he could not endorse the suggestions put forward by the Delegations of the United States of America and Japan. Extending the clause to all GRs and aTK acquired prior to the instrument's accession would preempt and prejudice the ongoing negotiations concerning the TK instrument. He emphasized the importance of maintaining the distinction between publicly available information and the public domain, particularly with regard to the TK instrument.
- 341. The Delegation of Nepal supported the current drafting of Article 5.
- 342. The representative of HEP highlighted the complexities associated with Article 5 and expressed concerns about the protection of TK and TCEs. She emphasized the lack of benefit-sharing and the need to address issues of misappropriation. The current formulation of Article 5 was deemed insufficient in resolving those issues, with some parties appearing to have more influence than others, and imposing conditions that disadvantaged marginalized communities.

- 343. The Chair opened the floor for comments on Article 2.
- 344. The Delegation of the EU, speaking on behalf of the EU and its Member States, believed a definition of "traditional knowledge associated with genetic resources" was needed. Regarding the definition of the country of origin of GRs, it supported the definition. Concerning the definition of the trigger, it endorsed the outcome of the virtual expert group which clarified that the trigger should be "materially and directly based on". This clarification specified that the GR or aTK must have been essential for the claimed invention, relying on the unique properties of the GR and insights derived from the aTK. It supported the current definitions of genetic material, GRs and *in situ* conditions. It suggested the removal of the term "PCT" and its definition, noting that it only appeared in a footnote.
- 345. The Delegation of Switzerland, speaking on behalf of Group B, supported the definition put forth by the virtual expert group for the term "materially and directly based on" in Article 2.
- 346. The Delegation of Ghana, speaking on behalf of the African Group, supported the article in its current drafting. Regarding the definition of TK, it emphasized that it should be left to national interpretation.
- 347. The Delegation of Venezuela (Bolivarian Republic of), speaking on behalf of GRULAC, proposed to replace the definition of "materially/directly based on" with the inclusion of the concept of "utilization" which was defined as "carry out research and development on genetic components and chemical components of GRs, including through the application of technologies". Additionally, it proposed the inclusion of the concept of "derivatives", in accordance with the definition contained in the Nagoya Protocol. It suggested not including a definition of TK.
- 348. The Delegation of Canada supported the amendments suggested by the virtual expert group. Those amendments included replacing "materially/directly based on" with "materially and directly based on", and revising the definition to "Materially and directly based on means that the GR and aTK must have been necessary for and material to be claimed invention". It supported to delete the phrase "the development of", as it clarified that GRs which might have been accessed in the development of the invention but were not material to the final invention needed not be disclosed. That amendment enhanced the efficacy and transparency of the patent system.
- 349. The representative of the Assembly of First Nations, speaking on behalf of the Indigenous Caucus, put forward several suggestions. For the term "source of GRs", he proposed the inclusion of "Indigenous Peoples, local communities" to ensure comprehensive coverage, considering the activities involving GRs often intersected with those groups. Concerning the definition of the source of TK, he suggested including "Indigenous Peoples, local communities, scientific literature, or other publications" after "such as". He explained that TK might be documented in various socio-economic and published works. He suggested removing "publicly accessible" from the term "publicly accessible databases" to account for the potential storage of their knowledge in various databases, enhancing the inclusivity of their interests.
- 350. The Delegation of Nigeria supported the statement made by the Delegation of Ghana, on behalf of the African Group. It noted certain divergences between the definition of "materially and directly based on" as presented by the virtual expert group and the definition provided in Article 2. Acknowledging the existence of those differences, it emphasized the need to reconcile those divergent definitions and find consensus. It supported not to define TK or aTK in the current document, noting the absence of a definitive and working definition. It proposed

to focus on the extensive notes related to this article which provided different definitions, with a specific focus on the language used for "materially", "directly", and the trigger mechanism.

