

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

**Twentieth Session**  
**Geneva, February 14 to 22, 2012**

### **OPTIONS FOR FUTURE WORK ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES**

*Document prepared by the Secretariat*

#### **INTRODUCTION**

1. The Third Intersessional Working Group ('IWG 3'), which met from February 28 to March 4, 2011, discussed the options for future work related to intellectual property (IP) and genetic resources (GR). IWG 3 considered and extensively discussed the three clusters of options as contained in document WIPO/GRTKF/IWG/3/6, with reference also to documents WIPO/GRTKF/IWG/3/2, WIPO/GRTKF/IWG/3/3, WIPO/GRTKF/IWG/3/4, WIPO/GRTKF/IWG/3/5, WIPO/GRTKF/IWG/3/11, WIPO/GRTKF/IWG/3/12, WIPO/GRTKF/IWG/3/14 and WIPO/GRTKF/IWG/3/15.
2. IWG 3 also discussed objectives and principles related to IP and GR, and which options are most likely to achieve the objectives and principles as prepared by a drafting group at IWG 3 as contained in document WIPO/GRTKF/IWG/3/17 ("Draft Objectives and Principles Relating to Intellectual Property and Genetic Resources prepared at IWG 3").
3. IWG 3 requested that a summary of its discussion on options be compiled as document WIPO/GRTKF/IWG/3/18 and be transmitted to the eighteenth session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee') for its consideration. Following on from the discussion on options as they related to objectives and principles, such document had to include, if necessary, a matrix taking into account a number of the suggestions made by the experts. Document WIPO/GRTKF/IC/18/10 fulfilled that request.

4. At its eighteenth session, held from May 9 to 13, 2011, the Committee discussed options for future work on IP and GR, based on WIPO/GRTKF/IC/18/10, and re-issued it as WIPO/GRTKF/IC/19/7 for its nineteenth session.

5. At its nineteenth session, held from July 18 to 22, 2011, the Committee further discussed options for future work on IP and GR, based on WIPO/GRTKF/IC/19/7. The Committee “requested the re-issue of document WIPO/GRTKF/IC/19/7, including Clusters A (“Options on defensive protection of genetic resources”) and B (“Options on disclosure requirement”), as a working document for the next session of the Committee.”<sup>1</sup>

*Preparation and structure of this document*

6. Pursuant to the decision above:

- (a) in the Annex, the original Clusters A (“Options on defensive protection of genetic resources”) and B (“Options on disclosure requirement”) from the Annex to document WIPO/GRTKF/IC/19/7 have been retained;
- (b) the original Cluster C (“Options on Mutually-Agreed Terms for Fair and Equitable Benefit-Sharing”) has been deleted. As requested by the Committee at its nineteenth session, document WIPO/GRTKF/IC/20/INF/14 provides information on the activities referred to in Cluster C.

7. The matrix in the Appendix to the document WIPO/GRTKF/IC/19/7 has been deleted, since the objectives and principles it referred to have been modified and Cluster C has been deleted.

8. *The Committee is invited to take note of this document and the Annex to it.*

[Annex follows]

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<sup>1</sup> Draft Report of the Nineteenth Session of the Committee (WIPO/GRTKF/IC/19/12 Prov.)

## INTRODUCTION

This document details the comments made by experts participating in the Third Intersessional Working Group (IWG 3) addressing the options for future work relating to the relationship between IP and GR. IWG 3 also discussed which options were most likely to achieve the objectives and principles as prepared by a drafting group at IWG 3.

As requested by IWG 3, this Annex contains a summary of its discussion on the options.

## OPTIONS

### *Cluster A: Options on defensive protection of genetic resources*

#### *A.1 Inventory of Databases and information resources on GR*

[Extension of already approved defensive protection mechanisms for traditional knowledge to address genetic resources more specifically], including the review and greater recognition of further sources of already disclosed information about genetic resources. The Committee could compile an inventory of existing periodicals, databases and other information resources which document the disclosure of the origin of genetic resources [disclosed genetic resources], with a view to discussing a possible recommendation that certain periodicals, databases and information resources may be considered by International Search Authorities for integration into the minimum documentation list under the PCT in cooperation with the national authorities responsible for access to genetic resources.

#### *A.2 Information systems on GR for defensive protection*

An Online Portal of Registries and Databases, established by the Committee at its third session, could be extended to include existing databases and information systems for access to information on the disclosure of the origin of genetic resources [disclosed genetic resources] (additional financial resources would be required to implement this option). A concrete proposal for such a system was presented at the ninth session which proposed that “a new system has to be a one-stop system where genetic resources ... can be searched once and comprehensively and not a system in which each database created by each country has to be searched separately. The one-stop database system thus proposed could be an all-in-one consolidated system or be composed of multiple systems easily searchable with one click. Sufficient discussion has to be conducted to determine how to create the most efficient database in the foreseeable future.”

#### *A.3 Guidelines or recommendations on defensive protection*

Recommendations or guidelines for search and examination procedures for patent applications to ensure that they better take into account the disclosure of the origin of genetic resources [disclosed genetic resources]. The Committee could discuss a possible development of recommendations or guidelines so that existing search and examination procedures for patent applications take into account the disclosure of the origin of genetic resources [disclosed genetic resources], as well as a recommendation that patent granting authorities also make national applications which involve genetic resources subject to ‘international-type’ searches as described in the PCT Rules.

## COMMENTS BY EXPERTS

1. Ken-Ichiro Natsume provided information on the proposal made by Japan on the one-stop database. Several countries considered as a problem the erroneous grant of patents for inventions using GR and associated traditional knowledge (TK) that did not comply with the requirements of novelty and inventive step, such as the cases of turmeric and neem. Examiners granted such patents because they could not access the evidence which verified that those inventions lacked novelty and/or inventive step. That was why Japan had proposed to establish a database related to GR and TK accessible by examiners in any country, in order to avoid the erroneous granting of patents for GR and TK. It was his understanding that examiners had been conducting prior art searches with databases in many patent offices. In order to conduct the most efficient prior art search, it was necessary to construct an access-friendly database. It was extremely difficult for examiners to review all of the available documents since there were countless documents referring to GR and associated TK. There might exist prior art only passed on by oral tradition. Therefore, it was necessary to construct a database of those documents in order to create an environment which enabled examiners to perform efficient prior art searches. The usage of languages had to be considered, since the database to be created should be easily utilized by examiners in each country. For efficiency reasons, each country should gather information on their own GR and TK for the database. The database should be one which examiners from all countries in the world could utilize on a one-stop-research basis. Japan had also highlighted three points, namely, structure of the system, how to prevent access from third parties, and registration of cited documents and other reference materials. Mr. Natsume recalled a hypothetical case included in Japan's proposal, in which the claimed invention was a synthetic resin, in which the juice of GR A was mixed with raw material. The invention had the effect that adding the juice of GR A increased the strength of the resin considerably. He pointed out that, generally, the specific characteristic of GR A would not change regardless of the country in which it was obtained. GR A from the country of origin X had been chosen and utilized in the invention by chance. It was not because GR A from the country of origin X was especially effective for increasing the strength of the resin. That was also true if the country providing the resource were considered instead of the country of origin. Additionally, obtaining prior informed consent (PIC) or sharing of benefits did not affect the invention. Judgments of novelty and inventive step were not associated with information about the country of origin, the country providing the resource, the source of GR and associated TK, or evidence of PIC or access and benefit-sharing (ABS). He stressed that the erroneous granting of a patent for an invention, which did not meet the requirements of novelty and inventive step, could not be prevented if information, which was not used for making judgments about novelty and inventive steps, was provided.

2. Preston Hardison raised concerns about international or even national databases. He clarified that he was not against databases as long as they were created with the free, prior and informed consent (FPIC) of indigenous peoples and local communities, and on mutually agreed terms (MAT). What seemed to be necessary to make information available to patent offices was interoperability among different database systems, so that they could be queried simultaneously from one search location. Rather than thinking of one giant database, it might be better to think about creating interoperable standards among databases, and to work on the protocols to ensure that databases followed some minimum standards of FPIC.

3. Steven Bailie wondered, regarding option A.1, what information about GR would be relevant for a patent examiner. He thought that information of relevance would be species names, in particular, the distribution of species across country boundaries and information on the phenotype of particular species, and for example, what chemicals were commonly found in particular species, secondary metabolites that might have an industrially applicable use. For instance, a database that related chemical compounds to species or GR in which they were commonly found would assist examiners' searches. Classification tools in such databases were also important. Currently, the international patent classification (IPC) system had a list of

species in A61K 36/00. He wondered whether that species list was sufficient and also how long a species list needed to be to be comprehensive and useful.

4. Lucia Fernanda Inácio Belfort expressed concerns regarding databases. She requested the inclusion of recommendations to ensure that the principle of free self-determination of indigenous peoples and local communities, and their rights to GR, were respected. There were countries in which indigenous peoples had rights to the exclusive use of natural resources, which included GR within a territory, and GR related to TK. She stressed that they needed some kind of legal certainty and that two particular issues needed to be focused on: when GR were disclosed and how GR were disclosed.

5. Heng Gee Lim agreed with Ken-Ichiro Natsume on that information about country of origin, PIC or benefit-sharing would not have any impact on the questions of novelty or inventive step. That was why requirements to disclose origin or evidence of PIC could not be based on the need to prevent misappropriation, but on a totally different principle. A principle that was suggested earlier was the duty of good faith and candor in application procedures. He pointed out that, in relation to application procedures in some countries, it was necessary to provide the name of the inventor when the applicant was not the inventor. For example, when the inventor was the employer who regularly owned the invention, the naming of the inventor was actually part of the moral rights of the inventor. On very similar principles, giving the origin of the GR was catering to the needs of the country to be recognized as the country which provided them, and information about PIC was part of the sovereign right of the TK holder.

6. Jesús Vega Herrera recalled the mandate of the IGC and believed that it was critical that, within the IWG, discussions were held as to whether it was necessary to create an international legal instrument which would ensure the effective protection of GR, and, if not, analyze and clearly discuss which existing instruments needed to be amended, and what modifications needed to be made to such instruments in order to ensure the effective protection of GR. He pointed out that clusters A, B and C should be considered together, and not in isolation, with a view to achieving true protection of GR as established by the mandate of the IGC. He believed that the analysis of the list of options should consider the link between the Nagoya Protocol and WIPO, particularly regarding measures to provide that GR and associated TK had been accessed in accordance with PIC and that MAT had been established, as well as regarding the various checkpoints in the stages of research, development, innovation, pre-commercialization and commercialization of such GR. As regards A.1, the following preventive measure should be considered to prevent the grant of IP rights to GR which were publicly available or in the public domain: the creation of a centralized database or the establishment of mechanisms which would make it possible to look at existing databases that contained technical information regarding GR, so that patent examiners were able to be fully informed as to the state-of-the-art. Mechanisms which would make it possible to search and find a particular GR within the databases should be established. Those databases or mechanisms should make if possible to obtain at least information about the taxonomy of the GR, the common names of that resource and the geographical distribution or country of origin of that GR.

7. Natalia Buzova suggested, regarding A.1, that additional or complementary work should be undertaken for the preparation of an inventory of existing databases, and other information resources. As to A.2, she agreed with the proposal to broaden the Online Portal of Registries and Databases, in particular, through the creation of a new system which should be universal, and would make it possible to conduct research on GR, both on a single search and complex search basis. She also supported A.3. She noted that such working arrangements achieve the objective of preventing erroneously granted patents for inventions based in the utilization of GR, and noted that the proposals were complementary and could be implemented in parallel.

8. N.S. Gopalakrishnan recognized the value of databases to find out what was the existing knowledge with reference to GR and associated TK. However, he believed that one of the

major limitations was that databases made TK static. Once documentation had taken place, continuously evolving knowledge did not get reflected, unless the database was constantly being updated. The second limitation was that databases made misappropriation easier because static knowledge was consolidated. In the absence of a strong positive protection, databases would further aggravate misappropriation rather than making it a useful instrument for defensive protection. So, the prerequisite of the creation of a database would be the internationally recognized principle of positive protection of TK and associated GR. From a practical point of view, databases created tremendous limitations from the patent offices' point of view. Databases put limitations in finding out the prior art, as understood by the patent system, and for determining inventive step, because of the science involved in TK, on the one side, and the science involved in modern knowledge, on the other side. Typically, a modern patent application was drafted using modern scientific techniques and scientific language, which involved largely the genetic analysis of the components of the GR associated with TK. On the other hand, typical TK documents in the database had not been documented using modern science language, but using the language of the science of TK. If a comparison was made between patent applications and TK, a tremendous difference between those two would be found. That put tremendous limitations on the patent examiner to determine prior art. He would conclude that what had been disclosed was different from what had been disclosed in the patent application form, unless there was an attempt to merge and understand the science of TK and modern scientific principles. Regarding the question of examination of the inventive step, the notion of inventive step had been developed considering modern knowledge systems. So, what was obvious in one system was not necessarily obvious in the other system. Unless a useful way of merging the obviousness requirements in both TK systems and modern systems was found, databases were not going to serve any purpose. Databases would only serve a purpose by saying that an application did not include misappropriated TK. However, in fact, applicants might have completely misappropriated TK but have camouflaged the knowledge taken from the database or the community with modern terminology used in modern science. It was necessary to appreciate the limits of databases in preventing the grant of erroneous patents and, in that respect, disclosure requirements took a very important place.

