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NOTE

From: General Secretariat of the Council
To: Delegations
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Subject: 42nd session of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) (Geneva, 28 February - 4 March 2022)
- Final EU/Member States statements

Delegations will find at annex, for information, the EU/Member States statements as delivered at the above-mentioned WIPO meeting.

42nd session of WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)

(28 February - 4 March 2022 – hybrid meeting)

Agenda item 1 – Opening statement

Thank you for giving me the floor. This statement is made by France, and, in its capacity as Presidency of the Council of the European Union, on behalf of the European Union and its 27 Member States.

At this dark moment for Europe and the international community, the European Union and its Member States condemn, in the strongest possible terms, Russia's unprecedented military aggression against Ukraine.

By its unprovoked and unjustified military actions, Russia is grossly violating international law and the core principles on which the international rules-based order is built. This is an attack against what Geneva, as a capital of multilateralism, and WIPO, as an agency of the United Nations, stand for.

The EU and its Member States also condemn the involvement of Belarus in this aggression against Ukraine.

We call on Russia to immediately cease hostilities, to withdraw its military from Ukraine and to fully respect Ukraine's territorial integrity, sovereignty and independence.

The EU and its Member States have made clear from the outset, and at the highest political level, that any further military aggression against Ukraine will have massive consequences and severe costs. Consequently, both sectoral and individual restrictive measures have been adopted by the EU, but also by many other WIPO members.

Finally, the EU and its Member States call on the WIPO membership, as well as the broader international community, to demand from Russia the immediate end of this aggression, which endangers international peace and security at a global scale.

Chair,

1. On behalf of the European Union and its Member States, let me first congratulate you and your Vice-Chairs Ms Lilyclaire Bellamy of Jamaica, Mr Jukka Liedes of Finland and Mr Yonah Seleti of South Africa on your re-election.
2. We very much welcome the convening of the 42nd session of the IGC to restart negotiations under the new mandate for the biennium 2022/2023. We appreciate the efforts of the Secretariat, both in having managed the challenge related to the nomination of the office of Chair, and on assisting Member States to reach consensus on the methodology for this important session.
3. We would like to thank the Secretariat for preparing this session, including the documents reporting and updating on various aspects of our work on Genetic Resources.
4. We appreciate that despite difficulties in continuing negotiations according to the work program for the previous biennium, the IGC Bureau facilitated to carry out several online commenting processes and other preparatory activities which took place in 2020 and 2021. In the framework of such activities, the EU and its Member States submitted comments to the Chair's Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources. We also take positive note of the organisation of a Virtual Seminar on Intellectual Property and Genetic Resources, as well as the Briefings on the IGC, including on background, key issues, and status of the negotiations, in the course of 2021.
5. We reiterate our commitment to engage constructively in the work of the IGC and our appreciation of your efforts to facilitate progress on Genetic Resources by means of providing a 'Chair's Text' intended to serve as a possible alternative for further discussions. In our view, the Chair's Text in document WIPO/GRTKF/IC/42/5 is cleaner and more focused, and its scope is better defined than the previous consolidated document. We look forward to actively engaging in discussions on the disclosure model in the Chair's Text and to giving our detailed technical comments on key issues in this context under agenda item 7.

6. We would like to thank the delegation of Switzerland for preparing its Contribution to the evidence-based approach as submitted in document WIPO/GRTKF/IC/42/12. We welcome this new document as a highly relevant and useful contribution in the context of negotiations on an international disclosure requirement for Genetic Resources and Associated Traditional Knowledge in patent applications. We will give more detailed comments under agenda item 7.
7. We fully acknowledge the importance of active participation of Indigenous and Local Communities in the work of the IGC. We are therefore pleased to welcome the organisation of the Indigenous Panel at this session.
8. Chair, the EU and its Member States stand ready to continue negotiations on Genetic Resources at the first two sessions of the IGC under our new mandate. We look forward to participating constructively in substantive discussions throughout this week.

Thank you.