- 351. The Delegation of Iran (Islamic Republic of), speaking on behalf of APG, expressed the support of the majority of the APG Member States for the current formulation of Article 2.
- 352. The Delegation of Ghana emphasized the concerns regarding the introduction of the word "and" between "materially" and "directly" in the phrase "materially/directly based". It suggested the possibility of formulating two separate definitions, one focusing specifically on "materially based on" and the other on "directly based on". It emphasized the importance of maintaining flexibility for Member States.
- 353. The Delegation of Poland, speaking on behalf of the CEBS group, supported the statement made by the Delegation of the EU, on behalf of the EU and its Member States. It highlighted the necessity of including the definition of TK or aTK to ensure a shared understanding of the term. It found the modified definitions proposed by the virtual expert group concerning the "country of origin", "materially/directly based on" and "source of GRs" acceptable. It welcomed all of the other definitions, but suggested deleting the definition of "PCT".
- 354. The Delegation of the United States of America supported the statement made by the Delegation of Switzerland, on behalf of Group B. It proposed two amendments to Article 2. It suggested adopting the term "materially and directly based on" instead of "materially/directly based on", which was in line with the recommendation of the virtual expert group. In line with the recommendation of the virtual expert group, it wished to modify the corresponding definition to replace "necessary or material to" with "necessary for and material to" and also delete the term "the development of". It emphasized the necessity for a precise trigger with a clear causal nexus between the claimed invention and the GRs and aTK, aiming to strike a balance between transparency benefits and transaction costs. That clarity was crucial for ensuring compliance and preventing legal uncertainty that could hinder innovation. The Delegation proposed to delete the definition of "PCT", which followed the related proposal to delete the footnote under Article 8. It did not support the proposal made by the Delegation of India regarding the terms "materially/directly based on", which would broaden the disclosure trigger and thereby dilute the causal connection required between GRs/aTK and the claimed invention. In particular, the trigger proposed by the Delegation of India would cover "research tools, such as experiment animals and plants, yeasts, bacteria, plasmids and virial vectors" which were standard consumables acquired from commercial suppliers, that did not fall under the "claimed invention". In contrast, the Delegation of the United States of America favored a precise trigger with a clear causal nexus between the claimed invention and the GR and aTK. The Delegation respectfully disagreed with the definition for TK associated with GRs proposed by the Delegation of India. Leaving that matter to national interpretation would prevent potential conflicts in achieving consensus, especially considering the lack of a universally recognized definition for TK, even among Indigenous communities. It highlighted concerns raised by certain GRULAC members.
- 355. The Delegation of the United Kingdom supported the language and the trigger mechanism proposed by the virtual expert group. It also supported the statements made by the Delegations of Canada and the United States of America.
- 356. The Delegation of Japan supported the statements made by the Delegations of Canada and the United States of America. It emphasized the importance of not prejudicing the concept of TK itself within the current instrument, considering the ongoing discussions on TK in other IGC sessions. It did not support the definition of TK proposed by the Delegation of India.

- 357. The Delegation of Brazil supported the statement made by the Delegation of Venezuela (Bolivarian Republic of), on behalf of GRULAC. It proposed the use of the term "utilization", highlighting that it was recognized language adopted by significant multilateral agreements referring to TK. The use of that language enhanced comprehension, minimized the possibility of misinterpretation, and ultimately bolstered legal certainty.
- 358. The Delegation of Mexico recommended the removal of the words "materially" and "directly", asserting that they referred to the "use" of GRs and aTK. It further suggested replacing "necessary and essential for the development" with "use", which resulted in a definition as follows: "Based on' means GRs and aTK must have been used or utilized for the development of the invention and the claimed invention must depend on the specific properties of the GRs and/or aTK". The Delegation emphasized the need for specificity in the definition of the source of GRs, indicating that the source could be either *in situ* or *ex situ*. It proposed to include examples such as the country of origin and lands and territories of Indigenous Peoples. Regarding the definition of source of TK, it proposed to add a reference to Indigenous Peoples, and suggested an inclusion at the end "or any other document or other source, including those based on the oral traditions of a people, that may not have been published". It proposed to add a definition for the term "confidential information", referring to TK considered secret or sacred by Indigenous Peoples.
- 359. The Delegation of Uganda supported the statement made by the Delegation of Ghana, on behalf of the African Group, and the subsequent proposals made by the Delegations of Ghana and Nigeria.
- 360. The Delegation of the Cook Islands expressed alignment with the position of APG. It reiterated the significance of safeguarding TK for the benefit of future generations and cultural preservation. Emphasizing its concerns about Article 9, it proposed to include the term "derivative" in Article 2, aiming to address the issue of third parties modifying aTK without acknowledging the source or the relevant Indigenous Peoples and local communities. It suggested utilizing the definition of "derivative" from the Consolidated Document related to Intellectual Property and Genetic Resources, which read as follows: "derivative means a natural occurring by a chemical compound resulting from the genetic expression or metabolism of biological or GRs, regardless of the presence of hereditary functional units".
- 361. The representative of INBRAPI supported the statement made by the representative of the Assembly of First Nations, on behalf of the Indigenous Caucus. Recognizing the *sui generis* nature of the instrument, she emphasized the importance of maintaining consistency with the legal frameworks concerning Indigenous Peoples' rights. She advocated for the definition of TK associated with GRs to be established in consultation with Indigenous Peoples. She echoed the statement made by the Delegation of Mexico to include "lands, territories, and countries of origin of Indigenous Peoples", as they were often the source of significant biodiversity and GRs.
- 362. The Delegation of Australia supported the references to "directly based on", "materially based on", or "materially and directly based on". It emphasized the importance of understanding those terms within the context of the provided definitions, indicating a need for clear content behind the terminology. Regarding the trigger, it supported the current form. Regarding the proposal to introduce a definition of aTK, it did not support the idea and suggested that that matter be addressed through domestic legislation. It supported the proposals put forth by the Indigenous Caucus concerning minor adjustments to the definitions of the source of GRs and the source of aTK.
- 363. The Delegation of India expressed general agreement with the definitions included in Article 2. However, it proposed certain modifications to the trigger requirement. The Delegation suggested removing the word "directly" to avoid any narrow interpretation during the

