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

Eighteenth Session
Geneva, May 9 to 13, 2011

DRAFT OBJECTIVES AND PRINCIPLES RELATING TO INTELLECTUAL PROPERTY AND GENETIC RESOURCES PREPARED AT IWG 3

Document prepared by the Secretariat

INTRODUCTION

1. The Third Intersessional Working Group (IWG 3) met from February 28 to March 4, 2011 to discuss genetic resources. The results of IWG 3 are reported on in the session's "Summary Report" (WIPO/GRTKF/IWG/3/16), made available at this session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC) as document WIPO/GRTKF/IC/18/8.

2. With reference to documents WIPO/GRTKF/IWG/3/7, WIPO/GRTKF/IWG/3/8, WIPO/GRTKF/IWG/3/9, WIPO/GRTKF/IWG/3/10 and WIPO/GRTKF/IWG/3/15, IWG 3 first discussed objectives and principles, in plenary. The text of objectives and principles as originally proposed in the IGC by Australia, Canada, New Zealand, Norway and the United States of America (as contained in document WIPO/GRTKF/IWG/3/7), as amended by the African Group (as reflected in document WIPO/GRTKF/IWG/3/8), was placed on a screen and experts made comments and drafting proposals on the text. Drafting proposals were incorporated in the text.

3. In particular, after extensive discussions in the plenary of IWG 3, the Chair of IWG 3 established an open-ended drafting group which met to review and, as far as possible, streamline and "clean up" the plenary's text. The drafting group's text was then presented to the plenary by the drafting group's rapporteur and all experts were invited to

comment thereon, during a session of the plenary that took place on the afternoon of Thursday, March 3, 2011. IWG 3 noted the text of objectives and principles but did not adopt or endorse them.

4. IWG 3 requested that the text, together with the rapporteur's introduction and comments on the text made during the IWG 3 plenary on the afternoon of Thursday, March 3, 2011, be compiled as document WIPO/GRTKF/IWG/3/17, and be transmitted to this session of the IGC for its consideration. This present document fulfils that request.

Preparation and structure of this document

5. The objectives and principles prepared at IWG 3 appear in the annex to this document. In respect of each objective and principle, there also appear: (i) the introduction made by the rapporteur; and, (ii) comments on the proposed objectives and principles made by the experts in the IWG 3 plenary in the afternoon of Thursday, March 3, 2011.

Related documents

6. The following documents also made available at this session of the IGC are directly related to the present document:

"Summary Report of the Third Intersessional Working Group (IWG 3)", which includes the List of Participants of IWG 3 (WIPO/GRTKF/IC/18/8); and

"Options for Future Work on Intellectual Property and Genetic Resources" (WIPO/GRTKF/IC/18/10).

7. The Committee is invited to review and comment on the objectives and principles contained in the Annex towards developing a revised and updated version thereof.

[Annex follows]

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WIPO/GRTKF/IWG/3/17
ORIGINAL: ENGLISH
DATE: MARCH 16, 2011

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

Third Intersessional Working Group
Geneva, February 28 to March 4, 2011

DRAFT OBJECTIVES AND PRINCIPLES RELATING TO INTELLECTUAL PROPERTY AND GENETIC RESOURCES PREPARED AT IWG 3

Document prepared by the Secretariat

DISCLAIMER

This document details the different options presented by experts participating in an Intersessional Working Group (IWG) addressing the objectives and principles relating to the relationship between Intellectual Property (IP) and Genetic Resources (GR), and associated Traditional Knowledge (TK).

The options were put forth by experts participating in the plenary of the IWG. The Drafting Group which had produced the text had attempted to best capture the intent of the experts, without prejudice. In addition, the options presented do not reflect any consensus or agreement on the options by the Drafting Group.

The document is without prejudice to the work of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), which retains full flexibility to accept, amend, add or remove any options listed herein.

INTRODUCTION BY RAPPORTEUR

Ian Goss recognized the Chair of the Drafting Group, Tom Suchanandan, for the professional and respectful way in which he managed the task, particularly considering the limited maturity of the text provided and the significant divergent views reflected in the text.

He also thanked the experts involved who ensured the success of the work of the Drafting Group, which was conducted in a cooperative and friendly environment, with only the occasional process discussion. Considering the divergent views held within the room, that spoke highly of those individuals and their willingness to work in a spirit of cooperation, in good faith. Indeed, experts with different views at times assisted in developing words which gave clarity to an opposing position.

He recalled the Terms of Reference provided to the Group. It was to review and rationalize the text in order to bring clarity to the views expressed within the plenary. That included removing duplicate or similar text, addressing any lack of clarity or ambiguity and presenting divergent views as clear options. The Group did not have a remit to introduce new ideas or text or remove an issue or idea presented by an expert during the plenary. However, the words might have been changed to improve clarity.

The revised text was clearly longer than the original document. That reflected the decision, in order to bring clarity to the work of the Drafting Group, not to bracket text but rather to present variations and divergent views as different options. A key aspect of that approach was that it enabled the IGC to clearly see the key and divergent policy positions and issues, which it would need to make informed decisions.

For example, there were some very similar options with one or two words changed. However, these changes were significant. In Objective 1, options 3 and 4, the only difference was the variation in terms relating to who the objective related to – those accessing/using GR, or applicants for IP rights. Whilst only a few changes in words, it went to a key issue the IGC would need to consider, namely, the scope of its work.

In essence, whilst the document was longer, it provided clarity on key issues and divergent views within the experts group, which would assist decision-making by the IGC.

OBJECTIVE 1

Objective 1 - Option 1
Ensure those accessing genetic resources and associated traditional knowledge comply with specific conditions for access, use and benefit-sharing under national law.

Objective 1 - Option 2
Ensure those accessing/using genetic resources and associated traditional knowledge comply with requirements for prior informed consent and fair and equitable benefit-sharing, including customary laws and procedures of the communities. States and indigenous peoples and local communities should determine any requirement for prior informed consent and fair and equitable benefit-sharing and the provision of information about the country of origin or source of genetic resources.

Objective 1 - Option 3
Ensure that applicants for intellectual property rights involving the utilization of genetic resources, their derivatives and/or associated traditional knowledge comply with requirements for prior informed consent, fair and equitable benefit-sharing and the provision of information about the country of origin or source of genetic resources, in accordance with national laws and customary norms.

