

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

**Thirty-Fifth Session
Geneva, March 19 to 23, 2018**

INITIAL DRAFT REPORT

Document prepared by the Secretariat

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 Thirty-Fifth Session (“IGC 35”) in Geneva, from March 19 to 23, 2018.
2. The following States were represented: Albania, Algeria, Argentina, Australia, Austria, Azerbaijan, Barbados, Benin, Bhutan, Bolivia (Plurinational State of), Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Côte d’Ivoire, Croatia, Czech Republic, Denmark, Democratic People’s Republic of Korea, Djibouti, Ecuador, Egypt, El Salvador, Ethiopia, Finland, France, Gabon, Germany, Ghana, Greece, Guatemala, Holy See, Honduras, India, Indonesia, Iran (Islamic Republic of), Iraq, Ireland, Italy, Japan, Jordan, Kazakhstan, Kuwait, Latvia, Lebanon, Lithuania, Malaysia, Malawi, Mexico, Morocco, Montenegro, Mozambique, Myanmar, Nicaragua, Niger, Nigeria, Oman, Panama, Paraguay, Philippines, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Saudi Arabia, Senegal, Seychelles, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Tajikistan, Thailand, Tunisia, Turkey, Tuvalu, Uganda, Ukraine, United Arab Emirates, United States of America, Uruguay, Venezuela (Bolivarian Republic of), Viet Nam, Yemen and Zimbabwe (90). The European Union (“the EU”) and its Member States were also represented as a member of the Committee.
3. The following intergovernmental organizations (“IGOs”) took part as observers: African Regional Intellectual Property Organization (ARIPO); African Union (AU); Food and Agriculture Organization of the United Nations (FAO); Organization of Islamic Cooperation (OIC); Patent Office of the Cooperation Council for the Arab States of the Gulf (GCC Patent Office); and South Centre (SC) (6).
4. Representatives of the following non-governmental organizations (“NGOs”) took part as observers: Assembly of Armenians of Western Armenia; Association of Kunas United for Mother Earth (KUNA); Center for Multidisciplinary Studies Aymara (CEM-Aymara); *Centro de Culturas Indígenas del Perú* (CHIRAPAQ); Civil Society Coalition (CSC); *Comisión Jurídica para el Autodesarrollo de los Pueblos Originarios Andinos* (CAPAJ); CropLife International (CROPLIFE); Culture of Afro-indigenous Solidarity (Afro-Indigène); Engabu Za Tooro (Tooro Youth Platform for Action); European Law Students’ Association (ELSA International); Foundation for Aboriginal and Islander Research Action (FAIRA); France Freedoms - Danielle Mitterrand Foundation; Health and Environment Program (HEP); Indian Council of South America (CISA); Indian Movement - Tupaj Amaru; Indigenous Peoples’ Center for Documentation, Research and Information (DoCip); International Federation of Intellectual Property Attorneys (FICPI); International Federation of Pharmaceutical Manufacturers Associations (IFPMA); International Law Association (ILA); Knowledge Ecology International, Inc. (KEI); Mbororo Social Cultural Development Association (MBOSCUDA); Native American Rights Fund (NARF); Tebtebba Foundation - Indigenous Peoples’ International Centre for Policy Research and Education; Third World Network Berhad (TWN); Tulalip Tribes of Washington Governmental Affairs Department; and University of Lausanne (26).
5. The list of participants is annexed to this report.
6. Document WIPO/GRTKF/IC/35/INF/2 Rev. provided an overview of the documents distributed for IGC 35.
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 IGC 35.

AGENDA ITEM 1: OPENING OF THE SESSION

9. The Director General, Mr. Francis Gurry, welcomed all participants to IGC 35, which was the first session under the 2018-2019 biennium. He recalled the IGC's mandate which was approved at the General Assembly ("GA") in October 2017. Six IGC sessions were to take place during the biennium, including two on genetic resources ("GRs") in 2018, two on traditional knowledge ("TK")/traditional cultural expressions ("TCEs") in 2018, and two on TK/TCEs in 2019. IGC 35 was the first session specifically devoted to GRs since June 2016. Document WIPO/GRTKF/IC/35/4 reflected the revised text on GRs. The new mandate of the IGC requested the Secretariat to "produce a report(s) compiling and updating studies, proposals and other materials relating to tools and activities on databases and on existing disclosure regimes relating to GR and associated TK, with a view to identify any gaps." Such reports had been produced as documents WIPO/GRTKF/IC/35/5 and WIPO/GRTKF/IC/35/6. Other working documents for this session were the re-submissions of the "Joint Recommendation on Genetic Resources and Associated Traditional Knowledge" (WIPO/GRTKF/IC/35/7), submitted by the Delegations of Canada, Japan, Norway, the Republic of Korea and the United States of America ("USA"); the "Joint Recommendation on the Use of Databases for the Defensive Protection of Genetic Resources and Traditional Knowledge Associated with Genetic Resources" (WIPO/GRTKF/IC/35/8), submitted by the Delegations of Canada, Japan, the Republic of Korea and the USA; and the "Proposal for the Terms of Reference for the Study by the WIPO Secretariat on Measures Related to the Avoidance of the Erroneous Grant of Patents and Compliance with Existing Access and Benefit-sharing Systems" (WIPO/GRTKF/IC/35/9), submitted by the Delegations of Canada, Japan, Norway, the Republic of Korea, the Russian Federation and the USA. He acknowledged the contribution of indigenous people and local community ("IPLC") experts to the IGC process. He acknowledged the contribution of the Government of Australia to the WIPO Voluntary Fund, which had enabled the funding of representatives of IPLCs at IGC 34 and IGC 35. He reminded delegations of the importance of that mechanism and the importance of ensuring the representation of IPLCs in the IGC discussions. The theme for the indigenous panel at IGC 36 was "Proposed Patent Disclosure Requirements related to Genetic Resources – Indigenous Peoples' and Local Communities' Perspectives", and he welcomed the three speakers who would share their experiences and views. He hoped that the IGC might be able to find the necessary compromises to enable WIPO to find solutions to the outstanding questions before the IGC.

AGENDA ITEM 2: ELECTION OF OFFICERS

Decision on Agenda Item 2:

10. *Upon the proposal of the Delegation of Switzerland, on behalf of Group B, seconded by the Delegation of Indonesia, on behalf of the Asia-Pacific Group, and the Delegation of Ecuador, on behalf of the Group of Latin American and Caribbean Countries (GRULAC), the Committee elected as its Chair, Mr. Ian Goss of Australia, unanimously and by acclamation, for the 2018-2019 biennium. As Vice-Chairs for the same period, upon the proposal of the Delegation of Switzerland, on behalf of Group B, seconded by the Delegation of Indonesia, on behalf of the Asia-Pacific Group, and the Delegation*

of Ecuador, on behalf of GRULAC, the Committee elected Mr. Jukka Liedes of Finland, and upon the proposal of Indonesia, on behalf of the Asia-Pacific Group, seconded by the Delegation of Switzerland, on behalf of Group B, and the Delegation of Ecuador, on behalf of GRULAC, the Committee elected Mr. Faizal Chery Sidharta of Indonesia.

11. [Note from the Secretariat: The Chair, Mr. Ian Goss, was chairing the session from this point]. The Chair thanked all participants for their continued support and he hoped that he could honor that trust. He looked to all participants for their guidance as the work progressed, recognizing that the advancement of the IGC's work was very much in their hands. He, together with the Vice-Chairs, Mr. Jukka Liedes and Mr. Faizal Chery Sidharta, could guide the participants, but ultimately they would need to work together to find outcomes that balanced the interests of all Member States and stakeholders, including IPLCs, industry representatives, and civil society. That would require participants to look outside their traditional positions and be prepared to consider those positions and the policy interests that underpinned them. In particular, he asked participants to reach out to each other in an attempt to gain a shared understanding of those different positions. He looked forward to working as a team with the two Vice-Chairs, who would be actively involved in managing all meetings. He thanked Ambassador Michael Tene for his work as the Vice-Chair over the past years as he had significantly contributed to the IGC's work. He thanked the Regional Coordinators for their support and constructive guidance ahead of the session. They would help build a constructive working atmosphere. He would be happy to meet with members and groups at any time on issues or concerns, particularly in relation to the process. He recalled that the session was on live webcast on the WIPO website, which further improved its openness and inclusiveness. All participants were required to comply with the WIPO General Rules of Procedure. The meeting was to be conducted in a spirit of constructive debate and discussion, in which all participants were expected to take part with due respect for the order, fairness, and decorum that governed the meeting. As the Chair, he reserved the right, where applicable, to call to order any participant who might fail to observe the WIPO General Rules of Procedure and the usual rules of good conduct or any participant whose statements were not relevant to the issue at hand. IGC 35 was a five-day session. He intended to use all of the time allocated as fully as possible. Under Agenda Item 3, opening statements of up to three minutes would be allowed by each Regional Group, the EU, the Like-Minded Countries ("the LMCs") and the Indigenous Caucus. Any other opening statements could be handed to the Secretariat in writing or sent by email and would be reflected in the report. Member States and observers were strongly encouraged to interact with each other informally, as that increased the chances that Member States would be aware of and perhaps support observers' proposals. He acknowledged the importance and value of indigenous representatives, as well as other key stakeholders, such as representatives of industry and civil society. The IGC should reach an agreed decision on each agenda item as it went along. On Friday, March 23, the decisions as already agreed would be circulated or read out again for formal confirmation by the IGC. The report of the session would be prepared after the session and circulated to all delegations for comments. It would be presented in all six languages for adoption at IGC 36. He thanked the WIPO Secretariat for its guidance, particularly in ensuring that meetings were efficiently managed and focused on substance rather than process. He recalled the mandate and focus of IGC 35. In support of Agenda Item 7, he had issued a Chair's Information Note, which summarized, from his perspective, some key issues on IP and GRs. The views in that Note were his alone and without prejudice to any Member States' positions. It was simply prepared for reflection only. It had no status, nor was it a working document for the session.

AGENDA ITEM 3: ADOPTION OF THE AGENDA

Decision on Agenda Item 3:

12. *The Chair submitted the draft agenda circulated as WIPO/GRTKF/IC/35/1 Prov. 2 for adoption and it was adopted.*

13. The Chair opened the floor for opening statements. [Note from the Secretariat: Many delegations which 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, as well as for the preparation of the documents.]

14. The Delegation of Indonesia, speaking on behalf of the Asia-Pacific Group, believed that the Chair's guidance would result in a progressive and successful session. It supported the working methodology and the work program proposed by the Chair. It took note and welcomed the reports produced by the Secretariat, compiling materials and studies on databases and disclosure regimes relating to GRs and associated TK. The Group was pleased that the mandate of the IGC had been renewed and looked forward to addressing unresolved issues and considering options in the draft texts. It was hopeful that the IGC would continue to expedite its work, with the objective of reaching an agreement on an international legal instrument(s), without prejudging the nature of outcome(s), relating to IP which will ensure the balanced and effective protection of GRs, TK and TCEs, as outlined in the mandate for this biennium. It favored the discussion on the core issues including objectives, subject matter, disclosure requirements, as well as defensive measures in order to narrow existing gaps and reach a common understanding on the core issues. While some members of the Group held different views, most of the members strongly believed that legally binding instrument(s) for protecting GRs, TK and TCEs could alone result in a balance between the interests of users and providers of GRs and TK. For those members of the Group, the conclusion of a legally binding treaty or treaties would provide a transparent and predictable regime necessary for the effective protection against misappropriation of GRs, TK and TCEs, thus ensuring their sustainable and legitimate use in the future. Therefore, most of the members of the Group were of the view that the misappropriation of GRs and associated TK could be adequately addressed through the establishment of a mechanism for appropriate benefit sharing from the utilization or exploitation of those resources based on prior informed consent ("PIC") and mutually agreed terms ("MAT"). While some members believed otherwise, most members of the Group strongly believed that it was imperative for the IGC to explore ways in which an effective mandatory disclosure requirement in accordance with national circumstances, which would protect GRs, their derivatives and associated TK against misappropriation, could be established. It wished to discuss the establishment of a database and other information systems in order to prevent the granting of erroneous patents in a constructive way. Most members of the Group believed that such mechanisms should be complementary to the disclosure requirement. It wished to reach a common understanding in providing an effective and balanced protection of GRs, including the rights of traditional and local communities that would still preserve legal certainty and predictability. It assured of its full support and cooperation in rendering IGC 35 a success. The Group remained committed to engaging constructively in negotiating a mutually acceptable outcome. It encouraged all Member States and stakeholders to demonstrate flexibility, while remaining steadfast to the core objectives of an international minimum standards legal instrument that would enhance transparency, efficacy and legal certainty in mechanisms for ensuring rightful access to GRs.

15. The Delegation of Kazakhstan, speaking on behalf of the Central Asia, Caucasus and Eastern European Countries Group ("CACEEC"), was confident that under the Chair's

leadership and professional approach the work of the IGC would be productive and ultimately guide members to beneficial results. It recognized the important task of the IGC to define a link between GRs and the IP/patent system with the view to improving the implementation of the latter. It had high expectations and firmly believed that under the Chair's skillful guidance Member States would be able to find a landing zone on core issues. It stood ready to undertake negotiations on GRs with a focus on unresolved issues. The Group remained engaged and would contribute in a constructive manner for a successful completion of the work of IGC 35.

16. The Delegation of Morocco, speaking on behalf of the African Group, was convinced that the efficient and effective protection of GRs, TK and TCEs could be achieved by the establishment of an international legally binding instrument. It reaffirmed its support for the process of deliberation in the IGC. It called for the consolidation of gains already made with a view to establishing such an instrument, which would reinforce the transparency and efficiency of the system and would protect the three thematic areas of the negotiations in the IGC within the modern IP framework. Accordingly, the IGC should make a decision toward the end of the 2018-2019 biennium to conclude the work that had taken place over the past 18 years and convene a diplomatic conference. The consolidated text on GRs had reached a sufficiently advanced stage to allow the IGC to make significant progress on the outstanding issues. The persistent divergences could be resolved by a show of good faith and a context of constructive participation. The main aim of the text on GRs was, undoubtedly, to guarantee the prevention of the misappropriation of GRs and associated TK. That confirmed the importance of the disclosure requirement, which the Group had always supported and which would allow the country of origin of GRs and the source of TK used in patents to obtain an equitable share of the benefits arising from their utilization. It remained committed to the principles of the new mandate. The creation of one or more expert groups should speed up the work of the IGC in accordance with the terms of the mandate and taking into consideration the above-mentioned concerns. Any draft study or recommendation that attempted to prejudice the outcome at that stage in the negotiations went against the terms and design of the current mandate. The IGC needed to concentrate on the revised version of the Consolidated Document (Document WIPO/GRTKF/IC/35/4). A constructive approach was essential in order to benefit from the diversity of the various proposals in a spirit of complementarity. The Group reaffirmed its trust in the Chair, the Vice-Chairs and the facilitators. It would do its utmost to make the IGC's work a success.

17. The Delegation of Ecuador, speaking on behalf of the Group of Latin American and Caribbean Countries ("GRULAC"), said that discussions at WIPO on the protection of GRs, TK and TCEs had been ongoing since 2000, with text-based negotiations dating back to 2009. Conscious of the vital importance of the issues addressed in the IGC and recognizing the progress made, the 2017 WIPO GA had decided to renew the mandate of the IGC for the 2018-2019 biennium. The new mandate enabled the IGC to address unresolved issues and move towards an agreement on one or more international legal instruments that ensured the effective and balanced protection of GRs, TK and TCEs. Discussions would build on the work already done by the IGC, focusing primarily on reducing the current imbalances and agreeing on a common position on key issues. It was essential to continue text-based negotiations, concentrating on document WIPO/GRTKF/IC/35/4 and making effective use of the time allocated for the IGC. There had to be significant efforts to ensure that progress be made at the end of each meeting. At IGC 35 and IGC 36, discussions would focus on GRs. An international legal instrument to protect GRs should balance the interests of users and providers of resources and knowledge. It would provide a transparent and predictable regime for effective protection against misappropriation of GRs, contributing to their sustainable use. It would also be aligned with the UN Sustainable Development Goals ("SDGs"), especially Goal 15, which called on the international community to take action to reduce biodiversity loss. The finalization of an international instrument would encourage research and innovation by providing a uniform legal framework for IP to parties interested in the utilization of GRs, while also contributing to the fair and equitable sharing of the benefits arising out of their utilization. The development of

measures such as disclosure of country of origin to help combat misappropriation of GRs and associated TK was central to the negotiations and was of great interest to GRULAC, given the mega-diversity, high degree of endemism and multiculturalism of the countries of the region. The negotiations had to also take into account the need to facilitate complementarity between IP rules and international agreements related to GRs, in particular the Convention on Biological Diversity (“the CBD”). GRULAC appreciated the organization of the indigenous panel. It was grateful to the Secretariat for preparing the reports contained in documents WIPO/GRTKF/IC/35/5 and WIPO/GRTKF/IC/35/6, which contributed to a better understanding of the key issues under discussion. The IGC, in fulfilling its mandate, might consider additional studies or activities. However, they should not delay progress or set preconditions for negotiations. It recognized the role that databases could play in the search and examination of patent applications. Those databases should be seen as complementary to the disclosure requirement, taking into account the challenges of consolidating all data related to GRs and associated TK into one database. It placed its trust in the working methodology proposed by the Chair as a roadmap for fulfilling the mandate that governed the IGC’s work. It urged all Member States to use the time to engage in constructive discussions and to work together in an atmosphere conducive to progress towards the goal of reaching an agreement on an effective legal instrument on GRs. The Chair could rely on the commitment of GRULAC to move the discussions forward during the session.

18. The Delegation of China believed that the session would achieve positive results under the leadership of the Chair and with the joint efforts of all parties. It had consistently supported the work of the IGC and looked forward to the conclusion of binding instrument(s) as substantive outcomes in the protection of GRs, TK and TCEs. It called on all parties to work together to focus on key issues and to narrow gaps with a view to concluding the relevant international instrument(s) as soon as possible so that the protection of the subject matters mentioned above could be substantiated. There were still a number of issues on GRs to be explored. The Delegation would continue to participate in the discussions with a positive attitude.

19. The Delegation of Lithuania, speaking on behalf of the Central European and Baltic States Group (“CEBS”), reconfirmed its commitment to working constructively at IGC 35 and IGC 36 with a view to achieving a balanced and effective protection of GRs. However, there was still a need to reach a common understanding on core issues in order to progress in the text-based negotiations. An evidence-based approach would facilitate narrowing the gaps. The 2017 WIPO study “Key Questions on Patent Disclosure Requirements for Genetic Recourses and Traditional Knowledge” was a very useful source of information. It looked forward to the Indigenous Panel. It highly appreciated the valuable input of IPLCs to the IGC discussions. It reassured of its constructive engagement in the IGC’s work that would lead towards a positive and realistic outcome.

20. The Delegation of Switzerland, speaking on behalf of Group B, was confident that the IGC would be able to make progress under the Chair’s leadership. As noted in the new mandate for 2018-2019, it acknowledged the progress made by the IGC on IP and GRs, TK and TCEs. More work needed to be done by the IGC to narrow existing gaps to reach a common understanding on core issues. The protection relating to those subjects should be designed in a manner that both supported innovation and creativity and recognized the unique nature and importance of those subjects. It recalled the new mandate and the work program for the 2018/2019 biennium. It hoped that Member States would be able to make meaningful advances, guided by sound working methods and an evidence-based approach. The reports compiling materials on databases and disclosure regimes relating to GRs and associated TK illustrated the enormous amount of work carried out by the Secretariat, the IGC, as well as individual Member States and various stakeholders, in order to advance the work of the IGC, using an evidence-based approach. Text-based negotiations should be undertaken in a manner that included discussion of the broader context and of the practical application and implication of

proposals, in order to narrow existing gaps and reach a common understanding on core issues. It looked forward to the active participation of IPLCs. It acknowledged the valuable and essential role of IPLCs for the work of the IGC. It remained committed to contributing constructively towards achieving a mutually acceptable result.

21. The Delegation of the EU, speaking on behalf of the EU and its Member States, welcomed the decision by the WIPO GA on the mandate of the IGC, which was an improvement on the previous one. It looked forward to using the various possibilities provided for in the mandate, such as conducting and updating studies, covering *inter alia* examples of national experiences, such as impact assessments, databases, and examples of protectable subject matter and subject matter that was not intended to be protected. It noted with appreciation an excellent overview provided by the WIPO study “Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge.” It also looked forward to discussions on document WIPO/GRTKF/IC/35/9. Looking back to IGC 30, despite some interesting informal discussions and the highly appreciated work of the facilitators, it remained difficult for the IGC to close existing gaps among diverging options in most articles contained in document WIPO/GRTKF/IC/35/4. It hoped that in the next biennium under the new mandate, the IGC could pave the way towards mutually acceptable outcomes. It remained open to discussing a mandatory disclosure mechanism with appropriate safeguards. Thirteen years had passed since it had first tabled its proposal in the IGC. In the meantime, the international landscape had changed considerably. In particular, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (“the Nagoya Protocol”) had come into force. In order to further the understanding of that new landscape, the IGC might wish to consider potential benefits of examining interfaces between the implementation of the Nagoya Protocol and the introduction of patent disclosure mechanisms in IP legislation. Against that background, it remained ready to continue its engagement, as was evident at IGC 30. The EU occupied the center ground in those polarized discussions. The IGC should focus discussions on realistic and achievable outcomes to reap tangible results of the IGC’s work. It stressed its willingness to contribute to such positive outcomes.

22. The Delegation of Indonesia, speaking on behalf of the LMCs, welcomed the reports produced by the Secretariat, compiling materials and studies on databases and disclosure regimes relating to GRs and associated TK. Those reports reflected the fact that materials and studies with regard to the importance of GR protection were in abundance. Taking note of the IGC’s mandate, the LMCs hoped that Member States and other stakeholders sufficiently appreciated the importance of IGC 35 to charting a progressive course for the rest of the Committee’s engagement within the biennium. Good faith, flexibility, and political will were of critical importance for engagement at the session. Pursuant to the IGC’s mandate, the LMCs welcomed and looked forward to the discussion on Agenda Item 8 and it was hopeful that the IGC would establish an *ad hoc* expert group(s) to address specific legal, policy or technical issues. The main objective of the draft instrument was to prevent the misappropriation of GRs and their derivatives, through the IP/patent system by applying a disclosure requirement. Utmost efforts needed to be delivered to protect GRs, which included their derivatives, as well as associated TK. In line with the objective to prevent misappropriation, it was imperative for the IGC to explore ways in which an effective mandatory disclosure requirement could be established, while also recognizing the valuable addition of establishing databases and other information systems as complementary to the mandatory disclosure requirement. Noting the significant progress achieved in the past biennium, it was optimistic that the IGC could soon reach the finish line. It was high time for all stakeholders to finalize the Consolidated Document, with some issues needing to be resolved at a political level. The technical work was almost done and the GRs text needed to be taken forward. The IGC had to show political commitment. The Consolidated Document provided clear options for Member States to consider, which could be brought forward for a positive decision. IGC 35 and IGC 36 would enable Member States to guide the GA for a work program that outlined key deliverables for future work, including the

possibility of convening a diplomatic conference. The LMCs reemphasized the urgent need to prevent the misuse and misappropriation of GRs and TK associated with GRs. A legally binding instrument could prevent and tackle the transnational problems through a full compliance mechanism.

23. The representative of the Tebtebba Foundation, speaking on behalf of the Indigenous Caucus, said that she was there not only to defend indigenous peoples' rights but to defend the rights of all living beings, including the rights of Mother Earth. The agenda for IGC 35 related to GRs and associated TK. However, those were not indigenous peoples' words, not their concepts. They not only had rights, but also had obligations to take care of all of their relations, and the negotiations touched upon every aspect of their life ways and identity. While there was value in discussing improvements that could be made to the patent system, the negotiations had to be founded on a rights-based approach that recognized and respected indigenous peoples' rights acknowledged under all relevant international instruments, including the UN Declaration on the Rights of Indigenous Peoples ("UNDRIP"). She was not just seeking to improve the patent system; rather she was concerned with advancing the recognition of indigenous peoples' rights over GRs and associated TK. She called for continuing discussions of the status of indigenous peoples' property rights under all relevant international instruments in relation to the IP system. All such instruments had to operate in a holistic way to support their rights. She supported the inclusion of mandatory disclosure requirements. Such disclosure should require evidence of the free, prior, and informed consent ("FPIC") of indigenous peoples based upon MAT. That requirement had proven workable and effective in the jurisdictions that had it. She reminded Member States which were not parties to the Nagoya Protocol that the majority of members in the IGC were parties and that those negotiations and the obligations developed thereunder should not run counter to and indeed had to be mutually supportive of the obligations of those Member States under that instrument. On the question of databases, it was not simply a matter of deciding whether or not to establish them. The IGC had to discuss the details of their nature and scope. That included the manner in which TK entered them; the rights conferred or not conferred on TK contained within them; whether they should be made public or only available to patent officers; and issues related to perpetual safeguards for TK contained in databases. The TK in such databases, even if it was published, was evidence of their property rights and not necessarily evidence of TK being in the public domain. Further, they had to be seen as supportive of and complementary to other measures, such as due diligence and disclosure of origin requirements, and protections for TK should not be dependent on them. The instrument being negotiated by the IGC had to include repatriation because negotiations could not just address future practices related to patent issues. They also had to address historical misappropriations and wrongdoings. Some of the submissions of members implied to take those historical wrongs and lack of State recognition of their rights off the table for negotiations. The lack of recognition by the States did not make those wrongs disappear, and the instrument must not allow past injustices. On the procedural matter of the establishment of expert groups, she was generally supportive of having an *ad hoc* expert group, as that could potentially speed up negotiations by unlocking contentious issues. However, indigenous peoples' full and effective participation had to be ensured in that group with the proper funding support from Member States and WIPO. The Voluntary Fund was depleted and did not allow for full participation in coming IGC sessions. She thanked countries that had contributed to the Voluntary Fund and encouraged others to contribute to ensure continued participation of indigenous peoples in the work of the IGC. As the negotiations at the IGC dragged on, she felt a growing sense of urgency. While the IGC continued negotiations year after year, the theft of GRs and associated TK continued unabated. The work of the IGC should be concluded soon, with a deadline set for its work, in order to prevent ongoing injustices.

