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NOTE

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Delegations will find attached, for information, the statements delivered on behalf of the EU and its Member States at the above mentioned WIPO meeting.

29th session of WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (Geneva, 15-19 February 2016)

Opening statement

Chairman,

On behalf of the European Union and its Member States we would like to congratulate you on chairing this important committee. We trust that you will guide us efficiently and in a balanced and transparent manner through this new IGC mandate. We also congratulate the vice chairs, who will be called upon to play a valuable support role over the next two years.

At the start of this 2016/2017 biennium, we would like to reaffirm our commitment to the IGC process. The new mandate agreed - it must be said with considerable difficulty - at the October 2015 General Assemblies, provides us with a fresh start and an opportunity for a new approach.

In this regard we note that the Committee will focus on narrowing existing gaps in our common understanding of the issues. Neither our work nor our working methods will prejudge the nature of the outcomes. The primary focus will be reaching a common understanding on core issues. Importantly, the work will be evidence-based, which includes studies and examples of national experiences.

The EU and its Member States are looking forward to ensure that our work is guided by solid evidence of the implications, and feasibility, in social, economic, and legal terms, as requested by the mandate. We also believe that the IGC should aim for realistic results if we want to make any progress which is acceptable to all.

This week's agenda contains 4 important documents, namely the consolidated document, a Joint Recommendation on Genetic Resources and associated traditional knowledge, a Joint Recommendation on a database and Terms of Reference for a study on measures related to the erroneous grant of patents and compliance with existing access and benefit sharing systems.

Until recently negotiations have focussed almost exclusively on the consolidated document. We believe that the new mandate provides us with new opportunities to move beyond the confines of the often sterile discussions of the past. We therefore believe equal consideration and time should be given on all issues and documents on the table.

Thank you Chairman

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Facilitator text

On behalf of the EU and its Member States, I would like to thank the facilitators for their text and hard work.

In relation to the scope of this exercise, we would like to draw attention to the fact that this committee is not in a position to deal with substantive patent law, such as article 4.3 in the facilitator text. Here we would like to stress that our proposal for a mandatory disclosure requirement in patent law would be a formal requirement, which would not alter substantive patent law.

As there are new concepts and ideas, we can only provide preliminary comments at this stage.

List of terms / directly based on

This definition is going in the right direction we believe. The last part however ("or access to non-tangible genetic resources or associated TK") substantially changes the scope of the proposal we have made.

We would therefore ask to include the original language for a definition on ‘invention directly based on’ as proposed by the EU and its Member States: "invention directly based on means that the invention must make immediate use of the GR, that is, depend on the specific properties of this resource to which the inventor mist have had physical access".

Source

The EU and its Member States believe that this is a very broad definition, which introduces the notion of primary and secondary uses, and would therefore complicate matters. We are not sure as to why this definition chosen over the other definition? Therefore we would like to retain option 1.

Policy

On a), the objective of the EU and its Member States is to "enhance transparency of the patent system to facilitate the possibility of ABS through the disclosure of country of origin or source"; we do not see that sufficiently reflected in the policy objectives.

As previous speakers, we would like to bracket b).

Article 1

We do not support this article at this stage.

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Policy objectives

The EU and its Member States believe that, when it comes to genetic resources and the patent system, our policy objective should be to enhance the transparency of the patent system to facilitate the possibility of ABS through the disclosure of country of source or origin of GR and, pending further discussions, possibly TK associated with GR. Thereby assisting providers of GR to monitor and keep track of their GR possibly subject to any ABS arrangement.

In order for us to avoid duplicating provisions already provided by the Nagoya protocol, we will need to get a clear understanding on the full range of existing measures contained in the Nagoya protocol, as well as the measures implementing the Nagoya protocol.

We would like to emphasize that ABS as such, e.g. requirements of PIC or MAT, are being dealt with in separate systems.

Further, we believe that the erroneous grant of patents should be prevented. In order to achieve this, patent offices should have access to the appropriate information on GR and TK associated with GR.

Subject matter

The EU and its Member States prefer at this stage, pending a full discussion of TK in respect of GR, the term "TK associated with GR". We would ask that, although we prefer this term over the other, the term be bracketed.

We believe derivatives should be excluded from this instrument. We have a preference for patent rights, instead of intellectual property. As stated by others, plant breeders rights are being dealt with by UPOV. We consider that the subject matter concerns patent applications for inventions directly based on GR.

Defensive measures proposals

The EU and its Member States would like to thank the delegations from the United States, Japan and Canada for their presentations.