Objective 1 - Option 4
Ensure that those accessing genetic resources, their derivatives and/or associated traditional knowledge comply with requirements of prior informed consent, fair and equitable benefit-sharing and the provision of information about the country of origin and/or source of genetic resources, in accordance with national laws and customary norms.

Principles of Objective 1

Principles of Objective 1 - Option 1
Recognize the wide variety of ownership arrangements pertaining to genetic resources, their derivatives and/or associated traditional knowledge, including the sovereign rights of States, the rights of indigenous peoples and local communities, as well as private property rights.

Principles of Objective 1 - Option 2
Recognize the wide variety of ownership arrangements pertaining to genetic resources and associated traditional knowledge, including the sovereign rights of States, the rights of indigenous peoples and local communities, as well as private property rights.

Principles of Objective 1 – Option 3
Sovereign states have the authority to determine access to genetic resources in their jurisdiction. Subject to national legislation, persons accessing traditional knowledge associated with genetic resources from the knowledge holder(s) and applying that knowledge in the development of an invention should obtain approval from the knowledge holder(s) and seek their involvement.

Principles of Objective 1 – Option 4
States have the authority to determine access to genetic resources. Persons accessing traditional knowledge associated with genetic resources from the knowledge holder(s) and applying that knowledge in the development of an invention should obtain approval from the knowledge holder(s) and seek their involvement.

Principles of Objective 1 – Option 5
Ensure respect for the principle of self determination of indigenous peoples and local communities, including peoples partially or entirely under occupation and their rights over genetic resources and associated traditional knowledge, including the principles of prior informed consent, mutually agreed terms, and full and effective participation, noting the United Nations Declaration on the Rights of Indigenous Peoples.

Principles of Objective 1 – Option 6
Ensure respect for the principle of self determination of indigenous peoples and local communities, and their rights over or to genetic resources and associated traditional knowledge, including the principles of prior informed consent, mutually agreed terms, and full and effective participation, noting the United Nations Declaration on the Rights of Indigenous Peoples.

[Commentary on Objective 1 follows]

COMMENTARY

INTRODUCTION BY RAPPORTEUR

Objective 1 related to ensuring that those wishing to access and use GR and related TK complied with conditions for access, which could include

- prior informed consent,
- fair and equitable benefit sharing,
- provision of information on source of origin.

Issues relating to this included:

- Role and rights of States, indigenous peoples, local communities in achieving this objective.
- Recognizing the wide variety of ownership arrangements across Member States, pertaining to GR and associated TK, including sovereign rights of States, indigenous peoples, local communities, as well as private property rights.
- Scope of the work of the IGC: was it narrowly related only to the intersection with the IP system and GR and associated TK, or broader as reflected in some options?
- Should the definition of GR incorporate derivatives?

COMMENTS BY EXPERTS

Pierre du Plessis made a general remark about language use in this objective, which applied to the rest of the document. He indicated that some of the options included “derivatives” and some did not, because in the IWG and also in the Drafting Group there was a clear difference of opinion about the extent to which derivatives of genetic resources should be included within the discussions. He stated that his view, which was shared by at least the African Group and many developing countries, was that since the Nagoya Protocol clearly put at least naturally occurring biochemical compounds within the scope, it only made sense that whatever work was carried forward on GR in the IGC should take cognizance of that scope, and should be harmonious with that scope. He considered important that this issue be flagged in the report from the IWG to the IGC for its resolution. It could be useful to have informal discussions between different interest groups about how this issue could be resolved in the intersessional period, without repeating the long debate that led to the resolution that eventually emerged out of the Nagoya Protocol discussions.

Kim Connolly-Stone made three observations related to all of the objectives. She indicated that the document contained a number of policy options, which were disguised as policy objectives. There was some overlap or duplication across the objectives. The principles under objective 1, for example, had found their way into the other objectives. She believed that a number of the objectives and principles appeared to be outside the scope of a WIPO agreement or some sort of WIPO outcome, and were quite distanced from the IP system.

Leslie Malezer wondered, in relation to the international obligations that should be dealt with in objective 1, whether it was the role of WIPO to determine where sovereignty and genetic access rested or whether that authority rest indeed with States or elsewhere. In that sense, option 3 and option 4 strayed into grounds which were not acceptable from the viewpoint of indigenous peoples. In relation to the principles of objective 1, options 1, 2, 5 and 6, he pointed out that references to rights were good, though he was uncertain about what private property rights would

be referred to in an international agreement. His understanding was that, in the international level, everyone had a right to property. He was not sure whether that was the right that was being invoked in the text. He was happy to see specific references to the Declaration of the Rights of Indigenous Peoples, but he considered a shortcoming if there was not an acknowledgment of international human rights principles and obligations. In the remaining four options, 1, 2, 5 and 6, there should be a reference to international human rights principles and obligations, even if that meant replacing any specific reference to the Declaration, which of course he supported. It was an obligation of WIPO itself as an intergovernmental organization, and an obligation of the Member States of WIPO, to ensure that international human rights, principles and obligations were part of this.

Martin Girsberger noted the intervention by the expert from Namibia regarding the issue of derivatives. Highlighting the existence of different views on that issue, he made two comments. First, lengthy and complex discussions on the issue of derivatives had taken place in the negotiations leading up to the Nagoya Protocol. The issue had been resolved by including a definition of “utilization” of GR and of “derivatives” in Article 2 of the Nagoya Protocol. Therefore, he would greatly regret if the IGC were to repeat those discussions. Second, nowhere in the mandate given to the IWG and also to the IGC was there a reference to the concept of derivatives. Both mandates only referred to GR. He considered that the IWG would be overstepping its mandate should derivatives be included in its discussions.

Steven Bailie made a general comment on the technical meaning of the words "objectives" and "principles." He believed that, throughout the document, there was some confusion about whether something was to be an objective or principle. He considered an objective was something that was to be achieved and a principle was a relevant law or norm. There were also mechanisms to achieve that objective, and those mechanisms should abide by agreed principles. He noted that objective 1, options 1, 2 and 4 did not appear to relate specifically to the IP system. It was his understanding that the Nagoya Protocol dealt with those objectives.