24. [Note from the Secretariat: the following opening statements were submitted to the Secretariat in writing only.] The Delegation of Colombia recognized, as an important precedent, the collective effort made by Member States at the GA in 2017 in renewing the IGC's mandate with a view to advancing and finalizing negotiations to reach an agreement on one or more

instruments. It stressed the importance of expediting the IGC's work by focusing on text-based negotiations, according to the mandate. Welcoming the statement made by the Delegation of Ecuador, on behalf of GRULAC, it emphasized that the IGC should focus its discussions on the consideration of unresolved issues for an effective and balanced protection of GRs, TK and TCEs. It wished to achieve consensus by the end of the current mandate. The fundamental components of a possible instrument had to necessarily include the requirement of disclosure of origin, contributing to the transparency and effectiveness of the patent system and avoiding the erroneous granting of patents with respect to the protection of GRs and associated TK. Colombia was a megadiverse and multicultural country. It highlighted the importance of the IGC, where dialogue and the exploration of common ground were imperative for reaching agreements, which had to result in sustainable growth and the implementation of the 2030 Sustainable Development Agenda.

25. The Delegation of Tunisia endorsed the statement made by the Delegation of Morocco, on behalf of the African Group. It expressed its deep satisfaction at the renewal of the IGC mandate by the WIPO GA for the 2018-2019 biennium. That provided an opportunity to move forward and make progress in drawing up normative texts designed to guarantee balanced and effective protection of GRs, TK and TCEs. It acknowledged the importance of the IGC's work. The adopted work program was a road map for the achievement of objectives assigned for the biennium. The IGC's work should take into account and build upon activities already carried out. The IGC should strive to reduce and allay any divergences in order to reach an agreement, on a consensual basis, on the core issues. It reiterated its interest in the issues placed on the IGC's agenda. The draft program and methodology prepared by the Chair provided a firm basis on which to initiate discussions during the first series of sessions on GRs. It highlighted the importance of recognizing the maturity of the discussions relating to the three thematic areas addressed. It hoped that the work would lead to the convening of a diplomatic conference on GRs in 2019, bearing in mind that the draft normative text in question was in a highly advanced state. The scheduling of three meetings of experts to examine outstanding issues, along with the three sessions of the IGC, was useful. The *ad hoc* expert group would make a substantial contribution towards the progress of the IGC's work. It would be appropriate to request that the 2018 GA carry out an assessment of the progress made on TK and TCEs and decide whether to convene a diplomatic conference or to continue negotiations.

26. The Delegation of the Republic of Korea said that, like many Member States of the Asia-Pacific Group, it had abundant and diverse GRs and associated TK. It recognized the importance of the discussions in the IGC. The spirit of fair and equitable benefit-sharing arising from GRs should be highly respected. It had concerns that the disclosure requirements presented an excessive burden and could raise unexpected obstacles to those wishing to utilize the patent system, which was recognized as a core momentum for innovation. During a series of meetings in the Republic of Korea, users and stakeholders had expressed their concerns on the legal uncertainties caused by disclosure requirements. That could lead them to avoiding the patent system, and even bypassing the IP system altogether. IP policies and patent systems existed for their users, therefore the IGC needed to focus on their convenience of use in order to encourage active use of the system. The most effective form of protection for GRs and associated TK in the patent system was to prevent erroneously granted patents through the establishment and use of database systems. It preferred non-legally binding instruments. Many issues discussed in the IGC had to be under private domain. The IGC should consider all aspects of the proposals, perspectives of the user, and any potential ripple effects on industry and relevant areas. It hoped that all WIPO Member States remained open-minded and sincere in the discussions to create new international norms.

27. The Delegation of Mozambique assured the Chair of its full support throughout the process. It was confident that under the Chair's wise leadership, the IGC would finalize its work on the negotiation of the draft articles on a mandatory disclosure of origin for GRs in patent applications. Mozambique was a country with abundant GRs and TK that were maintained and

expanded upon by over 250,000 traditional healers. It remained committed to progress towards an agreement on the text of an international legal instrument, which would facilitate transparency in the patent system and the appropriate use of valuable GRs and associated TK in inventive activity, for the benefit of both providers and users of such resources. It was pleased with the progress made at IGC 30. It hoped that the spirit and efficiency, which had prevailed at IGC 30, would be repeated at IGC 35. Agreement on remaining points of difference could be reached as members worked together with good faith, good will, and pragmatic cooperation. The Delegation was open to a process that would ensure that the GRs text advanced and matured meaningfully to a diplomatic conference. It was committed to ensuring no backward move on substance and, instead, that the work at IGC 35 be allowed to move as close as possible to the end goal in a meaningful and practical way. It looked forward to a highly productive session.

28. The Delegation of Japan recognized the importance of taking effective measures against the misappropriation of GRs and associated TK. It had been actively contributing to the discussions on those issues at the IGC meetings, making various proposals. There should be a clear distinction between two different factors inherent in the issue of the misappropriation of GRs, namely, the lack of compliance with the access and benefit sharing ("ABS") system and the erroneous granting of patents. The first issue should not be dealt with under the patent system. Hence, the IGC should be focused on the issue of erroneous granting of patents, especially on the utilization of databases for prior art searches, given that WIPO had a crucial role in understanding global issues from its vantage point as an organization specializing in IP. In that respect, together with the Delegations of Canada, the Republic of Korea and the USA, it had submitted document WIPO/GRTKF/IC/35/8. The mandatory disclosure requirement for ensuring compliance with the ABS system, which did not have a direct link with the patent system, could bring legal uncertainty, decrease legal predictability, and discourage R&D activities utilizing GRs. The same held true for not only developed countries but also emerging and developing countries. It was seriously concerned that the mandatory disclosure requirement might hinder the healthy growth of industries utilizing GRs in emerging and developing countries, both now and in the future. Since the mandatory disclosure requirement could negatively affect the patent system and eventually hinder innovation, it should not be introduced. It made more sense to conduct measures to protect GRs within the framework of the CBD and the Nagoya Protocol. The Delegation had no intention whatsoever to discourage the discussion. Rather, it was willing to actively contribute to ensuring the effective protection of GRs.

29. The Delegation of Nigeria supported the statements made by the Delegation of Morocco, on behalf of the African Group, and the Delegation of Indonesia, on behalf of the LMCs. It underscored the importance of the IGC's new mandate and observed the progress made over the past biennium, especially with regard to the GRs text, which was perhaps the most mature of the three IGC texts in progress. IGC 35 offered yet another opportunity to build on the progress made thus far. Over the years, it had strived to narrow the gaps and had demonstrated good will toward a substantive outcome that fulfilled the purpose for which the IGC had been established 18 years before. Member States would take advantage of the progress made and focus mainly on narrowing the existing gaps through constructive and mutual engagement in arriving at a common understanding of the core issues. With regard to the GRs text in progress, a majority of Member States in the IGC was also party to the CBD and the Nagoya Protocol, not to mention other regional instruments that had bearing on the subject of protection of GRs and associated TK. Therefore, the draft text on GRs gave a good basis, aiming at ensuring mutual supportiveness with international agreements, especially the CBD and the Nagoya Protocol. The issue of the disclosure of the source and/or origin of GRs and associated TK was desirable as it was mutually supportive of existing instruments. It underlined the need for an effective and legally binding instrument for the protection of GRs and associated TK. The Delegation was committed to simplifying the current text. The IGC's work could be more productive if one avoided activities that attempted to further cluster the text in obstructive

and counter-productive ways. The IGC was close to the finish line with regard to the GRs text. All that was needed was to move forward and make constructive progress, and to restore hope and confidence in the IGC process, which continued to wane with elongated negotiations.

30. The Delegation of El Salvador stated that the Chair could rely on its support in his work. It was confident to achieve significant progress. El Salvador was a fairly small country (21,000 square kilometers) with a population of more than six million inhabitants. That represented a population density of just over 300 inhabitants per square kilometer, which placed its valuable natural resources under considerable strain. The indigenous population was about 12 percent of total population, of which less than 1 percent was in a position to provide for their basic living requirements. Indigenous peoples, known among other things for their reverence for the Earth and their profound knowledge of it, were greatly affected by their geographical isolation, limited access to natural resources and the phenomenon of forced migration that had severed the younger generations from their roots, drastically unraveling their social fabric and causing other problems. The Government of El Salvador had been endeavoring to secure recognition and protection of indigenous peoples and their heritage. Efforts were continuing, and in line with them, the Delegation would be actively participating in the IGC throughout the biennium. It would also be contributing to the construction of one or more instruments to support the management of the protection of indigenous peoples around the world and their heritage, in accordance with the mandate adopted by the GA in October 2017.

31. The Delegation of Turkey expressed its confidence that the IGC would continue to work to reach desired results under the Chair's guidance. The new Turkish IP law had been in force since January 10, 2017, and combined trademarks, designs, geographical indications and patents into one piece of legislation. Together with many other novelties such as post-grant opposition and reinstatement of rights, the new IP law brought one new feature worthy of mention. Article 90 set out the necessary requirements in general for obtaining a patent application date. Article 90(4) stated that: "if the invention is based on genetic resources or traditional knowledge associated with genetic resources, the source shall be disclosed in the patent application." In accordance with Article 95, any patent application lacking one of the requirements mentioned in Article 90, "including the disclosure of the genetic resources", shall not be taken into process until the deficiency was corrected within two months. Otherwise the application would be rejected. Also, its online application module, which accounted for more than 95 percent of all patent applications, incorporated a new section where all applicants had to answer a simple question: "Is your application based on genetic resources? Yes/No" and if the answer was "Yes", the applicant had to specify the source. Thus far, 27 applications had disclosed the source. It was an effective tool for the purpose of tracing back and determining whether GRs had been obtained lawfully. It strongly supported the principle of disclosure of origin in all patent applications based on GRs and associated TK as a useful tool for both national and international patent applications.

32. The representative of Tupaj Amaru said that the IGC established in 2000 by the GA was mandated to examine the draft of an international instrument for the protection of GRs in the IP context. However, the IGC had not made substantive progress owing to a lack of political will. The great British astrophysicist Stephen Hawking, who had died on March 15, 2018 and who had discovered black holes in the universe, had said that both climate change caused by the destruction of GRs and artificial intelligence were a danger to the survival of humanity. Biodiversity and GRs were the material and spiritual source of survival of humanity, particularly necessary to strike a balance between man and nature, which was vital for the sustenance of all life on Earth. In the materialistic conception of the history of indigenous peoples, GRs and TK that involved an infinite number of living organisms and other life forms in constant transformation over millions of years, constituted the sustenance of all life on Mother Earth that gave life. The indigenous peoples, who were an intrinsic part of nature, knew how to live in harmony with the environment and considered themselves the product of Mother Earth. Their ancestors knew how to cultivate the land with respect, care for every tree that gave shade to

their tombs, hunt animals according to their material and spiritual needs and share the fruits of collective labor to ensure collective prosperity. Instead, the new neo-colonial order had destroyed the way of life of their ancestors. Accordingly, the IGC should examine genetic material not only in terms of market, financial gain, profitability and investments between providers and recipients of such intrinsic values, but in the spirit of their conservation and sustainable development for the survival of humankind.

AGENDA ITEM 4: ADOPTION OF THE REPORT OF THE THIRTY-FOURTH SESSION

33. The Chair referred to the draft report of IGC 34 and recalled that it was not a verbatim report, and it summarized the discussion without reflecting all the observations in detail. The rules of procedure stated that any intervention under this item had to be solely related to submissions made at and the report of IGC 34.

Decision on Agenda Item 4:

34. *The Chair submitted the draft report of the Thirty-Fourth Session of the Committee (WIPO/GRTKF/IC/34/14 Prov. 3) for adoption and it was adopted.*

AGENDA ITEM 5: ACCREDITATION OF CERTAIN ORGANIZATIONS

Decision on Agenda Item 5:

35. *Consideration of this item was deferred to the Thirty-Sixth Session.*

AGENDA ITEM 6: PARTICIPATION OF INDIGENOUS AND LOCAL COMMUNITIES

36. The Chair acknowledged the recent death of Mr. Thomas Alarcon who had actively participated in the IGC discussions. On behalf of the IGC, his heartfelt condolences went to his family, his people, and his nation. Regarding the Voluntary Fund, he called upon delegations to consult internally and consider contributing. There was sufficient money remaining to fund two individuals for IGC 36. Members were well aware of the importance of indigenous representation at the IGC meetings to the credibility of the IGC's work. He could not overemphasize the importance of the Fund being replenished. He drew attention to document WIPO/GRTKF/IC/35/INF/4, which provided information on the current state of contributions and applications for support, and document WIPO/GRTKF/IC/35/3 concerning the appointment of members of the Advisory Board. The IGC would later be invited to elect members of the Board. The Chair proposed that Mr. Faizal Chery Sidharta, the Vice-Chair serve as the Chair of the Advisory Board. The outcomes of the Board's deliberations would be reported on in document WIPO/GRTKF/IC/35/INF/6.

37. [Note from the Secretariat]: The Indigenous Panel at IGC 35 addressed the following topic: "Proposed Patent Disclosure Requirements Related to Genetic Resources — Indigenous Peoples' and Local Communities' Perspectives." The speakers were Mr. Ndiaga Sall, Head of Department at SEPCOM (Knowledge and Community Practices in Health), Head of Enda Health, Senegal; Ms. Neva Collings, Ph.D. candidate, University of Technology Sydney, Faculty of Law, Australia; and Mr. Q'apaj Conde Choque, Aymara lawyer, *Centro de Estudios Multidisciplinarios – Aymara*, Plurinational State of Bolivia. The Chair of the Panel was Mr. Nelson de León Kantule, Vocal-Directivo, Association of Kunas United for Mother Earth (KUNA), Panama. The presentations were made according to the program

(WIPO/GRTKF/IC/35/INF/5) and are available on the TK website as received. The Chair of the Panel submitted a written report on the Panel to the WIPO Secretariat which is reproduced, as summarized, below:

“The first speaker was Ms. Neva Collings, an Aboriginal lawyer from Australia. The main topic developed by Ms. Collings was the importance of using new protocols, such as the Nagoya Protocol. Ms. Collings called for the application of the Nagoya Protocol in the negotiations taking place at WIPO, and for the fair and equitable sharing of the benefits arising from its use of resources. Her intervention ended with an appeal for the full and effective participation of indigenous peoples in the IGC, as the process could otherwise have a very negative impact on them.

The second speaker was Mr. Ndiaga Sall, a native of the African nation of Senegal. He is Head of the Department of Knowledge and Community Practices in Health. He spoke about his experience working with traditional healers, who are rebuilding a way of life that guarantees the conservation and sustainable use of biodiversity. His concluding recommendations emphasized the need for the IGC negotiation process to consider other fora and instruments related to the protection of TK, such as the CBD and the UNDRIP, and to harmonize with them.

Mr. Q’apaj Conde, an Aymara lawyer from Bolivia, works with the *Centro de Estudios Multidisciplinarios – Aymara* (Center for Multidisciplinary Studies – Aymara). His presentation focused primarily on the system of disclosure requirements established for the Andean Community. He then discussed the human rights of indigenous peoples in relation to disclosure requirements, in view of the technical review by Prof. James Anaya presented at previous ICG sessions. Lastly, he turned to the lessons learned from the relationship between the Andean Community’s disclosure requirements and the human rights of indigenous peoples, with the hope that these lessons would be of assistance in the negotiation process undertaken by the ICG. At the global level, the Nagoya Protocol and its mechanisms for monitoring the use of GRs have shown that they have a crucial part to play. In the Andean region, Andean Community Decisions No. 486 and No. 391 appeared to have the same significant role. The Andean Community’s disclosure requirement system facilitated complementarity between the IP regime and the ABS regime, the established mechanisms for accessing and using GRs and for TK and GRs, respectively. It was important here to incorporate the principle of FPIC into the license negotiation process. This safeguard should be a fundamental part of the mandatory disclosure requirement. Lastly, the complete invalidation of the patent is the penalty provided for in the Andean Community regulation on disclosure requirements. From the perspective of indigenous peoples, non-compliance with mandatory disclosure requirements must also incur civil and criminal penalties.

Mr. De León Kantule concluded the panel by calling on Member States to contribute to the Voluntary Fund in order to ensure the participation of indigenous peoples in this process owing to the importance of their participation. The Indigenous Caucus noted with considerable concern the low rate of indigenous participation and the crisis in the Voluntary Fund, caused by the absence of contributions.”

38. [Note from the Secretariat]: The Advisory Board of the WIPO Voluntary Fund met on March 20 and 21, 2018, to select and nominate a number of participants representing indigenous and local communities to receive funding for their participation at the next session of the IGC. The Board’s recommendations were reported in document WIPO/GRTKF/IC/35/INF/6 which was issued before the end of the session.

39. The Chair strongly encouraged delegations to consider putting funds into the Voluntary Fund.

40. The representative of Tupaj Amaru stated that the indigenous peoples should be able to participate on an equal footing with Member States because they were the owners of GRs and TK.

Decisions on Agenda Item 6:

41. *The Committee took note of documents WIPO/GRTKF/IC/35/3, WIPO/GRTKF/IC/35/INF/4 and WIPO/GRTKF/IC/35/INF/6.*

42. *The Committee strongly encouraged and called upon members of the Committee and all interested public or private entities to contribute to the WIPO Voluntary Fund for Accredited Indigenous and Local Communities.*

43. *The Chair proposed, and the Committee elected by acclamation, the following eight members of the Advisory Board to serve in an individual capacity: Mrs. Ali Aii Shatu, Member of the Mbororo Social Cultural Development Association (MBOSCUDA), Cameroon; Mr. Nelson De Leon Kantule, representative, Association of Kunas for Mother Earth (KUNA), Panama; Ms. María del Pilar Escobar Bautista, Counselor, Permanent Mission of Mexico to the United Nations Office and other International Organizations in Geneva; Mr. Efren Jagdish Jogia, Senior Crown Counsel, Office of the Attorney-General, Office of the Prime Minister, Tuvalu; Mr. Gaziz Seitzhanov, Third Secretary, Permanent Mission of Kazakhstan; Ms. Grace Stripeikis, Assistant Director, International Intellectual Property Section, Department of Foreign Affairs and Trade, Australia; Ms. Polina Shulbaeva, Coordinator, Centre for Support of Indigenous Peoples of the North/Russian Indigenous Training Centre (CSIPN/RITC), Russian Federation; and Mr. George Tebagana, Second Secretary, Permanent Mission of Uganda.*

44. *The Chair of the Committee nominated Mr. Faizal Chery Sidharta, Vice-Chair of the Committee, to serve as Chair of the Advisory Board.*

AGENDA ITEM 7: GENETIC RESOURCES

45. The Chair recalled that he had consulted with Regional Coordinators and interested delegations on the work program and working methodology for the session, especially for Agenda Item 7. According to the new mandate, IGC 35 should undertake negotiations on GRs with a focus on addressing unresolved issues and considering options for a legal instrument. Regarding the results of IGC 35, a revised version of document WIPO/GRTKF/IC/35/4 would be produced. The same methodology as used in previous IGC sessions would be followed. Rev. 1 would be prepared and presented by Wednesday morning. Time would be given for comments and further suggestions, including textual proposals. Rev. 2 would be prepared and presented by Friday morning. Time would be given for general comments, which would be included in the report. The plenary would be invited to note Rev. 2, subject to the correction of obvious technical errors and omissions. Throughout the week, the facilitators would listen to all interventions in plenary and informals and undertake drafting incorporating the textual proposals. To enable more focused and incremental consideration of the facilitators' work by delegates, as the week progressed, the facilitators might introduce and present on screen progressive work on core issues as a work-in-progress for reaction and comment, if any. That could enable delegates to more actively guide the facilitators' work throughout the meeting. Work under Agenda Item 7 would begin in plenary. He might convene informals in order to facilitate in a smaller, informal setting, discussion on the issues and the text of the working document so as to narrow existing gaps and reach a common understanding. Concerning the working method for informals, he or one of the Vice-Chairs, with the active assistance of the facilitators, would lead the discussion. As to the composition of informals, each regional group would be represented by a maximum of six delegates, one of whom should preferably be the Regional Coordinator, noting that the presence of the Regional Coordinators in the informal process was important for communication throughout the groups. In order to maintain transparency and inclusiveness, other Member State representatives would be able to sit in the informals, only observing and without a direct speaking right. Indigenous representatives would be invited to nominate two representatives to participate and two representatives to observe without speaking rights. He had requested members to consider allowing industry representatives to also participate in those informals. Proposals from indigenous representatives could remain in the text only if supported by a Member State. All participants were requested to respect the informality of the informals. Depending on progress made in the plenary and/or informals, he might establish one or more small *ad hoc* contact groups to tackle a particular issue so as to further narrow existing gaps. Those could be particularly useful with regard to thoroughly discussed issues with divergent views. The composition of such contact groups would depend on the issue to be tackled but would typically comprise a representative from each region, depending on the issue and Member States' interests. He might appoint one of the Vice-Chairs or facilitators to coordinate the discussions in such contact groups. They would have a short-term mandate within the current session and would need to report back to the plenary or informals on their results, if any. The plenary remained the decision-making body. The facilitators had a very difficult and demanding task. They were there to help members and represented them. They might take the floor and make proposals, but if so, the Member States in plenary had to agree on any change. They would review all materials prepared during the session, including informals, and undertake drafting and prepare the revisions.

46. The Chair invited Ms. Margo Bagley, who had been the facilitator for the biennium 2016-2017, to give a factual presentation on document WIPO/GRTKF/IC/35/4, and Ms. Bagley did so. The Chair also invited the Secretariat to make a presentation on the resources available

on the WIPO website, and the Secretariat did so. [Note from the Secretariat: Two presentations are available on the WIPO Traditional Knowledge Division's web pages at [http://www.wipo.int/meetings/en/details.jsp?meeting_id=46369.](http://www.wipo.int/meetings/en/details.jsp?meeting_id=46369)]

47. After having sought proposals from Member States, the Chair nominated Mr. Paul Kuruk from Ghana to be the facilitator. He appointed Ms. Margo Bagley from Mozambique as the Friend of the Chair to provide continuity to the process and to aid the facilitator. Document WIPO/GRTKF/IC/35/4 incorporated two broad proposals, based on the policy objectives (noting that those policy objectives were not agreed): disclosure requirements and defensive measures. In relation to disclosure, the approach had been significantly refined with the inclusion of an administrative mechanism focused on ensuring transparency within the IP/patent system, rather than a regime based on a substantive patentability requirement, which had been the regime initially considered. There were three additional documents presented for consideration by the IGC, which were documents WIPO/GRTKF/IC/35/7, WIPO/GRTKF/IC/35/8 and WIPO/GRTKF/IC/35/9. In addition to those documents, at IGC 29, the Delegation of the EU, on behalf of the EU and its Member States, had referred to its disclosure proposal, which had been tabled in 2005, as noted in its opening statement. He noted the point raised by the Delegation of the EU, on behalf of the EU and its Member States, and some others in their opening statements that the landscape had changed significantly since the IGC had started its work, with protocols, domestic disclosure regimes and individual Member States' initiatives relating to databases. There were a significant amount of materials from which to develop a single approach aimed at reaching an agreement on an international legal instrument relating to IP and GRs, without prejudice to the nature of the outcome. Those materials were also supported by significant resources available on the WIPO website, including information on domestic disclosure regimes and databases. However, it was also clear that there was a fundamental difference of view as to the most appropriate mechanism to address the policy objectives, with a number of countries explicitly stating that they did not support a disclosure regime, and believing that defensive measures were sufficient to meet the policy objectives. Unless the IGC could address that difference, the negotiations would not move forward. The only way forward was to attempt to increase the clarity of the different approaches for Member States to have a greater understanding of how those mechanisms could achieve the policy objectives. He intended to progress the IGC's work along the two approaches and gave time to discuss core issues related to each approach. The disclosure approach had a number of alternative positions on key elements which included subject matter, trigger, content of disclosure, exceptions and limitations and sanctions and remedies. It was important to narrow those alternative positions, as they significantly changed the policy impact of any disclosure regime, particularly in relation to the scope of such a regime, its legal certainty and regulatory burden. Without narrowing positions in the area of disclosure, it would be difficult for Member States and stakeholders to make informed decisions on the merits of the disclosure regime. It was very important for the proponents of disclosure to attempt to narrow gaps. He asked the proponents of the defensive measures to address, in particular, issues regarding safeguards in relation to databases. He requested that if one clearly did not support a particular proposition or option that a Member State had put forward, one should refrain from suggesting textual changes, which fundamentally altered the policy intent of the position. It would be better for members to ask questions to the proponents in an attempt to understand the policy rationale of the proposal or query how the proposal would operate in practice. Member States needed to have the courage to move outside of the rigidity of their positions and consider what they were prepared to accept to make their primary policy interests reflected in the objectives. He intended to initially work through key issues within plenary, a number of which were reflected in the Chair's Information Note. The first of those was Objectives. There were three key elements within the objectives, which balanced the interests of GRs owners, GRs users, and the public interest. The three key elements were: (1) enhancing the efficacy and the transparency of the patent/IP system; (2) facilitating mutual supportiveness with other related international agreements; and (3) ensuring patent offices access to appropriate information to prevent the granting of

inappropriate IP rights. The article contained lots of duplications. He opened the floor for comments on “Objectives”.

48. The Delegation of Indonesia, speaking on behalf of the LMCs, said it was ready to engage constructively and was flexible with regard to simplifying the Consolidated Document, as long as any textual proposal was done with the objective of narrowing gaps and maintaining the integrity of the text. Article 1 was important because by extending the disclosure requirement, one could enhance the transparency of the IP/patent systems, in particular by monitoring the contribution of GRs to the new inventions. The disclosure requirement would also create a balance between those who held the GRs and those who owned the modern technology to exploit GRs associated with the inventions. Therefore, the objective of the instrument should be to prevent the misappropriation or misuse of GRs and associated TK through a disclosure requirement.