9. Tim Roberts pointed out that prior art, from the point of view of patents, was what invalidated patents. Not everything in the public domain invalidated patents. For example, in the United States of America, an inventor might publish his invention up to a year before filing a patent application, and still claim the published invention. The knowledge was in the public domain, but, from the point of view of the inventor, for that year, it did not take away his right. It would be helpful to know when published TK was to be considered in the public domain or as prior art for the purpose of invalidating patents. From the point of view of the user of knowledge, it was a difficult situation, since knowledge did not come attached with labels indicating that it originated in a certain country. Frequently, one did not know where knowledge had come from. How should somebody behave who wished to behave properly and not use protected TK? In IP protection systems, there were generally two alternatives. There was the copyright option, where one could copy ideas but not the form of those ideas. In order to prove copyright infringement, copying had to be proved and also access to the original. The alternative was the patent system, in which the patentee, in conjunction with the patent office, constructed a claim which defined the bounds of what was protected by the patent. If that was included on the prior art, then the patent would be invalid. If it was valid and if it covered what was done, then the right was infringed. In protecting TK, it was not clear whether a copyright type system was sought, in which copying had to be proved, or whether an absolute right of some kind was being given to the possessors of TK to prevent its use, whether there had been copying or not.

10. Nicolas Lesieur considered that databases represented a practical solution to the issue because databases reflected the idea that the patent system was there to record all granted patents. Databases were already recognized by patent offices. They existed within a certain context. The proposal from Japan was interesting, because it referred to the interoperability that could be created between several databases, enabling searches to be conducted using several

databases. Regarding the comments made by N.S. Gopalakrishnan, he considered that the issue about databases not necessarily being compatible with TK was in fact a false dilemma. It was possible that a database kept up with changing and evolving knowledge and with the course of TK as it evolved. Databases and TK were not incompatible. He stated that confidentiality of databases should not be an issue. The proposal from Japan, for instance, did refer to confidentiality and also to certain matters being in the public domain. It was possible to create appropriate protection for TK. GR and TK should not be seen as necessarily being in opposition to one another, since they were part of a single whole. He stressed that a clear, analytical and synthetic definition of GR and associated TK was needed. With respect to the options, he believed that the problem was related to corporate social responsibility. It was necessary to create partnerships between industry, consumers and communities. The kind of approach that had been taken under the umbrella of fair trade, for instance, could be taken here also. He believed that establishing that kind of partnerships and involving all stakeholders in the area could be very fruitful. Progress could be made by taking elements of the different options together. Options should not be seen as being mutually exclusive.

11. Aurora Ortega Pillman believed that it was important to create a database for GR and associated TK, in order to ensure that patents were not granted without taking into account information available on TK associated with GR and their use. She pointed out that in Peru they had a database, that incorporated knowledge that was found in the public domain only. It was important to include the scientific names of GR in the database, not only common names, and also information describing the characteristics of GR, as well as the source of information.

12. María Elena Menéndez Rodríguez proposed to look in greater detail at the last recommendation at the end of A.3, regarding national applications which involved GR being subject to international type searches, because there was a risk that was implied by that approach.

13. Pierre Du Plessis considered that conceptual distinctions needed to be made between GR and associated TK, because they did not always go together. Whereas a database could be a useful tool for preventing erroneous patents being granted over associated TK, he did not see that it could be similarly useful for GR. Considering that in the Nagoya Protocol PIC of the country of origin or the country that had acquired GR was required before a person was allowed to do research on a GR, if someone had accessed a GR without PIC, that person would not have the right to file IP claims over it, because he would not have had legal access to that resource. That was why a database system could not be a substitute for a disclosure system. GR were simply information. It was clearly the information that was the important part of a GR. Without PIC of the country of origin or the country that had acquired the GR in terms of the CBD and provided it to the user, there was no right to copy that information. He considered that the IP situation around GR had some elements in common with the copyright system. A resource might well be publicly available like a book that was bought in a bookshop, but it was not in the public domain. Neither had people the right to use it freely, nor to incorporate that information into inventions, without PIC. That should be made very clear and should be inscribed into the international IP system, because not doing so would not be harmonious with the Nagoya Protocol, would be patently unjust, and would, at least in some jurisdictions, contravene the rule that one was not allowed to patent products of nature without showing a clear inventive step.

14. Ronald Barnes considered that the proposal by Japan assumed that a single state could put into a database information from its own jurisdiction. He raised concerns regarding multiple jurisdictions or indigenous peoples who were covered by multiple jurisdictions. He proposed the establishment of an international indigenous mechanism to address this aspect, which included whether or not indigenous peoples wished to have their information placed in a database. If WIPO were to set up such a structure, as recommended by Japan, indigenous peoples would have to have their own international monitoring or jurisdictional process.

15. Suseno Amien supported the proposal from Japan to create an online database that provided information concerning novelty and inventive step in light of GR and associated TK. However, it would be useful if the database could also provide information on the complaints in light of ABS of GR and associated TK, based on the principles of PIC and benefit-sharing, as stated in the CBD and Nagoya Protocol.

16. Steven Bailie referred to the Indian Traditional Knowledge Digital Library (TKDL). He indicated that it was a very good database and that the Australian patent office was using it to great effect. That could be followed up by some part of the IGC or some other part of WIPO, in regard to A.2. Following on the comment from N.S. Gopalakrishnan about the differences of language of science and language of TK, he appreciated that he was referring to conceptual differences in the language, but noted that there were also clear differences in the words that were used. As indicated by Jesús Vega Herrera and Aurora Ortega Pillman, a database of GR should not be limited to species names, it should also include common names and the names used by TK holders. He endorsed A.3, but suggested additional recommendations or guidelines for search and examination as well as drafting procedures for patent applications to ensure the taking into account of disclosed GR and of the differences of languages between science and TK. For example, a patent application should include not only the scientific taxonomic name, but also the name given by the First Peoples. That would assist the patent examiner, who would be able to make a search not just limited to the taxonomic species name.

17. Lilyclaire Elaine Bellamy pointed out that, in Jamaica, in the case of plant GR for food and agriculture, there were not necessarily databases, but there were gene banks. Information in those gene banks was shared as necessary, and sought among other things to ensure retention of those resources, especially if there were natural disasters. The point made previously about the TKDL in India and the experience of South Africa showed why it was important to have a secure database and also the need for the monitoring of the access to be aware of who was using the information. She believed that the point raised by Tim Roberts was a critical one, because the need for certainty for users was something that had to be taken into consideration. Regarding the definition of the term “genetic resources”, she noted that document WIPO/GRTKF/IWG/3/13 included a possible definition of GR and suggested to consider and agree on a text for the final document.

18. Alma Toleukhanova pointed out that patent protection could be granted in a country to TK from somewhere else. She emphasized the importance of creating a database to prevent the erroneous granting of patents.

19. Emmanuel Sackey highlighted the need to clearly define the intended objective for defensive protection mechanisms. Communities developed databases for different purposes. Some of them used databases to safeguard against the disappearance of their knowledge. Others used them for positive protection, as well as for prior art search. Reading between the paragraphs, one got an understanding that maybe databases were meant to be used for prior art searches. In that case, the issue of the definition of prior art would become very critical for the Committee, because there was not a standard definition of what was meant by prior art. He pointed out that under the Standing Committee on Patents (SCP) one of the issues that was being considered was a clear definition of prior art. He stressed that prior art did not necessarily mean public domain. In some jurisdictions prior art would only be something that was written, and in other jurisdictions oral literature would also be considered prior art. If TK and its associated GR were fixed, particularly those that were oral in nature, how would that fixation be considered or qualified in terms of the definition of prior art? He supported Preston Hardison's and Ronald Barnes's comments. He believed that the whole question of developing multiple databases or one-stop databases needed to be given fairer consideration. Another issue that came up was administrative cost. He wondered who was going to pay for the development of databases. He also wondered how would TK be fixed, for instance in Africa, where TK was largely orally held. He believed that the budgetary implications of the proposal of Japan needed



to be considered. Regarding the comments of N.S. Gopalakrishnan and Steven Bailie, if one looked at the typical TK system, in relation to traditional medicine, one would find out that the form in which TK was conceived was such that the extract of a plant was taken and then remedies were associated with different disease situations. In a typical patent application, one would file a structural compound with its own microscopic parameters and properties. Those were different sets of regimes, in terms of knowledge. It was his understanding that that was what N.S. Gopalakrishnan was alluding to. If somebody came up with an extract of a plant, for instance, *hoodia*, then, another person who was maybe a scientist or a researcher was able to extract the active ingredient, which was in a structural form or what was called new chemical entity, and after that an application was filed for a new compound characterized by X and Y: how would one use a database which was in its entirety based on a TK system, which had not been able to determine the chemical composition of the extract? He wondered how would such a database help understand those issues and also determine the level of prior art. There was merit in what N.S. Gopalakrishnan said. He also referred to the Toolkit that WIPO had developed and considered that it could be further enhanced for those who might wish to develop databases, including ARIPO. ARIPO had a prototype of what they called ARIPO TK digital library. The Toolkit could also help communities that might wish to document their knowledge, not for the purposes of prior art search, but for safeguarding of their knowledge. He proposed to broaden the scope and operational ability of those options to embrace the different concepts and understandings, and also the different interest groups that might wish to pursue the course of defensive protection for their own purposes.

20. Margreet Groenenboom stressed the importance of taking up A.2. She considered that it was a particularly effective and practical option, as Steven Bailie and Aurora Ortega Pillman had explained. Some more work on the elements that should be included in such databases might be needed.

21. Khamis Al-Shamakhi pointed out that the activities that were being undertaken were to help build an instrument that promoted innovation and protected the benefits of the holders of the GR and associated TK used in the development of the invention. It was necessary to create a linkage between access and use. That linkage would be built if all parties interested sought a transparent instrument that would lead to trust among owners and users. He considered important that there was a mandatory requirement for disclosure of source or origin of GR and its associated TK, to promote legal access to GR and associated TK. As to the issue of databases, he believed that patent offices should have the possibility of tapping into national and community databases to prevent the illegal use of GR, though it might not be clear as to how patent offices could use those databases from a patent perspective. He noted that some species were endemic to specific regions, and therefore patent offices could cross-check and make sure that those GR were obtained legally. In terms of microbial GR, which had a huge potential for the biotechnology industry, he stressed that, depending on the geographical locations, some strains might have different enzymes and chemical properties that could be used in the biotechnology industry. Therefore, it would be important to have those databases that could be checked and cross-referenced by patent offices. If the origin of GR was not known, at least databases could be cross-checked. In terms of TK databases, he highlighted the example from South Africa, which was a wonderful example of how TK could be documented. That example showed that it was possible to allow limited access to patent offices to the TK to examine if that TK had been obtained with PIC, and that the TK could still be held by the communities.

22. Albert Deterville considered that databases, whether GR databases or TK databases, could be important not only for States, but also for indigenous and local communities. He supported Ronald Barnes' recommendation for an international system on behalf of indigenous and local communities. He also supported Emmanuel Sackey's comments about the cost of the establishment of such massive systems. The IWG shall recommend the establishment of indigenous and local communities' databases, if they so desired. Indigenous and local

communities could establish their own national, regional or subregional databases, which might fit into an international database, holding their TK and also their GR.

23. Kathy Hodgson-Smith believed that the challenges of merging world views and of merging domestic law and international law with customary law, was being faced. Adding to the contributions of N.S. Gopalakrishnan and Preston Hardison, it was necessary to think about how to address the limitations of databases. Generally speaking, the interface of the patent system with a local community or an indigenous people, who might or might not have an institution with which a patent office could interface, created a challenge. She considered that, where indigenous institutions existed, the capacity should be developed within those institutions to manage that important dialog. She stressed that the work was not just to categorize TK into scientific categories, so that one could link those databases, but also to promote the success of indigenous peoples and local communities in protecting their knowledge and deriving benefit from such knowledge. Much of the important work around database development should be done by the local communities or by the indigenous peoples. It was not the sole responsibility or expertise of a patent office.