Nicolas Lesieur supported the observations made by the experts from New Zealand and Australia. He considered that some of the objectives and principles seemed to go beyond the limits of the discussions of the IWG. That seemed to be a problem throughout the document. There seemed to be some confusion between objectives and mechanisms for putting in place the principles and objectives.

Debra Harry expressed concerns about the frequent references to “under national law”, because the work of the IWG should be setting an international standard, not creating 184 standards at the domestic level.

Steven Bailie noted the use of the word “utilization” in the first line of objective 1, option 3. “Utilization” was a word that was also used in another international instrument, the Nagoya Protocol, and it was his understanding that that word was used in that document to refer to scientific research and development on the chemical and genetic properties of a genetic resource. He indicated that if that meaning was to be applied here, put in front of associated TK, it did not make sense. He did not see how there could be research and development on the chemical and genetic properties of TK.

Ronald Barnes pointed out that the reference to national law was not acceptable. He stated that WIPO had been developed without indigenous peoples and that they needed to be part of an international system, in order to counter and to balance what they were not in control of. He disagreed with the idea of the sovereign rights of States and with the implication that sovereign States unilaterally, as it was implied in the principles of objective 1, option 3, determine access to

the GR, subject to national legislation. He highlighted that the right to self-determination of indigenous peoples and local communities was very important when drawing up further a standards-setting process. He disagreed with the level of participation in meetings where indigenous peoples "sat in the back of the bus".

Lucia Fernanda Inácio Belfort supported Debra Harry, regarding the deletion of the words "or to". She noted that in the principles of objective 1, options 3 and 4, the Drafting Group had unfortunately not adopted the term "holders". This term was important for indigenous peoples, because they considered that rights were collective. If an individual had or was an owner of knowledge, this did not necessarily mean that it was the individual's property.

Elena Kolokolova wondered how this text would be complied with in the future, because for the business sector the most important question was how to observe national laws and customary laws and move forward. In this document, there were no references to concrete things that would have to be put forward by the business sector. She highlighted that all the decisions taken here would be on the shoulders of the business sector, which would have to comply or eventually circumvent these national regulations. She believed that indigenous peoples should use their GR as a comparative advantage.

Katrien Van Wouwe supported the intervention made by the expert from Switzerland concerning derivatives. According to her understanding, derivatives were not covered in the mandate of the IWG and the IGC on GRs.

N.S. Gopalakrishnan considered that there were different ways of putting the objectives and principles, and that depended upon how one looked at the issue and how one wanted to solve that issue. That was why there were different options.

Leonila Kalebo Kishebuka noted the reference, in objective 1, options 2, 3 and 4, in the last sentence, to provision of information about the country of origin or source of GR. She highlighted that that could bring confusion, since people would have the option of not naming the country of origin even when they knew it, they could just name the source.

Lilyclaire Elaine Bellamy wondered, with regard to the comment raised by the expert from Australia on objective 1, option 3, if consideration could be given to the insertion of the terms "use and/or" before "utilization", in the first line.

Marcus Goffe believed that derivatives should be included in the discussions. He agreed with the expert from India on the intent of the Drafting Group. He considered that the way the principles were expressed, the language used, should be looked at.

Carmen Adriana Fernández Aroztegui considered that the use of the term "derivatives" should be handled with considerable caution. It was already defined in the Nagoya Protocol. Patent applications relating to derivatives, which contained biochemical elements obtained through extraction from a GR, could be treated differently from those patent applications which referred exclusively to GR per se.

OBJECTIVE 2

Objective 2 - Option 1
Prevent intellectual property rights being granted in error and/or bad faith on genetic resources, their derivatives and associated traditional knowledge.

Objective 2 - Option 2
Prevent intellectual property rights being granted on genetic resources, their derivatives and associated traditional knowledge, if access to such resources and associated traditional knowledge has been obtained illegally.

Objective 2 - Option 3
Prevent patents from being granted in error for inventions that are not novel or inventive in light of genetic resources and associated traditional knowledge.

Objective 2 - Option 4
Prevent intellectual property rights from being granted in error and/or bad faith for intellectual property applications relating to genetic resources, their derivatives and/or associated traditional knowledge that do not satisfy the eligibility conditions.

Objective 2 - Option 5
Ensure that no patents on life and life forms are granted for genetic resources and associated traditional knowledge, because they do not comply with the requirements of novelty and inventive step.

Objective 2 - Option 6
Prevent intellectual property rights being granted where there is no free, prior and informed consent, no arrangements on mutually agreed terms for fair and equitable benefit-sharing, and disclosure requirements have not been met, to increase transparency in access and benefit-sharing.

Objective 2 - Option 7
Increase transparency in access and benefit-sharing.

Principles of Objective 2

Principles of Objective 2 - Option 1
Patent applicants should not receive exclusive rights on inventions that are not new or inventive. The patent system should provide certainty of rights for legitimate users of genetic resources.

Principles of Objective 2 - Option 2
The intellectual property system should provide certainty of rights for legitimate users and providers of genetic resources, their derivatives and/or associated traditional knowledge.
The intellectual property system must provide for mandatory disclosure requirements ensuring that the intellectual property offices become key checkpoints for disclosure and monitoring the utilization of genetic resources, their derivatives and/or associated traditional knowledge.
Administrative and/or judicial authorities shall have the right to (a) prevent the further processing of the intellectual property applications or (b) prevent the granting of intellectual property rights, as well as (c) revoke intellectual property rights subject to Article 32 of the TRIPS Agreement and render unenforceable intellectual property rights when the applicant has either failed to comply with the objectives and principles or provided false or fraudulent information.

Principles of Objective 2 - Option 3
Administrative and/or judicial authorities shall have the right to (a) prevent the further processing of the intellectual property applications or (b) prevent the granting of intellectual property rights, as well as (c) revoke intellectual property rights subject to Article 32 of the TRIPS Agreement and render unenforceable intellectual property rights when the applicant has either failed to comply with the objectives and principles or provided false or fraudulent information.
The remedies listed under (a), (b) and (c) above shall be applied without placing the relevant subject matter in the public domain.