49. The representative of the Tebtebba Foundation, speaking on behalf of the Indigenous Caucus, identified the prevention of misappropriation and protection of rights over GRs and associated TK as the key elements under objectives, as mentioned by the Delegation of Indonesia, on behalf of the LMCs. She had been initially looking at Alt 2, however, she agreed with the Chair’s suggestion on minimalization of alternatives. She could work on Alt 1, as long as the concept of prevention of misappropriation and effective protection of the rights of GRs and associated with TK were reflected there.

50. The Delegation of the Islamic Republic of Iran aligned itself with the two statements by the Delegation of Indonesia, on behalf of the Asia-Pacific Group and the LMCs. The IGC’s deliberations should be in full conformity and not deviate from its mandate, which urged members to make their utmost efforts to narrow the gaps. One of such gaps was the policy objective. Based on its declarations at IGC 29 and IGC 30, the policy objective contained two different elements, which could be merged into a new paragraph capturing all the elements of all different options. It was ready to work with other Member States to narrow the gaps based on the current wording in order to prevent duplication.

51. The Delegation of the Plurinational State of Bolivia supported Alt 2. It proposed replacing “promote” by “ensure”.

52. The Delegation of Brazil stated that the objective of the instrument was to establish a coherent legal and policy framework to ensure the mutual supportiveness between the IP rules and the CBD and the Nagoya Protocol in national systems. That would facilitate monitoring and enforcing compliance with the requirements under the CBD and the Nagoya Protocol. The best way to do so was to introduce a disclosure requirement, as an additional enforcement tool to those instruments. It would also bring transparency to the IP system, allowing the traceability of GRs. The Delegation was open to discuss additional measures, such as databases, to complement the disclosure requirement. IP-related measures by themselves would not be sufficient to resolve all issues arising in the context of access and benefit-sharing and the protection of GRs, derivatives and TK. There was only one element, among others, to be integrated in a more global approach to fully address the issues. Additional measures were possible outside of the IP system, at other levels, in other areas. It supported the statement made by the Delegation of Indonesia, on behalf of the LMCs, regarding the preference for Alt 2.

53. The Delegation of Thailand aligned itself with the statement made by the Delegation of Indonesia, on behalf of the LMCs. The objective of the draft instrument was to prevent misappropriation of GRs, derivatives and associated TK by requiring a mandatory disclosure requirement in the whole IP system. Databases were very useful but should be used as a complementary measure and not as an alternative to the disclosure requirement. It was ready to engage constructively to narrow existing gaps and was ready to explore the recommendation made by the Delegation of the Islamic Republic of Iran on looking into wording to cover the concerns of all members.

54. The Delegation of Morocco, speaking on behalf of the African Group, said that the objective had to address protection against misappropriation, to enhance the effectiveness and transparency of the IP system, and to ensure mutual supportiveness with international agreements related to GRs, derivatives and associated TK. It preferred the first paragraph, while removing a number of square brackets.
55. The Delegation of El Salvador preferred Alt 2. Nonetheless, as the representative of the Tebtebba Foundation, on behalf of the Indigenous Caucus, had said, it could work on Alt 1, provided the language could be adjusted to reflect effective protection of GRs and associated TK and to avoid the erroneous granting of patents.
56. The Delegation of Egypt preferred Alt 2.
57. The Delegation of India wished to keep the essence of the Nagoya Protocol in the objectives. Alt 2 took care of those if it concerned the entire IP system, not only the patent system.
58. The Delegation of Switzerland said that the objective of the instrument should be drafted as simply and concisely as possible. While there should be a direct link between the objective and the substantive provisions in the instrument, the objective itself should not include any specific measures on how it might be achieved. Moreover, the objective should not contain any provisions that were already contained in other international agreements such as the objective of benefit-sharing in the Nagoya Protocol and other issues that were not relevant to the patent system. There was no agreement on the specific provisions, so it was difficult to draft a concise, straightforward objective at that stage. Nevertheless, it was key that the objective of the instrument was to enhance the transparency of the patent system. It supported to work on the first option. It could be improved by referring to enhancing the efficacy and transparency of the patent system with regard to GRs and associated TK. That would not cover the issues of misappropriation or ABS, which were currently reflected in Alt 1 and Alt 2. However, an instrument that would enhance the efficacy and transparency of the patent system would automatically also result in facilitating ABS and in preventing misappropriation.
59. The Delegation of Malaysia aligned itself with the statement made by the Delegation of Indonesia, on behalf of the LMCs, and supported Alt 2, which comprehensively captured the essence and aim of the instrument, primarily to prevent the misappropriation of GRs through the IP system by having a disclosure requirement. The language in Alt 2 was consistent with the aim of the IGC, which was to ensure the balanced and effective protection of GRs. It was ready to engage constructively on a simplified language as long as the aforementioned elements were taken into consideration.
60. The Delegation of Tunisia supported the statement made by the Delegation of Morocco, on behalf of the African Group. Alt 2 covered the entire IP system to avoid misappropriation.
61. The Delegation of Ecuador aligned itself with the statement made by the Delegation of Indonesia, on behalf of the LMCs. It supported Alt 2 because the policy objectives should cover the whole IP system, since there were other fields of IP, such as trademarks, which might cover TK. It should refer to other international treaties. The objective was an opportunity for IPLCs to ensure ABS from the use of GRs and to minimize the erroneous grant of patents.
62. The Delegation of the Philippines aligned itself with the statement made by the Delegation of Indonesia, on behalf of the Asia-Pacific Group. It was comfortable with policy objectives that were in line with its own national regulations, which already prescribed a disclosure requirement, jointly administered by the Environment Ministry, the Agriculture Ministry and the National

Commission for Indigenous Peoples, among other relevant agencies. It would engage constructively in the discussions to share its own national experience in that regard.

63. The Delegation of Australia said that the objective should be to ensure transparency in the patent system. It agreed with the Delegation of Switzerland that it was important to develop a simple and concise objective. Greater transparency in the patent system would also help facilitate the benefits of commercialization being shared appropriately in line with other international and national regimes. It could also help to promote collaboration in R&D. In any event, transparency was a key and central objective.

64. The representative of CHIRAPAQ stated that in order to protect GRs, the document should cover the entire IP system, and not just the patent system.

65. The Delegation of the Islamic Republic of Iran stated that the objective should be as concise as possible and relevant to having a balanced and effective protection of GRs and TK based on the mandate. The statements made thus far concerning the policy objective were not contradicting, but complementing each other. Most of the elements highlighted by different groups were already included in Alt 2. It would be better, rather than reiterating different positions, to see how to reflect all languages in one particular alternative. The main elements of Alt 1 had been included in original Alt 2, and Alt 2 had been reflected in new Alt 2. Thus, it suggested not reiterating positions and focusing on the possibility of improving the language of one paragraph, which could be comprehensive and capture all the different elements.

66. The Delegation of Japan stated that it was essential to make a clear distinction between the issues of ABS/PIC and the erroneous grant of patents. The first issue should not be dealt with under the patent system, so it would be inappropriate to include some requirement for the first issue in the patent system. In other words, the objective should be limited to measures to prevent the erroneous grant of patents. Measures to prevent the misappropriation of GRs were not suitable as an objective of the instrument.

67. The Delegation of China agreed with the position expressed by the Delegation of Indonesia, on behalf of the Asia-Pacific Group. Alt 2 was more in line with the objective of the IGC to protect GRs and TK. Based on Alt 2, some adjustments could be made in the wording or Alt 2 could be combined with Alt 1. The patent system could be focused on, but other IP systems could not be excluded in order to protect TK and GRs.

68. The Delegation of the USA stated that two of those alternatives were appealing. In the first objective, it suggested bracketing “and facilitate mutual supportiveness with international agreements relating to genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources]”. That language appeared to be directed towards the relationship with the Agreement on Trade-Related Aspects of Intellectual Property (“TRIPS Agreement”) and since it saw no conflict between the two agreements, that last phrase was not necessary. In Alt 2, it wished to replace “misappropriation” with “unauthorized use of”. It also suggested bracketing sub-paragraph (c) because that went back to the mutual supportiveness issue previously mentioned. It suggested a new Alt 3, as follows: “The objectives of this instrument are to: (a) 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, which could protect indigenous peoples and local communities from the limitations of the traditional use of genetic resources and their traditional knowledge associated with genetic resources that might result from the erroneous patenting thereof; (b) Ensure that patent offices have the appropriate available information on genetic resources and traditional knowledge associated with genetic resources needed to make informed decisions in granting patents; (c) Preserve a rich and accessible public domain in order to foster creativity and innovation.” Furthermore, there were a number of terms that were relevant in the context of the objectives, either included in the definitions or implicated in the objectives. On “traditional

knowledge associated with genetic resources” in Option 2, it suggested adding “generated in a traditional context, collectively preserved and transmitted from generation to generation” after the bracketed words “and their derivatives”, in order to make that definition complete. With respect to “country of origin”, it suggested replacing “possesses” with “first possessed”, and inserting “and still possesses those genetic resources” after “*in situ* conditions”. That was because it would be difficult or impossible for a patent applicant to disclose all of the countries that possessed or had possessed a particular GR. As to “country providing/providing country”, it wished to replace “in accordance” with “consistent”, because the USA was not a party to the CBD or the Nagoya Protocol and the work of IGC could be consistent with that instrument but would not have to comply with that instrument. With respect to “country providing genetic resources”, it asked to bracket “or taken from *ex situ* sources”, because the instrument should not extend to *ex situ* sources. “Or *ex situ*” should also be deleted in Alt. It did not support the concept of derivatives in the instrument, but to the extent that it would be included in the discussions, it was important to be clear on what they meant. It suggested bracketing “even if it does not contain functional units of heredity” because derivatives should contain functional units of heredity. With respect to “invention directly based on”, it wished to insert “the inventive concept must” before “depend on the specific properties”. It wished to clarify the definition of “genetic material” by inserting “or” before “microbial” and bracketing “or other origin”, as it did not understand what the “other origin” would be. With respect to “physical access”, it wished to add the word “physical” before “possession” and to bracket “or at least [...]” through the end of the sentence in order to simplify the definition. With respect to “source”, in Option 1, it wished to insert “or any other depository of genetic resources” after “botanical garden”, as there could be a number of sources of GRs, so the definition had to be comprehensive enough. Moreover, there was a relationship between the objectives and the preamble because the preamble was a condensed expression of objectives and it had seen some terms or ideas go from objectives to preamble and vice versa. The Delegation understood that the IGC’s work was intended to have a preamble and whatever was captured in the preamble would be important to the outcome of that work because of the interrelation between the preamble and the objectives. The second paragraph would be clearer by replacing “misappropriation” with the term “unauthorized use”. The second last paragraph could be simplified and clarified by bracketing “their” and adding “genetic” before “resources” since biological was already bracketed, and adding “within their jurisdiction other than those associated with human beings” to clarify that GRs did not include human GRs.

69. The Delegation of Indonesia, speaking on behalf of the LMCs, was delighted to see that the Delegation of the USA was ready to engage on the disclosure requirement within the text. It took it as a sign that it was ready to move on from the alternative text with regard to the objectives. However, if that was the intention, it suggested that any text should be alternative text to make sure that the integrity of the text remain intact. In fact, the suggestion for the objective was more likely to contribute to the unauthorized use of the GRs. It was delighted to learn that the Delegation of the USA thought that the IGC was nearing the end of the process, by commenting on the List of Terms and the Preamble. It was ready to discuss the List of Terms and the Preamble if that was the intention. All articles were connected and in relation to each other, not just with the Policy Objectives.

70. The Delegation of the Plurinational State of Bolivia said that the goal of IGC 35 after 15 years of meetings was to bridge the gaps. It thanked the Delegation of the USA for its proposals which should not affect the integrity of the text because they were new elements, and had to be put in as alternatives in order not to distract the discussion. A majority of countries had expressed a preference for Alt 2. The goal was to bridge the gaps, not to open greater ones, so all of the changes had to be acceptable to other Member States.

71. The Delegation of Brazil said it needed to see the intervention by the Delegation of the USA in written form. Alt 3 should be moved to “No New Disclosure Requirement”, as suggested by the Delegation of Indonesia. It was clearly not related to the disclosure requirements so it

should not be included in that part of the text. The proposed definition of “derivatives” by the Delegation of the USA was inconsistent with the Nagoya Protocol, which had more than 100 parties.

72. The Delegation of Ecuador supported the proposal made by the Delegation of the Islamic Republic of Iran. It was important that all parties made every effort to narrow gaps and tried to combine the two alternatives. It called on all parties to come to a better understanding of the need to have consistency and complementarity with other international instruments such as to enrich them and to overcome inertia within the IP system. It called on all Member States to unify their efforts and to make decisions on concrete alternatives.

73. [Note from the Secretariat: The following took place on the next day, March 20, 2018.] The Chair noted that the facilitator and the Friend of the Chair had reflected on the discussion that had taken place the day before and would present some initial proposals and thoughts based on those discussions. He emphasized that the material presented was simply work-in-progress, and it had no status and was not a revision. The Chair invited the facilitator to present their work.

74. Mr. Kuruk, speaking as the facilitator, said that he and the Friend of the Chair had prepared the “work-in-progress”, aiming at improving the text to provide for greater clarity, inclusiveness and simplicity. The work done had no status. The text read as follows: “The objective of the instrument is to contribute to the protection of genetic resources [their derivatives] and traditional knowledge associated with genetic resources within the [IP] [patent] system by: (a) Ensuring complementarity and mutual supportiveness with international agreements relating to the protection of genetic resources [their derivatives] and/or traditional knowledge associated with genetic resources and those relating to IP; (b) Enhancing transparency in the [IP][patent] system in relation to genetic resources [their derivatives] and/or traditional knowledge associated with genetic resources; and (c) Ensuring that [IP] [patent] offices have access to the appropriate information on genetic resources [their derivatives] and traditional knowledge associated with genetic resources to prevent the granting of erroneous [IP] [patent] rights.”

75. Ms. Bagley, speaking as the Friend of the Chair, said that it was a first attempt to incorporate the various concerns expressed regarding the objectives and to put them into a single provision. Language from the preamble had been included in one of the clauses: “reaffirm, in accordance with the Convention on Biological Diversity, the sovereign rights of States over their genetic resources, and that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.” That clause was currently in the preamble. The clause in italics could be added to the preamble. It read: “Recognizing that the IP system, which protects invention and innovation, intersects with the CBD and has a role to play in facilitating protection of GRAATK.” The idea of including language from the preamble was to help delegations think holistically about the document. The text which did not appear in the objectives might be in the preamble or in another article. That would also help set up the use of the more positively word “contribute to the protection of genetic resources” which was used as opposed to “prevent misappropriation”. The idea was to frame it positively and link it to the language in the preamble on the CBD, which was the primary instrument for the protection of GRs, recognizing that there was an intersection between the IP system and the CBD.

76. The Chair opened the floor for initial feedback.

77. [Note from the Secretariat: all speakers thanked the facilitator and the Friend of the Chair for their work.] The Delegation of the Islamic Republic of Iran congratulated the Chair on taking the constructive approach of coming up with a more structured text that was a very good attempt at bridging the gaps. With that spirit, the IGC would be able to come up with a better

text. It might not reach an agreement as such, but it was moving in that direction, making better use of the time and developing much better text. Members had to perceive themselves as both owners and users, equally, because in one way or the other, everyone was a user at the end of the day, either end user, middle user, commercializer, owner, protector, etc. The IGC had to pave the road for better use of GRs, by establishing a clear and transparent system allowing everyone to fairly use GRs, while recognizing the rights that some owned over GRs. A transparent system would benefit all of humanity. Both protection and facilitation of the use of GRs were required. It urged everyone to work towards the revised text with the mentality of seeing oneself as both users and owners. That would help bring views closer together.

78. The Delegation of Colombia said that balance had to be made for GRs providers and users. GRs had to be used sustainably, and that was only possible through the traceability of GRs. The concept of misappropriation had not been accepted in any multilateral forum. Its application might be more within environmental treaties. With regard to IP and GRs, innovation played a very important role. It was also a promoter of innovation, taking into account the Nagoya Protocol and the CBD. The aim of the instrument should be to protect GRs, to enhance the transparency and the effectiveness of the patent system, and to guarantee mutual supportiveness with other environmental international agreements.

79. The Delegation of Indonesia welcomed the work-in-progress text. With regard to “misappropriation”, Ms. Bagley, as the Friend of the Chair, had explained the reason for its absence from the text, but it was not convinced yet. If the element of misappropriation was eliminated, the Delegation wondered how preventing the granting of erroneous IP or patent rights could relate to the disclosure requirement of GRs, derivatives and associated TK, since the IP system did not normally require the disclosure of the origin and source of GRs and TK, because such information was often not strictly relevant to enable the invention or support the claims. It asked for clarification and reassurance that the objective covered the element of misappropriation.

80. Ms. Bagley, speaking as the Friend of the Chair, said that the objective was not an operative provision of the agreement. What would prevent misappropriation or contribute to the protection of GRs would be the actual disclosure requirement, whatever would be agreed to in Article 3. That would specify what had to be disclosed, the conditions for disclosure, and what the obligation on the patent or IP applicant would be. Having the word “misappropriation” in the objective was not going to create that operative provision. The objective of “contribute to the protection” was in fact introducing the operative provision. The goal was not to focus so much on any particular term in the objective but on what the agreement would actually accomplish.

81. The Delegation of the Plurinational State of Bolivia said that, technically speaking, the patent system granted an IP right to the person innovating or inventing on the basis of GRs. So the term “misappropriation” should be used to avoid granting a property right to somebody who had fraudulently or illegally gained access to the GR in question. Changing “preventing misappropriation” to “unauthorized use” also changed the focus of many elements of the text, including sanctions, because unauthorized use was not the same thing as gaining fraudulent access to a GR. “Unauthorized” could be through an error, or a very innocent act, which would have different implications in national law. It could be criminal or administrative in nature, based on the terms used.

82. The Delegation of Egypt said that, in addition to “contributing to the effective protection” of GRs, the text should also mention “preventing the misappropriation” of GRs.

83. The Delegation of El Salvador said that the text was very useful and responded to the comments made at the plenary. It agreed with the Chair and the Friend of the Chair that the objective was fairly general and that the details regarding the mechanism to deal with the

contribution of the instrument to the protection of GRs would be sketched out later on in the text within the IP or patent system according to what would be decided in due course.

84. The Delegation of Indonesia, speaking on behalf of the LMCs, said that the objective covered all three key policy motivations of the treaty: contributing to the protection of GRs; enhancing the efficiency and transparency of the IP and patent system (through disclosure); and mutual supportiveness with other international agreements.

85. The representative of the Tebtebba Foundation, speaking on behalf of the Indigenous Caucus, asked whether the phrase “and preventing the granting of erroneous patents” in paragraph (c) would include remedies. She recalled her concern over prior occurrences of misappropriation. The text could read as follow “remedy the erroneous patents that have already been granted.”

86. The Delegation of the USA supported the work-in-progress text to be included in Rev 1.

87. The Delegation of India supported the text, insofar as it concerned the entire IP system, subject to confirmation by the capital.

88. The Delegation of Morocco, speaking on behalf of the African Group, wondered whether the objective was to guarantee effective transparency or simply to contribute to the protection.

89. Mr. Kuruk, speaking as the facilitator, said that there was no specific reference to misappropriation in Article 1 because the matter was dealt with in the preamble.

90. The Chair opened the discussion on Article 2 “Subject Matter of the Instrument”. He asked whether an article on subject matter was really needed, if the issue was dealt with within the operative articles. There were three unresolved issues: (1) the inclusion of the term “derivatives”; (2) whether the subject matter of the instrument should encompass GRs and/or TK associated with GRs; and (3) whether the instrument should apply to only patents or patent applications or also to other rights under the purview of WIPO. He opened the floor for comments.

91. The Delegation of the USA was concerned about the breadth of the instrument, if it was to include derivatives. It preferred to avoid the use of “derivatives”. It was happy to consider TK associated with GRs in addition to GRs themselves. With respect to whether the subject matter of the instrument should be patents only or other IP rights, it did not see the relevance of copyright, trademarks and other forms of IP rights to GRs and to the instrument. It preferred to keep the subject matter focused on patents. That was a practical and reasonable approach. With respect to Article 2, in the ALT paragraph, the “shall/should” formulation was used and it suggested replacing that with “[shall]/[should]” where each word was in brackets to reflect its concern that the original formulation might imply that either “shall” or “should” might be selected and a decision had to be taken between those two terms. So bracketing each of the words individually was a more appropriate formulation. It suggested another global change to bracket each of the article designation at the top of each article. For example, Article 1 would be [Article 1]. In the first paragraph of the preamble of the work-in-progress document, it suggested bracketing the words “in accordance” and inserting in place “consistent”. In the second paragraph of the preamble, it suggested bracketing “IP” and replacing that with “patent”. In the same line, it suggested pluralizing the word “inventions” and inserting “foster” before “innovation”. It suggested bracketing “facilitating protection of” and replacing that with “protecting”. In Article 1, it suggested bracketing paragraphs (a) and (b). It had already discussed the concept contained in paragraph (a). With respect to paragraph (b), it was not convinced that the mechanisms proposed in the instrument would enhance transparency in the patent system. In paragraph (c), it suggested inserting “erroneous” before “granting” and bracketing “erroneous” after “granting”.

92. The Delegation of Egypt said that in the UPOV Convention, countries were obliged to protect derivatives created by plant breeders. The IGC should also allow indigenous peoples owning GRs to protect those and their derivatives. Derivatives should stay in the text.

93. The Delegation of Switzerland said there was no need to include a specific article on subject matter, as the subject matter should become sufficiently clear based on the specific provisions of the instrument. It was in favor that the instrument applied to both GRs and TK associated with GRs. It was also in favor for the focus of the instrument to be on patents. On whether to include derivatives or not, one should clarify if all members had the same understanding, mainly the one that was contained in brackets in the list of terms. If that was the case, it recalled that, although the Nagoya Protocol included the term “derivatives” in Article 2 on the use of terms, it did not have a single reference of that term in the operative provisions. In order not to run counter to previously found international consensus and in order to be coherent with the Nagoya Protocol, there should be no reference to derivatives in the operative provisions of the IGC instrument. If, for whatever reasons, the IGC decided to include the term “derivatives”, it was important to discuss the practical implications of including that term. To do so, it should be kept in mind that not every biochemical compound in an invention was naturally occurring, as defined in the Nagoya Protocol. Many biochemical compounds needed to be stabilized, formulated or otherwise modified in order to be included in a product such as a pharmaceutical product. Referring to derivatives in the instrument could unnecessarily limit the subject matter to only those inventions, which still contained the naturally occurring biochemical compound. The inclusion of “derivatives” could run counter to the objectives of achieving a better protection for GRs and associated TK. The same derivative could often be found in a variety of different GRs and not unique to a single type of GR in a specific country. Disclosing the source or origin of a derivative could certainly reduce the transparency about a specific GR. Derivatives were already sufficiently covered by referring to “inventions directly based on GRs”. It was happy to discuss that further, as those issues were quite technical.

94. The Delegation of Brazil stated that regarding the subject matter, derivatives should be in the scope of the agreement. Brazil was a party to the Nagoya Protocol, which gave a very clear definition of derivatives in Article 2. It was one of the triggers of ABS requirements. It wished to have mutual supportiveness between the CBD, the Nagoya Protocol and the instrument being negotiated in the IGC. The existence of an article facilitated the understanding of the scope and reach of the treaty. It would be for the benefit of users and providers of GRs. Regarding the definition of derivatives itself, it should be discussed at the Nagoya Protocol level where there were experts on biotechnology. The issue of derivatives was very technical, so WIPO was perhaps not the best forum to discuss it. A better way to trace and monitor the utilization of GRs through the IP/patent system should be the focus of the discussions at WIPO.

95. The Delegation of Nigeria noted that the protection of GRs engaged beyond patents. The IGC did not need to shut down other possibilities in which order IP regimes were engaged in the GRs context. It was important to include derivatives in the text.

96. The Delegation of Morocco, speaking on behalf the African Group, considered that it would be timely and essential to extend the scope to include GRs, their derivatives and TK associated with GRs so as to ensure complementarity.

97. The Delegation of Senegal supported the statement made by the Delegation of Nigeria. The language should extend to the entire IP system in order not to be restrictive as to the scope of protection.

98. The Delegation of Japan strongly supported the invention made by the Delegation of the USA, especially regarding the preamble, objective and subject matter. The term “derivative” was not used in the main provisions of the Nagoya Protocol, although its meaning was defined

therein. That was because the parties of the CBD had been afraid that the term “derivative”, which was likely to be interpreted too broadly, could expand the subject matter of the Nagoya Protocol unlimitedly and eventually lead to legal uncertainty. It requested that the term “derivative” be deleted throughout the instrument. As a result, its definition should also be removed. Regarding the objective, it did not see the relevance of the term “misappropriation” which was outside of the patent system.

99. The Delegation of India said that the CBD and the Nagoya Protocol related to IP and were not restricted to patents. Derivatives should be part of the instrument, in line with the Nagoya Protocol.

100. The Delegation of Indonesia, speaking on behalf of the LMCs, preferred that the subject matter of instrument applied to the IP system. The term “derivative” was an important element in the subject matter of the instrument. It took note of the explanation by the Delegation of Switzerland and understood that the term was not used in the operative text of the Nagoya Protocol but it was linked to the term “utilization”, which was used directly or indirectly in many provisions. It wished to see the term “derivatives” still reflected in the subject matter. It also strongly supported the inclusion of TK associated with GRs, because of the utmost need to preserve the rights of IPLCs.

101. The Delegation of El Salvador said that the relationship to GRs was more obvious in the field of patents. However, it did not want to absolutely rule out the possibility that it might apply to other forms of IP. To overcome that problem, patents could be defined in the text and the preamble or somewhere could clarify that, in those cases where it applied to another form of IP, patents would apply to those other IP forms. A clarification of that type might open the way forward and would cover the concerns expressed by some delegations.