implementation of disclosure obligations. It emphasized the importance of ensuring a comprehensive interpretation that included cases where GRs had been accessed physically, as well as the utilization of hereditary units. It proposed to clarify the scope by removing the term "necessary" and restricting it to "materially". It also proposed replacing the conjunction "and" with "or" between the two specific criteria mentioned in the definition, aiming for consistency with other international instruments and the objectives of Article 8. Moreover, it proposed the deletion of certain qualifiers such as "must" to allow for additional tests to be imposed while determining the trigger. It argued that the current definition might restrict the trigger requirements and fail to adequately protect GRs and TK within the framework of the patent disclosure regime established by the instrument. Regarding the proposed definition of aTK, the Delegation acknowledged the views of other delegations, but contended that the non-defining of aTK could potentially lead to challenges in the interpretation and implementation of the instrument. It advocated for a broader definition, relying on the work of the IGC. It recommended replacing the term "such as" with "including" in the definition of the source of GRs and TK to ensure the instrument's scope was interpreted inclusively and not restrictively.

- 364. The Delegation of the Russian Federation supported the current wordings of terms outlined in Article 2. However, it emphasized the importance of clarifying the term "materially/directly based on" to ensure enhanced transparency, certainty and predictability in the practical implementation of the provisions of the draft instrument. It noted that the use of the term "materially based on" might present challenges in adapting this term to various languages, as it was primarily associated with tangible matter or physical objects. In light of that, it proposed to use the term "substantially based on" instead of "materially based on". The Delegation emphasized its willingness to adopt a flexible approach in a wording of this term and expressed readiness to engage in constructive dialogue with the aim of reaching consensus.
- 365. The Delegation of Egypt supported the statements made by the Delegation of Ghana, on behalf of the African Group, and the Delegation of Nigeria, regarding the discussion on the terms "materially/directly based on". It wondered about the specific meanings of "materially" and "directly". It emphasized the ambiguity associated with those terms and the challenges in their measurement. It expressed its preference for the term "utilization", which deemed to be more concrete and straightforward in its application.
- 366. The Delegation of Namibia supported the statements made by the Delegation of Ghana on behalf of the African Group, and the Delegation of Nigeria, regarding the use of the terms "materially or directly based on". While acknowledging the clarifications provided by the virtual expert group on those terms, it supported the current form of the text.
- 367. The representative of CAPAJ fully supported the statement made by the Delegation of Mexico, particularly in relation to the protection of secret and sacred types of TK. She emphasized the necessity for the instrument to align with international frameworks that upheld the human rights of Indigenous Peoples.
- 368. The representative of TWN stated that the existing definitions, without amendments, might not fully meet the requirements on the ground. He supported some of the amendments proposed by the Delegation of India.
- 369. The Delegation of the Republic of Korea supported the statements made by the Delegations of the United States of America and Japan. It supported the proposal to change the term "materially/directly" to the term "materially and directly based on". It disagreed with the proposal made by the Delegation of India regarding "materially based on". It suggested deleting the definition of "PCT".