24. Jon P. Santamauro supported the points that were made by Ken-Ichiro Natsume and believed that the one-stop database proposal had the potential to be very helpful. From an industry perspective, the principle of legal certainty was of paramount importance, and the Japanese proposal would greatly contribute to that principle, and in that it would prevent or help prevent the granting of patents for alleged inventions that were not novel or that lacked an inventive step. As others had mentioned, there might be some opportunities for improvements to that proposal. He was generally supportive of the options A.1 and A.2. He would not be supportive of adding references to disclosure of origin of GR to those paragraphs. He agreed with Ken-Ichiro Natsume that disclosure of source or origin of GR would not contribute to preventing erroneous patents. A number of other experts also agreed with that point, even though they might probably disagree in other areas. He believed that that underscored the importance of establishing meaningful consensus on objectives and principles to structure the discussion. Whether disclosure requirements would help in preventing patents on inventions that lacked novelty or could help monitor compliance with ABS obligations or not, for the work to move forward in a sensible fashion, it was necessary to parse out the issues. It was important to have a better definition of objectives and principles and then to see which proposal would have the best chance of achieving those objectives and principles.

25. Debra Harry noted that the term defensive protection referred to a set of strategies to ensure that third parties did not gain illegitimate or unfounded IP rights over TK and related GR. However, registers or databases as means of protection raised many concerns for indigenous peoples, such as security of data. She was concerned about the public release of knowledge that they did not want to share, or that registers might become a one-stop shop for bio-prospectors. That also raised the question of who would manage the databases, States or bodies such as WIPO. Indigenous peoples could not accept a situation where a State or a new entity became a gatekeeper to their TK and GR. The idea that indigenous peoples would have the right to decide what information they would want included in the databases or registries was insufficient protection for the information that many indigenous peoples would not want to contribute. She stressed that collectively held knowledge was being dealt with, and not just the knowledge that an individual or some kind of entity might want to contribute. She also expressed concerns about setting up a hierarchy of protected knowledge, which may have the result of privileging some TK and GR over others, basically that which was included in the database and that which was not. Under those schemes, what was considered prior art, because it was fixed, would be protected, but all the collectively held previously known knowledge would not be protected. Fixation separated what was considered collectively held historical knowledge from contemporarily created collective knowledge held by indigenous peoples. It was assumed that TK was static and that it could be fixed for the convenience and review by patent officers. She highlighted that, given those limitations, additional effort had to

be taken to protect previously known knowledge in its own right, and not try to force those knowledge systems into an IP framework, or into categories such as prior art. Those knowledge systems greatly predated any IP rights regime. Nothing could replace the need for direct consultation, the free sharing of information, and the implementation of a specific FPIC process, when the TK or the GR of indigenous peoples was implicated in a patent application.

26. Dominic Keating pointed out that the United States Patent and Trademark Office (USPTO) was one of the signatories to an Indian TKDL access agreement. They had been using it for more than a year successfully. They had sent recently two scientists from their scientific and technical information center to the CSIR in Ghaziabad, India, for training on the TKDL, and also to have a technical exchange. As a follow-up, they were creating a manual for use of the TKDL at the USPTO. He was happy to hear that South Africa and Peru had developed databases that included GR and TK, and that Jamaica was using gene banks. A lot could be learnt from the implementation of a TK digital library or database at the national level. He pointed out that options A.1 through A.3 were all constructive, and they did not have to be mutually exclusive. Regarding the question posed by Steven Bailie about what should be included in a database, he considered that the species name and the secondary metabolites would be particularly helpful, in addition to the gene sequence or protein sequence of the GR, as well as any known properties of that GR. Concerning the question posed by ARIPO about how such a database could be helpful, he referred to the hoodia case, where an extract had been taken out of a root, and the San tribe had been chewing on the root to suppress appetite and gain energy on hunting trips. How would that database be useful? If one had the secondary metabolite in the database and something that linked the secondary metabolite to the GR, and had knowledge about the use of the root by the San tribe to suppress appetite, the patent examiner could use the data to examine a claim for a new use of a known product. The product being in the database could be very useful in that respect.

27. Tom Suchanandan explained that the purpose of the development of the database by South Africa was not to put undisclosed TK into the public domain, but to achieve multiple IP objectives, namely positive and defensive protection, and to ensure the rights of TK holders to the continued control and enjoyment of the knowledge. The database was only one set of tools in the documentation of TK. In developing the database, they had considered the following aspects: the contents and resource identification standards, which included standards, standardized data, structures, technological standards, as well as security transmission standards. In terms of the content and resource identification standards, they looked at how TK and associated GR were best described in the database. More importantly, those standards were determined by the holders of TK. The technological standards specified how the data, TK and associated GR were stored in the databases, taking into consideration the cultural and spiritual nature of TK. The existent security transmission standards specified how databases could be controlled and how the data about the TK and associated GR might be securely exchanged between databases and registries. Concerning the issue of public domain, they had proceeded on the assumption that there was no public domain TK. Although individuals might hold knowledge, their right was collectively determined, and it was rare that individuals had the right to use knowledge in a free and unconstrained manner. He stressed that what was public in the context of the community was sacred and secret.

28. Steven Bailie pointed out that the challenges of documenting TK expressed by Emmanuel Sackey sounded familiar in the Australian context. Many of Australia's First Peoples had an oral and symbolic record of their history. Much of that knowledge was threatened with extinction. Recording TK in a database or some other way, in addition to being useful for patent offices, was also very important for preserving threatened cultures. He noted that some definitions about GR could be found in the CBD and in the Nagoya Protocol. A further subject matter for those databases would be derivatives of GR. He agreed with Dominic Keating regarding how databases of secondary metabolites from GR would enable patent examiners to correlate a chemical structure with pre-existing prior art that was composed of TK.

29. Jianhua Song believed that, regarding the defensive protection of GR, setting up a database might be helpful. However, as mentioned by other experts, a database had its limits. Taking into account its mandate, the IGC needed to focus its work on improving the IP system and putting PIC and benefit-sharing into practice. In order to ensure that there was no misuse of GR, a clear link between the IP system and the CBD needed to be established. Options under cluster B alone were not enough. Other options also needed to be taken into consideration.

30. N.S. Gopalakrishnan referred to the Indian TKDL, which he considered a good experiment. However, it was necessary to understand the limitations of even the TKDL. The TKDL was an experiment in converting or digitalizing the knowledge of a medicinal system, Ayurveda, a traditional system of India, based on what was reflected in sacred texts available in Sanskrit language. It did not include all the information available on medicinal practices in India. In addition to those texts, there were many texts available in regional languages in each state, and also oral traditions on Ayurveda, which had been practiced by a large number of people cutting across India. That showed the large body of knowledge and practical problems encountered in putting it together in a database. It was practically impossible for any country to put even a small system of knowledge as a complete system into a database to prevent misappropriation or the grant of bad patents. Emmanuel Sackey understood clearly what he was trying to say on the difference between the two systems of knowledge. The explanation by Steven Bailie saying that that could be easily solved by including certain words which had been reflected from the traditional language seemed to be an oversimplification of the problem. Actually, what was seen was the reflection of the interaction between the two systems of knowledge, the western system of science and the eastern system of science. In the patent application, what was seen was the western system trying to undermine the other system, to some extent, not respecting the value of the holders of the eastern system of knowledge. That was precisely misappropriation, or erroneous patents. In that context, it was necessary to create a balance. That could not be achieved purely by creating databases, because they had limits, either on finding out the existing knowledge system or on finding out the inventive step involved in the new knowledge which had just been created. That required an institutional mechanism in the long term, having an interaction between the two systems of knowledge for the purpose of finding the right balance. In that sense, the TKDL was an experiment. He appreciated that countries from Europe and the United States of America were sending their experts to understand how the traditional system worked and what were the dynamics of it, and trying to understand, so that a right balance could be built. But that was not the complete solution for misappropriation. Regarding A.1, it should be very clear that it could not be a mandatory obligation on the part of States to put all TK into a database. There was a large amount of oral knowledge which could not be included for collection and put into a database. Any preparation of a database had to be with the PIC of the holders of knowledge systems. It should be very clear that the value and ownership of the knowledge held by the communities should not be undermined. Wherever the information was to be collected, it should be collected and kept with its normal sanctity. For example, if it was kept in secret, it had to be kept in secret. The database should be used by patent offices on the clear understanding that it could only be used for a limited purpose, it could not be shared with others for the purpose of doing any other activity, unless there was compliance with PIC and ABS. There had to be an obligation on the part of the patent offices, searching authorities and examination authorities, to use the database giving full respect to the ownership of the holders of the knowledge system. Regarding A.2, he believed that an online portal with one-stop was not going to be a practical solution, because of the practical difficulty in consolidating the knowledge systems available cutting across the borders of a country. A practical problem was the non-availability of the documentation in international languages. It was necessary to introduce an additional obligation on the searching authorities to coordinate with national patent offices for the purpose of finding out available databases. Even if a one-stop database was created, since it was not going to be exhaustive, a clear obligation had to be put on the part of the searching authorities to coordinate with the relevant national searching authorities from where the knowledge originated, as the

country of origin would be very important to locate where exactly the knowledge originated and what exactly the available information was. Regarding A.3, he believed that guidelines were important, specially guidelines on examination, particularly concerning inventive step or obviousness. Because of the limitations of databases, to have a productive examination system, there needed to be interaction between experts who were knowledgeable in TK along with experts who were knowledgeable in modern science. It was necessary to create institutional mechanisms for that, so that persons skilled in the art were not from modern science but from the TK side, to find a right balance between protecting the interests of creators of the modern knowledge system and giving due respect to the creators of the existing knowledge system. In his view, the limitations of the database system could be tackled with disclosure requirements.

31. Nicolas Lesieur pointed out, regarding the security of the databases, that there were IT systems with a high level of confidentiality. The issue of database security had been resolved to a large extent, and he did not think that it would be more difficult to protect information about TK and GR than other types of information included in databases. He believed that a kind of one-stop shop approach, with a database that potential applicants or inventors could use in order to get the information that they needed, could work. There could be an appropriate level of security, which was desirable to prevent any kind of illicit access to the database. As regards the benefits that might be derived from the use of a database, he noted that the disclosure was a process that was at least initially controlled by the patent applicant, whereas a database could be controlled by the communities from which the GR came. That should be looked at in more detail. Regarding disclosure requirements, he pointed out that they did not guarantee that full information on prior art would be made available. Databases would probably still be needed. If a patent examiner received information through disclosure requirements, he would still need to search information via databases. Regarding A.2 and A.3, he noted that there were references to disclosure, which should be looked at carefully. Some options referred to disclosure, others to databases.

32. Preston Hardison pointed out that there were some indigenous peoples that had elected to put information in national databases, and that there was some information that they might wish to share. However, he did not believe that that was going to be very extensive, because it was impossible to capture all of the details of TK, given the customary laws, the secrecy and the sacredness of a lot of the TK. There were also questions regarding whether building those international databases was going to be effective. He stressed that, if it was going to happen, it should happen with the PIC of indigenous peoples and local communities. The problem, as one stepped up and scaled, was that one got farther away from the indigenous peoples and local communities, and it became more difficult to verify that PIC had been obtained. Regarding the comments made by Steven Bailie about the fact that much of the TK was in danger of being lost, he indicated that indigenous peoples were concerned with keeping their knowledge and their traditions living on the ground. They were not interested in putting things in databases, because that was foreign to the nature of the knowledge. A lot of the elders from the Tulalip Tribes had said that their knowledge died with them. They thought the loss of the knowledge was a bad thing but believed that, as guardians of the knowledge, they had obligations before they passed it on to others or to the next generation. What those elders were seeing was that, within the tribe, the youth did not understand their obligations and were not ready to receive the knowledge. They also believed that sharing it with outsiders was a problem. So they were not really interested in having it recorded in a database system or archived. They did not believe that it was going extinct. If they needed it, they could talk to the plant people, talk to the trees, talk to the ancestors. It could come to them in dreams. There were many ways through which they could recover it. He stressed that the aspirations of the TK holders should be taken into account. If they wished it to be stored in a database, that was their decision, but they needed to give their FPIC. He noted that the issue of being informed about those databases was very difficult. It went beyond the *de facto* submission of some information, since indigenous peoples and local communities often lived in oral cultures. They did not publish, they did not patent, they

had no real direct connection with the IP system. There were a lot of steps that one had to go through to make sure that there was PIC.

33. Ken-Ichiro Natsume wished to clarify two issues, the structure of the database that Japan was proposing and the confidentiality. About the structure, he referred to figure 1 of the document WIPO/GRTKF/IWG/3/5, which showed that the system was composed of the WIPO portal site which would have links to the databases of WIPO Member States. It was not their intention to make one single huge database, but to provide an interface to the databases in each WIPO Member State. By entering a search formula on the WIPO portal site, an examiner could access the databases of other Member States through the direct links established in the portal site, the search result for all the relevant databases would appear on the display. Regarding confidentiality, he referred to item III of document WIPO/GRTKF/IWG/3/5. The proposal of Japan was that an Internet Protocol Address Authentication System was introduced. Using that system, the WIPO portal site would be made accessible only to an IP office which had a specific Internet Protocol address, which meant that users of the site would be limited to IP offices with a specific Internet Protocol address which had the authentication.