102. The Delegation of the Islamic Republic of Iran said that everyone was trying to reiterate its long-standing position, which was not helping much. It said that the exercise with regards to the objectives could be applied to the other articles. While respecting each other’s position, the IGC really needed to come up with a better text to make any progress. That could only happen if delegations were to respect and recognize each other’s position. Otherwise it would be very difficult to ask a party to withdraw from one key position to improve the text. The IGC still had the opportunity to develop a more balanced and inclusive text. Other international instruments such as the CBD, the Nagoya Protocol or the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (“ITPGR”) dealt with ABS issues. The IGC dealt with IP and had to clarify those issues relating to IP. As pointed out by the Delegation of India, those instruments were referring to IP in general. The IGC instrument would set out the provisions with regards to IP and there was a need to come up with the details required for that discussion. It wished to see the more recent instrument clearer, more up to date and to provide solutions for outstanding issues. As to derivatives, the IGC should not engage on the different aspects. The commercialization of specific chemicals and pharmaceuticals was not really dealing with the GRs themselves, not with material with functional units of hereditary, but rather with the metabolites and biochemical compounds contained in those GRs. The IGC could not restrict itself to addressing IP issues related to GRs. The IGC needed to provide solutions for the IP protection of derivatives as well. When it came to the IP versus patent system, patents did not refer to all IP issues affecting GRs. Specifically, plant GRs were generally governed by plant breeding rights, also a form of IP. It was not in a position to exclude a major chunk of agricultural GRs from the instrument. Those were major IP issues that needed also to be addressed, although they were not generally governed by patents but rather by *sui generis* systems or plant breeding systems.

103. The Delegation of the Plurinational State of Bolivia supported the inclusion of the term “derivatives”. The subject of derivatives in the Plurinational State of Bolivia involved the primary and secondary metabolites found in the medicinal plants of indigenous communities.

104. The Delegation of the Republic of Korea said that Member States had not reached a common understanding of the clear scope and definition of derivatives, which were so unclear that the applicants or examiners might be confused when filing patent applications. It wished to remove derivatives from the text. With regard to patent versus IP system, GRs and TK associated with GRs were much more related to patents than to other IP rights such as trademarks, designs and copyright. The subject matter should be limited to the patent system. It wished to keep Article 2 in the text. The scope of subject matter should be clearly defined to minimize confusion in implementing the instrument.

105. The Delegation of Colombia said that the IGC should include a section on unresolved issues, where the definition of derivatives could be placed, to be discussed once a discussion had already taken place elsewhere on that issue. That term was in the Nagoya Protocol and its inclusion made it operative throughout the instrument. It had been included as a definition because it had been recognized as an element different from GRs. The IGC should not discuss technical issues already resolved in other instruments. The instrument should cover TK associated with GRs. Based on experiences in various countries the scope needed to include all IP rights.

106. The Delegation of Brazil clarified its earlier intervention. It cautioned against redefining derivatives at WIPO. There was a definition under the Nagoya Protocol and it should not be changed. Concerning the inclusion or not of the derivatives in the operative parts of the Nagoya Protocol, it agreed with the statement by the Delegation of Colombia. Article 2(c) stated that utilization of GRs included the application of biotechnology, thus of derivatives. The term “utilization” of GRs in Articles 5, 6, 17 and so on was a rather economical way of progressing the discussion of the text in the Nagoya Protocol. There was no need to refer everywhere to derivatives. Derivatives were under the scope of the Nagoya Protocol throughout the text.

107. The Delegation of Australia said that it was most suitable for the instrument to focus on patents. It should include GRs and TK associated with GRs. Derivatives would be encompassed within GRs. It was interested in hearing from countries with existing domestic disclosure requirements that had a specific reference to derivatives. Such practical experience would be helpful in understanding how that term would impact the scope of the international instrument. It might also help to narrow down the relevance of that term to the specific instrument.

108. The Delegation of Canada said that, while it understood that the definitions of GRs and genetic material in the CBD, it was not necessary to directly import all those terms into the IGC text, at least not without first reaching a common understanding. The CBD pertained to biological diversity while the IGC was about the creation of an IP instrument. Without prejudice to the important work of the CBD and the Nagoya Protocol, biodiversity and IP were two different disciplines and the IGC needed to make sure that the terms in an IGC instrument could be applied in an IP context without prejudice to the nature of the outcome(s). With a view to enhancing a common understanding on that issue, it welcomed the views of Member States that applied those terms in an IP context so as to see how they had been interpreted by patent applicants or courts. That would help establish the best definitions for the specific purposes of the instrument. The same went for the term “derivatives”, over which it continued to have concerns and questions, including what the term meant for the breadth and scope of the instrument. It looked forward to a discussion of what that term meant not theoretically but in the concrete office practice of Member States providing for mandatory disclosure of derivatives. It echoed the comment made by the Delegation of Australia. It had a particular interest in the concrete application of the concept “even if it does not contain functional units of heredity”. It welcomed a discussion about what “mutual supportiveness” entailed for those Member States supporting that concept. It wondered whether an IGC instrument would essentially be an extension of the CBD and the Nagoya Protocol.

109. The Delegation of the Russian Federation said that the misappropriation of GRs was not within the competence of WIPO and should be deleted from Article 1. In Article 2, it considered that the subject matter related to the patent system. As regards derivatives, it supported the statement made by the Delegation of the Republic of Korea and asked for a clear definition.

110. The Delegation of Costa Rica said the word “derivatives” should be included in the text, as it was clearly defined in the Nagoya Protocol. Costa Rica had approximately 550 permits for access to biochemical or GRs, following the rules established in the CBD and its regulations. Approximately 10 percent of the applications were for biochemical access for bio-propagation. TK was associated to the empirical and tangible experience in the biochemical derivatives, which were produced by the genetic or metabolic expression of living organisms, which had a specific use. The inclusion of derivatives in the text clarified further the scope of TK associated with GRs.

111. The Chair closed the discussion on subject matter. He opened the discussion on Article 3 relating to the disclosure requirement. In Chair’s Information Note, he had identified some key issues that needed to be worked through: trigger, content, exceptions and limitations, subject matter eligibility and the consequences of non-compliance. There were number of different options within those core issues, some of which related to the scope of the instrument. He opened the floor for comments on the issue of the trigger.

112. The Delegation of the EU, speaking on behalf of the EU and its Member States, remained committed to constructively engaging in discussions on the disclosure requirement in patent applications. It was not a demandeur in the IGC. The disclosure requirement should not apply to derivatives and its coverage with regards to TK should depend on the results of ongoing discussions on the definition of TK. The trigger of the disclosure requirement should be that the invention was directly based on the subject matter. The applicant should declare the country of origin or, if unknown, the source of the specific resource to which the inventor had had physical access and which was still known to him/her. Exceptions and limitations should be provided for at the international level. Revocation of patents could not constitute a sanction. The consequence of non-compliance would be, on the one hand, that if the applicant failed or refused to declare the required information, the application should not be further processed. On the other hand, if the information provided was incorrect or incomplete, sanctions outside the field of patent law should be envisaged. Regarding defensive approaches, such as those focused on the databases or due diligence measures, it remained interested in discussing them to complement the policy debate on a disclosure requirement.

113. The Delegation of Brazil stated that the trigger should be the utilization of GRs as defined in the Nagoya Protocol. Alternatively, it could go along with the utilization of subject matter, which was not only the terminology used in the Nagoya Protocol but in the UN SDGs. Target 2.5 mandated to promote access to and fair and equitable sharing of benefits, and Target 15.6 mentioned that the global community should provide fair and equitable sharing of benefits arising from the utilization of GRs. WIPO, as part of the UN system, had to be consistent with those targets. The use of patent offices as checkpoints would do much to help the implementation of the Nagoya Protocol. It would not place additional obligations on IP offices, as they would not be obliged to verify the contents of the disclosure itself; it would be a formal requirement. The goal was to clearly define the respective implementing functions of IP offices and to contribute to allow provider countries to trace what might happen to the GRs, associated TK and derivatives once they had left the jurisdiction. It would also make possible for national authorities related to ABS to verify compliance with PIC and ABS requirements. That would not overburden IP offices. Its own national experience showed that the advent of IT systems facilitated simple notification procedure.

114. The Delegation of Switzerland said that it was important that the trigger clarified the relationship between the claimed invention and the GRs and/or associated TK. As mentioned by the Delegation of the EU, on behalf of the EU and its Member States, “directly based on” would exactly establish such a relationship. Seeing that the term “utilization” could be used as a trigger, it wondered how that term would be related to TK associated with GRs. The term “utilization” in the Nagoya Protocol context had been defined in the context of GRs but there was no definition on how actually it related to TK associated with GRs. It was questioning using it to define a trigger in an IP or patent application context.

115. The Delegation of Ecuador shared its legislation, which read: “According to the international treaties to which Ecuador is a party, if the subject matter of a patent application involves GRs and TK associated with GRs, the applicant should say so. The country and the source where these resources or knowledge are to be found, as well as the entity or persons from which these GRs were obtained have to be indicated” (approximate translation).

116. The Delegation of the Plurinational State of Bolivia agreed with the Delegation of Brazil regarding the trigger.

117. The Delegation of Morocco, speaking on behalf of the African Group, considered that disclosure was the cornerstone of the text and should cover GRs, derivatives and TK associated with GRs.

118. The Delegation of Lithuania, speaking on behalf of the CEBS Group, looked forward to more thorough discussions in informals. As the Delegation of Switzerland, the Delegation of the EU, on behalf of the EU and its Member States, and other delegations, it had issues with the inclusion of derivatives in the disclosure requirement and in the text of the instrument. It was not convinced about the need to include TK associated with GRs. The instrument should relate only to patent applications, not other IP rights. The trigger of the disclosure requirement should be that the invention was “directly based on”.

119. The representative of the Tebtebba Foundation, speaking on behalf of the Indigenous Caucus, said that Article 3 of the Nagoya Protocol referred to the utilization of associated TK. While the list of terms only defined utilization of GRs, several other articles referenced the utilization of TK, therefore it would be appropriate to identify utilization as the trigger in the IGC text.

120. The Delegation of Nigeria drew attention to the 2017 WIPO Study on the disclosure requirement. That document helped to look at the triggers constructively without necessarily restating hard fixed positions. The three key words that showed where the triggers would lie were: “utilization”, “derived” and “directly based on”. Some of those issues would be resolved at a national level through legislation or regulatory regimes.

121. The Delegation of the USA was still considering the issue of the trigger. Its current thinking was that “directly based on” might be the most practical approach. It did not support disclosure requirements, as it caused many concerns. A large gap existed around subject matter and it had some comments and proposals that could help to bridge those gaps. It suggested a global change to use “Member State” instead of “Party”, because it did not want to prejudge the outcome of the instrument. In Article 3.1(b), it suggested bracketing “and” before “local communities” and inserting “any other holder of patent rights over the genetic resource”. With that change, all rights over GRs would be treated equally. It proposed a new alternative Article 3.1, which read: “Where the subject matter of an invention is made using genetic resources obtained from an entity, that entity may, in the permit, agreement or license granting the applicant access to the genetic resource or the right to use the genetic resource, require a patent applicant to include within a specification of any patent application and any patent issuing thereon, a statement specifying that the invention was made using the genetic resource and

other relevant information.” In Article 3.2, it suggested bracketing “requirement” and inserting “of the geographic location where the genetic material was obtained”, and adding “as well as an opportunity for applicants or patentees to correct any disclosures that are erroneous or incorrect” after “disclosure requirement”. In Article 3.3, it suggested replacing “declaration” with “patent application”. It suggested a new Article 3.4 as follows: “Patent Offices should publish the entire disclosure of the patent on the internet on the date of patent grant and should also make the contents of the patent application publicly accessible over the internet.” It suggested adding a new Article 3.6, which read: “Where access to a genetic resource or associated traditional knowledge is not necessary to make or use the invention, information regarding the source or origin of the genetic resource or associated traditional knowledge can be provided at any time after the filing date of the application and without payment of a fee.”

122. The Delegation of India said that the Indian Patent Act included a mandatory requirement to disclose the source and geographical origin of biological material used in an invention. In Article 3.1, it wished to have wording: “The subject matter within an IP rights application includes utilization of GRs, their derivatives and/or TK associated with GRs. Each party shall require applicants to disclose the country of origin or, if unknown, the source of the GRs, their derivatives and/or TK associated with GRs.”

123. The Delegation of Egypt said that disclosure was a critical part of the instrument and of the IGC’s work. It suggested a compromised text: “The subject matter within an IP rights application is directly based on and/or includes utilization of GRs, their derivatives and/or TK associated with GRs. Each party shall require applicants to disclose its source, provided that this disclosure provides relevant information as required by national law regarding compliance with ABS requirements including PIC.”

124. The Delegation of Japan did not see the need for adopting a mandatory disclosure requirement, which would not be the most effective way to address issues concerning GRs. Introducing a mandatory disclosure requirement into the patent system could unnecessarily create legal uncertainty, diminish predictability, and harm the patent system under the aim of complying with ABS, which had no direct connection with the patent system. Eventually, the outcome of introducing the mandatory disclosure requirement would lead to discouraging R&D activities utilizing GRs.

125. The Delegation of South Africa stated that on the trigger, the term “utilization” had to refer to utilization outside of the community of the knowledge holders. South Africa had very clear legislation on biodiversity, which included a new definition of GRs. If the issue was still tied to an old-fashioned definition of “utilization”, which had a limited scope of bioprospecting, it was undermining the use. Utilization had to be understood in a broader context, up to date with the technological changes that had taken place.

126. The representative of the International Law Association said he had carried out a few studies on that specific question. Certain national approaches focused on the link with patent law and disclosure upon filing a patent application. Whether or not the mentioned patent relied upon TK in some form had to be disclosed. If there were relevant national laws on access to TK, PIC and MAT should be demonstrated or supplied to the patent office. If those were not supplied, the patent could not be granted. If incomplete information was provided, that constituted fraud and the patent could be revoked on that basis.

127. The Delegation of Indonesia, speaking on behalf of the LMCs, said that in order to narrow the gaps, clarity needed to be focused on. It agreed with the Delegation of Switzerland that the application of a disclosure requirement depended on the trigger. Everyone needed to be able to understand how the trigger would link the claimed invention to the GRs and TK associated with GRs. It preferred broader markers of proximity creating the boundaries on which the benefit-sharing requirements would apply. It supported the terms “utilization”, “subsequent

application” and “commercialization” to be used to trigger fair and equitable benefit-sharing obligations, as outlined in the Nagoya Protocol. The use of “utilization” as a trigger was consistent with the Nagoya Protocol. A narrow interpretation excluded the application of disclosure for subject matter simply based on a source of a non-tangible source of bio-information and that had to be included as well. Exceptions and limitations should be simple and straightforward and not too extensive so as not to compromise the scope of protection of the subject matter.

128. The Delegation of the Plurinational State of Bolivia said that Article 3 should cover applications for IP rights when an invention used GRs, its derivatives and TK associated with GRs. Article 3.3(5) was pertinent and useful for the instrument, and was in line with the terms of reference of the IGC, i.e. to design an instrument in line with the SDGs, particularly Target 15. The patenting of GRs without any inventive step created an imbalance that needed to be corrected. The preamble already included a paragraph concerning the patenting of genes and it needed to be included in the body of the instrument. The disclosure of the source was very important, since GRs should not be patented after having been isolated from their source. The disclosure of the source applied to any use of GRs. Article 3.5 filled a gap in the instrument. GRs, as they were found in nature, should not be considered as inventions.

129. The Delegation of China said that disclosure should be mandatory. On the question of the trigger, its patent law had laid down the principles for disclosure and for the materials for the patent application. It agreed that “based on” and “utilization” should both be included.

130. The Delegation of Uganda supported the comments made by the Delegation of Morocco, on behalf African Group, and the Delegation of Indonesia, on behalf the LMCs. The subject matter of the IP application had to be sufficiently related to GRs and associated TK so as to require the disclosure of relevant information. In Uganda, the Industrial Property Act of 2014 provided for a trigger. The applicant was required to provide a clear identification of the origin of genetic or biological resources collected in the territory of Uganda and that either directly or indirectly used in the making of a claimed invention as well as of elements of TK associated or not with those resources. Some delegations had expressed the view that the obligation to disclose be triggered only if the applicant had physical access or direct access to the GRs used. However, the rapid evolution of genetic manipulation and sequestering of genomes created a situation where direct access to GRs might be avoided. It therefore preferred the broad term of “utilization” of GRs.

131. The Delegation of India said that since the disclosure requirement was mandatory as per its patent law, there was no scope for an exceptions and limitations article.

132. The Delegation of Sri Lanka said that the IP regime had to be in agreement with the Nagoya Protocol to facilitate a more practical implementation. The inclusion of the term “utilization” was necessary in order to agree with the Nagoya Protocol. Disclosure had to be mandatory for GRs, TK and TCEs.

133. The Chair opened the floor for comments on the content of disclosure.

134. The Delegation of Canada looked forward to better understanding the terms under discussion, including “directly based on” and “utilization”, on the basis of the concrete experiences of Member States applying those terms in practice as well as on the experience of users navigating those concepts. While it acknowledged and appreciated that there were databases of Member States legislation on disclosure requirements, what it was mostly interested in was not so much the legislation that was on paper, but rather how that legislation was actually implemented in practice. For example, it wished to know how “directly based on” and “utilization” were concretely implemented in actual practice by the IP or patent offices of countries using those terms in their legislation. That would help advance the work by enriching

the discussions with the concrete relatable experiences of Member States, rather than on the basis of abstract language. While “directly based on” aimed at establishing a closer relationship between the GR and the claimed invention than some other triggers, that concept was still unclear, since the definition contained equally unclear elements, including “make immediate use of”, which was rather similar to “directly based on” itself such that the definition was somewhat recursive. On “utilization”, it was equally unclear how conducting R&D or conservation, for example, had direct IP implications. For example, if R&D occurred upstream of a patent application or even without it leading to a patent application, it did not see a link between utilization and any disclosure requirement. Notwithstanding its position on disclosure, the disclosure had to be about something in the application, rather than about some separate activity like conservation or collection, which might not even lead to an application for an IP right. With a view to clarifying that issue, it welcomed information on the concrete experiences of those Member States using utilization as a trigger for disclosure. It had interrogations on source and origin, including what “origin” meant, and how countries with disclosure requirements based on disclosing the origin of the GRs had implemented that term in practice. It wondered whether there was an expectation that the applicant would establish the provenance(s) of a GR up to its ultimate origin. It could relate more to “source”. “Origin” was unclear, as it seemed to expect that applicants would make determinations that might not have anything to do with their use of the GR.

135. The Delegation of Switzerland said that the content of disclosure needed to take into account the fact that there were various legal and factual circumstances under which GRs and associated TK could be sourced. Those circumstances included: (a) a diversity of sourcing locations, such as *in situ* locations in the country of origin, IPLCs, but also *ex situ* locations, outside or inside the countries of origin; (b) a diversity of legal situations, such as GRs which were subject to PIC and MAT, while orders might be sourced under the conditions of other international agreements such as the multilateral system of the ITPGR; (c) a diversity of types of GRs, some were naturally occurring, while others had been cultivated or modified over years and therefore, might contain GRs from multiple countries. Moreover, any requirement should not lead to unreasonable burdens neither for patent applicants nor for patent examiners. The concept of “source” which it had explained and illustrated in a number of submissions to the IGC would indeed take into account those important aspects. It recalled its submission WIPO/GRTKF/IC/31/8 where it had explained that in further details.

136. The Delegation of Brazil agreed with the Delegation of Switzerland that the content of the disclosure should not be burdensome on patent or other IP rights applicants. It should contain the minimal information necessary for the competent ABS authority of the patent office to assess that the access and utilization of GRs complied with PIC and ABS requirements under the Nagoya Protocol and the CBD. It should enable the traceability of the GRs, derivatives and TK associated with GRs, allowing the providers to keep track of the use of the resources. It should contain information regarding the country of origin or the country providing the resources, if from *ex situ* sources, and state that the resources were acquired in accordance with the CBD.

137. The Delegation of Egypt said the content of disclosure consisted in the resources that the claimants were using for their patents. It should contain sufficient information in line with national legislation in terms of prior knowledge.

138. The Chair opened the discussion on exceptions and limitations.

139. The Delegation of the Islamic Republic of Iran said that, in keeping with the agreed international instruments, the IGC should draft simple and straightforward exceptions and limitations. It supported the original text.

140. The Delegation of the USA suggested inserting “and public health,” after “public interest”. In Article 4.1 ALT, it suggested inserting a new paragraph (g) that read: “Genetic resources and

traditional knowledge associated with genetic resources necessary to protect human, animal or plant life or health or to avoid serious prejudice to the environment.” It would be extremely difficult from a practical perspective to include PIC or MAT in a disclosure requirement. It did not support a disclosure requirement, but to the extent that it was part of the discussion, it urged members to think of a practical solution. “Source” versus “origin” would be an advantage. It urged members to not include PIC, MAT, ABS or any other CBD related concepts.

141. The representative of the Tulalip Tribes, speaking on behalf of the Indigenous Caucus, supported Article 4 but with a text addition. He wished to add “or mutual supportiveness with other instruments” after “the implementation of the instrument”.

142. The Delegation of Nigeria supported the textual proposal by the representative of the Tulalip Tribes, on behalf of the Indigenous Caucus.

143. The Delegation of South Africa noted the positive contribution by the Delegation of the USA around the issue of disclosure. On exceptions and limitations, Articles 4.1 and 4.2 were inconsistent with the logic of disclosure. It proposed moving them to the alternative article “No New Disclosure Requirement”. The concept of public interest was wider than that of public health along with many others.

144. The Delegation of Morocco, speaking on behalf of the African Group, was in favor of the initial text of Article 4 and did not understand the purpose of adding “public health”.

145. The Delegation of Brazil said that a degree of flexibility was needed regarding exceptions and limitations to allow countries to better adapt the norm to their legal context. The first option in Article 4 contained a nice and elegant solution in line with Articles 13 and 30 of the TRIPS Agreement. It supported the statement made by the Delegation of South Africa that the ALT Article 4 was not in line with the spirit of that article and should be moved to “No New Disclosure Requirement”.

146. The Delegation of India said that as per the Indian Patents Act, disclosure was mandatory. In every case, the inventor, the applicant, had to disclose the source. There was no provision on exceptions and limitations.

147. The Delegation of China supported the statement made by the Delegation of Brazil. Different countries had different situations, so the article on exceptions and limitations should provide maximum flexibility.

148. The Delegation of Indonesia, speaking on behalf of the LMCs, said exceptions and limitations should be simple and straightforward, in line with international agreements. They should not be too extensive so as to compromise the scope of protection of the subject matter.

149. The Delegation of Egypt supported the statement made by the Delegation of Indonesia, on behalf of the LMCs. The protection of the public interest was ambiguous and might lead to a lot of exceptions, which would not be desirable for the instrument. Exceptions and limitations should not prohibit mandatory disclosure and should be clear, in line with the three-step test.

150. The Delegation of Colombia said that the exceptions and limitations were a burden, an overload of work on the patent offices. The IP system on GRs should not include exceptions and limitations.

151. The Chair opened the discussion on sanctions and remedies. The fundamental issue was that of revocation and its potential impact on innovation and commercialization opportunities. Some Member States had concerns over unintended consequences. At the same time, a

number of Member States had revocation within their domestic regimes. The instrument had to allow for policy space. He opened the floor for comments on sanctions and remedies.

152. The Delegation of India said the provision of sanctions and remedies was essential because it gave an opportunity to both the State as well as the inventor to correct what had happened, either knowingly or unknowingly. The Indian patent system had that provision applicable at the pre-grant and post-grant stages. It supported the inclusion of that provision in paragraph 5.

153. The representative of the Tebtebba Foundation, speaking on behalf of the Indigenous Caucus, said that there should be clear consequences spelled out in the instrument for non-compliance with the disclosure requirement. Invalidation should be on the table. There should also be penalties in all cases of non-compliance, similar to what was in the Yakuanoi film, there should be benefits given. [Note from the Secretariat: The Yakuanoi film is available online at <http://www.wipo.int/tk/en/>.] The difference between the instrument under negotiation and the fictitious story in the Yakuanoi film was that the latter was based on private contract. In cases of non-compliance, there should be a legal framework that required the GRs users to still share benefits. There should also be the possibility of reassignment of the patent to indigenous peoples in cases of non-compliance.

154. The Delegation of El Salvador supported the option of the original text. It was important that there be sanctions, when there was misappropriation or non-authorized use of GRs. There should be a series of sanctions established for those cases, and they should be proportionate to the size of the misuse.

155. The Delegation of the USA suggested bracketing Article 5 to reflect that it required additional work. To improve the text, it suggested the addition of a new Article 5(a)(iv): "Providing an opportunity for patent applicants to supplement the patent application with additional information to disclose the source or origin of any genetic resource or traditional knowledge used. Since such information is irrelevant to how to make and use the invention, there would be no impact upon the filing date of the application and no fee required for its submission after the filing date of the application." It suggested the addition of Article 5.4, which read: "Failure to examine a patent application in a timely manner shall result in an adjustment of the term of the patent to compensate the patentee for administrative delays."