In relation to the Terms of reference for the study, I would like to highlight that the Committees new mandate, in paragraph d), states that the work will be evidence-based, which includes studies and examples of national experiences. The EU and its Member States firmly believe that our work must be guided by solid evidence on the implications, and feasibility, in social, economic, and legal terms. Therefore we would like to thank the proponents of document 29/7. This document brings together the broad range of questions which should be addressed in a study on disclosure requirement. We support the Terms of Reference, and believe that the study can be conducted swiftly, with the aim of shedding light on many national experiences with disclosure requirements. Duplication of work should however be avoided, and where possible studies by other organisations, such as WTO and AIPPI, should be taken into account.

The EU and its Member States would like to express our support for the Joint Recommendation on Genetic Resources and associated TK, as contained in 29/5, which aims to prevent the erroneous grant of patents that are not novel or do not contain an inventive step. In our view this proposal merits further examination as the objective of preventing the erroneous grant of patents enjoys broad support amongst WIPO members, and could thus be low hanging fruit, ready to be harvested.

Finally, in relation to the Joint Recommendation on databases, the EU and it Member States believe it provides interesting food for thought for our discussions. We would like to ask the proponents to provide more details on how the database would work in practice, and how third party access could be provided.

Study

The EU and its Member States support a list of studies as proposed.

Subject matter and content of disclosure requirement

The EU and it Member States emphasize that our policy objective should be to enhance the transparency of the patent system to facilitate the possibility of ABS through the disclosure of country of source or origin of GR and, pending further discussions, possibly TK associated with GR.

The EU and its Member States have, in relation to this policy objective, proposed a mechanism under which we could contemplate agreeing a requirement to disclose the origin, or source, of genetic resources in patent applications. However, we would like to stress that a disclosure requirement which discouraged, undermined, or created legal uncertainty in the use of the patent system would not facilitate the sharing of benefits, and would not be in anybody's best interest. Therefore the system would have to contain safeguards as part of an overall agreement to ensure legal certainty, clarity, and appropriate flexibility.

The aim of the disclosure requirement would be to enhance transparency of the patent system, and thereby *facilitate* the possibility of access and benefit sharing, which is being dealt with in separate systems, e.g. under the CBD and the Nagoya protocol or the multilateral system of the International Treaty for Plant Genetic Resources for Food and Agriculture.

The disclosure requirement should be confined to patent applications and not to intellectual property in general. We would like to emphasize once again that plant breeders rights are being dealt with by another organization, namely UPOV, and should thus be excluded in our discussions here at WIPO.

The disclosure requirement foreseen concerns a formal requirement. The applicant should, when the invention is directly based on the specific GR, declare the country of origin or, if unknown, the source of the specific genetic resource to which the inventor has had physical access and which is still known to him. No additional research on the part of the applicant would be required.

To clarify, the term "source" refers to any source from which the applicant has acquired the genetic resource other than the country of origin, such as a research centre, gene bank or botanical garden.

The EU and it Member States do not support the inclusion of requirements relating to access and benefit sharing, or mutually agreed terms, as this is being dealt with in separate systems.

EU response to questions from the floor after subject matter

On safeguards; the EU and its Member States would like to stress that, if the patent applicant fails or refuses to declare the required information, and despite being given the opportunity to remedy that omission continues to do so, then the application should not be further processed. If the information provided is incorrect or incomplete, effective, proportionate and dissuasive sanctions should be envisaged outside the field of patent law.

We would also be interested in other delegations views on disclosure requirement.

As regards the trigger, we believe the invention should be directly based on the specific genetic resource.

Nature of the obligation to disclose

The EU and its Member States believe that the mandatory disclosure requirement would be a formal requirement, and the role of patent offices would be limited to checking whether the formal requirements are fulfilled, in particular, whether the applicant who declares that the invention is directly based on GR has subsequently disclosed information. There would be no assessment of the content of the submitted information.

On 3.2, the second part seems to be overly descriptive. Different countries may have different procedures. Sometimes only negative decisions are communicated to the applicant until the granting decision. Consequently, to communicate a particular positive decision on one aspect of the application would be alien to the normal processing of patents and put an additional burden on patent offices.

Exceptions and limitations to disclosure requirement

The EU and its Member States would like to keep all exceptions in article 4 in the text, as there are diverging views on the scope and modalities of disclosure requirement.

Consequence of non-compliance with disclosure requirement

The EU and its Member States would like to stress that, if the patent applicant fails or refuses to declare the required information, and despite being given the opportunity to remedy that omission continues to do so, then the application should not be further processed.