Principles of Objective 2 - Option 4
In recognizing the self determination of indigenous peoples, legal certainty for legitimate users of genetic resources associated with traditional knowledge shall include the obligation to gain free, prior and informed consent and to establish mutually agreed terms addressing fair and equitable sharing of benefits with the affected indigenous peoples and local communities.

Principles of Objective 2 - Option 5
To ensure the legitimate rights of the owners of genetic resources and associated traditional knowledge, in accordance with the international legal principle of self determination of peoples, indigenous peoples under their free political institutions need to be protected by an international judicial process accepted by indigenous peoples to ensure that the intellectual property system shall provide legal certainty when disputes arise over their genetic resources or associated traditional knowledge.

Principles of Objective 2 - Option 6
Intellectual property rights applicants should not receive exclusive rights where free, prior and informed consent and fair and equitable benefit-sharing requirements for accessing and using genetic resources have not been met.

Principles of Objective 2 - Option 7
Persons applying for intellectual property rights involving the use of genetic resources and/or associated traditional knowledge have a duty of good faith and candor to disclose in their applications all background information relating to the genetic resources and associated traditional knowledge, including the country of source or origin.

[Commentary on Objective 2 follows]

COMMENTARY

INTRODUCTION BY RAPPORTEUR

Objective 2 related to preventing IP rights relating to GR and associated TK being granted in error and/or bad faith. There were variations in relation to describing or not the eligibility criteria, and what those requirements were e.g.

- patentability requirements (novelty, inventive step),
- no prior informed consent, no arrangements for mutually agreed terms for fair and equitable benefit-sharing,
- disclosure requirements had not been met.

Issues raised in relation to this key objective included:

- Should patents be granted for GR and associated TK on life and life forms?
- Maintaining certainty within the IP system, including the legal effect and consequences of a failure to meet the eligibility requirements, e.g. revocation.
- Role and nature of disclosure in preventing patents on GR and on associated TK being granted in error or bad faith.
- Protection of indigenous peoples rights, by an international judicial process, accepted by indigenous peoples, to ensure certainty within the IP system, when disputes arose over GR and associated TK.

COMMENTS BY EXPERTS

Steven Bailie believed that objective 2 had two different objectives within it. One was option 3, where no patent should be granted when inventions were not novel or inventive. And options 6 and 2 seemed to have the objective that no patents be granted when there was no prior informed consent, access and benefit-sharing and mutually agreed terms. He wondered what the term “bad faith" meant in the context of options 1 and 4, and who would be displaying bad faith in this context, the patent office, the patent applicant, or the provider of the GR or TK. Under objective 2, option 5, it was stated that life forms should not be patented because they were not novel and inventive. From a technical expert point of view, novel and inventive life forms could be developed by traditional breeding techniques including those used by local farmers, as well as genetic technology. He questioned the accuracy of the statement that life forms were not novel and inventive. With regard to the principles of objective 2, option 2, it seemed to include a mechanism for achieving an objective. Regarding the principles of objective 2, option 3, the last sentence indicated that the remedies listed “shall be applied without placing the relevant subject matter in the public domain”. He wondered whether, if the patent specification had been published, the information was already in the public domain. He noted that option 6 of the principles of objective 2 was similar to objective 1. Regarding option 7 of the principles, third line, he wondered whether the purpose of the background information to be disclosed was the information for use in patent examination or to determine if prior informed consent, access and benefit-sharing, mutually agreed terms had been obtained from the providers of the GR and the associated TK.

Suseno Amien noted the comment made by the experts from Switzerland and Belgium on derivatives. He acknowledged that there was no specific reference to “derivatives” in the mandate of the IGC. However, the full text of the mandate should be read. To ensure the effective protection of GR in the patent system, protection had also to be extended to their derivatives, as part of the GR used in an invention.

Preston Hardison considered that the objectives did not seem to parallel the principles in that patent offices had multiple functions other than just preventing. Reviewing and revoking were other functions. References should be added to revoking IP rights that that had been granted. He agreed with the expert from Australia. The issue of the public domain needed to be taken up in greater detail by the IGC. He stressed that in the normal course of a patent knowledge that went into it was revealed. He wondered what the status of TK was that was used in a patent, if there was an agreement with indigenous peoples and local communities on developing patented products.

Ken-Ichiro Natsume wondered if the discussion about whether derivatives were under the mandate or not was suitable here. It could be discussed, for example, in the IGC, or some political areas. Regarding objective 2, option 1, he shared the Australian expert's view on the concept of bad faith. The IGC should consider that point. With regard to the principles of objective 2, option 7, on the last second line, reference was made to “country of source or origin”. It was better to refer to country of origin or source of GR, because the source could be, for example, some institution, gene bank or even a supermarket.

Pierre Du Plessis stated, regarding the principles of objective 2, option 6, that IP rights applicants should not receive any rights at all. He would replace “exclusive rights” by “any rights”. Concerning the question by Steven Bailie about whether published patents should be in the public domain, if they were granted on the basis of applications where there had been no prior informed consent, where there had been a false declaration of consent, or where there had not been legitimate access to the subject matter of the IP right application, this malfeasance should not destroy the development opportunities for developing countries or for providers of GR in general. He considered that the IGC would need to bring justice in this new instrument, new regime or new rules. He agreed with Steven Bailie and Preston Hardison on that under current rules a *mala fides* application or illegitimate application would put such knowledge in the public domain and make it unusable for legitimate owners. That was why the sentence was added here, to flag to the IGC the importance of changing the rules of the public domain doctrine.

Sharon Venne considered that it was very difficult to determine what “bad faith” was. Different people had different ideas of “bad faith”. She was not sure about whether it was a concept that should be imported into this document. Regarding objective 2, option 3, she considered that it could be problematic to prove lack of novelty or inventive step, when dealing with indigenous peoples who did not communicate in one of the six languages of the United Nations. Concerning objective 2, option 4, the reference to “error and/or bad faith” could cause more confusion. In relation to the comment on option 5, she clarified that in the text there was no reference to new life forms. In relation to option 6, she agreed with Pierre du Plessis on the point that no rights should be granted if there was no free and informed consent of indigenous peoples.