156. The Delegation of Brazil saw the need for effective sanctions that allowed for proper compliance with the disclosure requirement. The sanctions would deter deviations from the expected behavior of stakeholders by providing punishment. Those punishments could take the form of criminal sanctions, monetary fines or administrative sanctions, and in certain exceptional cases, they could affect the validity of a patent. They had to provide legal certainty and avoid moral hazard situations. If the willful or fraudulent lack of compliance with disclosure requirements entailed low costs, financial or otherwise, it was facing a situation of moral hazard. The Brazilian legislation on GRs contained administrative sanctions and followed a crescendo, they might go from mere written reprimand but might include fines, apprehension of the samples of the biodiversity or even partial interdiction of the establishment that had committed the offense. The competent authorities took into account the gravity of the offense, whether the offender was a recidivist or not as well as the economic situation of the offender. On the other hand, a formal requirement might also cause post-sanction revocation. In certain exceptional cases, it affected the validity of a patent. Those were not automatic processes, and the applicants were given the opportunity to present their argument, both in the course of an administrative procedure at the patent office and during an eventual judicial process. That ensured due process. The TRIPS Agreement provided for the revocation of a patent as a remedy. It was important to allow for policy space in national legislation and for the possibility to have extreme sanctions in cases of extreme failures to comply with ABS systems. Minimum

sanctions should be agreed by the IGC, leaving flexibility to Member States to include other effective, proportionate sanctions and dissuasive acts in accordance with their legal framework.

157. The Delegation of Uganda was in favor of mandatory disclosure. It supported the sanctions and remedies in the original text.

158. The Delegation of South Africa said it was important to have balance in terms of the measures in the sanctions, taking into consideration the nature of the disclosure. South Africa had administrative sanctions in the National Biodiversity Act, so the Minister could provide some mechanisms at the pre-grant stage. In the Patent Act, there was a provision for sanctions for failure to disclose. The Patent Amendment Act, which covered TK and indigenous knowledge, also had provisions on sanctions. The gaps that had been left out were being taken up by the Indigenous Knowledge Bill, which covered issues around sanctions that had not been covered. At the pre-grant stage, applicants were given an opportunity to go and find their TK sources and were subsequently given the permission to process. Around revocation, the Act allowed courts to arbitrate in that case. It was not just within the patent system but in the entire legal system.

159. The Delegation of Nigeria identified strongly with Article 5, in the interest of simplifying and closing gaps. It identified with the need for consequential sanctions for failure to disclose. The sanctions in Article 5 were merely enumerative and not necessarily prescriptive. Those types of sanctions allowed for flexibilities over the nature of specific sanctions that each State might be inclined to invoke. As indicated by the Delegation of South Africa, in specific national jurisdictions, that might be the realm of litigation. In essence, it identified strongly with the need for sanctions, which would be a matter of national law. In relation to ALT Article 5, Articles 5.1, 5.2 and 5.3 were irreconcilable if not inconsistent with substantive Article 5. It wondered if they could not be parked somewhere so as to make the article workable and help close gaps.

160. The Delegation of Indonesia, speaking on behalf of the LMCs, said that, with a disclosure requirement, the only burden on applicants would be their intent to provide relevant information, whether in good faith or fraudulent. As to "moral hazard", as mentioned by the Delegation of Brazil, for example, some companies based on a cost/benefit analysis might consciously prefer to run the risk of paying a fine at a later stage rather than disclose some information. That was not in a good faith. The article needed to strike a very fine balance between good faith and strict liability to make sure that the instrument could achieve its objective. It supported the original text. It agreed that since the text included "subject to national legislation", it was not really prescriptive but rather open and flexible. It remained open to any textual proposal aiming at narrowing gaps.

161. The Delegation of Egypt said that it was talking about non-disclosure in a pre-grant stage, the right to hold IP or a patent obtained via erroneous and fraudulent information. There were three elements. If the person requesting the patent did not include information in its request and it did have to do with TK, the State should review the national legislation. If the patent holder had achieved his patent via administrative fraud, the State would have to revoke or withdraw the patent. Those sanctions needed to be in line with national legislation, including complementary sanctions. Damages needed to be taken into account, in line with national legislation.

162. The Delegation of Morocco, speaking on behalf of the African Group, said that sanctions were highly important for the application of the text and should be based on administrative and legal measures, pre-grant and post grant. It preferred the initial text, because it was balanced, but some brackets could be alleviated.

163. The Delegation of the Islamic Republic of Iran was in favor of a mandatory disclosure requirement. Sanctions and remedies were an important part. Along with other LMCs, it was in favor of the original article, which provided enough policy space and flexibility for all Member States to prescribe any sanctions and remedies based on national law.

164. The Delegation of Australia said that sanctions and remedies should be limited to where they were needed to meet the objectives of the requirement. For a requirement focused on supporting transparency in the patent system, effective and proportionate sanctions and remedies would be aimed at facilitating honest and good faith disclosure. The sanctions should be focused on intermediate measures. Invalidation of a patent would place an unreasonable burden on patent applicants and should be avoided as a sanction. It preferred the ALT option. In the Australian context, the Patent Act provided for sanctions like revocation where a patent was obtained in fraud.

165. The Delegation of Colombia said that with a mandatory disclosure requirement there needed to be consequences for non-compliance. If the objective of the instrument was to protect GRs and also to enhance the transparency and effectiveness of the IP system, Member States had to implement administrative, legal or criminal measures that they considered appropriate. It supported the statement made by the Delegation of Brazil that the proportionality of the punishment would be included in national legislation, and could include criminal and monetary fines.

166. The Chair opened the floor for comments on defensive measures.

167. The Delegation of the USA said that while it did not have any particular concerns about defensive measures, it wished to make a few suggestions to the text. In Article 6, it wished to bracket “access and benefits sharing”. In Article 7.1(d), it wished to insert “containing” after “databases”, and to bracket “of” before “genetic resource”.

168. The Delegation of Japan supported Articles 7.1, 7.3 and 7.4 because the objective of the instrument was to prevent the erroneous granting of patents for inventions utilizing GRs. That article was based on its joint proposal, namely, document WIPO/GRTKF/IC/35/7. Regarding defensive measures, it wished to add one paragraph to Article 7, based on paragraph 17 of document WIPO/GRTKF/IC/35/8, to clarify the relationship between Member States and the WIPO Portal Site. The proposed paragraph read as follows: “7.5 Member States should provide effective legal, policy or administrative measures, as appropriate and in accordance with national law, to implement and administer the WIPO Portal.” The objective of the instrument was to prevent the erroneous grant of patents and the term “erroneous grant/granting of patents” was one of the most important concepts so it wished to add the concept to the List of Terms. That proposal read as follows: “Erroneous Grant/Granting of Patents. Erroneous grant/granting of patents means the granting of patent rights on inventions that are not novel, that are obvious, or that are not industrially applicable.” In addition, regarding the preamble, in relation to the prevention of the erroneous grant of patents, it wished to add three paragraphs, as essential elements of the preamble because the objective of the instrument was to prevent the erroneous grant of patents. The first proposed paragraph read as follows: “Ensure that patent offices have appropriate information available to them on genetic resources and traditional knowledge associated with genetic resources, which they need in order to make informed decisions in terms of granting patents.” The second paragraph proposed read as follows: “Reaffirm the stability and predictability of correctly granted patent rights.” The third paragraph proposed read as follows: “Recognize that the erroneous granting of patents can be effectively addressed by improving databases for storing information on genetic resources and non-secret TK associated with GRs, which can thus be used to search prior art and reference materials not only in the proceedings of examination, but also in the proceedings of opposition or invalidation against granted patents.”

169. The representative of the Tulalip Tribes, speaking on behalf of the Indigenous Caucus, said he could work on the basis of Article 6 on due diligence. The alternative was too long, too prescriptive and involved too many issues that needed to be settled in international law. That issue involved negotiations on TK that were not yet finished or agreed upon. The database

issue should be complementary to the other measures, which were the most important regarding problems in the development of IP. Those who were doing the development were in the economic and information position to know where the GRs and TK inputs had come from. If they did not know where their knowledge came from, they could do a due diligence to discover that. Focus should be on the prior prevention of things coming before a patent officer. Databases were useful as an adjunct in a patent review. He was very concerned about how databases were produced, how they came together, what the status of the TK therein was. Many indigenous peoples did not want certain kinds of TK stored in a database; it would be culturally wrong for them to do so. So the contents of the databases would never be perfect. TK not currently disclosed required the FPIC of indigenous peoples before it entered a database. The use of published literature by itself could not imply that TK in the publications was in the public domain. Even if it was published, it should be considered positive evidence of property rights of the TK holders. Databases should only be open to patent offices with safeguards for the perpetual protection of such databases. There was an inconsistency between the Consolidated Document and the documents submitted by some Member States. The latter proposed that databases were only open to patent offices, whereas Article 7.4 of the Consolidated Document proposed that they be open to the public. Opening databases to the public, even only information contained in published literature, could be harmful to IPLCs, because it made easily available information about their TK that could be exploited in a non-IP context. Those issues were also tied to the definition of misappropriation in Option 2. That option was related to some concepts on the status of TK in databases. Nothing in the definition said that there should be a test against customary law, although it was customary law, traditional law, and indigenous law that mattered for indigenous peoples. There was also the issue of reverse engineering within the IP system. The United States Digital Millennium Copyright Act allowed for reverse engineering of an artifact or process, as long as it was obtained legitimately. That raised the question of what was legitimate acquisition in the context of GRs databases. It was not misappropriation if it was obtained by reading publications. It did not say "public domain", but if using it was not misappropriation and there were no obligations for benefit-sharing, it was *de facto* public domain, because there was no control over that. The issue of independent discovery was under negotiation in the TK arena. He did not have a fundamental problem with that, but there needed to be a chain of evidence on independent discovery to show that it had not been obtained from TK. There could be extensive overlap between TK and an independent discovery, for example in the case of a single molecule or a simple effect. However, a lot of indigenous knowledge was actually related to complex compounds that required procedures for preparation, and it would be very unlikely for those to overlap. He did not know what inadvertent disclosure meant; it seemed to be a trade secret-like principle. Indigenous societies did not act like corporations, where employees signed contracts and there were brick-and-mortar buildings. The idea that an indigenous society should change its behavior in order to meet the expectations of the western IP system was a very big problem. The simpler framework definition in Article 6 was the one to work from.

170. The Delegation of Brazil recognized the value of databases and defensive measures, but as complementary to the disclosure requirement. They could only be effective together with a mandatory disclosure requirement system with sanctions. They were not an end in themselves but a means to achieve the goal of protecting GRs and TK in conjunction with the disclosure requirements. However, though they may be useful, they were not an encompassing solution. It was not feasible to have all GRs in a single database; it was simply out of reach. The question of how many species existed had intrigued scientists for centuries. Recently the census of marine life had tried to tackle the question. The census was a ten-year scientific initiative involving a global network of researchers from more than 80 nations. The goal was to assess and explain the diversity, distribution and abundance of life on earth. A study estimated the total number of species on earth and a staggering 86 percent of all species on land and 91 percent of those in the seas had yet to be discovered, described and catalogued. In the Amazon region, one new species was discovered every two days. That translated into 380 new animal or plant species discovered in the past two years. The concerns of the Indigenous

Caucus should be duly taken into account when designing databases. There were other practical issues related to databases, for instance, the responsibility for their compilation, structure, content, interoperability and costs. Nevertheless, the Delegation was not opposed to the inclusion of databases in the text.

171. The Delegation of India said that misappropriation of TK and biopiracy of GRs were of great concern to many countries and IPLCs. While those issues had been taken up within various multilateral fora, a global framework to protect TK had not yet been established. The IGC was going a step further. It supported including Article 6, as a defensive measure complementary to mandatory disclosure requirements. In order to protect TK and GRs, India had made a pioneering effort to establish a Traditional Knowledge Digital Library (“TKDL”). That was particularly for the medicinal plants and formulations used in Indian systems of medicine. It was a tremendous work. It had started in 2001, initiated by the Council of Scientific and Industrial Research and the Ministry of AYUSH with the objective to protect the country’s TK from exploitation through biopiracy and unethical patents, by documenting it electronically and classifying it as per the International Patent Classification system. As of 2010, the TKDL had transcribed 148 books on ayurveda, unani, siddha and yoga in the public domain into 34 million pages of information translated into five languages (English, German, French, Spanish and Japanese). More than around 0.3 million formulations had been digitized and more than 1,000 patent applications had been identified, scrutinized based on the TKDL. Considerable success had been achieved. There were more than 200 cases of patent applications withdrawn, canceled, declared dead or terminated. The example of turmeric was a glaring example in that regard.

172. The Delegation of South Africa said it was important to look at databases in the context of data sovereignty. Databases were very useful, because they were part of the age of data revolution. It referred to the statements by the Delegations of India and Brazil on the technical complexities around databases. The work of the IGC might be outdated by the time agreement was reached on the issues of technological changes. For instance, sequential information around GRs had been digitized. The IGC had to leapfrog into “today”. The IGC was still discussing physical data, but the world had changed. It was important to simplify the text. It supported a simple text beginning with a due diligence, but it had to be expanded. Some text proposals would have to come out. The text of Article 6 had to stay on a high level and address policy issues. The implementation of databases was an issue to follow up on and discuss.

173. The Delegation of the Plurinational State of Bolivia described its experience with databases, which it had started to implement within indigenous communities. However, there had been some problems, such as the degree of confidentiality. Many people from the communities distrusted everything and did not understand why there were databases. The other issue was the ownership of TK, which belonged to the whole community and not just to one person, because it was community knowledge. It would have difficulties in making any progress on databases.

174. The Delegation of Switzerland said that many databases relating to GRs and TK associated with GRs already existed, as illustrated by the compilation prepared by the Secretariat. It was important that any provision with regard to databases in a WIPO instrument not only lead to a proliferation of additional databases relating to GRs and TK associated with GRs, but also added a real value, including for patent examiners. Many of the existing databases were established for a completely different purpose than for prior art searches by patent examiners. It wondered how likely it was that one could manage to increase the interoperability of databases and their usefulness for patent examiners, based on a WIPO instrument. Specifically in the context of GRs, not all databases might necessarily facilitate the prevention of the erroneous granting of patents, because an invention was not necessarily consisting of a GR as such but was rather based on a GR. Therefore, even if the specific GRs were contained in the database, an invention based on the GRs might or might not

actually fulfill the patentability criteria. Moreover, as mentioned by the Delegation of Brazil, it was estimated that about 1.6 million species had been databased thus far and that over 80 percent of all species had not yet been described. However, GRs were not species and the number of GRs was far greater than the number of species. That raised a number of questions: what was the value of a database that was likely to contain only a very tiny amount of all GRs in a specific country? How comprehensive were existing databases with GRs? What exactly should be registered in the database: the precise description of the GRs, including all known properties and the precise origin, or just the name of a species? Keeping in mind the evidence-based approach, what were the practical experiences with databases in the context of GRs? How many erroneously granted patents could have been avoided so far by using databases on GRs? What were the costs of establishing and running and continuously updating such databases? And which databases relating to GRs were currently used by patent examiners for prior art searches?

175. The Delegation of Indonesia, speaking on behalf of the LMCs, welcomed Article 6, noting that due diligence obligations should complement a requirement of a declaration of source of the subject matter. Databases also had value to reinforce the due diligence approach. However, without proper security measures in place, the establishment of databases raised issues regarding access to the content and information made available in the databases.

176. The Delegation of the Republic of Korea said that the prevention of erroneously granted patents through the establishment and use of database systems was the most effective and efficient form of facilitating the protection of GRs and TK associated with GRs in the patent system. The Korean Intellectual Property Office (“KIPO”) had established a database for TK and TK associated with GRs. Currently, KIPO’s database of TK had a vast amount of documents on old Korean medicine and current patents and articles containing TK from the past and the present. The database was presented on-line through the Korean Traditional Knowledge Portal (“KTKP”). The database was made publicly accessible for the following reasons: (1) to lay the foundations for international protection of Korean TK, thereby preventing the grant of erroneous patents inside and outside the country; (2) to provide an abundance of information on TK and related research, thereby expediting the development of related studies and industries; and (3) to provide essential information for patent examinations, thereby enhancing the quality of IP applications for TK. Patent examiners at KIPO were obligated to search the said database for prior art in relevant patent applications. That method had been successfully used and efficient in KIPO to protect GRs and TK associated with GRs. A well-developed database was a very practical and feasible method for reducing the number of erroneously granted patents in each Member State.

177. The Delegation of Senegal said that most of its concerns had been developed by the Delegations of Brazil and South Africa. In the long history of mankind, people had used millions of GRs to ensure their survival. One should not give up in the face of difficulties involved in setting up databases. Patentscope and all the patent information therein had also needed time to be set up for the benefit of the progress of mankind to help people overcome problems of everyday life. If databases were to be a solution to resolve legal difficulties, it would be possible to do it. People who used and developed GRs had an extraordinary relationship with the GRs. In Senegal, a community produced myrrh oil that was used for treating complicated pathologies. In order to get that oil, certain conditions had to be met. It was work done exclusively by women of a certain age. The IGC was an extraordinary forum. One could come to the IGC and go home with important information about what was being prepared in terms of law.

178. The Delegation of Ecuador shared its experience in building databases. It had about 500 databases on TK. Experience had shown how tricky it was to set up a database on ancestral TK in a voluntary way, without due attention to how to respect confidentiality. It supported the statement made by the Delegation of Brazil. Ecuador was one of the countries with the greatest biodiversity. It had wanted to set up a national database on genetic

sequencing, and had realized that there were about 500,000 different sequences. It did not have the capacity, as a country, to maintain control over its database, to ensure safeguards for it. However, it was in the public interest and strategic, so it wanted all that information to be in one national repository held by the patent office. Discussions in an international forum had led to a number of themes. For example, for the megadiverse countries of the world and those rich in GRs, it wondered how feasible it might be to build databases, which in the long term could be connected with a center like WIPO that could check the origin of GRs deposited in foreign databases. It hoped that later on, one could go into details on databases. Article 6 should stay very general. The use of databases should be a complementary measure, in line with national rules and regulations. At a later stage, biotechnology, genetics and new information technologies might be the subject of another specific treaty. The IGC should not discuss databases in too much detail but keep it to generalities.

179. The Delegation of Egypt said it had listened very carefully to the concerns expressed by a number of representatives of indigenous peoples on the subject of including information in databases. Those were legitimate fears, because the text did not reflect the legal nature of the inclusion of the information. It wondered if that would provide protection. That concept should be cleared up in a way that satisfied delegations.

180. The Delegation of Canada stated that databases of GRs and TK associated with GRs could be a useful tool in addressing the erroneous granting of patents, particularly when looking at the positive experience of some existing databases such as India's TKDL to which Canada subscribed. The results of the TKDL in preventing the erroneous grant of patents showed that there was surely some usefulness there, at least on the TK side. It referred to the question by the Delegation of Switzerland as to the usefulness of databases. While it was probably impractical to catalog every possible GR in the world, GRs and TK holders could, for example, if they so wished, place in databases information on GRs with useful properties known by those holders, as well as information on TK associated with GRs pertaining to those properties. Patent offices could then have access to that information and identify those properties as prior art and therefore potentially refuse to grant a patent on an invention that was not novel or inventive with regard to that GR.

181. [Note from the Secretariat: This part of the session took place after the distribution of Rev. 1 dated March 21, 2018 prepared by the facilitator and the Friend of the Chair.] The Chair explained that he would invite the facilitator and the Friend of the Chair to introduce Rev. 1. He would allow participants to ask questions relating to a clarification, omission or misunderstanding. Members would then have time to review the text and provide comments. He noted that Rev. 1 was simply a document to help progress on the work and it would be further revised based on Member States' feedback. The facilitator and the Friend of the Chair had a remit to attempt to bridge gaps, give greater clarity to positions and remove duplications. In some instances, they might have revised textual proposals for clarity or in an attempt to merge similar concepts. Members could accept those or ask for their original text to be reinstated. Some new ideas had been introduced and any change would have to be supported by a Member State. Any omission, error or misunderstanding was not intentional.

182. Mr. Kuruk, speaking as the facilitator, presented Rev. 1, which included 12 articles. Article 12 had been added to take into account a provision proposed by one Member State. The reference to derivatives was found throughout the entire text, in brackets. He and the Friend of the Chair had not taken any position with regard to whether or not GRs should include derivatives but just for the purposes of simplifying and clarifying the text, all references regarding derivatives had been shifted to the definition section under the term "genetic material" which included "derivatives thereof". As to the preamble, for purposes of clarifying and simplifying the text, a revised preamble had been proposed as an alternative for consideration and review. He believed that the revised preamble was a very simple and succinct text that had a much better logical arrangement than the original preamble. The preamble was now in two

parts: original preamble and alternative preamble. In Article 1 on objectives, they had proposed a text for consideration to achieve broad consensus. Certain Member States had proposed some changes in the language as originally presented. There were no changes in Article 2, because no Member State had requested a change. Regarding Article 3, in paragraph 3.1, they had tried to simplify the provision by deleting the third of three previous options. There were then two provisions. They had deleted “is directly based on the utilization of genetic resources”, the rationale being that the preceding two options were dealing with precisely the same subject matter, so it was redundant to have that third option. They had deleted the option, but the issues raised therein were retained in the references to “utilization of” or “is directly based on”. As part of Article 3, they had retained the section on subparagraph (a) but moved the previous subsection (b) to a new place, current Article 3.2. The current and existing texts should be paragraph 3.1 (a) about the need to disclose the country of origin and (b) about the source or providing country or country of origin. Article 3.2, which was simply a replacement of previous subparagraph (b). Having listened to all the interventions from the Member States, there was a broad consensus on including reference to origin and source as part of the disclosure requirement. However, there was no similar consensus developed for ABS or PIC. Based on their understanding of the interventions, they had made the need to provide information regarding ABS subject to national legislation, including all the qualifying language in the current paragraph 3.2. Thus, paragraph 3.1 was more general and broadly applicable, but subject to national legislation. In paragraph 3.4 and the paragraphs following, the references to the clearing house mechanism had been deleted, because they were too specific to the relevant CBD provisions and as they related to the need to provide notification, that point was adequately captured in the immediately succeeding paragraph. Previous paragraph 3.5 had not been deleted on a permanent basis, but had been found a more comfortable place in Article 12. Regarding Article 4, there were requests made to move paragraphs 4.1 and 4.2 to a different part of the text, where one did not find much of an interest in a mandatory disclosure. However, upon serious review and critical examination of the provision, he and the Friend of the Chair had determined that paragraph 4.1 assumed the application of the disclosure requirement, but was more focused on inserting limitations. They had hence determined that the placement was proper and retained paragraph 4.1 in its current place.

183. Ms. Bagley, speaking as the Friend of the Chair, said that Article 5 on sanctions and remedies was important for a mandatory requirement. There were four alternatives for that article, in which they had tried to lay out the various approaches to that issue. Alternative 1 was a broad provision that left a lot of question about sanctions to national law. As a Member State had noted, countries wanted flexibility in determining what kind of sanctions might be effective and proportionate in light of their particular circumstances. That alternative did not limit revocation as a possible sanction for noncompliance with the disclosure requirement. Alternative 2 was designed to reflect the option for non-compliance. Revoking a patent did not prevent the patentee from continuing to use the GRs or TK associated with GRs, and more entities could use it because a patent document would disclose how to use it and patent holders would not have the right to exclude third parties. Yet none of those uses would necessarily provide any benefits to the owner of the GRs or TK associated with GRs. That provision thus allowed countries to decide appropriate sanctions under national law and allowed for revocation as a sanction only for willful or deliberate instances of refusal to comply and only after the patent holder had been offered an opportunity to reach a mutually satisfactory resolution with relevant parties defined under national law and such negotiations had failed. Alternative 3 reflected the approach of some of countries that had a mandatory disclosure requirement but did not employ revocation as a sanction for non-compliance. Rather, non-compliance was addressed outside of the patent system once the patent was issued, although application processing might be stopped if the disclosure requirement was not met. That alternative represented a ceiling on sanctions and remedies. Alternative 4 was the former main sanction provision. It left the question of sanctions to national law, but provided a non-exhaustive list of possible pre-grant and post-grant sanctions. She said that Alternative 4 could be deleted and Alternative 1, which provided maximum breadth under national law, could be retained for countries that sought such

an approach, and she welcomed a Member State's intervention to that effect. The section on complementary measures contained Articles 6 and 7. They had sensed broad agreement that Article 6 on due diligence, including databases, could be a useful complement to a mandatory disclosure requirement. Article 6.1 was former Article 7.2 and explicitly stated that a Member State might consider the use of databases on TK and GRs in accordance with the needs, priorities and safeguards as might be required under national laws and special circumstances. Article 6.2 was former Article 6 and had not been meaningfully changed. Several Member States had articulated concerns with Article 7. In light thereof, the title had been modified slightly and only Article 7.1 (b) (c) and (d) had been included in the mandatory disclosure requirement provision. They were now identified as paragraphs (a), (b) and (c). Article 7 was entitled "Prevention of the Erroneous Grant of Patents, Databases and Voluntary Codes of Conduct".

184. Mr. Kuruk, speaking as the facilitator, presented the alternatives to Articles 1 to 4. Regarding ALT Article 1 on objectives, the very first part had been placed in brackets, but it was a previous provision and no substantive changes had been made to that text. However, there was an ALT to Article 1, which represented a proposal of a Member State.

185. Ms. Bagley, speaking as the Friend of the Chair, presented the changes to ALT Articles 6 and 7. She said that Articles 8 through 11 remained unchanged, as the plenary had not discussed them. She stated that the goal of the facilitator and the Friend of the Chair had been to incrementally streamline the text to further narrow gaps, enhance clarity, and maintain the integrity of positions. She apologized for any errors, noting that the compressed timeframe made avoiding errors nearly impossible. She looked forward to collaborating on Rev. 1.

186. The Chair opened the floor for any technical questions.

187. [Note from the Secretariat: all speakers thanked the facilitator and the Friend of the Chair for their work in producing Rev. 1.] The Delegation of El Salvador referred to its suggestion on the issue of IP rights versus patent rights. Its suggestion was to leave only patents in the text and draft some language to the effect that everything said about patents could be applicable to IP, similar to the solution found with regard to derivatives.

188. Ms. Bagley, speaking as the Friend of the Chair, said it had been an oversight on their part that they would remedy with Rev. 2.

189. The Delegations of Italy and Japan pointed out the errors regarding "the data are obvious" instead of "the data are not obvious".

190. [Note from the Secretariat: This part of the session took place after a short break when delegations reviewed Rev. 1.] The Chair opened the floor for general comments on Rev. 1.