34. Song Kijoong considered that, in order to avoid the erroneous granting of patents for GR and related TK, the most effective solution was to establish a database related to GR and TK which was accessible by patent examiners in all nations. However, considering the amount of work, time and money that had to be put into establishing such a database, some countries were reluctant to accept the necessity of establishing a database system, and argued that TK was evolving and that some people could take advantage of the database system without PIC and MAT. Though it was true that TK was evolving in nature, the database could be updated periodically. If the database system was not secure enough, accessibility to confidential information could be given to patent examiners only, so that the information could be used only in the process of prior art search. He believed that it was not really appropriate to obtain the FPIC from each owner of TK, because the purpose of establishing a database was not to use GR and TK, but to protect them. Therefore, one should not impose an undue burden on patent offices that tried to protect GR and TK. Holders of GR and TK should be supportive of establishing a database system.

35. Marcus Goffe supported the last intervention made by N.S. Gopalakrishnan. Like Preston Hardison, he thought that the issue of databases ought to be moved forward with care, appreciative of the fact that not all communities might want to engage in that way. He considered that if a search in the database did not produce any relevant TK, there should be a further requirement to contact the national, regional or international focal points or competent authorities to further ascertain or confirm the existence or nonexistence of relevant TK. There should be limited access for patent purposes, if it was agreeable for the communities. It was hard to divorce that context from the important requirements of mandatory disclosure and benefit-sharing without which the database solution was not sufficient. As for A.2, he believed that it was a good starting point, and WIPO's assistance in that respect would be greatly appreciated. Likewise, A.3 could also be very useful for patent offices.

36. Sharon Venne pointed out that indigenous peoples kept their information in their own languages. Since indigenous languages were not recognized by WIPO, she wondered how the data would be kept, whether it would be translated, who would be involved in the translation and how would the material be accessed by indigenous peoples to ensure that it had been properly stored. The integration of the databases of 184 states would create a problem.

37. Martin Girsberger considered that options A.1 to A.3 were complementary. Work should continue on all three of those options, taking into account the concerns expressed by various experts, including those expressed by Preston Hardison and Sharon Venne. In his view, the term "disclosed" in A.1 through A.3 was used differently than "disclosure requirements" which were dealt with in cluster B. He suggested to put the text which was added in A.1, A.2 and A.3

in square brackets. He wished to add in the three underlined sections of the text after “the disclosure of the origin” the terms “or source”, to be consistent with previous discussions.

38. Dominic Keating supported Nicolas Lesieur and Martin Girsberger in pointing out that the language that had been added to options A.1 through A.3 related to disclosure requirements should be bracketed. In his view, that should be a separate proposal that should be taken up under cluster B when discussing options on disclosure requirements.

39. Maria Serova fully supported the work in cluster A, since the establishment of databases was a fundamental element for the correct evaluation of patentability. She noted that those databases had to be accessible to everyone, not just patent offices, because, for the purposes of evaluating patentability, only generally accessible information could be used. If those databases were only accessible to patent offices, not everyone would be able to make decisions on patent applications based on those databases. If a patent was granted for an invention included in a semi-open database, it might not be appealed against, since for appealing against patents only generally accessible information could be used. She referred to the example given by Emmanuel Sackey, regarding disclosure of an extract and application for a chemical substance. She considered that, in that case, a patent on the chemical substance would be granted in a fully justified manner, because knowledge of the extract was not sufficient to deny the novelty and inventive step of a particular substance. However, if some knowledge was used by developers of technological inventions, indigenous peoples and communities that had provided that knowledge should receive remuneration. She believed that the key aspect was developing special agreements. She welcomed hearing from Steven Baillie that the indigenous peoples of Australia understood what the patent system was, and were proud that their knowledge was used for inventions that served the humanity. The patent system, in general, was not intended for patenting GR as such. The patent law protected material objects created or transformed by mankind, as well as means of creating or transforming those objects. She pointed out that there was a certain distance between a GR and a patent application. Applicants had to strictly fulfill requirements for filing applications, for disclosure of inventions, in order to be able to receive patents. She noted that the patent laws of most of the countries of the world contained exhaustive requirements on disclosure of inventions, *inter alia*, those dealing with biological materials.

40. Clara Inés Vargas Silva pointed out that the concept of disclosure as set out in options A.1 and A.2 was interpreted along the lines of its known use or public domain use, rather than to prove the legal access to the GR. While the two concepts were different in scope, and, within the context of cluster A, they were part of the assessment of prior art when analyzing a patent application associated to GR, it was important to stress the need that that assessment was not to the detriment of the consideration of the requirement of legal access to the GR and the implications that the compliance or not of that requirement might have on the patent application. Cooperation between examiners for the determination of prior art should not replace the need to comply with the requirements of legal access to the GR. Although the issue of legal access was more related to cluster B, a distinction should be made between the erroneous granting of IP rights, which was a substantive issue, and the misappropriation of GR.

*Cluster B: Options on disclosure requirements*

*B.1 Mandatory disclosure*

Development of a mandatory disclosure requirement such as has been tabled in the Committee.

*B.2 Further examination of issues relating to disclosure requirements*

Further examination of issues relating to disclosure requirements, such as the questions addressed or identified in earlier studies and invitations.

Related analysis of patent disclosure issues making use of the information submitted by Committee Members in the context of questionnaire WIPO/GRTKF/7/Q.5 (Questionnaire on recognition of TK and GR in the patent system). The Committee could consider whether there is a need to develop appropriate (model) provisions for national or regional patent or other laws which would facilitate consistency and synergy between access and benefit-sharing measures for genetic resources on the one hand and national and international intellectual property law and practice on the other.

*B.3 Guidelines or recommendations on disclosure*

Guidelines or recommendations concerning the interaction between patent disclosure and access and benefit-sharing frameworks for genetic resources. The Committee could consider the development of guidelines or recommendations on achieving objectives related to proposals for patent disclosure or alternative mechanisms and access and benefit-sharing arrangements.

*B.4 Alternative mechanisms*

Other work on provisions for national or regional patent laws to facilitate consistency and synergy between access and benefit-sharing measures for genetic resources and national and international patent law and practice. The Committee could consider the creation of a dedicated international information system on the disclosure of the origin of genetic resources [disclosed genetic resources] as prior art in order to prevent the erroneous grant of patents on genetic resources.



## COMMENTS BY EXPERTS

41. Maria Serova supported the idea that at that stage it was not advisable to make any amendments to patent law regarding disclosure requirements, because those requirements did not have any direct relevance for the evaluation of the patentability of inventions. Making amendments could create confusion and complicate the work of patent offices.

42. Krisztina Kovács explained the proposals of the European Union (EU) and its Member States regarding disclosure of origin or source of GR and associated TK in patent applications, submitted in 2005 and included in document WIPO/GRTKF/IWG/3/2, which was originally document WIPO/GRTKF/IC/8/11. The EU and its Member States had proposed the introduction of a mandatory requirement to disclose the country of origin or source of GR in patent applications. The requirement should apply to all international, regional and national patent applications at the earliest stage possible. The applicant should declare the country of origin or, if unknown, the source of the specific GR to which the inventor had had physical access and which was still known to him. The invention had to be directly based on the specific GR. There could also be a requirement to declare the specific source of TK associated with GR, if the applicant was aware that the invention was directly based on such TK. Due consideration should be given to the ongoing in-depth discussion concerning the concept of TK. If the patent applicant failed or refused to declare the required information, and despite being given the opportunity to remedy that omission continued to do so, then the application should not be further processed. If the information provided was incorrect or incomplete, effective, proportionate and dissuasive sanctions should be envisaged outside the field of patent law. A simple notification procedure should be used by the patent offices every time they received a declaration; it would be adequate to identify, in particular, the Clearing-House Mechanism of the CBD as the central body to which the patent offices should send the available information. She pointed out that those proposals attempted to formulate a way forward that should ensure, at global level, an effective, balanced and realistic system. The introduction of disclosure requirements as described would also facilitate the monitoring of any benefit-sharing arrangements. She informed about the readiness of the EU to discuss those proposals.

43. Martin Girsberger provided an introduction to the proposals by Switzerland on the declaration of the source of GR and TK in patent applications. The proposed disclosure requirement intended to increase transparency in ABS with regard to GR and associated TK. It should also allow the providers of GR and TK to keep track of the use of their resources or knowledge in research and development resulting in patentable inventions. The use of the terms “genetic resources” and “associated traditional knowledge” was to ensure consistency with the terminology used in the CBD, the Nagoya Protocol and the International Treaty of the FAO, the three principal international instruments on ABS. The concept of source ensured consistency with the three instruments just mentioned. Those instruments foresaw a multitude of different entities to be involved in ABS. Those included, for example, the contracting party providing GR, indigenous and local communities or peoples, and the Multilateral System of the FAO International Treaty. In order for the requirement to apply, the invention had to be directly based on the GR or TK in question. Switzerland proposed to apply the disclosure requirement to international patent applications. It was proposed to apply the sanctions currently provided for under the Patent Cooperation Treaty (PCT) and the Patent Law Treaty (PLT) for failure to disclose or wrongful disclosure of the source. Additional sanctions outside of the patent system might be imposed including criminal sanctions and the publication of the ruling of a judge. In order to further strengthen the effectiveness of the requirement to disclose the source, Switzerland proposed to establish an internet-based list of government agencies competent to receive information about the declaration of the source. Patent offices which received patent applications containing a declaration of the source would inform the competent government agency about that declaration. He pointed out that more information on those proposals could be found in document WIPO/GRTKF/IWG/3/4. He viewed disclosure requirements as one measure in the context of IP rights and GR. In addition to working on disclosure requirements,

he believed that the IWG and the IGC should carry out work on all options of the clusters A through C mentioned in document WIPO/GRTKF/IWG/3/6. In that context, he noted with interest the proposal submitted by Japan, as well as the work on the Online Database of Biodiversity-related Access and Benefit-sharing Agreements, and the IP Guidelines for Access and Equitable Benefit-sharing as contained in document WIPO/GRTKF/IWG/3/12.

44. Following up on the descriptions of the proposals of the EU and Switzerland, Steven Bailie indicated the six technical issues that he considered relevant to those proposals, namely: the relevant instrument that those proposals dealt with, the legal effect of those proposals, the content of the disclosure requirement, the trigger for the disclosure requirement or when would a disclosure be required, the consequences of failing to disclose or incorrectly disclosing and what was to be done with the disclosed information, and for who was that information relevant. The earlier study by WIPO at the request of the CBD in document WIPO/GRTKF/IWG/3/14 referred to five of those issues on page 38. The paper also dealt with the first issue he raised which was the relevant instrument. The study made reference to articles and rules within the PCT and PLT dealing with the documents a patent office could require of an applicant to meet the formality requirements for patenting. He noted that both proposals, of Switzerland and the EU, referred to amendments of the PCT and the PLT.

45. Tim Roberts suggested to add a further option, B.5, which would say that there should be no general requirement for disclosure of origin of GR in patent specifications. If a disclosure requirement helped to prevent biopiracy, there might be some point in it. However, he believed that it would not have that effect at all, it would not be useful for that purpose. He referred to three classic cases of biopiracy: the neem tree, the US patent on turmeric and the attempt to patent a strain of basmati rice. The origin of those resources was the Indian sub continent. That information was generally available. The information about sources of such genetic materials was generally available, because the materials themselves were also generally available. Turmeric was found in all western supermarkets. He pointed out that neither the source nor the origin would contribute in any way to knowledge. There were important and difficult theoretical and practical questions as to what one had to disclose. The information suggested to be put was generally available and very frequently irrelevant. He estimated that perhaps 1% of the patent applications that were filed and were related to GR or derivatives referred to a biopiracy or bioprospecting situation, where someone had gone out and looked for rare materials with interesting properties. The remaining 99% related to widely available and widely circulating GR, such as crops and potatoes. There was no benefit in disclosing every time a patent application was filed on the use of a potato or an improved potato that the Vavilov centre for the potatoes was Peru or that the source was the local supermarket. He highlighted that in neither case was any useful information added to the sum of mankind's knowledge and it was of no use to people who had hoped to benefit from that.

46. Ken-Ichiro Natsume stated that the disclosure requirement put some additional burden not only on applicants but also on patent examiners, because applicants had to do some paperwork in order to disclose the origin of the GR and examiners were supposed to deal with applications with the viewpoint of the disclosure requirement. Regarding legal certainty, there was ambiguity about what kind of application had to be under the scope of the disclosure requirement. Sometimes applicants might wonder if the disclosure requirement had to be complied with or not. If the applicant thought that his application was not under the scope of the disclosure requirement, after the patent was granted, somebody could challenge the patent because of lack of compliance with the disclosure requirement and the patent could be revoked, which led to legal uncertainty. Such legal uncertainty was not desirable for the benefit of both patent applicants and third parties. If disclosure requirements included some very sensitive information, like confidential information, the inventor might be discouraged to file a patent application, which meant that a patent would not be granted and there would be no benefit from patent rights. That would neither contribute to the patent applicant and the user country nor to

the provider country. For both the user country and the provider country such discouragement of filing a patent application was not favorable.