- 370. The Delegation of Switzerland supported the recommendations made by the virtual expert group and several other delegations on the trigger. It respectfully disagreed with the proposal by the Delegation of India regarding the trigger, as well as the suggestions made by other Member States that would erode the link between GRs and aTK and the claimed invention. It supported the proposal made by the Indigenous Caucus regarding the inclusion of "Indigenous Peoples and local communities" after "such as", and it endorsed the same approach for the definition of the source of aTK.
- 371. The Delegation of Peru, along with other Member States from the Andean Community, emphasized the importance of maintaining the link to the country of origin. It proposed to amend the definition of "country of origin" as follows: "the country that possesses GRs *in situ*, including those who had been in that condition". In addition, for clarity, it suggested adding "ex situ conditions" to the definition, referring to conditions where GRs existed and had been *in situ* conditions but were now out of the ecosystems and natural habitats.
- 372. The Delegation of Ecuador supported the statement made by the Delegation of Peru and proposed the following definition: "Indigenous Peoples and local community means the holders of TK associated with GRs, who authorized their access through prior informed consent".
- 373. [Note from the Secretariat: This part of the session took place on the afternoon of September 6, after the presentation of Rev. 1.] The Chair highlighted the importance of the Special Session. With the aim of fostering collaboration, the Chair invited participants to engage in an ad hoc contact group on the following day to refine the text further. The guidelines for the ad hoc contact group were outlined. The Chair then went through the changes to the text as outlined in Rev. 1. Firstly, the acronyms were replaced with their complete forms, such as "genetic resources" for "GRs" and "traditional knowledge associated with genetic resources" for "aTK", and "intellectual property" for "IP". Secondly, in the preamble, a new paragraph was suggested: "Recognizing and reaffirming the rights of Indigenous Peoples and local communities as set forth in the United Nations Declaration on the Rights of Indigenous Peoples". All personal references were eliminated in the notes as the text had evolved from the former Chair's perspective. In Article 2, the chapeau was modified to read as follows: "For the purposes of this instrument". In the definition of "Source of Genetic Resources", a reference to "Indigenous Peoples and local communities" was added. In Article 3 and its notes, "Indigenous Peoples" was capitalized. She then stated that there had been no changes to Article 4 or Article 5. In Article 6 and its notes, a change was made from "adequate dispute mechanisms" to "alternative dispute resolution mechanisms". In the notes to Article 6, a change was also made to read "all parties concerned" instead of "all parties". The Chair then explained the insertion of "Indigenous Peoples and local communities and other" in Article 7. She stated that there had been no changes to Article 8 or Article 9. Lastly, she stated the adjustment of "forums" to "fora" in the notes to Article 9.
- 374. [Note from the Secretariat: this part of the session took place on the afternoon of September 8, 2023, after the *ad hoc* contact group which took place on September 7, 2023, and on the morning of September 8, 2023. Rev. 2 was made available before the session recommenced.] The Chair expressed gratitude to all participants. Reflections on the discussions within the *ad hoc* contact group underscored the comprehensive consideration of views, positions and proposals related to various articles. Resulting from that process, a revised version of document WIPO/GRTKF/IC/SS/TGE/23/2 Rev. 2 had been compiled and shared with Group Coordinators. It contained the changes agreed during the *ad hoc* contact group, along with the changes that had been introduced in Rev. 1. The Chair recalled that it was decided that the notes on each article would be published separately as an information document for the upcoming Diplomatic Conference. The Chair reminded that the notes were prepared by the previous Chairperson, Mr. Ian Goss, in April 2019. She recalled the fact that any change to the text would have to be agreed to by the plenary in order to be transmitted to

the Preparatory Committee. The Chair commented on the comprehensive and meaningful deliberations held both in plenary and the *ad hoc* contact group, highlighting the collective efforts made to advance the text throughout the week. The Chair would present the modifications as included in Rev.2, going article by article. She reminded participants that the floor was not open to revisions or renegotiations.

- 375. Mr. Felipe Cariño, one of the Vice-Chairs and the Chair of the *ad hoc* contact group, expressed his gratitude to the Chair and extended his appreciation to the delegates. He reported on the *ad hoc* contact group, which met on September 7, from 10am to 6pm, and on September 8, from 9:30am to noon. The *ad hoc* contact group benefited from the assistance of the Friend of the Chair who had led the discussions on some articles and provided her technical suggestions. The discussions within the *ad hoc* contact group had been informal, with no recording or webcast. Progress was made on Articles 8, 7, 6, 3 and 2. Participants contributed insightful textual proposals, aligning with the objective of propelling the discussions forward. The principle of consensus was emphasized, ensuring that any proposal put forth had been subject to unanimous agreement. In cases of opposition, the text had reverted to its original form.
- 376. The Chair thanked the Vice-Chair for his valuable contribution during the *ad hoc* contact group. The Chair emphasized that each change in Rev. 2 would be carefully examined and either accepted or rejected based on the consensus reached. In cases where no agreement was reached, the original text from document WIPO/GRTKF/IC/SS/GE/23/2 would be retained. She recalled the presentation of Rev. 1, highlighting the adjustments made to the acronyms in the document. "GRs" and "aTK" were expanded to "genetic resources" and "traditional knowledge associated with genetic resources" respectively. The Chair announced that the changes had been made in the preamble and throughout the text. Furthermore, a specific change was made in the final paragraph of the preamble, "*Recognizing and reaffirming* the rights of Indigenous Peoples and local communities, including as set forth in the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP)". The Chair asked whether there was any objection regarding those modifications.
- 377. The Delegation of the United Kingdom was unable to endorse the language used in regard to the recognition and reaffirmation of the rights of Indigenous Peoples and local communities. The language appeared to imply collective rights, which it could not support. It referred a statement delivered by the Delegation of the United Kingdom at the Sixty-First Session and 107th plenary meeting of the United Nations General Assembly.
- 378. The Chair announced the change to the last paragraph of the preamble was not accepted. She confirmed the replacement of "GRs" with "genetic resources" and replacement of "aTK" with "traditional knowledge associated with genetic resources", to which there were no objections. Those changes were accepted. The Chair addressed the replacement of the acronym "UNDRIP" with "United Nations Declaration on the Rights of Indigenous Peoples", which was accepted without any objection.
- 379. The Delegation of Nigeria requested for clarification on whether there was any reference to "local communities" in the document.
- 380. The Chair acknowledged the presence of a reference to "local communities" in Article 3. She then continued to present the changes, the replacement of "IP" with "Intellectual Property", which encountered no objections and was accepted. For Article 1, there were no changes. In Article 2, the phrase "The terms defined below shall apply to this Instrument unless expressly stated otherwise" had been replaced with "For the purposes of this instrument", which was accepted without any objection. The Chair mentioned the deletion of the definition of "PCT", due to the deletion of the footnote referring to the "PCT".