191. [Note from the Secretariat: All speakers thanked the Facilitator and Friend of the Chair for their work in producing Rev 1.] The Delegation of Indonesia, speaking on behalf of the LMCs, recognized and acknowledged the great efforts by the facilitator and the Friend of the Chair to come up with Rev. 1 trying to reflect all the interventions and positions of Member States in the IGC. It reiterated that it had full trust in the Chair, the Friend of the Chair and the facilitator to look at the integrity of the text, not only structurally, but in terms of the various approaches as well. It had been respectful of the IGC's mandate and the Chair's methodology and guidance not to make any textual proposals that were not narrowing the gaps and trying not to engage on any other approaches that it could not agree on. At that point, it was not in the position to engage in the text of Rev. 1 at all. It asked for more guidance from the Chair on where the negotiations were taking place. Some members had put forward positions and proposals, some of which were reflected. Those proposals trying to respect the mandate, to build clarity and to narrow gaps were not reflected.

192. The Delegation of Morocco, speaking on behalf of the African Group, recalled the IGC mandate and the need to reduce gaps. Rev. 1 was going to solidify differences rather than reduce them. It was much attached to the integrity of the text.

193. The Delegation of Indonesia, speaking on behalf of the Asia-Pacific Group, acknowledged that it was not easy to reflect all interventions of Member States in Rev. 1. It had been respectful of the Chair's methodology and guidance and of the IGC's mandate.

194. The Delegation of Ecuador, speaking on behalf of GRULAC, said that Rev. 1 was work in progress. It was open to continue working on Rev. 1 in a general way to continue with the discussions within the IGC's mandate. It would make more detailed comments later.

195. The Delegation of the EU, speaking on behalf of the EU and its Member States, said that it had considered Rev. 1 and had detailed technical comments, which would be presented later.

196. The Delegation of Lithuania, speaking on behalf of the CEBS Group, was not in favor of the instrument but, even though it was not a demandeur, it appreciated the efforts of the facilitator and the Friend of the Chair in preparing Rev. 1. There were positive aspects in Rev. 1, but there were also areas of difficulty, e.g., on definitions, sanctions, and provisions touching upon substantive patent law. It was in favor of disclosure provisions, but there were some aspects that went beyond what was practically workable and realistic.

197. The Delegation of China said Rev. 1 contained lots of major modifications. Some of them were simple, but there were many issues still subject to further debate. The main focus should be to resolve those issues.

198. The Delegation of Australia stated that Rev. 1 was a useful document to continue the discussion. With only two sessions on GRs, it was important for the IGC to focus on reaching consensus. The facilitator and the Friend of the Chair had provided a good basis. Article 3 on disclosure requirement and Article 5 on sanctions and remedies were a good reflection of the discussions and efforts to streamline. However, the facilitator and the Friend of the Chair could only do so much. Member States needed to be open and hear what others had to say and resolve existing gaps. It looked forward to engaging on specific aspects.

199. The Delegation of Egypt was very surprised and rather pessimistic when reading Rev. 1 because it only reflected the very limited positions of some Member States. Rev. 1 did not respect the IGC's mandate to iron out difficulties. After 18 years of work, the IGC was back to square one. It would be wise to go back to document WIPO/GRTKF/IC/35/4 as the reference.

200. The Delegation of the Islamic Republic of Iran said that it had expected the text on objectives to narrow the gaps. It was surprised that the text was taking a different direction, basically crystallizing the differences and boldly showing the gaps. It was a very good text in understanding each other's positions much more clearly. At the end, the IGC needed to come up with a text that was agreeable to everyone. Showing the differences was good to indicate differences and gaps. The IGC had to go back and bridge those very clear gaps. That would take extra efforts.

201. The Delegation of Nigeria noted the Chair's emphasis on the need to preserve the integrity of the Consolidated Document. It shared and deeply respected that sentiment. The text on the objectives shared the day before reflected a narrowing of gaps and had raised its hopes. However, Rev. 1 contained a lot of new text and concepts that had moved the IGC further away from closing the gaps. If the free flow of drafting suggestions continued to be allowed, it would be counterproductive to the mandate. It was inclined to revert to document WIPO/GRTKF/IC/35/4 with stronger, clearer direction that really assisted moving forward.

202. The Delegation of South Africa said that the role of the facilitators was to summarize the general outpouring of comments within the IGC. Over the past four years, the IGC had taken the approach of preparing Rev. 1, having no status, and then Rev. 2, which was given status by default and forwarded to the next session, without ever being seriously debated, except for flagging issues of clarification and omissions. The IGC had to make a decision on Rev. 2, rather than forward it to the GA by default and without debate. That important procedural issue needed to be considered. Rev. 2 did not reflect consensus but was simply noted. The IGC had to look at its methodology as a way of going forward. It was not ready to engage with Rev. 1 and, like the Delegation of Nigeria, it wished to revert to document WIPO/GRTKF/IC/35/4 as the negotiating text. It had not had a chance to negotiate and there had been only general discussions.

203. The Delegation of India said that there were two approaches in the text: (1) mandatory disclosure oriented text; and (2) no disclosure oriented text. It said that a majority of Member States was aligned with a mandatory disclosure requirement. It had requested the proponents of a no-disclosure requirement to show flexibility and to support mandatory disclosure in the text. In that way, the IGC could move forward. Document WIPO/GRTKF/IC/35/4 should be considered for further discussions.

204. The Delegation of Indonesia was not in a position to engage in Rev. 1, which was not narrowing existing gaps or reaching a common understanding of core issues as per the mandate. Therefore, it was not ready to discuss the recently introduced issues and concepts. It very much appreciated the efforts put forward by the facilitator and the Friend of the Chair, but it was concerned that a number of new issues introduced in Rev. 1 created major modifications. Rev. 1 was widening the gaps and not providing clarity. It maintained its trust and support for the Chair and stood ready to engage constructively in any process to expedite the work, in accordance with the mandate.

205. The Delegation of Brazil supported the statements made by the Delegation of Indonesia, on behalf of the LMCs, and agreed with the Delegations of Nigeria, South Africa and others regarding the procedural aspects. It had refrained from making specific textual proposals because the three first days of the session were to try to take the temperature of the plenary so that the facilitator and the Friend of the Chair could reflect and make proposals aimed at narrowing existing gaps. The “work-in-progress” circulated the day before on objective was going in the right direction. However, Rev. 1 widened the gaps and did not lead to the desired result. The IGC had to reflect on potential ways to proceed. The WIPO Rules of Procedure, for instance, included voting as one of the options to reach an agreement. That was something for the IGC to consider. It was ready to engage on further discussions if that was the consensus.

206. The Delegation of the Plurinational State of Bolivia supported the statement made by the Delegation of Indonesia, on behalf of the LMCs.

207. The Chair said that he could not reduce the gaps himself and neither could the facilitator nor the Friend of the Chair. Many delegations were not happy with Rev. 1. He took their advice on that. He felt that the text was helpful in clarifying the gaps for the negotiators to narrow. He took the point of the Delegation of South Africa that the IGC had been using a process for a long time, and maybe it needed to reflect on its efficiency. The Chair concluded that there was no consensus on Rev. 1 being used as the basis for further discussions. As an information document only, Rev. 1 could be a resource available to all Member States, as it contained useful ideas. The next revision would start from the baseline of document WIPO/GRTKF/IC/35/4.

208. [Note from the Secretariat: The informal, chaired by one of the Vice-Chairs Mr. Liedes, took place on the morning of March 22, 2018. Three contact groups were established to

address the issues of the preamble, the list of terms, and the disclosure requirement, and they met on the afternoon of March 22, 2018. This part of the session took place on March 22, 2018 after the meeting of the contact groups.] The Chair invited the rapporteur of the contact group on the preamble, the Delegation of Brazil, to present on the results of their work.

209. The Delegation of Brazil, speaking as the rapporteur for the contact group on the preamble, said that the preamble explained the purpose and philosophy of an instrument and provided guidance for the interpretation of the operative clauses. Members had recognized that the alternative preamble was a good basis, because it was more solid than the previous version of the preamble, with the caveat that there were pending discussions with capitals to further address the preamble. The group recognized three main streams in the preamble: (1) relationship between the instrument on GRS and the CBD and the Nagoya Protocol; (2) a traditional IP approach; and (3) the interface between those two aspects. Parts of the paragraphs related directly to an agreement on GRs and others were specific to IP. There was some interconnection between some of them, and there was a need to better clarify that relation in other cases. The preamble was directly linked to the discussions on the operative articles, hence some of the paragraphs were contingent on further discussions among members on the operative part of the instrument, in order to enable a drafting exercise. Lastly, the group had discussed whether some paragraphs were not too operative to remain in the preamble and had considered ways to streamline them. He invited the Chair of the contact group to provide his views on the utility of the exercise and ways to further progress.

210. Mr. Faizal Chery Sidharta, speaking as the Chair of the contact group, expressed his appreciation to the members of the group. He said that their cooperation and active engagement had enabled to go through all the paragraphs in the preamble. With several improvements, revisions and consultations at a later stage, the alternative preamble as drafted by the facilitators could be the way ahead on the draft instrument under negotiation.

211. The Chair opened the floor for questions and comments.

212. The Delegation of Egypt said that the preamble had to come before the list of terms, because otherwise the latter would have no legal status.

213. The Chair invited the Delegation of Nigeria, the rapporteur of the contact group on the list of terms, to provide his report.

214. The Delegation of Nigeria, speaking as the rapporteur of the contact group on the list of terms, said that they had looked at seven key terms reflected in the operative articles relating to disclosure. The group had tried as much as possible to close gaps and to harmonize the competing drafts. The first term was “traditional knowledge associated with genetic resources”. They had tried to marry the first option with the second one, in order to have a synergistic definition. The second term was “country of origin”. It preferred the definition that appeared first. It was possible to stick to the CBD for a more scientific expression of the authenticity of origin on a practical, scientific and evidentiary basis to avoid the rest of the definition of selecting an origin of convenience by anyone seeking to access GRs. The choice was whether to stick with the CBD text or to get a unique definition. The third term was “providing country”. It wondered if that definition was necessary or dispensable. Some members in the group had expressed reservations over a reference to the Nagoya Protocol, and some had preferred consistency with the Nagoya Protocol, which was actually what that text had done. There was an alternative definition that was neutral and made no reference to the Nagoya Protocol. On the term “derivative”, although the group had not been assigned to tackle that term, the group noted that it could be addressed in the definition of GRs, as the facilitator and the Friend of the Chair had demonstrated. One member of the contact group had suggested deleting the reference to “functional units of heredity”. The following term “directly based on” was the elephant in the room. The group had considered deleting it but one member had opposed the deletion. The

debate was on physical access or use of information. The group wondered what the reference to “immediate use of GRs” was in relation to: the digital sequence of information, the physical GRs, or both. Both “utilization” and “directly based on” did not give causality for purposes of IP and disclosure of origin, yet those were the key terms to work on. The next definitional issue was GRs. The definition in the text was good and consistent with other documents. The group wondered if it could be merged with the definition of genetic material. In trying to define GRs, the group wanted to address the notion of derivatives and digital information. On the term “source”, the group preferred the first option because it was simpler and closed the gap. Regarding “utilization”, the group wanted to work with the first alternative in the text, and it recommended linking it with innovation that could trigger disclosure, consistent with the proposed definition of TK. It had been impossible to develop a single trigger and content option within the allocated time period.

215. Mr. Jukka Liedes, speaking as the Chair of the contact group, said that there was high level of knowledge, experience and analytic capacity within the group. It was obvious, early on, that it would be impossible to draft any new text, and the group had decided not to treat those elements in the list of terms which were not within its remit. That made it possible to work through the terms. The group had been able to put together some observations but the package of issues was far too big for a group of ten people to deal with within two hours. In the future, the package should be smaller. All in all, the pilot had been an enjoyable and successful exercise and it was proof that that working method might function.

216. The Chair opened the floor for questions and comments.

217. The Delegation of Morocco thanked the contact group for its remarkable work. It asked to see the comments and the revised list in writing to be able to look at it in detail.

218. The Delegation of Brazil thanked the participants of the contact group. Despite the very short time, they had made a very impressive number of statements in relation to the core issue. It asked if the group had discussed the conversion of the list of terms into an article, or whether that had been left to future discussion.

219. Mr. Liedes, speaking as the Chair of the contact group, said that the text would most probably be turned into an article on definitions.

220. The Delegation of Canada thanked the contact group for its commendable work. It echoed the statement made by the Delegation of Morocco and requested to see the changes in writing. It asked for details about the discussion on the proposed merger within the GRs definition.

221. The Delegation of Nigeria said it would engage directly with the Delegation of Canada outside the room.

222. The Chair invited the representative of NARF, the rapporteur of the contact group on sanctions of disclosure requirement, to present the result of their work.

223. The representative of NARF, speaking as the rapporteur of the contact group, said that the group had had a challenging task, but had worked hard to narrow gaps and clarify the options. On the first provision, the general language was agreed to commonly by everyone, not subject to any objection. That language was included in the different alternatives. Regarding the list of indicative possible measures for non-compliance with Article 3, it had identified three options. The first option was essentially what was included in the previous draft. The second option would be to have no list of indicative measures. The third option was to develop a different list by the parties. On the issue of revocation, it had identified three options. The first option would allow revocation; the second had been identified by the facilitator and the Friend

of the Chair in Rev. 1 and allowed revocation with a process included; and the final option was “no revocation”. The dispute resolution measures had become a separate provision because it was more appropriate to have it identified separately, not as a particular sanction or remedy.

224. Mr. Kuruk, speaking as the Chair of the contact group, thanked all members of the group for sharing their views. All regional groups were well represented in the meeting and the deliberations had started on time. Its first task had been to identify the universe of proposals on the matter of sanctions and to attempt to narrow the gaps and reduce the number of options. It had engaged in very robust discussions, and in the end, there was unanimous agreement to include the need for Member States to provide for effective and proportionate legislative and administrative measures. Generally, the exercise had been quite useful. It had allowed the members of the group the opportunity to explain different perspectives and to agree to certain compromises. He wholeheartedly endorsed the process of contact groups.

225. The Chair opened the floor for comments.

226. The Delegation of the Plurinational State of Bolivia welcomed the work done by the contact groups and congratulated them on trying to narrow gaps. Nonetheless, it did not necessarily reflect the position of members. The instrument under negotiation was an IP instrument that guaranteed the protection of GRs, which had a specific definition in the Nagoya Protocol. The suggestions made in the text should be presented in writing to the members for further analysis and consultation with capitals, in order to be able to provide more substantive comments.

227. The Delegation of the USA appreciated the opportunity to participate in one of the contact group. It also appreciated the work of all the contact groups. Like the Delegation of the Plurinational State of Bolivia, it noted that the recommendations of the contact groups had not yet been considered and discussed by all members. If the facilitator and the Friend of the Chair decided to incorporate them into Rev. 2, they should do so in a bracketed form and should not replace the existing options. They would be additional options for consideration and review by all members and they would be discussed before determining their fate.

228. The Chair agreed that not all Member States had had the opportunity to look at all the materials provided by the contact groups. As to the pilot process, there was a general feeling that there was some benefit in it, and, to a degree, it had been successful. The IGC would consider whether that mechanism could be brought into IGC 36. The facilitator and the Friend of the Chair would work on Rev. 2 on the basis of document WIPO/GRTKF/IC/35/4, considering all the interventions made in plenary, including textual proposals. They would consider the materials provided by the contact groups just like observers’ interventions, i.e., it needed a Member State’s support to stay in the text. The Chair invited the Delegation of the USA to introduce document WIPO/GRTKF/IC/35/7.

229. The Delegation of the USA was pleased to introduce its proposal, co-sponsored by the Delegations of Canada, Japan, Norway, the Republic of Korea and the USA. It had previously introduced it at IGC 34, as document WIPO/GRTKF/IC/34/9. The document could be used as a confidence-building measure to help the IGC move forward on key issues concerning GRs and TK associated with GRs. The co-sponsors had resubmitted the document in some IGC sessions when the delegations had expressed interests in that document and its objective, which included preventing the erroneous grant of patents. The proposed joint recommendation could be negotiated, finalized and adopted without slowing down the work of the IGC. It would promote the use of opposition systems to allow third parties to dispute the validity of a patent and the development and use of voluntary codes of conduct and the exchange of access to databases, among other things, in order to prevent the erroneous granting of patents for inventions based on GRs and TK associated with GRs. With respect to opposition systems, US patent law provided a mechanism for third parties to submit printed publications of potential

relevance to the examination of a patent application with a concise description of the asserted relevance of each document submitted. That provision had been introduced in 2012 under the America Invents Act. Such submissions might be made prior to the date of a notice of allowance. Third-party submissions did not delay or otherwise interfere with the examination of patent applications because they merely provided additional information to patent examiners without creating new procedural requirements for those examiners. Almost half of the third-party submissions between 2012 and 2015 had been filed in technology centers that examined biotechnological, pharmaceutical and chemical inventions, as well as those related to food and chemical engineering. Those submissions might include non-patent literature such as published GRs and TK. In fact, over 30 percent of the submitted documents for the same time period were non-patent literature. With respect to voluntary codes of conduct, a number of pharmaceutical and biotechnology inventions, including life-saving medicines, biofuels and agricultural products, utilized compounds and processes that existed in nature. Many companies had established guidelines and rules for proper bioprospecting. For example, the Biotechnology Organization, a global trade association that included SMEs and other companies, academic institutions, biotechnology centers and related organizations in more than 30 nations had developed bioprospecting guidelines for its members. The guidelines identified certain best practices that could be followed by companies that elected to engage in those activities. The guidelines also attempted to provide a roadmap for member companies to use if and when the company engaged in bioprospecting activities. Thus the guidelines identified steps that companies should take before engaging in bioprospecting, such as obtaining PIC. They also provided useful information on benefit-sharing, sharing of research results, IP procurement and it protected the rights of indigenous and local communities and the steps for the conservation and the sustainable use of biological diversity. Those guidelines provided a useful example of how private sector innovators were taking proactive steps to preserve biodiversity, promote sustainable use of GRs and equitably share benefits arising from the use of GRs. It wished to continue the discussion on the proposed joint recommendation because it captured key objectives and facilitated the establishment of effective mechanisms for the protection of GRs and TK associated with GRs. It invited other delegations to express their support for the proposal and welcomed additional co-sponsors. It looked forward to continued discussions on the proposal.

230. The Chair opened the floor for comments.

231. The Delegation of Japan thanked the Delegation of the USA for the explanation. As a co-sponsor, it supported document WIPO/GRTKF/IC/35/7. It was a good basis for the discussion on the issues regarding IP and GRs, especially on the prevention of the erroneous grant of patents. It looked forward to continuing discussions.

232. The Delegation of the Republic of Korea, as a co-sponsor, supported the joint recommendation. The prevention of erroneously granted patents through the establishment and use of database systems and using opposition measures would be an effective and efficient form of promoting protection of GRs and TK associated with GRs in the patent system.

233. The Delegation of the Russian Federation supported document WIPO/GRTKF/IC/35/7. It was a good basis for the IGC's work and could be adopted in the future by the IGC as guiding principles for GRs and TK associated with GRs, especially as there had been examples in the past of work developed on the basis of that document.

234. The Delegation of Morocco, speaking on behalf of the African Group, thanked the co-sponsors for the recommendation. It considered that the ideas put forward complemented document WIPO/GRTKF/IC/35/4, because they were already reflected in the text and were part of the discussion. However, it prejudged some of the terms. Discussions should focus on document WIPO/GRTKF/IC/35/4.

235. The Delegation of Canada was pleased to co-sponsor the proposed joint recommendation as one of several possible positive ways forward, including as means to consider the full range of options available, without prejudice to the IGC's work and eventual outcome(s).

236. The Delegation of Ecuador welcomed the initiative by the Delegation of USA and other proponent countries. There was a need to contribute with defensive protection measures, which were directed at guaranteeing due access to GRs. They should not be confused with measures, which ensured the protection of GRs of originating countries.

237. The Delegation of India was delighted to see that the proposal also recognized the essence of the proposal in document WIPO/GRTKF/IC/35/4, i.e., respect for biodiversity, PIC, benefit-sharing and prevention of erroneous grant of patents. There were a lot of points of convergence between two documents. It requested the supporters of the proposal to relook into document WIPO/GRTKF/IC/35/4, and find out ways to come to a mutually agreed document.

238. The representative of Tupaj Amaru said that the contribution by the proposal was positive, but it should be in the context of the CBD and the Nagoya Protocol. The document did not mention the fight against the erosion of GRs or biopiracy of associated TK. The main problem, for many years, had been to determine how to confront biopiracy, which occurred in all impunity.

239. The Chair invited the Delegation of Japan to introduce document WIPO/GRTKF/IC/35/8.

240. The Delegation of Japan, together with the Delegations of Canada, the Republic of Korea, and the USA, was pleased to offer a brief explanation of document WIPO/GRTKF/IC/35/8. Most of the Member States shared a common recognition of the importance of taking effective measures to prevent the misappropriation of GRs and TK associated with GRs. Based on that recognition, it had been contributing to the discussions on that issue at the IGC and other fora, proposing creating a database for GRs that would prevent the erroneous granting of patents. As also indicated in the Secretariat's report (document WIPO/GRTKF/IC/35/5), ever since the IGC had been established, Member States had submitted a number of proposals on databases relating to GRs and TK associated with GRs. In order to achieve that purpose, it would be more appropriate to establish databases on GRs, which would provide information that examiners needed to determine novelty and inventive steps of inventions claimed in patent applications. That should be done instead of introducing a mandatory disclosure requirement. Such databases enabled patent examiners to make efficient searches for relevant prior art among thousands of patent documents and non-patent literature. By examiners' utilizing the proposed databases during the patent examination process, the quality of patent examination in the area of GRs would be improved and the protection of GRs would be enhanced. It hoped that the document would foster a better understanding of its proposal for creating databases among Member States.

241. The Delegation of the USA supported the comments made by the Delegation of Japan. It viewed that proposal as a valuable contribution to the work of the IGC that aimed to provide an international legal instrument(s) for the effective protection of GRs and TK. In particular, it helped to address concerns raised in the IGC relating to the erroneous granting of patents. Moreover, it was essential that the IGC further engaged on that proposal in order to address questions and concerns raised about the use of databases in past discussions. Some questions that had been raised in the IGC included: what was the value added of a new GRs database, given that there were already excellent databases of GRs as well as databases of scientific literature in existence? If information placed in a database was not intended to be in the public domain, what, if anything, could be done to ensure that GRs and TK did not fall into the public domain once in the database? Which databases relating to GRs and TK were searched by national patent offices? Through the IGC's work, one had learned that there were a variety of approaches to databases at the national level. While the joint recommendation would not be prescriptive, the Delegation would provide responses to many of the questions

raised from a US perspective. In response to the first question, having a centralized database could help to simplify search procedures by making it easier to conduct more systemic searches that covered the content of several databases. In response to the second question, if a database was made available to patent examiners, as well as to the public, that database should only contain information that was eligible to be prior art. Regarding the third question about which databases relating to GRs and TK were searched by national patent offices, USPTO patent examiners searched a wide variety of databases, including the KTKP, the Indian TKDL, Malta Wild Plants, the Northern Ontario Plant Database, South Africa's Traditional Medicines Database, the University of Melbourne Multilingual Multiscript Plant Name Database and the US Department of Agriculture Plants Database. It looked forward to discussing the WIPO portal proposal and any follow-up questions. It asked other delegations to support the proposal.

242. The Delegation of the Republic of Korea, as a co-sponsor, supported the joint recommendation. A well-developed database was a very practical and feasible method for reducing the number of erroneously granted patents in each Member State and promoting the protection of GRs and TK associated with GRs. Developing an integrated, one-click database system, a WIPO Portal system would effectively and efficiently enhance the protection of GRs and TK associated with GRs in the patent system. It looked forward to discussing the joint recommendations in a constructive way during the IGC session.

243. The Delegation of the Russian Federation supported document WIPO/GRTKF/IC/35/8. It would help patent examiners carry out more effective searches of prior art and find out about background material related to GRs and non-secret TK associated with GRs. It would reduce the probability of erroneous grants of patents.

244. The Delegation of Canada was pleased to co-sponsor the joint recommendation, as one of several positive possible ways forward including as a means to consider the full range of options. Databases played a valuable role in the prevention of the erroneous grant of patents with regard to GRs and TK associated with GRs. It fully acknowledged the concerns expressed by IPLCs in the IGC. Its support was without prejudice to the IGC's work and eventual outcome(s).

245. The Delegation of Morocco, speaking on behalf of the African Group, thanked for the recommendation. Databases were an important issue, which could be addressed once an international treaty had been established. In any case, defensive measures were already included in document WIPO/GRTKF/IC/35/4 and parallel discussions on the same subject would only detract from the time devoted to the debates. Databases were only one measure among others for the protection of GRs and TK associated with GRs. It invited Member States to concentrate on document WIPO/GRTKF/IC/35/4, which covered all concerns.

246. The Chair invited the Delegation of Canada to present document WIPO/GRTKF/IC/35/9.

247. The Delegation of Canada was pleased to co-sponsor document WIPO/GRTKF/IC/35/9, which it had initially co-sponsored in 2013 along with the Delegations of Japan, Norway, the Republic of Korea and the USA. The proposal set out a list of questions intended to update the 2004 WIPO Technical Study related to Genetic Resources and Traditional Knowledge with information regarding disclosure requirements and related ABS systems, as they were being implemented by Member States. That type of information was important for consideration of any proposal centered on GRs and TK associated with GRs. That was in line with the IGC's mandate for 2018-2019, which called for an evidence-based approach and contemplated studies. Some Member States might not have been convinced of the value of such a proposed study, citing that such studies already existed. While the existing studies were indeed certainly informative and useful, they fell short of providing quantitative and qualitative comparative data regarding the practical application and implementation of disclosure and its implications and

rather tended to focus mostly on the features of legislation. That sought to enrich the discussions with information on concrete national experiences of those Member States implementing disclosure requirement. With a view to generating more support for the proposed study, it remained available to discuss the proposal with other Member States and the Indigenous Caucus.