Lucia Fernanda Inácio Belfort wished to clarify what “bad faith” meant. She preferred to use another expression. The idea was that there was bad faith when a natural or legal person asked for rights without respecting other rights and knowing that they existed, for instance, requesting IP rights without respecting other rights recognized in legal instruments at the international level, such as the ILO Convention 169, the United Nations Declaration on the Rights of Indigenous Peoples, the CBD or the Nagoya Protocol. There should be consistency between the objectives and the principles. Objective 2 needed to include a reference to the rights of indigenous peoples and local communities, to be consistent with the principles of objective 2, options 4 and 5. Legal certainty required a specification of who the beneficiaries of the rights were.

Ronald Barnes agreed with the comments made by Sharon Venne and Lucia Fernanda Inácio Belfort regarding “error and/or bad faith”. Regarding the principles of objective 2, options 2 and 3, he highlighted that the existing system was put together without the participation and consent of the indigenous peoples. He did neither agree with the system recommended in those options nor with the reference to administrative or judicial authorities. He stressed that indigenous peoples needed to have their own international judicial process or system, to counter some of these systems of law. In some jurisdictions, indigenous peoples could not obtain justice and were still discriminated by the whole process and the institutional mechanisms in place. Therefore, more legal certainty was needed.

Heng Gee Lim addressed the issue of what “bad faith” meant, as used in objective 2, options 1 and 4. He considered that the text referred to bad faith on the part of the applicant for IP rights, for example, when someone willfully provided false information or misleading information on whether there was access, whether there was free prior informed consent or whether there were benefit-sharing and contracts entered into and so on.

Mohamed El Mhamdi considered that the issues of good or bad faith, illegality and erroneous patent delivery were to be determined by the competent legislation. It was important to understand what the relevant legislation was. Given the stakes and what was to be protected, namely GR, he considered that the law of GR was the competent law by which error, illegality and good or bad faith had to be defined.

Debra Harry noticed that, in objective 2, there was no specific mention of indigenous peoples and local communities. She wished to put on record that, when reference had been made to associated TK and GR, there had been an implicit reference to indigenous peoples and local communities, though those words fell out in the drafting process. She supported the comments made by Sharon Venne on requesting a specific definition of some of those problematic terms, so that there was certainty for all parties involved. She also requested a specific definition of the process for determining bad faith. She wondered who carried the burden of proving bad faith, how that was determined, and whether the term error referred to an error in law or to a factual error.

Maria Serova pointed out that objective 2, option 5, was inappropriate, since only an expert could decide on the patentability of life and life forms. She believed that this option was against the TRIPS Agreement, the Patent Cooperation Treaty and the Patent Law Treaty. She preferred option 3.

Marcus Goffe highlighted that in some of the options of objective 2, reference was made specifically to patents, and in others to IP rights. Noting Steven Bailie’s comments pertaining to the lack of reference to IP, he believed that the objectives and principles should not be looked at only in the context of IP, but considering the total protection of GR as the overall objective.

OBJECTIVE 3

Objective 3 - Option 1
Ensure patent offices have available the information needed to make proper decisions in granting patents.

Objective 3 - Option 2
Ensure that intellectual property offices have appropriate and available information on genetic resources, their derivatives and/or associated traditional knowledge needed to make proper and informed decisions in granting intellectual property rights.
The information should include measures to ensure that prior informed consent has been obtained through the mandatory disclosure requirements, which can be made through an internationally recognized certificate of compliance described in the Nagoya Protocol.

Objective 3 - Option 3
Ensure at an international level the right of indigenous peoples and local communities to permit or deny the documentation of traditional knowledge and genetic resources and that such documentation shall not be a prerequisite for protection.

Objective 3 - Option 4
Ensure patent offices have available the information needed to make proper decisions in granting patents based on the free prior and informed consent of the provider of the genetic resources and associated traditional knowledge, in accordance with relevant international legal instruments.

Objective 3 - Option 5
Ensure that national intellectual property offices do not grant patents on inventions based upon traditional knowledge and genetic resources which lack novelty or inventive step and where there is no compliance with the principles of prior informed consent and benefit-sharing recognized in the relevant international legal instruments.

Objective 3 - Option 6
Ensure that intellectual property offices are regulated by an internationally recognized standard to ensure that indigenous peoples and local communities maintain control over genetic resources and associated traditional knowledge, and have appropriate and available information on genetic resources and associated traditional knowledge and benefit-sharing, based on their free prior and informed consent, and relevant international legal instruments when granting intellectual property rights.

Principles of Objective 3

Principles of Objective 3 - Option 1
Patent offices must consider all relevant prior art when assessing the patentability of an invention.
Patent applicants must indicate the background art which, as far as known to the applicant, can be regarded as useful for the understanding, searching and examination of the invention.
There is a need to recognize that some holders of traditional knowledge may not want their knowledge documented.

Principles of Objective 3 - Option 2

Intellectual property offices should consider all relevant prior art information relating to genetic resources, their derivatives and associated traditional knowledge when assessing the eligibility for grant of intellectual property rights.
Intellectual property applicants should disclose all background information of genetic resources, their derivatives and associated traditional knowledge relevant for determining the eligibility conditions.

Principles of Objective 3 - Option 3
Recognizing the unique aspects and inherent limitations of databasing all relevant traditional knowledge, in addition to prior art searches, the status and content of information relied upon in determining the legitimacy of an application for the granting of intellectual property rights in relation to genetic resources and associated traditional knowledge shall be determined in consultation with the indigenous peoples or local community from which the genetic resource or traditional knowledge is being accessed.

Principles of Objective 3 - Option 4
The national authority is responsible for documenting and digitizing traditional knowledge-related information. This responsibility shall be fully supported financially and through capacity-building.

Principles of Objective 3 - Option 5
States shall recognize that holders of traditional knowledge may not want their knowledge documented as a requirement for protection. States must recognize the rights of indigenous peoples and local communities to genetic resources and traditional knowledge with a view of guaranteeing legal certainty with regard to databases that are currently managed by states or other third parties. States shall recognize that traditional knowledge holders shall designate the procedure for non-disclosure of their traditional knowledge.

[Commentary on Objective 3 follows]

COMMENTARY

INTRODUCTION BY RAPPORTEUR

Objective 3 related to:

- Ensuring IP Offices had the information, relating to GR and associated TK, to make proper decisions when granting IP rights.
- Establishment of international standards or norms in relation to the information requirements.
- Role of National IP offices and indigenous peoples in ensuring compliance.