- 381. The Delegation of Colombia did not support the removal of the definition of "PCT", emphasizing its preference for retaining the footnote to Article 8 related to the PCT.
- 382. The Chair confirmed that the definition of "PCT" in Article 2 and the footnote to Article 8 would be retained. Moving on to Article 3, the Chair mentioned the capitalization of "Indigenous Peoples", which was accepted without any objection. There were no proposed amendments to Articles 4, 5 and 6, and thus they remained unchanged. The Chair then moved on to discuss Article 7. No objections were raised concerning the addition of the phrase "where applicable" in Article 7.1. The new Article 7.2 "Contracting Parties should, with appropriate safeguards developed in consultation, where applicable, with Indigenous Peoples and local communities and other stakeholders, make such information systems accessible to Offices for the purposes of search and examination of patent applications. Such access to the information systems may be subject to authorization, where applicable, by the Contracting Parties establishing the information systems." received no objections. The Chair then noted a minor change in Article 7.3, where an extra full stop had been identified and subsequently deleted. There was no objection on that change. Moving on to Article 8, the Chair acknowledged that the Delegation of Colombia had requested to reinsert the footnote, which would be added accordingly.
- 383. The Delegation of Nigeria sought clarification regarding the reinstatement of the footnote.
- 384. The Delegation of Colombia stated that no consensus had been found regarding the deletion of the footnote as it wished to keep the definition of the PCT and the footnote.
- 385. The Delegation of Venezuela (Bolivarian Republic of), speaking on behalf of GRULAC, supported the statement made by the Delegation of Colombia.
- 386. The Delegation of Peru supported the statements made by the Delegation of Colombia and the Delegation of Venezuela (Bolivarian Republic of), on behalf of GRULAC.
- 387. The Chair stated that Articles 8 and 9 remained unchanged. The Chair confirmed that the agreed changes to the preamble and Articles 1 to 9 would be transmitted to the Preparatory Committee.
- 388. The Chair opened the floor for comments regarding publishing the notes of each article as an information document for the Diplomatic Conference.
- 389. The Delegation of Ghana, speaking on behalf of the African Group, proposed that the Chair's Text be published separately from Rev. 2.
- 390. [Note from the Secretariat: this part of the session took place after an informal consultation.] The Delegation of Switzerland, speaking on behalf of Group B, suggested referring to document WIPO/GRTKF/IC/43/5, corresponding to the Chair's Text as prepared by the former Chair, Mr. Ian Goss. Furthermore, it proposed the addition of an additional sentence on the cover page of the information document: "These notes were prepared by Mr. Ian Goss, in April 2019, when he was the Chair of the IGC." That inclusion would accurately reflect the mutual understanding reached between Group B and the African Group.

Decisions on Agenda Item 4:

391. The Committee reviewed and revised the text of the Preamble and Articles 1 to 9 of document

WIPO/GRTKF/IC/SS/GE/23/2. The agreed revisions are reflected in the text annexed to this document. The Committee decided that this text. as annexed to this document, be transmitted to the Preparatory Committee of the Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources as the substantive articles of the Basic Proposal for the Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources.

392. The Committee agreed that the notes on each article, as contained in document WIPO/GRTKF/IC/43/5, be published separately as an information document for the Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources. These notes were prepared by Mr. Ian Goss in April 2019, when he was the Chair of the IGC.

393. The Committee took note of and held discussions on documents WIPO/GRTKF/IC/SS/GE/23/3. WIPO/GRTKF/IC/SS/GE/23/INF/2, WIPO/GRTKF/IC/SS/GE/23/INF/4, WIPO/GRTKF/IC/SS/GE/23/INF/5 and WIPO/GRTKF/IC/SS/GE/23/INF/6.

AGENDA ITHEM 5: ADOPTION OF A REPORT TO THE PREPARATORY COMMITTEE OF DIPLOMATIC CONFERENCE TO CONCLUDE AN INTERNAATIONAL LEGAL INSTRUMENT RELATING TO INTELLECTUAL PROPERTY, GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

Decision on Agenda Item 5:

394. The Committee adopted its decisions on agenda items 2, 3 and 4 on September 8, 2023, and agreed that these decisions be transmitted to the Preparatory Committee of the

Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources.