47. Dominic Keating considered that a patent disclosure requirement was not an effective way to achieve the objective of ensuring PIC and MAT. One of the reasons was that most commercialized products were not protected by patents. A mechanism outside of the patent system would be necessary to ensure appropriate PIC and MAT before the relevant GR or TK was accessed or used. Accordingly, even if a patent disclosure requirement existed, a completely separate mechanism would be required in order to ensure PIC and MAT. Furthermore, there was no evidence that existing GR disclosure requirements in national laws had significantly increased the policy goals that had been agreed, PIC and MAT. In addition, new patent disclosure requirements would add new costs and uncertainties to the patent system, particularly where sanctions for non-compliance included invalidation of the patent. If a patent were invalidated based on failure to disclose the genetic materials, that would create uncertainty that could undermine the role of the patent system in promoting innovation. Binding mandatory norms on GR disclosure in patent law would also limit each country's policy space. He noted that a one-size-fits-all approach had been frequently criticized by Member States. He was mindful that many Member States had spoken eloquently on the need for flexibilities in the implementation of IP norms. Therefore, he could not support options B.1 through B.3. He agreed with Tim Roberts that an additional option under B should be no disclosure requirements.

48. Kim Connolly-Stone was interested to learn how the disclosure option could achieve policy objective 1. Since there were many formulations of the disclosure proposals, as a policy analyst, she was interested mostly in the variants that would have the least impact on the IP system, including impacts on innovation and changes to examination practices or criteria. There was a basic principle in the policy world that one should first consider light-touch options and not impose additional burdens on users of a system, unless it was clearly shown with evidence that the benefits outweighed the costs. For that reason, the starting point for the discussion of the disclosure options needed to be the disclosure requirements that already existed in the patent system and perhaps disclosure as a formality, which had been suggested by the EU and Switzerland. She asked the patent examiner experts that were in the room whether the existing disclosure requirements in the patent system already provided sufficient information that enabled providers of GR and associated TK to track the patenting of such resources or knowledge. She recalled a side-event that had taken place in the last IGC, which had shown that there was already quite a lot of data available which could be searched with the right technical capabilities, so one possible option that could be recommended to the IGC would be for WIPO to offer technical assistance to countries wishing to use those existing datasets. She asked those that were very keen on the disclosure idea whether voluntary disclosure could address policy objective 1. The Swiss proposal contained an interesting suggestion that a voluntary requirement could provide the providers of GR and associated TK with enough information to track those applications and to take action on the relevant existing benefit-sharing rules. The issue that flowed from voluntary disclosure was whether that provided enough certainty for users of the patent system in the sense of a level playing field. One solution was harmonizing the method of disclosure. Harmonization did not necessarily mean an amendment to the PCT, one could harmonize procedures through guidelines or a joint statement. Some New Zealand patent examiners had suggested a small amendment to the parts of the PCT regulations that dealt with declarations rather than to the formality requirements. They had pointed out that a tick box could be added to the PCT application form and provide an option, not a mandatory requirement, for applicants to provide a declaration as part of their application when the invention involved GR or TK. The PCT receiving office would send those applications to WIPO, as they normally did, and WIPO could then identify which PCT applications had checked the box and provided the declarations. That information could be reflected through a special field in the existing PCT database or perhaps in a new database. She highlighted that those databases could be searched by providers of GR, which was in practice similar to the EU

proposal, where there might be some sort of database in the CBD Clearing-House Mechanism. The advantage of that proposal, according to the New Zealand patent examiners, was that it could save applicants money because, if they did a declaration at the international phase, they wouldn't need to then do several declarations at the national phase. Her last question to the experts of the EU was what was meant by "directly based".

49. Clara Ines Vargas Silva considered that B.1 was the most appropriate option, but work on complementary and parallel alternatives should not be excluded. The disclosure of the legal origin of genetic material should be a necessary condition for the integrity of a patent or of the IP right. It was important not to mix up the identification of the prior art and the identification of the legal origin of the material. A distinction should be made between the erroneous granting of IP rights and the misappropriation of genetic material. Protective measures under cluster B should try to establish a causal link between the misappropriation of GR or associated TK and the revocation of a granted IP right.

50. Natalia Buzova stated that for her the issue of including disclosure remained open. There were a number of questions that needed clarification. Experiences of national patent offices would be interesting. Though it seemed premature to ask patent offices practicing the procedure of disclosure of origin of GR about the effectiveness of introducing that procedure, it would be interesting to find answers to some practical questions: What was included in the documentation to be submitted to a patent office when filing an application for an invention? How did a patent office verify that information, if it did? If there were several GR listed in an application, did all of them require documentation? Was it required to provide a copy of an agreement on transfer of a GR, or any other document? An agreement itself might be quite long and it might contain commercial information that was confidential in nature. Furthermore, if a GR was a wild growing plant but it was received from a botanic garden and the country of origin of the plant was known but properties of that GR might have changed as a result of its cultivation in a different environment, was it sufficient to specify the name of the botanic garden and to provide an agreement with the botanic garden? Was it necessary to develop special instructions (guidelines) for patent examiners and applicants, and how was it possible to review those instructions or guidelines? Which part of the information on the origin of GR submitted by an applicant was published when the patent was published? How was the information on the origin of a GR going to be used in the future? Was it planned to establish some database if the information received from applicants was verified? She indicated that the list of questions could be extended, and answers to the questions raised could be received in a centralized manner and prepared for general information, as a separate document. It was also necessary to discuss issues related to the scope and term of validity of requirements that might be related to GR and TK in the country of origin and in foreign jurisdictions, as well as to what degree those requirements impacted further inventive activity and patent applications. She agreed with other experts on the fact that clarity in that area was necessary to ensure that patent offices, as well as patent applicants and patent holders, knew when the requirements for disclosure entered into force and when, on the other hand, the relationship between the original GR and TK was so distant and non-essential that it might not lead to such a requirement. She considered that there were a lot of questions, and without discussing and receiving answers to such questions it seemed that introducing such a requirement was premature and required further discussion.

51. Pierre Du Plessis very strongly supported B.1 and did not believe that there were any other viable alternatives. That was a question that went to the heart of the credibility of the international IP System. Numerous studies had shown conclusively that the IP system benefited some countries at the expense of others. Regarding B.1, a place had been identified where the IP system could help developing countries. And some experts were saying that that would be a burden, a barrier to innovation, not practical and too expensive. He was beginning to wonder whether the IP system was at all a useful tool for developing countries. He was talking specifically about GR, but if that uncertainty started spreading to things like creative works and to industrial property, he believed that the consequences of that were worth

considering. It was also important, when considering the disclosure requirement, to take into account that ABS of GR had fundamentally shifted with the adoption of the Nagoya Protocol. It was no longer possible to buy potatoes from a local supermarket and utilize them as GR. If someone wanted to work on potatoes, he would have to get the PIC of the country of origin or of a party that acquired them in accordance with the CBD. Regarding the allegation that there would be an additional burden on applicants and patent examiners, there would be no additional burden to applicants beyond filling in one box to indicate where was the GR obtained, and the only obligation that the patent examiner would have was to check if the box had been filled in and to enter that information into a database. If that was not an acceptable level of effort to safeguard the whole of the international IP system, it raised serious questions about how much it was valued. As of the point that most commercialized products were not patented and, therefore, disclosure in patent applications served a small purpose and maybe none at all, was why he was in favor of a mandatory disclosure of source or origin in all IP as well as product registration applications and not just patent applications. He would like to know before any exclusive rights were granted, be they IP rights or marketing rights, where did PIC come from and what MAT or, at least, that MAT had been established. He agreed to a certain extent with the point that disclosure requirements should not compromise confidentiality, but revealing the source of the PIC and stating that there were MAT would not compromise such commercial confidentiality. Details about how that information was managed could be discussed. He recalled that one of the purposes of the IP system was to put such information in the public domain, after a period of protection. Searching existing datasets could help to track the country of origin, but at the moment that depended on essentially a voluntary arrangement or an accidental arrangement. One of the reasons for having a mandatory disclosure requirement was to create a level playing field, so that everyone had to disclose, not only the ethical operators but those who did not have PIC and MAT. That would give them an opportunity to seek PIC and conclude MAT before filing an IP application. B.1 was a way for developing countries to track what had happened with their GR and associated TK when inventions were made and were protected by the IP system, which did not in any way change the fundamental criteria of patentability. Concerning the point that it would introduce new costs and uncertainties, it would introduce new uncertainties only for those who thought that they had some divine right to take exclusive property rights and to be protected by the international system. For those who were prepared to play by the rules of fairness and equity and justice, as agreed in the CBD, it would not be an additional burden. Developing countries would have a mandatory disclosure requirement. The question before the IWG was whether they would have it only as developing countries or whether the whole world would collaborate to have it. The answer to that question had very important consequences for much more than just the discussion on GR.

52. Ronald Barnes considered that the CBD, the Nagoya Protocol and existing national and international law needed to be examined for their deficiencies as they applied to indigenous peoples. He believed that the interaction between patent disclosure and ABS frameworks for GR in its current state was discriminating. The development of guidelines or recommendations on achieving objectives related to proposals for patent disclosure or alternative mechanisms and ABS arrangements needed to be improved. Indigenous peoples needed specific language to protect themselves, which would allow them to stop bioprospectors and biopirates. That was why the IGC itself needed to allow openness and transparency by allowing indigenous peoples to participate as equals according to the equal right and self-determination of peoples. He believed that States and corporations had to be corrected. Indigenous peoples needed an internationally legally binding framework based on the right to self-determination. He noted that MAT should be based on that internationally legally binding framework. Only then patent law would facilitate consistency and synergy with ABS, and the erroneous grant of patents would be prevented.

53. Steven Bailie asked other experts with knowledge of the patent system if they considered that a disclosure requirement as proposed was relevant to substantive patentability, to issues such as novelty, inventive step and industrial application, or if it was a formalities issue, such as the name of the applicant, the content of the application being a request, a description and claims. He read out article 27.1 of the PCT: “No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this treaty and the regulations”. He considered that it was quite relevant because the Swiss proposal contemplated the amendment of the PCT and PLT in that regard. He asked Tim Roberts to provide details of the statistics he mentioned and to make them available to the IWG. He asked experts from countries with disclosure requirements how many disclosures had been made under their laws, and how many failures to disclose there had been. He also asked what their expert perception of the administrative burden of those disclosure requirements was and what applicants submitting applications to their patent offices thought of disclosure requirements. He also asked for examples of when inventions involving biological materials would not require a disclosure of origin or source and examples of when biological materials required a disclosure of origin or source. He asked Natalia Buzova what she meant by to what degree those requirements impacted further inventions.

54. Salma Bashir asked whether the mandatory disclosure was a substantive or formal requirement and wondered what the consequences would be.

55. María Elena Menéndez Rodríguez considered that misappropriation of GR was a problem which often involved the acquisition of material in one country and the application for a patent using that material in another. Therefore, a binding mandatory disclosure requirement for all patent applications was needed.

56. Nicolas Lesieur noted that, during the discussions on cluster A, there had been a certain opposition to databases. He wondered how patent examiners would verify the information provided through a disclosure requirement without having access to a complete network of information. There was a paradox in terms of what the patent offices were being asked to do and the information they were being provided. What would a mandatory disclosure requirement bring to the table in terms of information about prior art, how would it improve the assessment of the patentability of an invention and how would it help a patent examiner in his task. He also wondered what was the advantage of mandatory disclosure regarding existing patent practices, such as providing information on essential materials, which had to be provided anyway under current practices. He pointed out that disclosure proposals seemed to be based on the presumption of coincidence between an invention, and a GR, a territory, a community, a country and an utilization. He believed that that was not always the case. Sometimes GR were not specific to a territory, a community, a country or an utilization. He mentioned as an example the vincristine which was used for chemotherapy and came from a plant called *Catharantus roseus*, whose common name was Madagascar periwinkle. That name could be confusing, because though the plant came from Madagascar, it could also be found elsewhere, in Jamaica for instance, where it had been used for its anti-diabetic properties originally. Its anti-cancer effects were discovered later in laboratories. In that case, the GR was not exactly where one would have thought it would be. He pointed out that a disclosure requirement would not have helped in that case, especially because the use of the plant in the community did not match the use of the commercialized invention that the plant was related to. He wondered which would have been the country of origin and who would have given the consent in that particular case.