Item 7 – Genetic Resources

Chair,

1. The EU and its Member States would like to make some detailed technical comments on key issues related to an international disclosure requirement for Genetic Resources and Associated Traditional Knowledge in patent applications.
2. As regards Objectives, we note that there is no adopted definition of TK/ATK at the international level. Pending ongoing negotiations in the IGC, the reference to TK/ATK creates legal uncertainty as to what is covered by the disclosure requirement. Leaving the definition of TK/ATK to national laws would not eliminate such uncertainty. It would be preferable to link the term with the consensual outcome of the TK work track in the IGC, as reflected in Articles 1 and 3 of the Consolidated Document on TK (WIPO/GRTKF/IC/40/4).
3. Concerning the List of terms, we would like to share our views on two terms. First, as to the term '*[Materially/Directly] based on*', we appreciate a trigger concept depending on a close connection between the invention and the GRs and/or ATK used in the invention. We support the requirement that '*the claimed invention must depend on the specific properties of the GRs and/or ATK*'. We prefer the term 'directly based on' but we are open to further exploring possible advantages of 'materially based on'. We are concerned about the absence of clarity on whether Digital Sequence Information is covered. In our view, the disclosure requirement should not be extended to DSI. (The DSI issue is to be resolved in the CBD framework and not in the IGC.)
4. Second, as to the term '*Source of Traditional Knowledge Associated with Genetic Resources*' we note again that there is no adopted definition of TK/ATK at the international level. We would like to refer to our comment made on Objectives (WIPO/GRTKF/IC/40/4).
5. Turning to the trigger of a disclosure requirement, as regards the term '*[materially/directly] based on*', we would like to refer to our comment on such term in the context of the List of Terms as made above (WIPO/GRTKF/IC/40/4). As regards a reference to 'Associated TK', we would like to refer to our respective comment in the context of Objectives as made above. We also note that more discussion is needed for example as to the possible ways guidance could be given by the Offices.

6. Next, as to Exceptions and limitations, we would call for clarity on whether limitations would narrow or broaden the scope of the disclosure requirement.
7. Finally, as regards Sanctions and remedies, the EU and its Member States are of the view that more discussions are needed before we can reach a final conclusion on scope and wording. Non-compliance with the disclosure requirement needs to be addressed by leaving it up to Parties to decide which measures are appropriate, effective and proportionate, whereby post-grant sanctions should not have any effect on the validity of the granted patent or on its enforceability against patent infringers.
8. We appreciate the aim of establishing a ceiling for non-compliance with the disclosure obligations, that is, no revocation. We fully support such objective. Nevertheless, our concern is that any concrete wording should adequately safeguard such ceiling. The notion '*fraudulent intent in regard to the disclosure requirement*' is not sufficiently clear since there is no common understanding what it is supposed to mean. Clarification is needed.
9. We hope that our comments will prove useful in further discussions and we are interested to hear the views of other delegations.

Thank you.

Comments on “Rev. 1” – 2 March 2022

Chair,

- We thank Vice-Chair Mr Jukka Liedes for chairing Informals and facilitators Ms Margo Bagley and Mr Paul Kuruk for preparing Rev. 1.
- **Alternative preamble (p. 4):**
 - Para 3: Seek clarification on consistency with paras 14 and new 1 and 2, while recognising complexity of underlying interests.
 - Para 8: Appreciate removal of „mutual supportiveness” from Objectives (Art 2(a)) to Preamble language.
 - In general: Appreciate reflecting our preferred focus on the patent system by inserting “[IP]/[patent] system” throughout the Alternative preamble.

- **Article 1 – Definitions (p. 6):**
 - Term „Traditional Knowledge Associated with Genetic Resources”: Appreciate new ALT 4 (taking on board EU comment)
- **Article 2 – Objectives (p. 12):**
 - Deletion of para (a): Appreciate removal to Preamble language
 - Changes in new para (a): Appreciate insertion of “[efficacy] and quality”
 - Change in new para (b): Prefer “ensuring” to “desiring to ensure”
- **Article 4 – Disclosure requirement (p. 12):**
 - 4.1 (b): Appreciate insertion of “is not known to the patent applicant”
 - 4.3: Comfortable with new language “as well as an opportunity for applicants or patentees to correct any disclosures that are erroneous or incorrect”.
 - New ALT 2: While not opposed to new alternative, inserting more ALTs does not appear to be the desired tendency.