Additional issues raised included:

- Nature of the information e.g. access to prior art data bases on GR and related TK, disclosure requirements relating to background art and evidence of prior informed consent and mutually agreed terms.
- Recognition that holders of TK might not want their knowledge documented.
- Protection of TK databases held by third parties or states.
- Limitations of databases pertaining to TK and role of indigenous peoples in determining the status of the information and recognition of the need to consult with indigenous peoples on this issue.
- Capacity building and financial support for member states to meet the information requirements.

COMMENTS BY EXPERTS

Leslie Malezer indicated,that each option to objective 3 seemed to deal independently with an issue. Not any particular option dealt with the list of matters that the rapporteur had read out. Some options referred to the role of the patent offices, some to national institutions and others to indigenous peoples in various ways. There might be elements in the different options that should be associated with each other.

Tom Suchanandan flagged that objective 3, options 1 and 2 put the burden on indigenous and local communities to ensure that patent offices had available the information. That was going to be an onerous task on indigenous and local communities. Regarding national authorities involved in the digitizing of TK, in South Africa the *onus* was also on local, since it had a decentralized system, where local communities had also the responsibility of documenting their own TK. He noted that objective 3, option 5 created a regional or international policing or oversight institution.

Steven Bailie noted objective 3, option 3, indicating that the documentation of TK “shall not be a prerequisite for protection”. He stressed that there was a technical similarity to the results of the work produced by IWG 2 on TK including a statement to the effect that there should not be any formalities for the protection of TK. Regarding the principles of objective 3, he compared options 1 and 2. In option 1, the second paragraph mentioned that “Patent applicants must indicate the background art which, as far as known to the applicant, can be regarded as useful for the understanding, searching and examination of the invention”. Option 2 had a similar second paragraph, but the phrase “as far as known to the applicant” was missing. He requested the IGC to consider whether option 2 of the principles of objective 3 intended that applicants must disclose information that they did not have.

Preston Hardison echoed Tom Suchanandan's comments regarding national compilations or databases. He wished to put on record that that was not the only option for compiling and digitizing TK that was discussed or presented.

Song Kijoong indicated, regarding the principles of objective 3, option 4, that he had proposed the first sentence of that option, but not the second sentence. He requested to take the second part out of that option or to make a new option.

Albert Deterville stressed, with regard to the documentation, that indigenous peoples and local communities also had the right to document their TK and that they, where necessary and if so desired, did have the right to establish their own authority to handle that particular issue.

Ronald Barnes pointed out that he made a specific proposal, which was objective 3, option 6, in response to objective 3, option 2, relating to the certificate of compliance in the Nagoya Protocol. He stated that he reserved his rights and did not agree with some of the language that came out of the Nagoya Protocol, because the certificate of compliance dealt with national legislation. Therefore, he proposed objective 3, option 6, in order to ensure that indigenous peoples and local communities had the right to control through an internationally recognized standard. He had proposed principles of objective 3, option 5, so that legal certainty could be provided in reference to objective 3, option 6, to ensure that there was compliance with international legal standards.

Rida Shibli wondered whether NGOs could be considered as national authorities, as regards the principles of objective 3, option 4, since in some countries NGOs were involved in the documentation of TK.

OBJECTIVE 4

Objective 4 - Option 1
Promote a mutually supportive relationship with relevant international agreements and processes.

Objective 4 - Option 2
Promote a mutually supportive relationship with relevant international and regional agreements, processes, instruments and regimes related to genetic resources, associated traditional knowledge and human rights, in accordance with applicable rules of international law.

Objective 4 - Option 3
Establish a coherent system which links intellectual property of genetic resources, their derivatives and associated traditional knowledge with the existing international agreements and treaties.

Objective 4 - Option 4
Ensure consistency with international legal standards in the promotion and protection of the collective rights of indigenous peoples to their genetic resources and/or associated traditional knowledge by establishing a transparent, independent, accessible mechanism for oversight and dispute resolution, with associated rights to local communities.

Principles of Objective 4

Principles of Objective 4 - Option 1
Promote respect for and seek consistency with other international and regional instruments and processes.
Promote cooperation with relevant international and regional instruments and processes.

Principles of Objective 4 - Option 2
Promote respect for and seek consistency with other international and regional instruments and processes.
Promote cooperation with relevant international and regional instruments and processes.
The work of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore should not prejudice the work pursued in other fora.

Principles of Objective 4 - Option 3
Respect the decisions adopted by the United Nations treaty bodies pertaining to cases submitted by indigenous peoples.

Principles of Objective 4 - Option 4
Support, in particular, the implementation of the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention of Biological Diversity.

Principles of Objective 4 - Option 5
Affirm indigenous peoples' rights to maintain, control, protect and develop their intellectual property, including their traditional knowledge according to Article 31 of the United Nations Declaration of the Rights of Indigenous Peoples.

Principles of Objective 4 - Option 6
Promotion of awareness raising and information sharing among different relevant and related international and regional agreements, instruments and processes related to genetic resources.

[Commentary on Objective 4 follows]

COMMENTARY

INTRODUCTION BY RAPPORTEUR

Objective 4 dealt with promoting a mutually supportive relationship between relevant international treaties, agreements and frameworks, the terms used included consistency and mutually supportive.

Additional issues raised included:

- Relationship between the work of the IGC and other fora, e.g. CDB, WTO, etc.
- Supporting implementation of the CBD and the Nagoya Protocol.
- Transparent dispute resolution mechanisms.
- Rights of indigenous peoples to maintain, control, protect and develop their IP.
- Education, awareness and information sharing between related international and regional agreements, instruments and processes.

COMMENTS BY EXPERTS

Marcus Goffe stressed the importance that the objectives were not limited to IP or to access and benefit-sharing alone, in order to seeking a supportive relationship with international agreements and processes. The objectives and principles had also to support international agreements and processes related to human rights, which might include social, economic and cultural rights, rights of indigenous peoples, rights of minorities, right to development and right to self-determination.

Tom Suchanandan highlighted the need to streamline the language. He noted that the term “promote” was used in the objectives and in the principles.