AGENDA ITEM 6: ANY OTHER BUSINESS

Decision on Agenda Item 6:

395. There was no discussion under this item.

AGENDA ITEM 7: CLOSING OF THE SESSION

- 396. The Chair thanked the three Vice-Chairs, Mr. Yonah Seleti, Mr. Felipe Cariño and Mr. Jukka Liedes for their valuable contributions throughout the session. She thanked the Friend of the Chair, Ms. Margo Bagley, for her dedicated assistance, especially during the ad hoc contact group. The Chair expressed her sincere appreciation to the Secretariat for their support. The Chair specifically acknowledged the Group Coordinators for their critical role in keeping the discussions on track and ensuring effective communication between her and Member States. She emphasized the importance of collaborative efforts and urged Member States to work collaboratively toward a successful Diplomatic Conference. She underscored the significant contributions of the Indigenous Caucus to the discussions, emphasizing the importance of contributions to the Voluntary Fund. She also acknowledged the vital role of industry representatives and civil society. The Chair thanked all Member States for their crucial role in the success of the IGC Special Session. She praised the constructive atmosphere of the meeting and expressed hope for its continuation towards the Diplomatic Conference. The Chair opened the floor for any closing statements.
- 397. The Delegation of Venezuela (Bolivarian Republic of), speaking on behalf of the GRULAC, recognized the productive nature of the week in reconciling different regional positions and addressing the existing gaps. It acknowledged the global challenges, emphasized the triple planetary crisis posed by pollution, climate change and biodiversity loss, and underlined the critical role of an international instrument on IP, GRs, and TK in combating those threats and preserving the GRs and aTK of Indigenous Peoples and local communities. It expressed appreciation for the Chair, the Vice-Chairs, the representatives of Indigenous Peoples and local communities, experts and the Secretariat. It emphasized their continued commitment to the process and the shared goal of achieving ambitious outcomes through constructive dialogue. It expressed pleasure in their ongoing collaboration with the other Group Coordinators.
- 398. The Delegation of Ghana, speaking on behalf of the African Group, thanked the Chair and Vice-Chairs for their leadership during the Special Session. It extended thanks to the Secretariat for their diligent work in documenting proposals and amendments throughout the *ad hoc* contact group discussions and in preparing Rev. 1 and Rev. 2. It remained committed to negotiating the articles at the Diplomatic Conference
- 399. The Delegation of Iran (Islamic Republic of), speaking on behalf of APG, expressed its gratitude to the Chair and Vice-Chairs, especially Mr. Felipe Cariño, and the Secretariat for their dedicated support and leadership during the session. Recognizing the considerable effort and collaborative spirit demonstrated in bridging differences and striving for a comprehensive legal instrument, APG expressed optimism for continued progress during the upcoming Diplomatic Conference.
- 400. The Delegation of Switzerland, speaking on behalf of Group B, expressed gratitude to the Chair, Vice-Chairs, the Friend of the Chair and the Secretariat and all participants for their dedicated efforts throughout the session. Emphasizing the significance of collaboration, the Delegation conveyed its appreciation to their fellow Group Coordinators for their productive collaboration. It concluded the statement by thanking all delegations and expressing its anticipation for continued collaboration at the upcoming Diplomatic Conference.
- 401. The Delegation of Poland, speaking on behalf of the CEBS Group, expressed appreciation for the Chair's leadership and management in guiding the Special Session. It also extended its gratitude to the Vice-Chairs, Friend of the Chair, and experts for their dedication and efforts in advancing the IGC's work. It further conveyed its thanks to the Secretariat for their contributions to ensuring an excellent working environment. It expressed heartfelt

appreciation for the Group Coordinators and all WIPO members, highlighting the friendly atmosphere and cooperation observed throughout the week. Acknowledging the valuable contributions of Indigenous Peoples and local communities, the Delegation emphasized the importance of reaching a consensus during the ongoing discussions for the international legal instrument. It recognized the progress made during the negotiations and stressed the need for compromise as a fundamental concept for achieving success at the Diplomatic Conference. In conclusion, the Delegation extended gratitude to all participants and pledged its commitment to constructive engagement and guidance during the Diplomatic Conference.

- 402. The Delegation of China expressed appreciation for the progress made during the week and emphasized the importance of approaching the upcoming stages with a serious and dedicated attitude. It acknowledged the agreements made on various aspects, although some aspects were yet to be fully reflected. The Delegation conveyed its commitment to the process and their willingness to contribute to the negotiations. It reiterated its earlier call for all parties to demonstrate flexibility, bridge differences, and consider the circumstances of all countries while addressing their own concerns. It also stressed the importance of taking into account the legitimate concerns of developing countries and pursuing balanced and practical solutions for issues related to GRs and TK. In conclusion, the Delegation extended its gratitude to the Chair, Vice-Chairs, Friend of the Chair, the Secretariat and all the delegates for their hard work. It hoped that the constructive spirit during the meeting would continue into the upcoming Diplomatic Conference and future sessions of the IGC.
- 403. The representative of INBRAPI, speaking on behalf of the Indigenous Caucus, underscored the significance of safeguarding GRs and aTK. She emphasized the active role of the Caucus in the process, reiterating their collective rights recognized by UNDRIP, specifically in Articles 31 and 41. Highlighting the integral connection between their TK, GRs, identities and cultures, she emphasized the importance of protecting those resources from misappropriation, especially through the erroneous granting of patents. She called for an improved IP system that respected international human rights and that promoted ethical use with mutual respect for the interests of all parties. She stressed the need for economic redress and fair benefit-sharing practices that upheld justice and equity for Indigenous Peoples. Expressing disappointment at the lack of progress made during the Special Session, she acknowledged the delegations that had supported the inclusion of language related to UNDRIP in the text. She expressed gratitude to WIPO, and the Governments of Mexico. Germany and Australia that had contributed to the Voluntary Fund, which would allow the attendance of indigenous representatives at the upcoming Diplomatic Conference. Furthermore, she emphasized the necessity of the full and effective participation of Indigenous Peoples at the Diplomatic Conference, without which its legitimacy would be called into question. She thanked the Chair, Vice-Chairs, and Secretariat for their contributions and support throughout the session.