Comments on “Rev. 2” – 4 March 2022

Chair,

- We thank the facilitator for preparing Rev. 2.
- In general, we can accept Rev. 2 as document to be transmitted to IGC 43. Comments to be made on points where we may wish to make further suggestions in continued discussions.
- **Preamble (p. 4):**
 - Paras 3 and 15: Appreciate that our comment as to “consistency” has been taken on board and note facilitators’ intention to fine-tune language.
 - Para 14: Though we requested removal, acknowledge that following re-insertion as requested by other Members the text has been bracketed.

- **Article 1 – Definitions (p. 6):**
 - Term “Traditional Knowledge Associated with Genetic Resources”: Appreciate new text taking on board EU comment. Note proposal by Chair to remove ALTs. However, our comment on linkage with ongoing work on TK was in general terms and any concrete wording moved from the 40/4 document is considered work in progress. No parallel discussion on definition should take place.
- **Article 4 – Disclosure requirement (p. 12)**
 - 4.4: Cannot see how newly inserted wording adds to the clarity of this paragraph.
- **New Articles X – Non-retroactivity and XX – Reciprocity (p. 15)**
 - Welcome and support these changes.
- **Article 6 – Sanctions (p. 16)**
 - 6.4 – Support insertion.
- In general on Rev. 2: reiterate preference for Chair’s text as a better basis for further discussions. Chair’s text is cleaner, more focused and its scope is better defined.

Item 7 – Genetic Resources

An International Disclosure of Source Requirement for Genetic Resources and Associated Traditional Knowledge in Patent Applications – A Contribution to the Evidence-Based Approach

Document submitted by Switzerland (WIPO/GRTKF/IC/42/12)

Chair,

1. The EU and its Member States would like to thank the delegation of Switzerland for preparing its Contribution to the evidence-based approach as submitted in document WIPO/GRTKF/IC/42/12.
2. We welcome this new document as a highly relevant and useful contribution in the context of negotiations on an international disclosure requirement for Genetic Resources and Associated Traditional Knowledge in patent applications. We share the understanding that the IGC should take into account the significant changes in the legal landscape related to GRs/ATK since discussions on patent disclosure requirements began in WIPO. In particular, we can only concur that aspects which have been addressed in existing international agreements such as the Nagoya Protocol should not be duplicated in an international legal instrument of WIPO.
3. We also share the view that without a standard for Patent Disclosure Requirements agreed at the international level, the variability of national PDRs is likely to increase further, leading to fragmented regulations and possible negative impacts on innovations based on GRs/ATK.
4. Likewise, we agree that the Chair's Text on GRs and ATK goes in the right direction to achieve consensus regarding a carefully drafted international patent disclosure requirement. However, the Chair's Text should be further improved.
5. Finally, we are interested to further discuss and explore new concepts of a 'reciprocity clause' and an 'international information system', as outlined in points 3.2 and 3.3 of the document.

Thank you.

Item 8 – Establishment of an *Ad Hoc* Expert Group(s)

Chair,

The EU and its Member States support the establishment of (an) *Ad Hoc* Expert Group(s) to be organised in line with the IGC's mandate and work programme for 2022/2023 before IGC 43, according to the modalities adopted in the corresponding decision taken at IGC 37.

Thank you.

Closing statement

Chair,

1. The EU and its Member States would like to thank you, your Vice-Chairs, the facilitators and the Secretariat for guiding us through our agenda successfully this week. We note with appreciation that during our first full-blown negotiating session since the outbreak of the COVID-19 pandemic, we have managed to cope with the multiple challenges of the hybrid format. Our thanks go to the IGC Bureau and all delegations for the significant efforts and flexibility implied by our discussions with both physical and online participation as well as Plenary and Informal sessions throughout the week.
2. We welcome the adoption of the REV.2 document resulting from this challenging session. While we see some additional value in changes made to the Consolidated Document at this session, we are still of the view that the Chair's Text in document 42/5 is cleaner and more focused, and its scope is better defined than REV.2, and would therefore constitute a better basis for our further discussions. We look forward to a revised version with interest.
3. Finally, the EU and its Member States would like to thank the outgoing IGC Chair, Mr Ian Goss of Australia for all his efforts and dedication to facilitate work in this Committee and promote a consensual solution based on a fair and balanced approach, taking into consideration highly divergent perspectives and complex technical issues in cooperation with all interested delegations.
4. We look forward to participating constructively in the work of the IGC at the next session.

Thank you.