248. The Delegation of the USA supported the statement made by the Delegation of the Canada. It recalled the 2018-2019 mandate of the IGC and its reference to studies. The IGC had had constructive discussions about national laws and about how disclosure requirements and ABS systems functioned. Those discussions had helped inform the text-based negotiations. The questions in the study explored issues such as the impact that national disclosure requirements had had in securing compliance with ABS systems and the penalties associated with non-compliance. The study was intended to generate important information to support the IGC's work. It was not intended to slow down its work. It invited other delegations to express their support and other documents or questions that people might have on the study.

249. The Delegation of Japan thanked the Delegation of Canada for the explanation. It supported document WIPO/GRTKF/IC/35/9. Many Member States had recognized the importance of an evidence-based approach. The proposed study was an effective and productive way to foster a common understanding on core issues on GRs without delaying text-based negotiations.

250. The Delegation of the Russian Federation supported the concerns about disclosure of sources of GRs and the interest in further looking into that issue. In determining the mechanisms for the disclosure, it noted that the questions set forth in the document were aimed at patent offices which already practiced the procedure of disclosure. It believed that the study should not detract at all from the work of the IGC.

251. The Delegation of the Republic of Korea supported document WIPO/GRTKF/IC/35/9. Currently, it did not fully comprehend the impact of disclosure requirements in the patent system. The proposed study would provide fact and evidence-based information on current national experiences. Through the study, one could hear diverse opinions or experiences not only from GRs providers but also from patent examiners and patent users, who would be directly influenced by the introduction of a disclosure requirement. The study would help reflect the views from various stakeholders in a balanced manner and contribute to assessing the possible impact of a disclosure requirement in the patent system, and better understanding of core issues in the IGC.

252. The Delegation of Brazil said that the WIPO Secretariat had produced various studies over the past 18 years. It was concerned with the timing of the study, as it might delay the text-based discussions on the disclosure requirement. It preferred to look at that under a positive light. That was confirmed by the many delegations that had spoken. If that was indeed the case, it referred to documents WIPO/GRTKF/IC/35/5 and WIPO/GRTKF/IC/35/6, which compiled materials on databases and disclosure regimes and to the 2017 WIPO Study on Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge, which incorporated the latest practical and empirical information provided by Member States and other stakeholders on key legal and operational requirements for patent disclosure requirements for GRs and TK. Those three documents answered many, if not all, of the questions contained in document WIPO/GRTKF/IC/35/9.

253. The Delegation of Indonesia appreciated the proposal and supported the statement made by the Delegation of Brazil. All the questions listed in the proposal were somewhat ill timed, as the IGC could not agree on an international framework with regard to the disclosure requirement. More than 30 countries had already applied disclosure requirements. It was not really the purpose of the IGC to try to make sure what kind of impact that would have on the patent

system. In order to be supportive of what the patent offices had to do, the IGC had to speed up its work to make sure to agree on an international framework with regard to GRs so that everything would be in mutual support of each other. Trying to decide the impact without first having an international agreement was ill timed and not appropriate.

254. The Delegation of Colombia welcomed the proposal, which allowed looking at all of the various delegations' perspectives. It could identify the interest of those delegations with regard to contributing to the protection of GRs and TK. Based on the same principles, it appealed for studies in the future to assist in supporting a binding instrument. As mentioned by the Delegation of Brazil, future studies should not lead to a repetition of what already existed at WIPO.

255. The Chair closed the discussions on the three proposals.

256. [Note from the Secretariat: this part of the session took place after the distribution of Rev.2 on March 23, 2018.] The Chair invited the facilitator and the Friend of the Chair to introduce Rev. 2 and explain the content and rationale underlining the changes made.

257. Mr. Kuruk, speaking as the facilitator, said that their goal in preparing Rev. 2 had been to develop a document that narrowed gaps, removed duplications and ensured that the integrity of Member States' inventions was maintained. They had attempted to ensure clarity and to present the proposals in a holistic manner. Rev. 2 had 13 articles. The List of Terms was a stand-alone article (Article 1) and a provision within an article in the original document had been re-drafted as a separate article. They had also introduced an alternative preamble. Regarding the document's structure, it had four main parts. Part I focused on articles that were relevant to mandatory disclosure. Part II centered on alternatives to mandatory disclosure. Complementary measures formed Part III. Part IV was about the final provisions dealing with matters that were routine in instruments. The preamble had two alternatives: the original from document WIPO/GRTKF/IC/35/4 and an alternative prepared by the facilitator and the Friend of the Chair, which had no status. It was followed by what used to be the List of Terms, now Article 1 "Definitions". In Part I, Article 2 was on objectives, Article 3 on the subject matter of the instrument, Article 4 on the disclosure requirement, Article 5 on exceptions and limitations and Article 6 on sanctions and remedies. Part II provided alternatives to Articles 2 to 6, i.e., to the mandatory disclosure requirement. Under the complementary measures, Article 7 was on due diligence and Article 8 on the prevention of the erroneous grant of patents and voluntary codes of conduct. In terms of the final provisions, Article 9, which had been formerly found in an earlier provision, was on preventive measures for protection. He then presented the main changes to the text. Article 1 on definitions had been separated into two parts, where the first part included terms used in the operative articles and the second part included other terms that were useful in understanding the instrument but did not appear in the operative articles. In the definition of TK, they had made a significant change by replacing Options 1 and 2 with ALT 1 and ALT 2. As to Article 4 on the disclosure requirement, Article 4.2 isolated the requirement with regards to PIC and ABS requirements and would allow Member States to provide for such information pursuant to national law. ALT 4.2 was there to accommodate the Members States who did not want to see ABS and PIC requirements as part of the disclosure requirement. In Article 4.4, there was an obligation to make the disclosed information publicly available except where it was confidential. That was to accommodate the request that the references to privacy, business secrets, etc. were all part of confidential information. The previous Article 3.5 had been moved to new Article 9. In Article 5 on exceptions and limitations, the major change was the addition of the phrase "mutual supportiveness with other instruments" and the introduction of a new sub-paragraph as part of paragraph 1.

258. Ms. Bagley, speaking as the Friend of the Chair, emphasized that in attempting to maintain the integrity of positions, they had tried to minimize bracketing where it seemed to accurately reflect a Member States' position in the text. The structure of Article 6 on sanctions

and remedies had been changed, based largely on Member States' comments in informals. Paragraph 6.1 was the base provision that was essentially the first line of the chapeau in the prior article in the original document. It was a broad provision that left the question of sanctions to national law. It did not limit revocation as a possible sanction. Paragraph 6.2 indicated that such measures might include pre-grant and/or post-grant measures and the ALT to paragraph 6.2 provided an indicative list of such measures, as found in the main sanctions provisions of the original document with the addition of paragraph 6.2(a) (iv) as per a Member State request. She hoped that paragraph 6.2 was sufficient and said that articulating possible measures as in the alternative was unnecessary and suboptimal in a framework agreement. Paragraph 6.3 was designed to reflect the approach of some countries that had revocation as an option, but were rarely if ever using it and treating it as a sanction of last resort. That provision allowed for revocation of the sanction but only for willful or deliberate instances of refusal to comply and only after the patent holder had been offered the opportunity to meet a mutually satisfactory resolution with the parties under national law and such negotiations had failed. The alternative to paragraph 6.3 reflected the positions of countries that did not want revocation to be an option in the agreement, due to legal certainty concerns. Under that agreement, it should have a floor, "mandatory disclosure," as well as a ceiling, "no revocation," to enhance legal certainty for applicants. It might be helpful for Member States to include a floor for sanctions and remedies, such as a minimum sanction, and a ceiling to achieve a middle ground in the text. Finally a new paragraph 6.4 had been added that gave dispute resolution, which was previously in the chapeau, its own paragraph. Alternative to Articles 2 through 6 did not involve a new disclosure requirement and were entitled "Defensive Measures." In the alternative to Article 2, there were two similar alternative objectives. The first was present in the original document and the second had been added by a Member States in plenary. The alternative for Article 3 on subject matter was the alternative from the original document. Alternative Article 4, entitled "Disclosure," was the same basic provision as in the original document. However, a Member State had made an intervention to have paragraphs 4.2 through 4.4 and 4.6 in alternative Article 4 moved to the mandatory disclosure requirements section. However, paragraphs 4.2 to 4.4 appeared to relate to voluntary or contract-based disclosure, not a new mandatory disclosure requirement and so they had retained it in that section. Paragraph 4.6 was a broad provision that required patent offices to extend the terms of patents that had lost patent terms due to any kind of patent office delay. As such, being a broad provision that did not clearly and directly relate to a mandatory disclosure requirement, it was better to fit it in that section of the text. There were no alternatives to Articles 5 or 6, because no mandatory disclosure was required under those. Paragraph 8.5 had been added by a Member State and related to the envisioned WIPO Portal. There were a minimum number of changes in the final provisions, other than the numbering of the articles. Article 9 was now titled "Preventive Measures for Protection" and was prior Article 3.5. She reiterated that their goal had been to streamline the text in hopes of further narrowing the gaps and maintaining the integrity of positions. She apologized in advance for any errors and looked forward to receiving corrections and comments.

259. The Chair opened the floor for comments on the revised document, starting with general statements and then specific statements and finally discussions on omissions and errors.

260. [Note from the Secretariat: all speakers thanked the facilitator, the Friend of the Chair and members of the contact groups for their work.] The Delegation of Indonesia, speaking on behalf of the LMCs, said that it was not an easy task to come up with Rev. 2 while still reflecting all the positions delivered in the discussions. In general, Rev. 2 could serve as a basis for further discussion. It would not go into details on the text itself because LMCs members might want to ask for clarifications and indicate their preferences. It would be very good to work on the alternative preamble to make sure that the text would have a simple, straightforward preamble. For consistency, "derivatives" was part of "Other Terms", but it was actually used in the operative articles because it was inside the definition of GRs. In paragraphs 4.1 and 4.2, references to "Member State" should be together with "Party", as a matter of consistency. On

exceptions and limitations, the original text looked simple and straightforward, but it had concerns with the alternative, however, and further work needed to be done on that.

261. The Delegation of Indonesia, speaking on behalf of the Asia-Pacific Group, said that Rev. 2 could serve as a basis for further discussion.

262. The Delegation of the EU, speaking on behalf of the EU and its Member States, said that Rev. 2 constituted a basis for further work at IGC 36. IGC 35 had not provided sufficient time for all issues to be discussed exhaustively and there had been no opportunity to discuss some issues at all in the right format to allow its comments to be taken on board, for example, on the question of subject matter, for which it would have liked more time and latitude to explore its position. It had some substantive comments and expected those points to be taken up into Rev. 1 at IGC 36 in due course. It wished to provide comments on subject matter, as it had not had the opportunity to do so either in plenary or in informals. Regarding Article 3, there previously was an alternative text, which had been moved to the second part of the document in the alternatives to Articles 2 to 6, because it was probably perceived that that text did not relate to the disclosure option, but to the alternative approach of “no disclosure”. That interpretation was problematic, and it did not share that assessment. That alternative option should remain in the first part of the document, under Article 3 ALT. As to the preamble, it supported the idea of a more streamlined, shortened, condensed, and coherent preamble, as in the alternative preamble. It would be happy to make more substantive and detailed comments later on. As to Article 1, it preferred ALT 1 in the definition of “invention directly based on”. It preferred “invention” and not “subject matter” in the alternative. There were two definitions in “Other Terms”, namely “physical access” and “conditions”, which were closely related to the understanding of definitions in the operative parts because “physical access” was closely linked to the definition of “invention directly based on” and “conditions” were related to definition of “country of origin”. It preferred those definitions to be considered relevant for the operative parts of the text. Regarding Article 4, it was very pleased to support ALT paragraph 4.2 because it had requested that its position, as expressed in the informals, should be more accurately reflected in the text. In paragraph 4.5, its position had not changed and it preferred the bracketed parts. It could support paragraph 4.3 as well. As regards paragraph 4.4, the paragraph that appeared right above had been deleted because, as explained by the facilitator and the Friend of the Chair, paragraph 4.4 was perhaps a more flexible, more open formulation relating to how the received information should be handled by the IP or patent office. It welcomed that Article 3.5 had been deleted from the text. It supported that idea very much. As regards exceptions and limitations, it preferred ALT paragraph 5.1. On sanctions and remedies, it had some difficulty following what had exactly happened: there should be an alternative capturing “no revocation” and “no list.”

263. The Delegation of Morocco, speaking on behalf of the African Group, said that Rev. 2 could be a good basis on which to evolve and make progress towards the next negotiations, given that it included all of the initial texts. It would be able to present its opinions at the opportune time concerning major legal issues.

264. The Delegation of Ecuador, speaking on behalf of GRULAC, said that Rev. 2 took into account the concerns of the different groups and was a good basis to continue the future discussions concerning specific topics. The term “derivative” should not be included in the definitions but should be used within the operational text. It wished to make efforts on the discussions on origin and source.

265. The Delegation of Lithuania, speaking on behalf of the CEBS Group, agreed to have Rev. 2 as a basis for the next IGC, however, mistakes and omissions should be eliminated beforehand. The main lines of its position remain unchanged: the subject matter of the instrument had to be focused on the patent system but not on GRs *per se*. The trigger of disclosure should be based on the concept of inventions that were “directly based on” GRs.

Sanctions should not encompass an option for patent revocation. It did not support the inclusion of derivatives into the definition of GRs. The provision containing substantive patent law still remained in the text, in Article 9, and it had difficulties with its inclusion. It would thoroughly consider the text in capitals and looked forward to discussing it in detail at IGC 36.

266. The Delegation of Switzerland appreciated the efforts of the facilitator and the Friend of the Chair to bring more clarity in Article 1 around the terms currently used in the operative provisions and other terms, which might be relevant in the context of the instrument. At the same time, it was increasingly concerned with the section. It was not clear for which terms the definition might be useful. Definitions usually had far-reaching implications and they should only be decided on once further progress on operative provisions had been made. Otherwise, one could run the risk of defining terms, which were not used in the finally adopted international instrument, as was the case, for instance, of the Nagoya Protocol. It was not in a position to support any changes to existing definitions of other international agreements to which it was a party. That would not only add legal uncertainty in the international legal system related to GRs and TK associated with GRs but it would also strongly interfere with national regulations in place in Switzerland and in other countries that were consistent with international agreements. It requested, in the future work of the IGC, that definitions existing in other agreements be reintroduced into the IGC document exactly as was, as standalone options. Moreover, in order to avoid confusion, it requested to clearly mark all the definitions currently used in other international agreements by referring to those agreements. Regarding the mandatory disclosure requirement in Part I, it recognized some improvements, yet further work was needed to draft a system that was workable in practice, provided benefits for all parties, ensured legal certainty in the patent system and supported innovations on GRs. In Part II, some of the paragraphs were not in brackets, yet they should all be in brackets. In paragraph 4.5, there should be brackets around “geographic location”. It requested looking at those terms in the future.

267. The Chair said the use of brackets in the text was confusing and he, together with the Secretariat, would look into ways of dealing with brackets in future documents.

268. The representative of International Law Association supported the statement made by the Delegation of Switzerland in terms of adopting different definitions for terms. For example, the alternative definition of “genetic material”, due to new understandings of biology, would exclude fungal genetic material from being contained within the scope of the instrument, which was not the intention, seeing that it was not plant, animal, or microbial. He was not sure that was a wise decision. On the definition of “physical access”, he said that there had been a lot of technical developments in terms of access to GRs. He referred to the report of the *Ad Hoc* Technical Expert Group on Digital Sequence Information on Genetic Resources, released on February 20, 2018, which discussed non-physical access to GRs and showed how in reality and in practice that was more or less overtaking physical access as a way to create inventions based on GRs.

269. The Delegation of El Salvador supported the statement made by the Delegation of Ecuador, on behalf of GRULAC. In Article 1, it requested bracketing the new alternative definition of TK associated with GRs. In ALT 3, it asked to have an introduction bracket before “from generation to generation”, independently of its preference for any alternative.

270. The Delegation of Japan said that the newly introduced title of Part II “Defensive Measures” failed to appropriately reflect the essential concept of the section, which was that no disclosure requirements could be imposed upon patent applicants or patentees for patents related to GRs and TK associated with GRs, for reasons other than those related to novelty, inventive step, industrial applicability or enablement. It requested that the title be bracketed and the original title, “No New Disclosure Requirement”, be revived. It also requested that the title of Part III “Complementary Measures” be bracketed and the original title “Defensive Measures” be kept. Those measures were not complementary but essential and effective. It did not support

the concept intended to prevent patenting any life form, as indicated in Article 9, as well as the related paragraphs of the preamble. Article 9 and the related paragraphs of the preamble, which were intended to make GRs ineligible for patents without any exception, were not appropriate, because the patent system served as an essential incentive for developing biological and medical technology.

271. The Delegation of Chile endorsed the statement made by the Delegation of Ecuador, on behalf of GRULAC. Rev. 2 was a good basis for continuing the work at IGC 36, and would facilitate the work of the *ad hoc* expert group. It appreciated the inclusion of new texts reflecting the different positions of Member States, such as the alternative text for the preamble, the inclusion of the definitions as Article 1, and the new alternative to paragraph 4.2 in the disclosure requirement. Nonetheless, the instrument should refer to both genetic and derived resources. As noted by the Delegation of Indonesia, on behalf of the LMCs, it was more appropriate that the definition of that term be considered within the definitions used in the operative articles. The patent system was naturally called upon to collaborate in the protection of GRs, their derivatives and TK associated with GRs. The instrument should establish mandatory disclosure of origin in the patent system, incorporating sufficient flexibility to allow for balanced implementation in those countries that did not yet have it incorporated in their own systems. It was important to reconcile positions on the trigger that would activate the disclosure requirement and therefore recognize the need to further discuss the concepts of “utilization of the genetic resource” and “invention directly based on genetic resources”. Although it preferred more familiar concepts such as the use of GRs, it would be possible to reach consensus at IGC 36 on the language to be used as long as there was a more dynamic exchange of ideas and explanations around it.

272. The Delegation of China said that there was still a lot of work to be carried out on the document. Rev. 2 could comprehensively reflect all positions and could be the basis for future work. Regarding mandatory disclosure, it preferred the original text on exceptions and limitations. Regarding sanctions and remedies, it hoped that there would be clear regulations. As to databases, it was very important, but it should be only one of the tools. It had more detailed comments and needed to further study the document before it could submit its opinion.

273. The Delegation of Republic of Korea agreed with the comments made by the Delegation of Switzerland on Article 1. The definitions needed to be consistent with those used in other international instruments. Some of the definitions contained a lot more than the definitions in other international instruments. It was not in a position to support Article 9, which was in conflict with its patent system. With regard to the titles used in Part II and in Part III, it supported the comments made by the Delegation of Japan.

274. The Delegation of the USA recognized the comments on the necessity of using brackets and their utility. It had noted in plenary specific concerns about Article 2(a) and (b) on objectives that were not reflected in Rev. 2. It asked that the IGC continue to follow the WIPO procedure. It had not had the opportunity to consider and comment on the alternative preamble and other language contained in Rev. 2.

275. The Delegation of Ecuador supported the inclusion of Article 9 as proposed by the Delegation of the Plurinational State of Bolivia. It reflected one of the basic principles of the IP system, the non-patentability principle, and it also formed part of the norms existing in many countries such as Ecuador. It wished to discuss Article 9 in future negotiations.

276. The Delegation of Indonesia supported the statements made by the Delegation of Indonesia, on behalf of the LMCs and the Asia-Pacific Group, according to which the discussions could be based on Rev. 2. It welcomed and preferred the alternative preamble proposed by the facilitator and the Friend of the Chair. In paragraph 9 of the preamble, the language about the stability and predictability of granted patents would prejudice the outcome

and subject matter of the document. That language should be bracketed. Regarding the definitions, it shared the position of the LMCs that the “derivative” definition should be under the term used in the operative articles. With regard to derivatives, it understood the explanation by the facilitator and could go along with that idea, but there was no guarantee that Member States would agree on the definition of GRs. Regarding Article 2(c), it was a defensive measure and it should be complementary. Moreover, the word “ensuring” would put a burden on IP offices. It wished to discuss further that provision. With regard to Article 5, ALT paragraph 5.1, for the sake of consistency with the other paragraphs (a) to (f), paragraph (g) should also be put in brackets. It supported Article 6, paragraphs 6.1 and 6.2. With regard to alternative 6.2(a)(iv), there was an addition providing an opportunity for IP/patent applicants to supplement the IP, and that was not actually part of sanction or remedies, so another place should be found for that provision, perhaps under Article 8. With regard to paragraph 6.3, it understood that the reason that the facilitator and the Friend of the Chair had put it was because Member States were reluctant to include revocation, but paragraph 6.3 was too descriptive, especially as compared to other measures.

277. The Delegation of Canada said that there was a proposal to remove the brackets around the term “mandatory”. That had not been discussed in plenary and, with respect, it was an error. While it understood that some Member States advocated for the text, the removal of the brackets created a problem, excluding the opportunity of voluntary disclosure as an outcome. Voluntary disclosure should remain an option so as to enable consideration of the full range of policy options and to avoid creating mutually exclusive black-and-white options with no room for mutual landing zones. ALT Article 4 was not about voluntary disclosure and was seen as the counterpart of the mandatory disclosure provisions found in Article 4. It fully contemplated that possibility with a view to allowing all options, including voluntary disclosure, to remain on the table. To avoid causing false issues, it requested square brackets. IGC 35 had not discussed voluntary disclosure and new wording was needed to better reflect that option in the text. That could be done at IGC 36. It did not want voluntary disclosure to disappear as an option. Without prejudice to its positions, Rev. 2 was a useful basis for further discussions.

278. The Delegation of Mexico said it could continue to work on Rev. 2 at IGC 36.

279. The Delegation of Brazil said that the definition of “derivatives” should be under the scope of the treaty and therefore it could not feature under “other terms” and should be moved to the operative part. It noted that the definition was contained in the definition of GRs. More discussions were needed at IGC 36 as to the proper place of the derivatives. Derivatives were also mentioned in ALT Article 5.1(b) and therefore there were many references to that concept. Regarding Article 3, it supported the statement made by the Delegation of Ecuador, on behalf of GRULAC, that “utilization of” should be added before GRs. Article 4 should include “Party” after “Member States”, both in paragraphs 4.1 and 4.2, as suggested by the Delegation of Switzerland in informals; maybe it was an accidental omission. It preferred the first proposal of paragraph 4.2, as there was a need for flexibility for those countries that wished to require ABS and PIC. In paragraph 4.3, it preferred to use the term “should” to read “the disclosure requirement should not place an obligation”, because Member States wanted to have the possibility to use their patent office to do that. It was not the case of Brazil, but the international instrument should have that flexibility. In Article 5, it preferred the first option on exception and limitations. The alternative had no relation with exceptions and limitations and it should be moved to Part II as an alternative, as previously requested. It asked to bracket paragraph 5.1(g), which was a new proposal that demanded further analysis. It wished to comment on a possible inconsistency between paragraph 5.1(f) and paragraph 5.2. It suggested that Article 5.2 be moved to the final provisions of the instrument. Turning to Article 6, the list of the pre-grant and post-grant sanctions should be preserved and paragraph 6.3 should preserve the possibility of revocation. It preferred the first option, which did not oblige those that did not have it in their legislation to have it while allowing for those countries that had it to maintain it. It offered an opportunity for the applicant to reach mutually satisfactory resolutions and that was the good

faith existence of the provision. On the title of Part III, it wanted to maintain “complementary measures”. It had very clearly pointed to databases’ substantive and practical limitations as a way of protecting GRs. In general terms, it was happy with Rev. 2 and looked forward to discussing it at IGC 36.

280. The Delegation of Nigeria supported the statement made by the Delegation of Morocco, on behalf of the African Group, on the fact that Rev. 2 could be used to make progress. It suggested that, in the definition of “country of origin” and its alternative, the phrase “and still possesses those genetic resources” be in brackets. The document was about GRs and TK associated with GRs for purposes of IP as a trigger for disclosure of GRs and TK associated GRs. Recognizing that there was a need for synergy with other international instruments, one needed to avoid reinventing the wheel. There was no other instrument that had direct bearing on GRs and TK associated with GRs in the context of IP, especially the patent regime. The ITPGR related to food and agriculture, the CBD was in the context of conservation, and the Nagoya Protocol was about ABS. The IGC had to be creative in drafting a unique instrument, while not deviating from the norms of other international instruments. Some of the definitions that the facilitator and the Friend of the Chair had put in this text were very creative and responsive to the context of negotiation. Some of the references to existing international documents required recognizing that some of those instruments had been made in the context of a different technological reality. It noted the intervention by the representative of International Law Association to the effect that genetic sequencing and information constituted the basis of contact with GRs as opposed to physical contact. That had been reflected in the attempt to define “directly based on”. The IGC had to discuss how to define “TK,” “utilization” and “directly based on” in relation to the trigger.

281. The Delegation of India considered Rev. 2 as a starting point for IGC 36. It understood that the entire document was in brackets. Its concerns were at different levels. On some issues, it had less concerns, but on the majority of issues, it had serious to very serious concerns, because Rev. 2 was a mix of two approaches. It would provide detailed comments at IGC 36.

282. The Delegation of the Plurinational State of Bolivia aligned itself with the statement made by the Delegation of Ecuador, on behalf of GRULAC. It could go along with Rev. 2, which was a good basis for the work of the IGC. Regarding the disclosure of source, it should be also disclosed and used for utilization. It preferred the option over the alternative. Regarding the final provisions, it could support the new wording. The heading of Article 9 should read “measures for protection” because that better reflected the terms of the paragraph. However, discovery should not be patented. The idea was to protect GRs from misuse or misappropriation.

283. The Delegation of Venezuela associated itself with the statement made by the Delegation of Ecuador, on behalf of GRULAC, and considered that Rev. 2 be a good basis for continuing the IGC’s work. It reserved its right to come back and make comments on it at IGC 36 after having looked at it closely. It attached importance to Article 9 because that corresponded to its national legislation. It associated itself with those who had said that there was a need to include the term “derivatives” in the operative part of the text.