404. The Chair closed the session.

Decision on Agenda Item 7:

405. The Committee closed the session on September 8, 2023.

[Annexes follow]

ANNEX I

LISTE DES PARTICIPANTS/LIST OF PARTIPANTS

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[Annex II follows]

ANNEX II

DRAFT

INTERNATIONAL LEGAL INSTRUMENT RELATING TO INTELLECTUAL PROPERTY, GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

September 8, 2023

The Parties to this instrument,

Desiring the promotion of the efficacy, transparency and quality of the patent system in relation to genetic resources and traditional knowledge associated with genetic resources,

Emphasizing the importance of patent offices having access to appropriate information on genetic resources and traditional knowledge associated with genetic resources to prevent patents from being granted erroneously for inventions that are not novel or inventive with regard to genetic resources and traditional knowledge associated with genetic resources,

Recognizing the potential role of the patent system in contributing to the protection of genetic resources and traditional knowledge associated with genetic resources.

Recognizing that an international disclosure requirement related to genetic resources and traditional knowledge associated with genetic resources in patent applications contributes to legal certainty and consistency and, therefore, has benefits for the patent system and for providers and users of such resources and knowledge,

Recognizing that this instrument and other international instruments related to genetic resources and traditional knowledge associated with genetic resources should be mutually supportive,

Recognizing and reaffirming the role that the intellectual property system plays in promoting innovation, transfer and dissemination of knowledge and economic development, to the mutual advantage of providers and users of genetic resources and traditional knowledge associated with genetic resources,

Acknowledging the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP),

Have agreed as follows:

ARTICLE 1 OBJECTIVES

The objectives of this instrument are to:

- (a) enhance the efficacy, transparency and quality of the patent system with regard to genetic resources and traditional knowledge associated with genetic resources, and
- (b) prevent patents from being granted erroneously for inventions that are not novel or inventive with regard to genetic resources and traditional knowledge associated with genetic resources.

ARTICLE 2 LIST OF TERMS

For the purposes of this instrument:

"Applicant" means the person whom the records of the Office show, pursuant to the applicable law, as the person who is applying for the granting of a patent, or as another person who is filing or prosecuting the application.

"Application" means an application for granting of a patent.

"Contracting Party" means any State or intergovernmental organization party to this instrument.

"Country of origin of genetic resources" means the country which possesses those genetic resources in in situ conditions.

"[Materially/Directly] based on" means that the genetic resources and/or traditional knowledge associated with genetic resources must have been necessary or material to the development of the claimed invention, and that the claimed invention must depend on the specific properties of the genetic resources and/or traditional knowledge associated with genetic resources.

"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

"Genetic resources1" are genetic material of actual or potential value.

"In situ conditions" means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"Office" means the authority of a Contracting Party entrusted with the granting of patents.

"PCT" refers to the Patent Cooperation Treaty, 1970.

"Source of Genetic Resources" refers to any source from which the applicant has obtained the genetic resources, such as a research centre, gene bank, Indigenous Peoples and local communities, the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), or any other *ex situ* collection or depository of genetic resources.

"Source of Traditional Knowledge Associated with Genetic Resources" means any source from which the applicant has obtained the traditional knowledge associated with genetic resources, such as scientific literature, publicly accessible databases, patent applications and patent publications.

¹ The definition of "genetic resources" is, in line with the manner in which the term is understood in the context of the CBD, not intended to include "human genetic resources".