Kathy Hodgson-Smith made reference to the mandate given by the WIPO General Assembly, which was to look at the development of an instrument for the effective protection of TK, GR and traditional cultural expressions. She also referred to Article 8 (j) of the CBD and to other international instruments which applied to indigenous peoples and local communities. It was her understanding that the task was not to protect existing national IP regimes. It was necessary to approach this on a *sui generis* basis and to look at complementary options in addition to those in association with existing IP regimes.

Salma Bashir made reference to the decisions taken by the Office of the High Commissioner on Human Rights addressing IP issues, mainly Resolution 7400.

OBJECTIVE 5

Objective 5 - Option 1
Review the impact of the current intellectual property system that was developed without the recognition and protection of the rights of indigenous peoples with the aim of addressing the rights of indigenous peoples to their intellectual property.

Objective 5 - Option 2
Maintain the role of the intellectual property system in promoting innovation.

Objective 5 - Option 3
Recognize and maintain the role of the intellectual property system in promoting innovation and transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, noting the relationship with genetic resources, their derivatives and/or associated traditional knowledge.

Objective 5 - Option 4
Recognize the role of the intellectual property system in the protection of traditional knowledge, genetic resources and traditional cultural expressions.

Objective 5 - Option 5
Address the opportunities and challenges that the intellectual property system poses in the transfer and dissemination of technology relevant to genetic resources, their derivatives and associated traditional knowledge.

Objective 5 - Option 6
Recognize and maintain the role of the intellectual property system in promoting innovation, transfer and dissemination of technology, to the mutual advantage of knowledge holders and users of genetic resources, their derivatives and/or associated traditional knowledge, and in a manner conducive to social and economic welfare, while contributing to the protection of traditional knowledge, genetic resources, their derivatives and traditional cultural expressions.

Objective 5 - Option 7
Recognize and maintain the role of the intellectual property system in promoting innovation and transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, whilst also recognizing the rights of States and indigenous peoples to their genetic resources, their derivatives and associated traditional knowledge.

Objective 5 - Option 8
Ensure the effective protection of the genetic resources, traditional knowledge and traditional cultural expressions of the indigenous peoples and local communities in the intellectual property system.
Ensure the protection of the rights of indigenous peoples to develop, create and protect their knowledge and innovations in relation to the intellectual property system.
Maintain the role of the intellectual property system in promoting innovation within indigenous peoples and local communities in relation to their genetic resources, traditional knowledge and traditional cultural expressions.

Objective 5 - Option 9
In conjunction with indigenous peoples and local communities, to develop sui generis protection of traditional knowledge and associated genetic resources of indigenous peoples and local communities consistent with international legal standards.

Objective 5 - Option 10
Recognize and protect the rights of indigenous peoples to develop, create and protect their knowledge and innovations in relation to genetic resources in situ and external to the intellectual property system.

Objective 5 - Option 11
Promote innovation, certainty and clarity of intellectual property rights by transparency and dissemination of information regarding the source and content of traditional knowledge, where appropriate and with respect to obligations arising from prior informed consent and fair and equitable sharing of benefits.

Principles of Objective 5

Principles of Objective 5 - Option 1
Maintain the incentives for innovation provided by the intellectual property system.
Promote certainty and clarity of intellectual property rights.
Protect creativity and reward investments made in developing a new invention.
Promote transparency and dissemination of information by publishing and disclosing technical information related to new inventions, so as to enrich the total body of technical knowledge accessible to the public.

Principles of Objective 5 - Option 2
Recognize and maintain the role of the intellectual property system in promoting innovation, noting the relationship with genetic resources and associated traditional knowledge.
Promote certainty and clarity of intellectual property rights, noting the relationship with genetic resources and associated traditional knowledge.
Protect creativity and reward investments.
Promoting transparency and dissemination of information by publishing and disclosing technical information related to new inventions, where appropriate and when publicly available, so as to enrich the total body of knowledge accessible to the public.

Principles of Objective 5 - Option 3
Recognize and maintain the role of the intellectual property system in promoting innovation, noting the relationship with genetic resources, their derivatives and/or associated traditional knowledge and in the protection of traditional knowledge, genetic resources, their derivatives and/or associated traditional knowledge and traditional cultural expressions and fair and equitable sharing of benefits arising from their use.
Promote certainty and clarity of intellectual property rights, noting the relationship with genetic resources, their derivatives and/or associated traditional knowledge and obligations with respect to the protection of traditional knowledge, genetic resources, their derivatives and/or associated traditional knowledge and traditional cultural expressions and certainty and clarity for prior informed consent and fair and equitable benefit-sharing.
Protect creativity, reward investments and ensure prior informed consent and fair and equitable benefit-sharing with the knowledge holders.
Promoting transparency and dissemination of information by disclosing country of origin and publishing and disclosing technical information related to new inventions, where appropriate and

where publicly available, so as to enrich the total body of technical knowledge accessible to the public.

Principles of Objective 5 - Option 4
Promote innovation through intensive investments in research and development and with the aim of increasing legal certainty and trust between users and providers of genetic resources and traditional knowledge.

Principles of Objective 5 - Option 5
Increase legal certainty and trust between users and providers of genetic resources and traditional knowledge through a mandatory disclosure of origin or source.

Principles of Objective 5 - Option 6
Encourage investors to promote high level technology.

Principles of Objective 5 - Option 7
Increase the quantity of technological knowledge by publicizing with the consent of the owners/knowledge holders/beneficiaries any new inventions inspired by genetic resources and associated traditional knowledge.

Principles of Objective 5 - Option 8
Provide transparency, capacity, access, transfer and dissemination of technology to the owners/knowledge holders/beneficiaries of the genetic resources and traditional knowledge.

Principles of Objective 5 - Option 9
Recognize the rights of indigenous peoples and local communities to genetic resources and associated traditional knowledge inappropriately considered to have become part of the public domain, having been obtained without free prior and informed consent and equitable benefit-sharing.

Principles of Objective 5 - Option 10
Consider for the application of the intellectual property rights, the objectives and principles of the WIPO Development Agenda.

Principles of Objective 5 - Option 11
Ensure appropriate funding for conservation of genetic resources and traditional knowledge.

Principles of Objective 5 - Option 12
Promote transparency and dissemination of information where not in contrast with public morality and/or public order.