If the information provided is incorrect or incomplete, effective, proportionate and dissuasive sanctions should be envisaged outside the field of patent law. For reasons of legal certainty, the submission of incorrect or incomplete information should not have any effect on the validity of the granted patent or on its enforceability against patent infringers. Revocation of patents cannot be a sanction.

Moreover, revocation of a patent is an extremely strong penalty, and one which not only undermines legal certainty, but runs counter to our policy objectives, namely to enhance transparency in the patent system in WIPO, and protecting innovation, in order to facilitate the possibility of access and benefit sharing.

Trigger of disclosure requirement

The EU and its Member States propose that the disclosure of the information be organised by including questions to be answered in the standard patent application form. The applicant then can give either a negative or a positive response to the question whether the invention is directly based on genetic resources, and pending further discussions, associated TK. If the answer is negative, the applicant does not need to fulfill any other administrative requirement on this issue. A positive answer triggers the requirement to disclose the country of origin or source as foreseen. In the exceptional case that both the country of origin and the source are unknown to the applicant, this should be declared accordingly.

On the connection between the material and the patented invention: the applicant must have used the genetic resources in the claimed invention. A notion should be applied that makes it possible for the applicant to disclose the material used in the invention in an adequate way, without having the obligation to make further research on the origin of the resource, taking into account the interests of the applicant, the patent office and other stake holders. A good balance can be found by requiring that the invention must be “directly based on” the specific genetic resources. In such circumstances, the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource.

The inventor must also have had physical access to the genetic resource, that is, its possession or at least contact which is sufficient enough to identify the properties of the genetic resource that are relevant for the invention. As a consequence, we would request a definition of 'directly based on' should be included in the list of terms.

Relationship with national and domestic ABS regimes

The EU and its Member States support 3.3. A simple notification procedure should be introduced by the patent offices that receive a declaration. The notification should be as simple as possible and must not lead to an unnecessary administrative burden for patent offices. The exchange of information should be managed in a cost effective way, and without unnecessary additional charges imposed on patent applicants.

The EU and its Member States do not support the inclusion of requirements relating to access and benefit sharing and mutually agreed terms, as this is being dealt with in separate systems, and we should not duplicate this at negotiations at WIPO. Further, to include PIC and MAT in a patent disclosure requirement would change patent application procedures in a substantive manner, resulting in different patentability criteria, which we do not support. Also, the patent offices do not have the competence to assess this to the merits and do not have the expertise for this. Therefore the EU and its Member States do not support the inclusion of requirements relating to access and benefit sharing.

Misappropriation

The EU and its Member States welcome the discussion on this term. We believe the function of the term 'misappropriation' in the operative parts of the text is not yet clear and we are not convinced that the term should be included in the consolidated document.

We believe that the policy objective of this instrument should, more positively, focus on enhancing transparency of the patent system to facilitate the possibility of ABS which is being dealt with in separate systems, and on preventing the erroneous granting of patents. And this should determine the operative parts of the text. The concept of misappropriation therefore falls outside of the scope of our discussions under the WIPO aegis.

Paragraph 3.5

The EU and its Member States do not support 3.5 as it extends into the area of substantive patent law. Further, it is unrelated to a formal disclosure requirement, and it is in contradiction to the EU directive on the legal protection of biotechnology inventions.

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Closing Statement

Chairman,

I am speaking on behalf of the EU and its Member States.

Recognizing the difficulty of your task, we would like to thank you, your co-chairs as well as the Facilitators for their unstinting efforts this week. This is a team that clearly works well together. We would also like to thank the secretariat for its support.

The EU and its Member States appreciate the high quality of the interventions that we have heard during this 29th session of the IGC and we would like to commend all delegations for their constructive engagement. We have held a number of meaningful exchanges that have helped to deepen understanding for the respective positions of the Membership in a number of key areas.

In line with our mandate at the end of this week's work we have identified an indicative - and therefore non exhaustive - list of outstanding / pending issues to be tackled at our next session. As regards the question of revocation, the EU and its Member States understand that the principle itself is up for further discussion and that no agreement has been reached on this issue.

The EU and its Member States believes that in order to register progress at our next meeting it will be essential to reach agreement on our objectives. Without a common understanding on this central issue our discussions on other substantive provisions will serve no real purpose. We need this clear sense of direction if we are to move forward meaningfully towards the goal set out in the mandate. This is the rationale that underpins the entire process.

Our work at the 30th session will be based on all available documents, including document 29/4.

We are looking forward to the seminar on IP and Genetic Resources, which will be organized ahead of the 30th session of the IGC. In order to make the most of the seminar, we believe it should be focused on a few core issues. Participation of patent experts on the panels would be welcomed to inform our discussions.

Thank you.