57. N. S. Gopalakrishnan stated that mandatory disclosure requirement would overcome the limits of databases, by giving information necessary to identify the existing knowledge and its holders, which was not new, because the existing IP system required the disclosure of the prior art, on one side, and the disclosure of the details of existing IP rights, if the new inventions were based upon existing IP rights. The disclosure requirement was primarily intended to extend the

credibility of the patent system by reducing the issue of questionable patents. The first part of the mandatory disclosure requirement system was to disclose the country of origin and the source, from where the information had been collected by the researcher. In addition, there was a need for disclosure of the information on the existing knowledge collected by the researcher upon which the new knowledge had been built. It included the way in which the knowledge had been described by the existing TK system, the holders of it, the way in which the holders identified the knowledge system, understood the knowledge system and used the knowledge system, on the one side, and what type of innovations had been added by the researcher into the new existing knowledge system to bring out the new results, on the other side. That was essential for the patent office to find out the difference between the two knowledge systems and to ask whether what had been disclosed was the existing system as understood by the traditional communities. A disclosure requirement would be further useful for the patent examiner to locate prior art. If the country of origin was mentioned, the examiner could find out by the database available in that country of origin whether the disclosure was correct or seek more information from the patent applicant. It would enable interested parties to bring more information to the patent office in an opposition procedure to make sure that the patent granted was genuine and not based upon concealment of information or a non-understanding of the two knowledge systems. It would also enable the patent examiner to improve the inventive step test by tracking the information and coordinating with other patent offices. The second part of the disclosure requirement was related to the compliance requirement. He cited the example of disclosure of existing patents in the patent application, in the case of a dependent patent, which brought in the principle of recognizing the existing right holders before granting a new patent and also built the bridge between the existing knowledge holders, erroneous knowledge holders plus new knowledge holders. GR and associated TK were new categories that had their own characteristics, but the principle remained the same. The purpose was to ensure that questionable patents were not granted. He supported the emergence of a new knowledge system based upon the interaction and right balance for the respect between the existing knowledge system and the new knowledge system. A disclosure requirement was one tool to ensure that. Regarding the issues of additional burden and uncertainty, a disclosure requirement would not imply more than asking a researcher what type of information he had collected for research and, in the case of GR and associated TK, additionally the information directly collected from knowledge holders. He believed that the certainty of the patent system depended on how one could trust the patents granted. Issuing more questionable patents, would put the burden on the other side, to challenge it before the appropriate authorities. However, preventing bad patents would enhance efficiency and reduce costs. A disclosure system properly understood and implemented in collaboration with different patent offices would further strengthen the international patent system rather than reduce its capability and scope for innovation.

58. Jon P. Santamauro recognized that the disclosure requirement was a long-standing and controversial issue. His view was that those proposals for new patent disclosure requirements related to GR would not achieve the goals that had been stated by the proponents. Those proposals would introduce serious risks and uncertainties in the IP system and, in the context of patents, they would undermine the role of patents in innovation and in the generation of benefits consistent with the rules of the CBD, and also would imperil innovative companies. Such requirements could have a disproportionate negative impact on innovative small and medium-sized enterprises. Those concerns also applied to voluntary or formal type requirements. Looking at the proposals made, he did not see any of them as a check box, which was perhaps the reason why so many questions were being asked. In addition to disclosure proposals and, perhaps, because there were faults within those proposals, there were several alternatives that had been discussed and that were noted in B.4. He believed that, to resolve the different views on the issues, it was important to better understand the goals to be achieved, to articulate those clearly and then to examine how the various proposals would work to achieve those goals. For example, some had suggested that new disclosure requirements would prevent patents on alleged inventions that were not novel or lacked inventive step.

Different views on that had been put forward. His view was similar to Ken-Ichiro Natsume's view. Those requirements were not effective for that purpose and the type of information involved would generally not be relevant to considerations of novelty and inventive step. Perhaps, it was necessary to clarify that that was an objective that needed discussion and to further examine that situation. Other experts had also mentioned that a disclosure requirement might help monitoring compliance with ABS requirements. His view was that those new patent disclosure requirement proposals would not be effective for that purpose. If one looked at the Nagoya Protocol, it was open to a more centralized type of checkpoint arrangement that would be superior for that purpose and that would not interfere with the IP system or would not impact it in a negative way. Maybe that concept needed to be examined in much more detail. A solution could be found in alternative proposals that would complement the Nagoya Protocol in the IP context in a meaningful way and that could achieve the objectives, but would not have negative effects on the patent system.

59. Deyanira Camacho Toral believed that IP should be considered as a mechanism for the development of peoples and that it should include considerations such as megadiversity, which included cultural and natural diversity. She considered that only disclosure requirement would not be a sufficient response for a megadiverse developing country like Ecuador. It was important to have a mandatory clause for the disclosure of the origin of the GR. She shared some of the questions raised by Nicolas Lesieur and Steven Bailie. She agreed with Dominic Keating that some of the issues needed to be solved outside of the IP system. In Ecuador they had begun to work on some alternatives regarding disclosure, and one of the proposals that was being discussed was that disclosure requirements should also be applied to sanitary registers. Not only the patent system should be referred to, since there were other relevant systems within IP, such as the plant variety protection system. She noted that her office had received applications from some companies that were based and had their headquarters in a certain country, but their applications were related to GR based in another country, as was voluntarily declared by them. She wondered whether, in that case, benefits would be shared with the country of origin of the GR. Though it was true that legal certainty was needed for the patent system, it was also true that law was dynamic and that it had to be drafted for general cases and not specific or exceptional cases. She requested the Secretariat to conduct a study of practical cases, as the one mentioned by Nicolas Lesieur, which should include the experiences of patent offices. That would help clarify how difficult it was for a patent office to deal with a disclosure requirement and how many exceptional cases there were, for instance. She pointed out that to deal with legal issues, it was not only necessary to look at historical, sociological and legal rationale aspects, but also at factual and technical aspects.

60. Lucia Fernanda Inácio Belfort considered that it was necessary to include a mandatory disclosure requirement in an international instrument dealing with GR. Following up on Steven Bailie's questions, she explained this was needed because the sovereignty of states over their GR was limited to national borders. She pointed out that Brazil had national legislation which included disclosure of origin. Article 31 of the Provisional Measure No. 2186-16 of 2001 stated that granting of industrial property rights was subject to compliance with the provisional measure. That Provisional Measure also provided that the applicant had to inform the origin of the genetic material and the associated TK, as appropriate. Resolution 34 of 2009 was issued later by the Genetic Heritage Management Council and included a disclosure requirement of the origin of genetic material and associated TK, when necessary, and also the requirement of providing the access authorization granted by the Government, which included the FPIC of indigenous peoples and local communities. In response to Steven Bailie's comments, she mentioned the example of the cupuacu, a fruit from the Amazon. In 1998, patents were applied for in several parts of the world on the cupuacu, which was a traditional food source of the peoples of the Amazon, without complying with the national law and the requirements of the CBD, precisely because there was not, on the international scene, a requirement for the disclosure of origin. She provided the example of the copaiba, which had been used by the indigenous peoples for many years for its anti-inflammatory and



anti-carcinogenic properties. In 1993, several patents were granted on the copaiba without complying with the requirements of PIC and national legislation. She cited the example of the andiroba, which was an insecticide. In 1999, patents were granted on the andiroba, because there was not a requirement for the disclosure of origin and compliance with national legislation. She stressed that, despite the fact of having national legislation, to prevent those cases, it was necessary to have a binding international instrument that included requirements for mandatory disclosure.

61. Heng Gee Lim supported Pierre du Plessis's comments. With regard to Steven Bailie's question on whether disclosure of the country of origin was relevant to substantive patentability, he fully agreed with Ken-Ichiro Natsume. The disclosure requirement related to country of origin basically was not related to the patentability criteria of novelty and inventive step. He believed it had a very different basis, which was that disclosure should be based on good faith and honesty in providing information in the patent application form. That was reflected in principle 6 to objective 1. The indication of origin functioned as a form of acknowledgement of the source of inspiration for the invention. He supported B.1 and considered that the EU proposal provided a very good starting point, but maybe it was necessary to go further. Regarding the remarks by other experts that such a disclosure requirement was very burdensome on the applicant and the patent office, basically the role of the patent office was just to check that such disclosure had been made. The patent office was not required to go into the truth or falsity of the information required. The truth and falsity of the information required might be relevant later after the patent had been granted. The country of origin might be difficult to determine because plants might come from different countries, but there was also the alternative to specify the source, which might not be that difficult. In relation to the proposal by the EU, he requested further clarification on what was meant by "the invention must be directly based on the specific GR". He wondered what was the degree of proximity that was required for the disclosure requirement to apply. As regards the question of what happened if the information was found to be incorrect or incomplete, he agreed that that should not lead to invalidation or revocation of the patent, because neither would be beneficial to the user or the supplier of the GR. Sanctions could take place outside the patent law for breach of the disclosure requirement. He proposed a special provision under patent law, as a disciplining mechanism to ensure that applicants complied with disclosure requirements, which could read as follows: "If a patent has been granted, where it was later found that information provided was incorrect, incomplete, misleading or false, the patent shall not be invalidated on those grounds alone. However, domestic law may provide that in such a case the patent shall be subject to a royalty free license for the whole of the duration of the patent for the use of the Government or anybody acting on behalf of the Government". He pointed out that that was not something new, it was very similar to a concept applied in the United States in relation to the doctrine of patent misuse.

62. Tom Suchanandan cited the example of the pelargonium in South Africa which made a very compelling argument as to why a mandatory disclosure was needed. He pointed out that South Africa, as well as other African countries, had largely supported proposals for the revision of the TRIPS Agreement to include disclosure of origin, on a series of submissions made by Brazil, India and Peru. His view was that an incarnation of the disclosure of origin would make that requirement mandatory. Imposing an obligation on the disclosure of GR would improve the quality of the IP rights and provide transparency, facilitating efforts to prevent the IP system from rewarding and perpetuating unjust conduct. The users should declare the specific source of indigenous knowledge that was associated with the GR.

63. Song Kijoong considered that the core purpose of the disclosure requirement was to monitor access to GR and to ensure compliance with benefit-sharing. However, disclosure of information relating to GR in patent applications would not enable patent examiners to examine patent applications fully and it would not ensure ABS. So-called erroneously granted patents would not be prevented. That would only be possible through establishing database systems on GR and TK. Disclosure would not ensure that benefits from commercialization of GR were

shared with the provider country. Disclosure would not be able to cover commercialized GR that had not been patented. A disclosure requirement might create problems. He believed that there was no relevance between the origin or source of GR and patentability or revocability. He stressed that under no circumstances should the principles of the IP system be undermined.

64. Violet Ford pointed out that the IP system reflected the political system from where it derived. In Canada, the IP system, including the patent system, was based on the economic values that immigrants had brought into Canada in the 1800s. That was one of the challenges that indigenous people in Canada were faced with. In response to comments alluding to lack of experience in working with the patent system or as patent lawyers, she pointed out that they had experience in dealing with patent systems, though that experience had not been very favorable. Another possible disclosure scenario to be considered was when a TK holder applied for a patent and did not meet the patent requirements, because of the lack of mandatory disclosure dealing with TK. In that scenario, she wondered how could the lack of mandatory disclosure requirements as presently stated in patent systems assist legal certainty for TK holders and indigenous communities, and how could legal certainty be created. She suggested that any future mandatory requirement of disclosure be based on the goals of indigenous self-determination. She recommended the Secretariat gather case studies of indigenous peoples' experiences with the patent system.

65. Debra Harry considered that the age of biopiracy was not over. No life form was safe from biopiracy. Much of the world's modern products were based on the innovations and knowledge of indigenous peoples and related to medicines and food sources. Mechanisms for restitution of the wrongly gained profits derived from misappropriated GR and TK should be looked at first. Establishing a global fund could be one possibility. There was an ongoing obligation for any use of GR and TK derived from indigenous peoples and their territories. As Lucia Fernanda Inácio Belfort had indicated, patents were being applied for in many cases over genetic material that was nurtured and developed by indigenous peoples since time immemorial. In recent years, there had been patent issues related to ayahuasca, neem, enola beans, maca, quinua, yacon and many rice varieties. Those acts of misappropriation were not insignificant to indigenous peoples. Indigenous peoples had a deep cultural and spiritual relationship to those foods, to those medicines and to their environments. It was necessary to prevent the wrongful grant of patents. Disclosure requirements could serve that purpose. Most indigenous peoples did not have the capacity or the means to challenge wrongful patents on their own. It was necessary to set those standards at an international level, because there was insufficient security for indigenous peoples at the domestic level. Those requirements should ensure the right of indigenous peoples to FPIC.