284. The Delegation of the Islamic Republic of Iran aligned itself with the statements expressed by the Delegation of Indonesia, on behalf of the LMCs, and the delegations of other LMCs, according to which Rev. 2 was a considerable step forward in the work of the IGC. With regard to the preamble, it should establish equal interrelations with other existing instruments, such as IP-related instruments and GRs-related instruments. The CBD was not sufficient, because it was just about the bilateral approach to GRs, while the IGC was dealing with a multilateral approach, which was getting more attention with regard to the use of GRs. The preamble also had to establish more clearly that providing a clear IP system would shed light on the environment surrounding the use of GRs and promote the use of GRs for the better livelihood of

mankind in all countries. As to definitions, there was no need to differentiate the terms of the operative articles and other terms. All of them were equally important for the document and it was better not to create a hierarchy among them. With regard to dispute settlement, there was a difference of views on sanctions and remedies and specifically concerning the revocation of rights. That was not only still a matter of dispute, but some also contended that revocation, as a sanction, should be the last resort in preventing the grant of erroneous patents. Instead of a focus on punitive measures, there should be more focus on preventive measures. It would be timely to have dispute settlement measures in pre- and post-grant stages, rather than revocation as a last resort. There needed to be a strong, comprehensive dispute settlement mechanism instead, not as an alternative, but as a priority. Revocation or punitive measures could be the last resort. It was very costly and very difficult for a developing country to challenge a patent in developed countries. It would be a good idea to pay equal attention to the development of a workable dispute settlement mechanism in the future of the work of the IGC. With regard to Article 9, it was a basic principle of IP that GRs, as they were found in nature, could not be patented or subject of an IP right.

285. The Delegation of South Africa aligned itself with the statement made by the Delegation of Morocco, on behalf of the African Group, and the statement made by the Delegation of Indonesia, on behalf of the LMCs. It did not want to give a shopping list of things that it found to be wrong. The IGC needed to look forward and look at possibilities of using those particular documents as a basis for finding creative solutions. The *ad hoc* expert group could consider the list of issues. It asked to focus on more positive steps for the work ahead.

286. The Delegation of Egypt said that Rev. 2 was a good basis for future work. The IGC members were not competing but a team working with a team spirit. It felt a lot of compassion for the experts because the work that lied ahead of them would be full of pitfalls. It had great expectations for them. The terms “misappropriation” and “derivatives” should be defined in relation to the operative part of the document, particularly the objectives and the disclosure requirement.

287. The Delegation of Thailand supported the statements made by the Delegation of Indonesia, on behalf of the LMCs and the Asia-Pacific Group. Rev. 2 was a reflection of joint efforts in trying to narrow the gaps and could serve as a good basis for further discussion at IGC 36. Still, it had some concerns over the draft. For example, the definitions of “derivatives” and “misappropriation” should be placed under the terms used in the operative articles. It reserved the right to make further comments at IGC 36.

288. The Delegation of Gabon aligned itself with the position expressed by the Delegation of Morocco, on behalf of the African Group. Rev 2 could be a good basis for future work.

289. The Delegation of Malaysia aligned itself with the Delegation of Indonesia on behalf of the LMCs. Rev. 2 would provide a useful basis for further discussions. It supported the inclusion of “derivatives” and “misappropriation” in the operating articles. In Article 3 on subject matter, it wished to include “utilization” as well. It looked forward to engaging further at the next IGC.

290. The Delegation of Sri Lanka was opposed to having separate sections for the definitions in Article 1. It was not happy about deleting the word “derivatives” from the text and having it included into the alternative definition of GRs.

291. The Delegation of China said that in the definition part, TK associated with GRs, ALT 2, the first square brackets “rightful holders including” could also include countries as holders, as had been reflected in the preamble. Regarding the subject matter, it suggested to add square brackets.

292. The Chair closed item 7.

Decision on Agenda Item 7:

293. *The Committee developed, on the basis of document WIPO/GRTKF/IC/35/4, a further text, “Consolidated Document on Intellectual Property and Genetic Resources Rev. 2”. The Committee decided that this text, as at the close of this agenda item on March 23, 2018, be transmitted to the Thirty Sixth Session of the Committee, in accordance with the Committee’s mandate for 2018-2019 and the work program for 2018, as contained in document WO/GA/49/21.*

294. *The Committee took note of and held discussions on documents WIPO/GRTKF/IC/35/5, WIPO/GRTKF/IC/35/6, WIPO/GRTKF/IC/35/7, WIPO/GRTKF/IC/35/8, WIPO/GRTKF/IC/35/9, WIPO/GRTKF/IC/35/INF/7, WIPO/GRTKF/IC/35/INF/8 and WIPO/GRTKF/IC/35/INF/9.*

AGENDA ITEM 8: ESTABLISHMENT OF AN AD HOC EXPERT GROUP(S)

295. The Chair said that, based on discussions with the Regional Coordinators, he had issued an initial proposal for the *ad hoc* expert group. He said his proposal was balanced and addressed the mandate in terms of ensuring technical expertise to help with the IGC’s work and support the evidence-based approach. The expert group should look at the material and specific technical issues and come forward with oral recommendations that the IGC could take on board in relation to the text itself. The nominations for the expert group members would need to be sent in advance to allow them to prepare ahead of the meeting. He, together with the Vice-Chairs, would select a chair or co-chairs for the meeting. It was difficult to get everyone to agree on the detailed questions that the group would address. Regional groups should present to the Chair their proposed issues, and the Chair and the Vice-Chairs would consider those and decide on the final list, in order to avoid lengthy discussions by all members. The final list would be submitted to the Regional Coordinators for comments before being issued. He opened the floor for comments.

296. The Delegation of Indonesia, speaking on behalf of the Asia-Pacific Group, supported the Chair’s proposal, which was balanced and took care of different fields and perspectives.

297. The Delegation of Ecuador, speaking on behalf of GRULAC, supported the balanced proposal. It hoped that the exercise would provide useful inputs to the debate, assist in reflecting upon fundamental issues, and facilitate the future work of the IGC.

298. The Delegation of Switzerland, speaking on behalf of Group B, thanked the Chair for his proposal. The IGC's mandate foresaw the possibility to establish an *ad hoc* expert group(s). It noted that IGC 36 would take place over six days and that the mandate of the expert group would be limited to that session. The indicative list of issues should be more focused and balanced. It noted that the regional groups would present their proposals for issues to be tackled. It supported an inclusive process and the inclusion of all key stakeholders, including indigenous experts, academia, civil society and industry representatives. The conclusions of the expert group would be presented in the plenary of IGC 36 and it would be up to Member States to decide on how to use those conclusions.

299. The Delegation of Morocco, speaking on behalf of the African Group, welcomed the Chair's proposal, which was a good basis for finding solutions to pending issues. The role of the expert group should be to accelerate the work of the IGC on GRs and to smooth out the differences, taking into account what had been achieved thus far.

300. The Delegation of Lithuania, speaking on behalf of the CEBS Group, supported in principle the Chair's proposal. It noted that, after taking stock of the discussions on GRs at IGC 35, it saw the value in establishing such an expert group, thus making use of this possibility provided in the mandate. The expert group had to be as inclusive as possible and include indigenous communities, academia, industry, civil society and all other relevant parties. It supported narrowing the list of issues, in order to have a discussion on topics where experts' opinion would give an added value to the future work of the IGC. It supported the Chair's leadership of the process and would contribute constructively as needed.

301. The Delegation of the USA supported the statement by the Delegation of Switzerland, on behalf of Group B, and thanked the Chair for his proposal. Among other things, the expert group would benefit from the participation of indigenous experts and industry as well as other external experts. It did not oppose the proposal and noted the comments concerning the establishment of the *ad hoc* expert group. The report of the expert group on its work should not result in making recommendations on the text, as that was not envisioned in the mandate. The expert group should provide its conclusions in plenary and it was up to Member States to decide what to do with the conclusions. In order to help with the IGC's mandate, the expert group's work should help structure the discussion in a manner that would inform the IGC, based on the experts' national experiences. It emphasized the need to balance and condense the indicative list of issues. Having a smaller set of issues made it easier to complete the work on time.

302. The representative of Tupaj Amaru supported the proposal. However, the establishment of *ad hoc* expert groups would dilute the IGC's work. The adoption of an instrument should be discussed in plenary with the participation of all Member States and indigenous peoples. Indigenous experts had to be included in those groups, particularly those who had contributed to the work of the IGC.

303. The Delegation of Canada supported the statement made by the Delegation of Switzerland, on behalf of Group B. It thanked the Chair for preparing the document. Striking the proper balance was not an easy task. It supported in principle the convening of an expert group, which could inform and even advance the IGC's work. It could include a variety of perspectives: indigenous peoples, academia, civil society and industry. The expert group would require some guidance for its work and the indicative list provided seemed appropriate. However, the list should be realistic to give the experts sufficient time to have a substantive and substantial discussion. A streamlined list could foster that discussion. The experts should take a step back from the text to engage in a more bottom up exchange of concrete national experiences relevant to the IGC's work, so as to enrich its work with new information and perspectives. It was key that the expert group advance the IGC's work and not replicate it. Any proposals or recommendations had to be fully discussed in plenary prior to and independent

from any discussion about the working document to avoid any text being automatically included in the working document.

304. The Delegation of Egypt expressed its support. However, the indicative list of issues should include Article 1 on the objectives of the instrument, which included the misuse and misappropriation of GRs and TK. With regard to the choice of three experts representing academia, civil society and industry, it hoped that in future those choices would represent the views of all delegations and not only one single view.

305. The Delegation of Indonesia supported the Chair's proposal, in line with the position of the Asia-Pacific Group. Experts could share their national experience, but what the experts could do should not be restricted. Their mandate would most likely focus on providing legal and policy options and technical analysis and not just on national experiences. It should be ensured that all experts be specialists.

306. The Delegation of India welcomed the establishment of an *ad hoc* expert group.

307. The Delegation of Nigeria supported the statement made by the Delegation of Morocco, on behalf of the African Group. It thanked the Chair for the balanced and thoughtful framework. It hoped that the expert group would be sensitive to the urgency to make progress on the GRs text. The complementary experts from academia, civil society and industry would have to be selected with sensitivity to geographical inclusiveness and to diversity of predetermined ideas shared by those representatives. The indicative list of issues should be kept as narrow as possible to enable progress. Experts would work in their personal capacities and would not be glued to the national positions.

308. The representative of CISA said that the expert group would enable indigenous participants to better contribute to the important work.

309. The Delegation of the Plurinational State of Bolivia supported the proposal and agreed with the statement made by the Delegation of Ecuador, on behalf of GRULAC. The list of issues should be kept short.

310. The Chair closed Agenda Item 8.

Decision on Agenda Item 8:

311. The mandate of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC or Committee) for the biennium 2018/2019 provides that the IGC "may establish ad hoc expert group(s) to address a specific legal, policy or technical issue", and "the results of the work of such group(s) will be submitted to the IGC for consideration". The mandate also notes that the "expert group(s) will have a balanced regional representation and use an efficient working methodology", and "work during the weeks of the sessions of the IGC".

312. *With this background, the Committee agreed that an ad hoc expert group on genetic resources be organized as follows:*

Mandate

The IGC plenary is the negotiating and decision-making body. The ad hoc expert group is to support and facilitate the negotiations of the IGC.

The ad hoc expert group will provide advice and analysis on legal, policy or technical issues such as those in the indicative list of issues in the Annex. Member States, through the Regional Coordinators, will be invited to suggest the specific issues to be considered by the ad hoc expert group. The IGC Chair and Vice-Chairs will identify the list of specific issues from the suggestions made by Member States. The list should be balanced and as short and focused as possible. The draft list will be provided by the IGC Chair to the Regional Coordinators for comments and the experts in advance of the group's meeting.

The ad hoc expert group will report to the IGC plenary at IGC 36 on the outcomes of its work.

The agenda for IGC 36 will make provision for such a report by the ad hoc expert group, which will be presented by the Chair or co-Chairs of the ad hoc expert group and will be included in the report of IGC 36.

Composition

Each Regional Group will be represented by a maximum of four experts. The European Union (EU) and the Like Minded Countries will be invited to nominate two experts,

without additional funding requirements. The Indigenous Caucus will be invited to nominate two indigenous experts to participate. The experts, who should preferably be subject-matter specialists, shall participate in their personal capacities.

The Regional Groups, the EU, the Like-Minded Countries, and Indigenous Caucus will be invited by the Secretariat to nominate their experts by a date to be advised, so that the necessary arrangements can be made.

The Secretariat is authorized to invite up to three experts from academia, civil society and industry, to assist in the ad hoc expert group, such as by making presentations and answering technical questions. They will also participate in their personal capacities.

The Chair and Vice-chairs of the IGC will be invited to attend the ad hoc expert group meeting.

Date and venue

The ad hoc expert group on genetic resources will meet on Sunday, June 24, 2018, at WIPO Headquarters in Geneva, in Room NB 0.107, from 09h00 to 17h00.

Funding

According to the agreed funding formula for the IGC process, one participant each from 36 countries (seven countries from each region and China) will be funded for the 36th session of the IGC. Regional Coordinators will be invited, as usual, to provide the names of the countries to be funded. Funded countries will then be

invited to nominate the funded participants to the IGC.

For those experts from each Regional Group attending the ad hoc expert group who are the funded participants to the IGC, one more daily subsistence allowance at the usual IGC rate will be provided by WIPO. WIPO will not cover the expenses of other experts or any other additional expenses.

This funding arrangement for the ad hoc expert group does not constitute a precedent for other WIPO meetings.

If the indigenous experts to participate in the ad hoc expert group are funded by the Voluntary Fund as decided by the Advisory Board or are the panellists for the Indigenous Panel at the 36th session of the IGC, WIPO will provide one daily subsistence allowance at the usual IGC rate. WIPO will not cover the expenses of other indigenous experts or any other additional expenses.

Languages

The working languages of the ad hoc expert group will be English, French and Spanish.

Chair or co-Chairs of the ad hoc expert group

The Chair or co-Chairs will be identified by the Chair of the IGC from among the participating experts before the meeting of the ad hoc expert group so that they have adequate time to prepare.

Informality

The ad hoc expert group will not be webcasted, or reported on in the same manner as the IGC plenary.

All participants are requested to respect the informality of the ad hoc expert group, and not to communicate to the public, whether 'live' or at any future time, the content or nature of the discussions taking place in the ad hoc expert group, whether in general terms or by way of quoting specific experts. This includes restrictions on tweeting, blog posts, news stories and email list-serves.

Secretariat services

The WIPO Secretariat will facilitate the conduct of the meeting and provide secretariat services.

AGENDA ITEM 9: ANY OTHER BUSINESS

Decision on Agenda Item 9:

313. There was no discussion under this item.

AGENDA ITEM 10: CLOSING OF THE SESSION

314. The Chair said that IGC 35 flowed into IGC 36. He thanked all Member States for their positive contributions during the week. It was a difficult and complex negotiation, as there were some divergences of views. He was keen to see IGC 36 make progress on those divergences. Members should take the time between IGC 35 and IGC 36 to consider the discussions held during the week, including the materials prepared by the contact groups, which had provided some further ideas for thought. Members should come well prepared to make decisions. He had attempted to introduce new processes and procedures, particularly the contact groups that appeared to have support in principle. It was important to consider carefully the appropriate time to establish them, together with format issues. He took notice of the lessons learned from the pilot. He and the Vice-Chairs would carefully consider the processes and procedures for IGC 36, to try to make meetings as efficient as possible and to make progress. They were always open to constructive ideas from Member States and observers on how to do the work. It was also very important for industry representatives to be involved in the discussions, as observers, similar to the Indigenous Caucus, and to have the ability to engage with the process, whether in informals, contact groups or plenary. There would only be a successful outcome if it balanced all of the interests of the stakeholders. The Chair appreciated everyone's frankness. He thanked the Vice-Chairs, with whom he worked as a team. He took advice from everybody, not just from the Vice-Chairs but also from Member States. He thanked the facilitator, Mr. Paul Kuruk, and the Friend of the Chair, Ms. Margo Bagley. He also thanked the Secretariat that made sure meetings were efficient, effective and successful. Without the work behind the scenes, the meeting would not be efficient or successful. There was a huge amount of work that went on and the Secretariat had a lot of work to do in a fairly limited amount of time in planning the ad hoc expert group. He thanked the Regional Coordinators that played a critical role in keeping him informed and working between him and Member States to ensure that the

IGC could go forward and have a successful meeting, in particular, making the atmosphere enjoyable. He thanked the chairs and rapporteurs of the contact groups. He indicated his support for the Indigenous Caucus and the work they did within the negotiations. He reemphasized the need to find some funds. He thanked industry representatives, civil society as well as other key stakeholders in the discussion. Their views and comments had to be carefully considered, for many of them had to practically implement the instruments that hopefully would be agreed on in the future. He thanked all delegates. He appreciated the honor of having been re-elected as the Chair, together with the Vice-Chairs. He tried to be independent as he could. He would continue to endeavor to do that and expected to be told by the members when he would not. The Chair thanked the interpreters for their flexibility because they ensured clarity and understanding.

315. The representative of KUNA, speaking on behalf of the Indigenous Caucus, thanked the Chair, as well as the facilitator, the Friend of the Chair, the Member States, and the Secretariat for supporting their participation at the meeting. The Indigenous Caucus was committed to contributing its best efforts toward negotiating an international IP instrument(s) for the protection of GRs and associated TK in fulfilling the mandate given to the IGC by the WIPO GA. In finalizing the negotiations, Member States should take into account the minimum international human rights standards embodied in UNDRIP and other international instruments. Those were summarized in document WIPO/GRTKF/IC/34/INF/8. Those were minimum standards, which the IGC must not fall below. However, the IGC was fully competent to develop stronger and *sui generis* measures related to the use of indigenous peoples' GRs and TK within the patent system. The preamble and objectives of the proposed instrument(s) had to address the aspirations, interests and rights of indigenous peoples, and not only reflect balance among existing objectives within the patent or other IP systems. Those considerations extended beyond the IP system, involving considerations such as secret and sacred TK, cultural sensitivities and customary laws. A human rights-based approach was necessary to achieve mutual supportiveness - it could not be avoided by appeals to the lack of competency of the IGC in human rights. While the IGC might lack competence to author human rights, Member States were fully competent and obligated to observe human rights standards to which they were bound. He strongly supported disclosure requirements, that had to be viewed as relevant to the patentability of an innovation. Patents could not be given for innovations based on stolen or misappropriated TK or GRs. Disclosure of origin remained the major system for safeguarding indigenous peoples' rights prior to the granting of patents. It provided benefits to promoting the recognition and respect of indigenous peoples' right to FPIC. The approach avoided the potentially high costs and risks to developing and maintaining databases of TK. It avoided placing the burden on those who had developed TK in traditional contexts to document their knowledge in violation of customary laws and beliefs. It avoided placing them at risk beyond the patent system if such knowledge was made public. Even if a Member State was not a party to the CBD or the Nagoya Protocol, it was within the competence of the IGC to adopt *sui generis* provisions on patentability related to GRs and TK. On sanctions and remedies, there needed to be significant punitive measures beyond post-grant requirements or benefit-sharing in cases of willful mischief. Patent revocation had to remain as a potential outcome in extreme cases. He had no issue with the concept of due process and the potential to correct mistakes. But he did not believe that willful deceptions and violations of the rights of indigenous peoples to control the use of their TK or GRs should be addressed by fines and weak penalties. Not all of indigenous peoples' issues, many of which were spiritual and connected to identity, dignity, and obligations to their creators, ancestors and Mother Earth, could be addressed by benefit sharing. Indigenous peoples should be involved at the national level in the development of any sanctions and remedies. He supported the inclusion of derivatives in the instrument. There was a need for new terminology to address issues related to genetic and biological information that were wider than encompassed by the concept of derivatives. New developments in genetics, such as metagenomics, microbiomics, metabolomics, and other "omics" as well as synthetic biology were expanding the causal chains connecting genetic source materials to final products in the patent system. In an ever-growing number of cases, physical access to original genetic material

was not required to generate copies and make modifications that were still causally related to original source materials. There was substantial TK related to those non-physical chains. The “omics” and digital genetics revolutions would create challenges and create a new generation of patent forensics to ensure that indigenous peoples’ rights were respected in the innovation process. Finally, he appreciated the Government of Australia and other countries that had contributed to the Voluntary Fund. However, their full and effective participation was critical as negotiations were nearing the end. He called on Member States to contribute to the Voluntary Fund to ensure participation of at least one indigenous expert from each of the seven regions recognized by the UN. Failure to do so would jeopardize the legitimacy of any outcomes. He looked forward to continued participation in the negotiations.

316. The Delegation of Ecuador, speaking on behalf of GRULAC, thanked the Chair and the Vice-Chairs. It recognized their energy and determination to achieve success. It thanked the facilitator, the Friend of the Chair, and members in the contact groups for their devotion and dedication to the work. It thanked the Secretariat for always being available and for their work. It had been a week of very hard work. It had examined issues of priority for GRULAC members. The IGC’s approach should be aimed at narrowing gaps so as to reach a common understanding and agreement for the conclusion of an instrument on GRs. Promoting such a regime would promote innovation and provide a uniform legal framework for interested parties in respect of GRs, while involving benefit-sharing as well. There had been substantive debates. It welcomed the willingness of delegations to work openly and in a flexible way. It welcomed the setting up of an *ad hoc* expert group and trusted its work. It hoped to have a work methodology for IGC 36 that provided time for informals and contact groups on specific issues, without neglecting flexibility. Adjustments to the methodology should be made in a clear and timely way before the session. It called on the pragmatism of all Member States to achieve minimum areas of consensus.

317. The Delegation of the Russian Federation addressed its thanks to the Chair, the Vice-Chairs and the Secretariat. It thanked the Traditional Knowledge Division for regularly providing a lot of new materials in many languages. That enabled it to update its work on the spot and to inform all interested parties who should be informed, including the small nations in the country.

318. The Delegation of Indonesia, speaking on behalf of the Asia-Pacific Group, extended its appreciation to the Secretariat for all the hard work and for ensuring a successful meeting. It was a complex discussion with a divergence of views, and the IGC had obtained important results under Agenda Items 7 and 8. It thanked the Chair, the facilitator, the Friend of the Chair, all regional groups, including the regional coordinators, and all representatives of Member States. Despite the divergence of views, it had been possible to maintain a friendly, open, frank, and meaningful discussion with results. It would remain constructive and committed and looked forward to future meetings of the IGC. It thanked the conference services and the interpreters, without whom it would be hard to have a smooth and successful meeting throughout the week.

319. The Delegation of Morocco, speaking on behalf of the African Group, expressed its trust in the Chair’s leadership and his efforts, and thanked him for his professionalism, which had allowed the IGC to move forward and adopt a changing methodology. It also thanked the Vice-Chairs, the facilitator, the Friend of the Chair, and the contact groups for the wonderful work accomplished. It thanked the Secretariat for its efforts in facilitating the work. It reiterated its attachment to the process of discussion within the IGC with a view to achieving a legally binding instrument that would strengthen the transparency of the system to protect GRs. It also reiterated its attachment to the principles and terms of the new mandate, which meant that during IGC 35 and 36, the IGC would be discussing pending issues on GRs and finding an approach for agreeing on a binding instrument. It welcomed the creation of an *ad hoc* expert group, which would help overcome differences in a spirit of continuity while maintaining the progress made. The African Group had contributed actively and would do so in the future with a

cooperative spirit, capitalizing on what had already been done. It invited all members to show flexibility in order to provide the necessary protection to GRs. It thanked the interpreters for their efforts in order to facilitate the work.

320. The Delegation of Lithuania, speaking on behalf of CEBS, thanked the Chair, the Vice-Chairs, the facilitator, the Friend of the Chair and the Secretariat for their hard work and efforts to move the discussion forward. It appreciated the intensive work of the IGC and thanked the representatives of indigenous people and other stakeholders for their valuable contribution to the discussion. It seemed that gaps in its understanding on key issues of the potential instrument on GRs remained, but the discussion had laid good grounds for IGC 36. The IGC would be able to progress towards a positive and realistic outcome. It commended the Chair's able guidance of the IGC.

321. The Delegation of Switzerland, speaking on behalf of Group B, thanked the Chair, the Vice-Chairs, the facilitator, the Friend of the Chair and the Secretariat for their hard work during the week and for their efforts to facilitate the discussions. It also thanked the interpreters. It appreciated the discussions that had taken place during the week and the work done by the IGC on GRs. More work needed to be done to narrow gaps to reach a common understanding on key issues. It was hopeful that IGC 36 would move forward in the right direction. It remained committed to contributing constructively towards achieving a mutually acceptable result.

322. The Delegation of China thanked the Chair, the Vice-Chairs, the facilitator, the Friend of Chair and the Secretariat and all the participants who had contributed to the work. Without their effort, the meeting could not have been successful. It had always supported the work of the IGC. It hoped to have a legally binding international instrument to protect GRs, TK and TCEs.

323. The Delegation of Brazil thanked the Chair for his efforts in conducting the meeting as well as the work put in place by the Vice-Chairs, the facilitator, the Friend of the Chair, the delegates, the Indigenous Caucus and observers. As Brazil was a megadiverse country, the issue of GRs was of great importance. It noted the thorough discussions during the week as well as the *ad hoc* expert group. It looked forward to engaging in discussions at IGC 36.

324. The Chair closed the session.

Decision on Agenda Item 10:

325. The Committee adopted its decisions on agenda items 2, 3, 4, 5, 6, 7 and 8 on March 23, 2018. It agreed that a draft written report, containing the agreed text of these decisions and all interventions made to the Committee, would be prepared and circulated by May 18, 2018. Committee participants would be invited to submit written corrections to their interventions as included in the draft report before a final version of the draft report would then be circulated to Committee participants for adoption at the next session of the Committee.

[Annex follows]

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[End of Annex and of document]