[Commentary on Objective 5 follows]

COMMENTARY

INTRODUCTION BY RAPPORTEUR

Objective 5 (which had a rather large number of options) related to:

- Recognizing and maintaining the role of the IP system in promoting innovation, and transfer and dissemination of knowledge and technology, in a manner which was conducive to social and economic welfare.
- Recognizing the role of the IP system in the protection of GR and associated TK.
- Recognizing the rights of states and indigenous peoples to their GR and associated TK.
- Recognizing and protecting the rights of indigenous peoples to develop, create and protect their knowledge and innovations in relation to their GR and associated TK.

Key issues raised in relation to this objective included:

- Maintaining certainty within the IP system.
- Promoting transparency and dissemination of information relating to:
  - the source and the country of origin of GR and related TK,
  - evidence of prior informed consent and fair and equitable distribution of benefits,
  - technical information to new inventions.
- Promote legal certainty through a mandatory disclosure of origin of source.
- Rights of indigenous peoples over GR and related TK inappropriately considered part of the public domain.

COMMENTS BY EXPERTS

Lucia Fernanda Inácio Belfort stated, regarding the principles of objective 5, option 9, that indigenous peoples believed that GR and TK were part of the public domain when they had been obtained with free, prior and informed consent and equitable benefit-sharing under mutually agreed terms. Publicly available GR and TK had inappropriately been considered to be part of the public domain. Governing these matters in accordance with the international treaties was wrong and unacceptable. She noted that there was no reference to her suggestion to include the notion of “illegally obtained”.

Steven Bailie recognized Article 7 of the TRIPS Agreement in objective 5, option 3, noting further words concerning GR, derivatives and associated TK. Regarding objective 5, option 10, he wondered whether cosmovision of seeds was an example of the knowledge and innovations in that option. With regard to the principles of objective 5, option 11, he noted that there was no reference to the IP system.

Preston Hardison considered that many different issues had been put together in some of the passages. He noted that the phrase “so as to enrich the total body of technical knowledge accessible to the public” was repeated through many options of the principles of objective 5. There was no consensus on the use of that phrase and he was concerned that the repetition of that phrase through different options gave the implication to the IGC that there was widespread consensus. Making knowledge available to the public was a general objective of the IP system. However, when dealing with TK, a number of concerns had been raised.

Ken-Ichiro Natsume believed that objective 5, option 3, was based on a proposal he had made, though his proposal did not include the expressions “their derivatives” and ”/or”. He wished that those expressions be removed or included in a different option.

Ronald Barnes explained that the reason to review the IP system was to ensure that it was consistent with international legal standards.

Mohamed El Mhamdi believed that some of the options were complementary and could not be eliminated, but others could. For instance, option 2 could be deleted, because it was already part of option 6.

Tom Suchanandan pointed out that objective 5 had a lot of terms that needed definitions, for example, “innovation”, “high level technology”, “investments” and “publicly available”.

Pierre Du Plessis stressed, regarding the principles of objective 5, option 9, that not only the rights of indigenous peoples and local communities could be compromised in this manner, but also the rights of provider States, where resources had been misappropriated and inappropriately considered part of the public domain, even though there had not been free, prior and informed consent and benefit-sharing. He noted that GR shared certain characteristics with the copyright system. Only because an illegal photocopy of a book was available, it did not mean that it was possible to make more illegal photocopies. It was important to bear in mind that just because a GR had been illegally obtained once, it did not mean that it was forever illegally available afterwards.

Lilyclaire Elaine Bellamy pointed out that throughout objective 5 and in some of the other objectives the term “sharing of benefits” was used, but in other instances reference was made to the term “benefit-sharing”. It would be advisable to have consistent language throughout the document. She supported the points raised by Pierre Du Plessis. However, the development of a *sui generis* protection that included the relevant provisions in other international instruments should not be excluded.

Natalia Buzova considered that the document should deal with GR and TK. However, there were references to TCEs, which was not correct. She noted that the objectives and principles seemed to go beyond the mandate of the IWG and the IGC, and perhaps even beyond the competence of WIPO.

Marcus Goffe indicated, in relation to objective 5, option 1, that though the IGC was somehow in the process of reviewing the IP system for many years, it had not produced solutions. Objective 5, option 1 could also be related to objective 5, option 9, which sought to develop *sui generis* protection. He supported Lucia Fernanda Inácio Belfort’s comments regarding the principles of objective 5, option 9. He shared similar concerns as expressed by Preston Hardison on the phrase “so as to enrich the total body of technical knowledge accessible to the public”.

Debra Harry supported the statement by Kathy Hodgson-Smith. She acknowledged that there was a fundamental tension between the needs and desires of bolstering the IP system and the need to protect misappropriated, misused TK, TCEs and GR while fearing that the latter was kind of falling by the wayside.

Bala Moussa Coulibaly considered that the constant nature of intellectual research and the coverage of the interests of all parties were well captured by the document. Objective 5, options 6 and option 7, seemed very close to one another, and took into account in a systematic manner his concerns on this issue. He believed that GR was the cornerstone of social and economic

development of the countries. He was pleased to note that objective 5, options 6 and 7, took into account that particular aspect of development.

Salma Bashir believed that in objective 5, option 2 the phrase “and enforcing IP rights” was missing. The legal issues that might arise concerning the ownership of rights were also missing, as the structure of databases was protected under copyright systems.

Edna María Da Costa E. Silva proposed the addition of the phrase “and local communities” after “indigenous peoples” in objective 5, options 1, 7 and 10.

GENERAL COMMENTS BY EXPERTS

Katia Marzall pointed out that the document on objectives and principles expressed several very important concerns of very different interest groups. She wished to add, as an expert coming from an agricultural background, an opening objective in this document focusing specifically and exclusively on GR and the existing interface with the IP system as the focus of IWG 3. By doing that, not only the large set of GR with associated TK, or even a larger set of GR found within indigenous peoples and local communities' territories would be covered, but a much broader universe of GR, which constituted the Earth's biodiversity. The IP system had an important role in the conservation and protection of GR in collaboration with other national and international existing instruments. Discussions within the IGC would only strengthen that role.

Teresa Aguero Teare supported the comment made by Katia Marzall.

[End of Annex and of Document]