66. Carmen Adriana Fernández Aroztegui referred to the question of whether the analysis of the patentability requirements of an invention would be or not modified with the disclosure of origin or source. She recalled that the patentability requirements were novelty, inventive step and industrial application, according to national legislation. If those requirements were complied with, a patent could be granted. The analysis of novelty and inventive step was based on the prior art. The prior art was understood as the set of information that had been made public before the application date or the priority date, if priority was claimed. Whether prior art could be oral or written varied depending on national legislation. She pointed out that if disclosure of the origin or source of the GR was required, it would be done when the application was filed and it would not be part of the prior art for the analysis of that application. Consequently, the origin or the source of the GR, if disclosed, would not have an impact on the novelty or inventive step of that particular application. Nevertheless, she pointed out that IP offices could contribute, directly or indirectly, to prevent the grant of erroneous patents involving GR and associated TK in different ways. One of the options involved databases, which could provide information on prior art to patent offices. She also mentioned that many national legislations provided that patents could not be granted for plants or biological material, as existing in nature. Another possibility would be to use higher standards when assessing the inventive step of applications

involving GR and associated TK, which would be allowed by the TRIPS Agreement. For instance, applications in the pharmaceutical sector very often were filed for compositions that contained active principles stemming from GR. In the pharmaceutical sector, inventive step was very often associated with the activity of that active principle. If associated TK, which had the same pharmaceutical activity, was identified as prior art, that patent would not be granted because of lack of inventive activity. She indicated that the Patent Office of Uruguay only received 5% of biotechnical applications out of a total of chemical applications in the pharmaceutical sector, so they had not faced yet an application involving GR and associated TK.

67. Suseno Amien shared the views expressed concerning the importance of mandatory disclosure requirements. With regard to the EU's proposal, the term "source of GR" needed to be defined clearly, as the Nagoya Protocol and the CBD did not have any definition of that term. It would be better to use the term "country of origin" in disclosure requirements, which would be consistent with the CBD and the Nagoya Protocol. He also believed that GR, both directly and indirectly used in an invention, should be protected, disclosed in the patent application and in compliance with the PIC, MAT and ABS as recognized in the CBD and the Nagoya Protocol. Regarding the proposal that "if the patent applicant fails or refuses to declare the required information, the application should not be further processed", he believed that further discussion was needed to decide whether those conditions would be applied in the substantive or formal examination of the patent application process.

68. Tim Roberts replied to the specific question asked by Steven Bailie on what statistics he could provide in support of the claim that only 1% of biological patent applications related to bioprospecting situations. It was only his own estimate, which was based on over 40 years experience on patents in the biological area. Research on actual facts and figures was needed. But one of the difficulties to do such research was that the researchers wanted to know in detail exactly the parameters that they had to meet and those remained very unclear. Regarding the three specific examples given by Lucia Fernanda Inácio Belfort, he wondered whether there was a disclosure of the origin of those materials and where they actually came from, because clearly there was not disclosure of formal permission. He believed that Pierre du Plessis was a little harsh on people doing research on biological materials because he seemed to regard any such research without formal permission as stealing.

69. Dominic Keating believed that a new patent disclosure requirement might lead to significant administrative burdens for the patent offices that would in turn create additional costs, particularly with respect to those requirements that would demand compliance with foreign laws. A patent office was not positioned to examine documentation provided by applicants in response to requirements proposed regarding source of origin, PIC or evidence of benefit-sharing. To implement an appropriate standard of review within the patent system for those matters would create significant new administrative burdens and substantial new costs, including training and system development for patent offices. Even with additional resources and costs, it did not seem possible that patent examiners would make such determinations with any degree of legal certainty, particularly decisions involving interpretations of foreign laws to determine the validity of PIC or adequate benefit-sharing according to the custodians' legal regime. Some experts believed that disclosure requirements would help to prevent erroneously granted patents. However, he believed that the proposed disclosure requirements would be ineffective in achieving that objective and would only complicate an already overburdened patent system. None of the suggested new patent disclosure requirements would ensure compliance with patentability requirements, such as proper inventorship, novelty or inventive step. Disclosure of source could be expressed in a variety of ways. Information indicating country of origin, *ex-situ* collection sites, etc. would do little to ensure appropriate inventorship, novelty or inventive step because such information did not generally address the considerations underlying those requirements, such as acts of invention or the state of the relevant prior art. As in the examples of basmati, neem and turmeric, the source of those resources was already

known but did not prevent the improper granting of patents. He wondered how far back GR had to be traced. GR had been traded within regions and bred throughout the world for more than 1,000 years. It would be extremely difficult to trace the source back very far. The inherent uncertainty in the process of tracing back the GR might create a cloud over patent rights and have negative implications on investment and research and development.

70. Song Jianhua stated that the IGC had conducted very useful work to protect GR and IP since its establishment ten years ago and those efforts had laid down a good basis for forming a solution that was acceptable to all parties. She believed that the disclosure requirement could help to establish a balanced mechanism between the CBD and the IP system to promote PIC and ABS. Therefore, she proposed that, on the basis of practices of relevant national legislations and proposals made by various countries, the IGC should continue its work on options B.1, B.2 and B.3 in the future.

71. Karima Ahmed Mohamed Hussein answered the questions raised by Steven Bailie. She stated that the disclosure requirement was closely linked to patentability and it was not a part of registration. Egyptian law stated that, if a patent application was related to life forms, TK, GR, crafts or heritage, the inventor had to indicate the source and prove that he had obtained it legally. If the inventor did not prove it, he would not receive a patent. Disclosure requirement was vital and she supported B.1 on mandatory disclosure.

72. Albert Deterville supported mandatory disclosure of origin of GR and associated TK. With regard to the periwinkle mentioned by Nicolas Lesieur, some authorities were linking the periwinkle to Madagascar and the expert from Canada mentioned Jamaica. The periwinkle was also common for the Caribbean. Two anticancer agents were isolated from the periwinkle in Jamaica and they were vincristine and vinblastine. People in St. Lucia used the periwinkle to treat coughs and cold. Another example was turmeric, which was used for medicinal purposes not only in India but also in the Caribbean. Another issue was "parallelism", which was the term used by anthropologists, in particular, with regard to the migration or the forced migration of Africans in the Caribbean, carrying with them their own TK and medicines. He proposed to take into account the special circumstances and needs of indigenous peoples and local communities in small islands of developing countries and least developed countries when establishing an international database.

73. Magnus Hauge Greaker responded to some of the questions raised by Steven Bailie. Norway had introduced a disclosure requirement in its Patent Act in 2004. This requirement would apply when an invention concerned or used biological material. From 2009, those disclosure requirements were expanded to cover also TK. Non-compliance with the Norwegian disclosure requirement did not affect the processing of the patent application or the validity of a granted patent. Breach of the disclosure requirement was, however, subject to penalty in accordance with the provisions on false statement to a public authority in the General Civil Penal Code. The Norwegian disclosure requirement only applied to national patent applications, not PCT applications. In the period from 2004 until now, the Norwegian patent office had received 17 applications where the disclosure requirement applied. In 8 out of those 17 cases, the disclosure requirement was complied with already in the application. In 3 cases, the requirement was complied with after the patent office asked the applicants to provide the information. In the remaining 6 cases, the application was withdrawn or refused at a very early stage. It was his understanding that applicants did not consider that the Norwegian disclosure requirement was burdensome to comply with. If, through the disclosure mechanism, it was discovered that there was breach of PIC or MAT, according to the Norwegian system, that would not affect the patent application or the validity of the patent. However, the Norwegian Biodiversity Act contained some provisions that addressed that situation.

74. Horacio Gabriel Usquiano Vargas considered that a mandatory disclosure requirement, as provided in B.1, with respect to patent applications related to GR and associated TK, was very

important. Biopiracy had undermined natural resources and associated knowledge, distorting the symbiosis between indigenous peoples and nature. Bolivia had diverse GR throughout its territory. He stressed that disclosure of origin of GR was as important as the creation of mechanisms to fight against biopiracy, because through that practice and the principle of territoriality of IP and patent offices patents had been applied and granted over GR and associated TK.

75. Andrew P. Jenner believed that it was important for any new regulation to state clearly how it would first achieve the objectives and not result in undue burdens or adverse consequences. The discussion had provided more clarity as to the different objectives that disclosure could ultimately achieve. If ultimately the objective was benefit-sharing, he still needed to be convinced that the patent system was the appropriate way to achieve that goal. There were always very important considerations when using existing systems for new objectives for which they were not designed or intended. As an ex-patent examiner, he believed that it was very difficult to determine in relation to disclosure of origin or source whether such an obligation had been triggered, and that was compounded even further when considering TK. An examiner had appropriate training to determine novelty, inventive step and industrial application and they had the proper tools to determine those components. However, it was not possible for an examiner to determine whether the disclosure obligations were being complied within a legal and effective manner. He suggested discussing what the overall objective was, which was, perhaps, benefit-sharing with the providers of TK, and whether or not such requirements would be workable in practice. The vast majority of companies wished to comply with the objectives of the CBD, but such requirements in the patent system created significant amounts of legal uncertainty which caused quite a significant amount of concerns. Eli Lilly and Merck both entered into agreements with INBio which was located in Costa Rica to investigate whether or not certain GR had commercial properties. There was transfer in knowledge, but there was no product. He highlighted the difficulty, complexity and risks involved with natural product research. There were four main risk categories: an initial investment risk in order to start investigating certain GR and entering into agreements; to check whether or not there was appropriate pharmacological activity and whether that activity could have some use or utility in the real world; clinical trials, which was getting harder in many jurisdictions particularly in relation to natural products because of uncertainty; and to find a market that was willing to purchase those products. He believed that the IP system had been established to incentivize research and development. If such disclosure requirements created legal uncertainty and risk, the ultimate objective, which was benefit-sharing, would not be achieved.

76. Teresa Agüero Teare believed that the IWG offered an opportunity to make further progress beyond what could be called a political statement in agreeing or not with the disclosure of origin. It was an opportunity to discuss the modalities for the technical and practical implementation of that requirement, to look at the difficulties encountered, the possibilities involved and the benefits or costs of disclosure. She supported the proposal of Deyanira Camacho Toral regarding the preparation of a study of the experiences of patent offices.

77. W. L. Gamini Samarasinghe supported the idea that the mandatory disclosure was an essential requirement in patent applications because it compelled the inventor to look for the origin, obtain the PIC, and have a good benefit-sharing mechanism before making use of the GR. For example, if the plants were endemic to a particular country, it was not difficult to disclose the origin. However, in case of new introductions, there might be some issues that needed to be clarified.

78. Pierre Du Plessis believed that it was a misunderstanding that the patent examiner would have to make a value judgment about the disclosure of origin or source. It was not the intention of the mandatory disclosure requirement. It would amount to providing the information that was necessary to use the existing IP database system to track what happened to GR. It would become a tool for developing countries to check the MAT that they had negotiated with users of

GR and associated TK. It would not in any way change the patentability criteria. It was a false argument that disclosure was intended to lead to better patents being granted or to prevent patents being granted in error. He believed that databases were the instruments to prevent patents being granted in error because databases had the ability to reveal prior art. Some experts had raised questions about how far back the origin of GR should be traced and what to do about GR that occurred in more than one jurisdiction. Those questions were answered already in the CBD. A country of origin would be a country where a resource occurred *in-situ*. A resource was defined as occurring *in-situ* if it was grown in a country for long enough to acquire unique characteristics for its own. Tim Roberts thought it was harsh to regard the research on biological materials without formal permission as stealing. GR were essentially about genetic information. The same case would apply when someone bought a CD and made thousands of copies and sold them. There would be no argument that it was stealing. He believed that there was no necessary link between the original source and the particular use that the resource was put to. That was another reason why disclosure was not going to help to improve the quality of patents granted. He also believed that the obligation would be triggered when an IP application claimed an invention derived from GR or associated TK. The inventor knew the basis of what he was inventing. If a patent examiner could not read a patent and understand that that obligation had been triggered, he was probably not competent in the first place. He refuted that disclosure requirement would create illegal uncertainty. What created legal uncertainty was that someone could not establish that he had legally obtained PIC and had negotiated MAT and put it on record in the IP system. The United States of America allowed patenting of DNA sequences for years until very recently in the Myriad Breast Cancer Gene Case that was overturned by the court. DNA was a product of nature and no matter how much one purified it, it could not be patented.

79. Steven Bailie stated that there was a need for further research on the value of GR for innovation, including: what percentage of patenting activities involved GR; what was the monetary and economic value of that innovation; and what were the possible costs involved in some of the proposals. Patent examiners did not have the capability to assess whether or not a particular contract was a proper legally binding contract and what it meant. In Australia, the patent applicant made a declaration that he was entitled to apply for a patent. There was no need for the patent examiner or the patent office to assess whether the contracts that supported the entitlement to apply for the patent were valid or not. If at some point in the future that entitlement was challenged, the courts could look at that. There were also specialist departments within the Australian patent office that would look at the validity of that contract if required. Regarding the EU proposal on mandatory disclosure and the Swiss proposal on enabling countries to choose to require disclosure, he preferred the EU proposal. But it would be administratively easier that provider countries should have some responsibility to monitor how their GR were used. If they were able to search patent literature and find out where their particular countries were named, they would be able to follow up with patent applicants on their acquisition of the GR. He believed that the variety of regimes around the world undermined certainty for users of the patent system and providers of GR.