ARTICLE 3 DISCLOSURE REQUIREMENT

- 3.1 Where the claimed invention in a patent application is [materially/directly] based on genetic resources, each Contracting Party shall require applicants to disclose:
 - (a) the country of origin of the genetic resources, or,
 - (b) in cases where the information in sub paragraph (a) is not known to the applicant, or where sub paragraph (a) does not apply, the source of the genetic resources.
- 3.2 Where the claimed invention in a patent application is [materially/directly] based on traditional knowledge associated with genetic resources, each Contracting Party shall require applicants to disclose:
 - (a) the Indigenous Peoples or local community that provided the traditional knowledge associated with genetic resources, or,
 - (b) in cases where the information in sub paragraph (a) is not known to the applicant, or where sub paragraph (a) does not apply, the source of the traditional knowledge associated with genetic resources.
- 3.3 In cases where none of the information in paragraphs 3.1 and/or 3.2 is known to the applicant, each Contracting Party shall require the applicant to make a declaration to that effect.
- 3.4 Offices shall provide guidance to patent applicants on how to meet the disclosure requirement as well as an opportunity for patent applicants to rectify a failure to include the minimum information referred to in paragraphs 3.1 and 3.2 or correct any disclosures that are erroneous or incorrect.
- 3.5 Contracting Parties shall not place an obligation on Offices to verify the authenticity of the disclosure.
- 3.6 Each Contracting Party shall make the information disclosed available in accordance with patent procedures, without prejudice to the protection of confidential information.

ARTICLE 4 EXCEPTIONS AND LIMITATIONS

In complying with the obligation set forth in Article 3, Contracting Parties may, in special cases, adopt justifiable exceptions and limitations necessary to protect the public interest, provided such justifiable exceptions and limitations do not unduly prejudice the implementation of this instrument or mutual supportiveness with other instruments.

ARTICLE 5 NON-RETROACTIVITY

Contracting Parties shall not impose the obligations of this instrument in relation to patent applications which have been filed prior to that Contracting Party's ratification of or accession to this instrument, subject to national laws that existed prior to such ratification or accession.

ARTICLE 6 SANCTIONS AND REMEDIES

- 6.1 Each Contracting Party shall put in place appropriate, effective and proportionate legal, administrative, and/or policy measures to address an applicant's failure to provide the information required in Article 3 of this instrument.
- 6.2 Each Contracting Party shall provide an applicant an opportunity to rectify a failure to include the minimum information detailed in Article 3 before implementing sanctions or directing remedies.
- 6.3 Subject to Article 6.4, no Contracting Party shall revoke or render unenforceable a patent solely on the basis of an applicant's failure to disclose the information specified in Article 3 of this instrument.
- 6.4 Each Contracting Party may provide for post grant sanctions or remedies where there has been fraudulent intent in regard to the disclosure requirement in Article 3 of this instrument, in accordance with its national law.
- 6.5 Without prejudice to non-compliance as a result of a fraudulent intention as addressed under Article 6.4, Contracting Parties shall put in place adequate dispute mechanisms that allow all parties concerned to reach timely and mutually satisfactory solutions, in accordance with national law.

ARTICLE 7 INFORMATION SYSTEMS

- 7.1 Contracting Parties may establish information systems (such as databases) of genetic resources and traditional knowledge associated with genetic resources, in consultation, where applicable, with Indigenous Peoples and local communities and other stakeholders, taking into account their national circumstances.
- 7.2 Contracting Parties should, with appropriate safeguards developed in consultation, where applicable, with Indigenous Peoples and local communities and other stakeholders, make such information systems accessible to Offices for the purposes of search and examination of patent applications. Such access to the information systems may be subject to authorization, where applicable, by the Contracting Parties establishing the information systems.
- 7.3 In regard to such information systems, the Assembly of the Contracting Parties may establish one or more technical working groups to:
 - (a) Develop minimum interoperability standards and structures of information systems content;
 - (b) Develop guidelines relating to safeguards;
 - (c) Develop principles and modalities related to the sharing of relevant information related to genetic resources and traditional knowledge associated with genetic resources, especially periodicals, digital libraries and databases of information related to genetic resources and traditional knowledge associated with genetic resources, and how WIPO Members should cooperate in the sharing of such information;
 - (d) Make recommendations as to the possible establishment of an online portal to be hosted by the International Bureau of WIPO through which Offices would be able to directly access and retrieve data from such national and regional information systems, subject to appropriate safeguards; and,
 - (e) Address any other related issue.

ARTICLE 8 RELATIONSHIP WITH OTHER INTERNATIONAL AGREEMENTS

This instrument shall be implemented in a mutually supportive manner with other international agreements relevant to this instrument.²

² Agreed Statement to Article 8: The Contracting Parties request the Assembly of the International Patent Cooperation Union to consider the need for amendments to the Regulations under the PCT and/or the Administrative Instructions thereunder with a view towards providing an opportunity for applicants who file an international application under the PCT designating a PCT Contracting State which, under its applicable national law, requires the disclosure of GRs and Associated TK, to comply with any formality requirements related to such disclosure requirement either upon filing of the international application, with effect for all such Contracting States, or subsequently, upon entry into the national phase before an Office of any such Contracting State.

ARTICLE 9 REVIEW

The Contracting Parties commit to a review of the scope and contents of this instrument, addressing issues such as the possible extension of the disclosure requirement in Article 3 to other areas of intellectual property and to derivatives and addressing other issues arising from new and emerging technologies that are relevant for the application of this instrument, no later than four years after the entry into force of this instrument.

[End of Annex II and the document]