80. Lucia Fernanda Inácio Belfort pointed out that some experts had mentioned that in the patents she cited earlier there were references to the origin of the GR. When those patents were filed, it was after the coming into force of the CBD, thus, even when the disclosure requirement had been complied with, the sovereign rights of the states had not been respected. Brazil, as well as other countries, had authority to determine the appropriate access to GR and would have to ensure the rights of Indigenous Peoples, on a national basis. She believed that the disclosure of origin was a complementary mechanism which facilitated the traceability of the information. However, in the Nagoya Protocol, for instance, an internationally recognized certificate of compliance was needed, which had to be granted by the providing country of the GR for the sake of legal certainty. She provided a link (<http://www.amazonlink.org/biopiracy/index.htm>) to a website, which was an illustrative example

of why the IP system needed to be improved facing other international obligations and existing rights that had not been respected.

81. Jesús Vega Herrera considered that B.1 required further discussion within the IGC, given the recent approval of the Nagoya Protocol. It was necessary to discuss whether the mandatory disclosure requirement would provide certainty to the users of GR in the various IP systems, particularly within the patent system, and whether that requirement would be in line with the Nagoya Protocol. If the mandatory disclosure requirement was to be part of the IP system, further analysis was required to determine the pros and cons of that requirement and considering which would be the objectives and principles that it would aim to cover. New elements which had emerged from discussions on this topic in different fora were: the terminology or glossary that would be used for a possible mandatory disclosure requirement; the mechanism needed to include that terminology in the existing IP measures or legislations; the consequences and practical issues in the use of terminology for the disclosure requirement in the formal or substantive examination of an IP application, in particular, within the patent system; whether the disclosure requirements would be established for the purpose of determining the patentability of an invention or to comply with measures established outside the IP system, for instance, the requirements set out in the Nagoya Protocol; the international legal instrument or instruments which could be considered in order to include the disclosure requirement within its procedures; whether the measures for disclosure requirements would be formal or substantive or perhaps a combination of both; the legal criteria and measures which would trigger the disclosure requirement; the sanctions if the disclosure requirement was not complied with, either inside or outside of the IP system; the costs and benefits of implementing the disclosure requirements in the various procedures relating to the different IP rights, in particular, patents; and the information that needed to be disclosed in IP applications, particularly in patent applications, to achieve the objectives of the disclosure requirement, for instance, the following: the source of the GR and/or associated TK, the country of origin of the GR and associated TK, the country that granted access to the GR and associated TK, the proof that PIC was granted and MAT were established, utilization of the GR and associated TK claimed by an IP application, whether this information was authorized by PIC or under MAT, and access permits or internationally recognized certificates of compliance. If the mandatory disclosure requirements were established to support the compliance measures set out in the Nagoya Protocol, it would be necessary to analyze the following aspects: The pros and cons of the IP offices as checkpoints; how the IP offices could help to monitor and enhance transparency on the use of GR and associated TK, and support compliance measures in the user countries established in the Nagoya Protocol, considering the most efficient way how those offices could help to achieve those objectives, and the pros and cons of establishing such measures; whether the internationally recognized legal certificate of compliance established in the Nagoya Protocol could be part of the disclosure requirement and the pros and cons of establishing such a measure; how a link could be established between the IP offices and the Clearing-House Mechanism set forth in the Nagoya Protocol and what information would be disclosed and later transmitted by the IP offices to the Clearing-House Mechanism or to the relevant international authorities identified in the Nagoya Protocol. It was necessary that all the proposals on the negotiating table on the disclosure requirements would be part of and related to the objectives and principles while determining whether they would make it possible to achieve such objectives and principles. It was also necessary to determine the relationship or link with the texts which were being negotiated in the IGC on TK and TCEs, and to clusters A and C. The IWG should send out a clear recommendation so that the IGC continued with the compilation of practical cases, pertaining to cases of disclosure, particularly providing information available in countries that already had a mandatory disclosure requirement, specifically, information disclosed in a particular country, the consequences of not complying with the requirements, and the possible benefits and issues identified by both, the users and the IP offices themselves, whether it be during the process of substantive examination or in post-grant situations.

82. Imad Abou Fakher supported options A.1 and B.1.

83. Martin Girsberger stated that the Swiss proposals were submitted because the importance of increasing transparency with regard to ABS was recognized. The new provisions on the disclosure of the source of the Swiss Patent Law entered in force in 2008, so there had been only a limited number of cases where this requirement applied. The patent experts in Switzerland stated that there had been no problems with putting those provisions into practice. He was also not aware of any negative reaction of patent applicants so far. As regards to the trigger of the disclosure requirement, the disclosure of the source was required where the inventor had had access to the GR or related TK. Furthermore, the invention had to be directly based on the GR or TK. As regards the concept of source, he did not see how patent applicants were unnecessarily burdened. In fact, the concept of source was specifically chosen to avoid any undue burden. Source should be understood in a broad sense to include all possible sources of GR and TK. Consequently, no complicated inquiries or searches were to be carried out by the patent applicant. He recalled that Article 17 of the Nagoya Protocol in the context of checkpoints referred to the concept of source. According to his national solution, the patent office did not have to verify the truthfulness of the declaration of the source. The disclosure of the source to the competent authorities was intended to further enhance the transparency and increasing function of the disclosure requirement. With regard to a national and contractual approach as the means to resolve the issues arising with regard to ABS, he wondered: how a purely national and contractual approach would address problems arising with regards to transboundary ABS; how a purely contractual approach would address cases where no ABS had been concluded between the provider of GR or TK; and how the proposed approach would take into account the generally long-term nature of research and development activities involving GR. In particular, how a purely contractual approach could ensure that the obligations arising from the contract would be fulfilled, even if between the conclusion of that contract and the end of the research activities lied several years and the people originally involved might no longer be involved. He also wondered what specific proposals beyond the establishment of a database would increase transparency in ABS.

84. Lilyclaire Elaine Bellamy stated that, regarding mandatory disclosure, the benefits accrued and to be accrued from the use of GR should be considered. Relating to the traceability of GR, for endemic GR it was easy to find out the location from where it was obtained. Regarding the specific situation in the Caribbean in terms of sharing of GR, since the climatic conditions varied throughout the region, results were not always the same, for example, the arabica which was planted for the coffee in the Blue Mountain Range had a distinct taste from the one that was planted in the low lying region. She understood all the difficulties that were raised and the burdens, but she suggested considering the benefits. For that reason, she supported the mandatory disclosure as in B.1.

85. Carmen Adriana Fernández Aroztegui stated that specific examples of patents that involved GR and associated TK were very useful to identify the problems experienced by some holders of resources. It would be important to have a numerical assessment of how many cases had actually occurred in order to find the best way of protecting the resources. The importance of establishing databases needed to be assessed and those databases could be a parallel protection system to the patent system. She believed that disclosure of origin or the source of GR and associated TK could be done in several ways. For instance, a certificate could be submitted apart from the description in the application, or the disclosure could be part of the description of the invention. In the last case, the disclosure would contribute to fulfill the requirement of sufficient disclosure. That disclosure would not change the assessment of novelty, inventive step or industrial application. If the disclosure requirement was not complied with, the patent application might not be further processed.

86. Nicolas Lesieur welcomed that, though the experts' views expressed so far on a mandatory disclosure in the context of a possible international instrument were different, it was



useful to focus more and more on technical issues, so as to make progress. A number of experts had noted important points on disclosure requirements, in particular, that having a system of disclosure requirements did not improve the quality of patents, nor did it make it easier to decide whether or not an invention was patentable. However, this was seen by others as one of the main benefit and reason for introducing such a requirement. If the disclosure requirement contributed neither to determine novelty nor to examine inventive step, it could only have marginal benefits for the patent system and the examination of those criteria. He believed that that was the reason why the main arguments for the disclosure requirement were questioned, and he noted an inequality between the function and the potential benefits of the requirement. The potential solution was far from a panacea, if one would consider the difficulties, if not impossibilities and undesirability, for communities putting GR and TK into databases alongside the remaining option of an eventual disclosure process. In this process, the patent applicant would disclose the source, if this was possible without causing legal disputes in the case of more than one source of GR or TK. Since the objective of that system was to enhance transparency, awareness raising and participation of indigenous communities, it was clear that different complementary mechanisms had to be considered.

87. Krisztina Kovács emphasized that the EU proposal was seeking to serve as a tool in order to provide information for GR. That would facilitate the monitoring of the respect of any benefit-sharing arrangements. The proposal did not lead to new requirements with regard to patentability and there was no intention to change the existing criteria. Regarding the burden on patent offices, it was clearly set out in point 5, paragraph 2 of the EU's proposal that competent patent authorities were not required to make an assessment on the content of the submitted information. They should not be obliged to keep track of whether the patent applicant obtained the relevant material in a way compatible with benefit-sharing and PIC. They were required to check whether the formal requirements were fulfilled, in particular, whether the applicant declared whether it was based directly on GR and associated TK. Therefore, she did not believe that this would put an undue burden on patent offices. Regarding legal uncertainty, she believed that the scheme was very clear about the consequences of not meeting the formal requirement on the disclosure. It worked as any formal requirement in patent law. If the requirement was triggered, there would be a formal check of whether or not the application was in accordance with the new requirement. There would be a possibility to remedy the omission. If the applicant continued to fail to make the declaration, the application would not be further processed. This was the normal sanction in patent law. Sanctions outside the field of patent law would be imposed in the case of incorrect or incomplete information. Exactly for the reasons of legal certainty, the submission of incorrect or incomplete information should not have any effect on the validity of the patent or on its enforceability. So those points were actually tackled by points 5 and 6 of the EU's proposal. The term "directly based on" meant that the invention had to make immediate use of the GR, that it was dependent on specific properties of this resource. Regarding the burden on applicants, point 3 of the EU's proposal clearly stated that the applicant should be required to declare the source of GR if he was aware of it. No additional research on his part would be required. If the country of origin was unknown, the applicant should declare the source to which the inventor had had physical access. Thus, she did not believe that there would be a burden on the applicant in having to trace back the GR. She endorsed the questions raised by Martin Girsberger.

88. Tom Suchanandan stated that there was a recurrent theme throughout the interventions made by the experts from developed countries, namely that there was a need for a fact-based discussion centered on a cost analysis of national experience regarding the disclosure issues. The industrialized countries had a valid fear of losing protection and revenue. In a recent study conducted by the Pacific Research Institute, it was estimated that uncertainty of patent protection would result in 27 per cent decrease in biotechnical and pharmaceutical research and that would result in approximately 150 to 200 drugs. But there was a need to do a social impact study on patents derived from developing countries, particularly those developing countries which paid a very high premium for patented products that were reintroduced in their countries.

Regarding the administrative costs, a study should be conducted in terms of the cost that resulted from fraudulent and false submissions, as well as the cost that resulted from the verification of patents. He also believed that there should be a study on the incentive measures, rather than the administrative costs and the other costs mentioned by Steven Bailie.

89. Marcus Goffe believed that any concern that related to burdens, additional costs, reorganization of systems and offices would be subsidiary and secondary to that primary objective. He supported Debra Harry on the point that the objective was to repair the injustices of the past. A system which was more balanced and recognized the rights of nations would provide certainty. The argument on the costs and the personnel was not a suitable response to object to mandatory disclosure. As Martin Girsberger pointed out, contracts which were managed by private parties could not really secure the rights and safeguard against misappropriation. Therefore, unless the opponents of the current mandatory disclosure proposal could provide alternative safeguards that could effectively and adequately safeguard GR and TK, what should be done was to provide something that could work, keep the costs down and seek to address the overarching objective to protect GR and TK. Regarding the proposals from the EU and Switzerland, he believed that whereas the disclosure requirement should not be a criterion of patentability, it should be a condition for the granting of a patent and upon which it could be revoked if not complied with. That was the best way to enforcement and recognition of those rights to prevent misappropriation. In terms of alternative proposals, unless there was some tangible proof on those grave concerns, he suggested moving forward and seeing how to bridge the gaps with some sensible alternatives that could meet the objectives.

90. Heng Gee Lim indicated, with reference to the problem of confidentiality of certain information that was kept in the proposed database, that some of the experts had stated that that information would only be used by patent offices and examiners and, therefore, the information would be kept secret and not be made available publicly. However, in a situation where an examiner refused an application on the grounds of lack of novelty because of the content of the database, the patent office would have to submit a copy of that prior information in the database to the applicant, in fairness to the applicant, so that he might be able to carry on further arguments in the course of his prosecution. Once that that document was given to the applicant, he wondered what would prevent the applicant from making use of the information, showing it to his colleagues or to other firms. In that case, the confidentiality would be destroyed forever.

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