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

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RESPONSES TO QUESTIONS REGARDING NATIONAL-LEVEL DATABASES AND AN INTERNATIONAL PORTAL

Document submitted by the Delegations of Canada, Japan, Norway, the Republic of Korea and the United States of America

1. On March 26, 2014, the International Bureau of the World Intellectual Property Organization (WIPO) received a request from the Mission of the United States of America to the United Nations Office and other International Organizations, on behalf of the Delegations of Canada, Japan, Norway, the Republic of Korea and the United States of America, to make available a document entitled "Responses to Questions Regarding National-Level Databases and an International Portal" as an information document for the Twenty-Seventh Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, under Agenda Item 6.

2. Pursuant to this request, the Annex contains the document referred to above.

3. The IGC is invited to take note of this document and the Annex to it.

[Annex follows]

#### Responses to Questions Regarding National-level Databases and an International Portal

1. National Offices and other entities have been compiling databases of knowledge, including traditional knowledge (TK) associated with the use of genetic resources (GR), and information about GR, for some time. In addition to existing databases, there is ongoing work to create new databases. Some databases may contain only knowledge that is deemed TK in that community. Other databases are broader and collect all knowledge about a specific topic, such as the use of GRs. Some offices may collect TK and GR information together, while other offices treat information about GR and TK as two different types of data, or even make a distinction between TK and TK associated with the use of GR (TKa). Definitions of TK may vary. Also, national practices may differ regarding whether or not TK (particularly oral TK) can be considered when determining the novelty of an invention in a patent application.

2. The purpose of this document was to compile questions that have been asked in the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) regarding the creation and use of databases for GR and/or TK, questions that were asked outside of the IGC, and possible answers to these questions. The objective of this document is to inform the creation of future databases and decision making with respect to a portal that could facilitate the searching of these databases together.

3. This document compiles the comments of Canada, Japan, Norway, South Africa, the Republic of Korea, Sweden, and the United States of America that respond to these questions. Additional questions and responses are welcome so as to have a good basis upon which to inform future decision making. As discussions on databases continue, the responses to the questions compiled below may change, and further questions may arise. In this respect, we welcome further questions and additional responses to these questions, as well as the questions below.

#### **General comments:**

#### South African comment

4. South African Department of Science and Technology, the custodian of the Indigenous Knowledge Systems' (IKS) portfolio in government have developed a National Recordal System to document IKS for multiple purposes ranging from research, bioprospecting, preservation and knowledge management and governance.

5. The participation in this questionnaire does not imply that we have conceding to the view that the use of databases is the only measure for the protection of Genetic Resources and its associated TK. Our participation signifies recognition of databases as useful tools that compliment the effective protection through legal instruments that attribute the right to grant or deny access to indigenous knowledge to local and indigenous communities; recognize the need for prior informed consent, mandatory disclosure of origin and source and recognizes local and indigenous communities as beneficiaries to their knowledge.

6. We further note that the questions were extremely biased towards the use of databases for patent search; we have consistently preferred the application to more than the patent system. The limitations and the narrowness of the questions have also been noted.

7. We acknowledge also that this is not a WIPO commissioned study and to that extent it is voluntary to participate in the process. We participate knowing consciously our different

approaches to the subject matter. We just wish to reiterate our position that it is in the interest of all parties to subscribe to a mandatory disclosure as it is a critical element in the use of genetic resources.

#### Swedish comment

8. Regarding prior art our law is in line with the European Patent Convention articles 54(2) and 54(3) e.g. including oral disclosure and prior use.

9. Regarding secret information including secret TK, as prior art, this has to be decided on a case to case basis. I cite the Swedish AIPPI group concerning "Current standards for prior art disclosure in assessing novelty and inventive step requirements, Q167". "Whether the disclosure is public or not has to be determined in casu. Relevant aspects are i.a. the number of people who received the information, the relation between the persons who received the disclosure and the inventor and whether there is any explicit or at least implicit agreement on confidentiality. A generally applied rule is that, if a large or indefinite group of persons have had an opportunity to receive the information, then the disclosure has taken place. It is irrelevant whether anybody did actually make use of that possibility, it being sufficient that the opportunity has existed".

10. Regarding (in) proper title to an invention, this is handle by the courts (see section 17, 18, 64 and 65 of the Swedish Patent Law available@WIPO Lex) and hence not an issue for the patent office.

#### National Level Databases

#### Purpose, Utility and Legal Effect:

#### How is the database used/how will the database be used?

#### Canadian comment

11. The database will be a tool for examiners to search for prior art which may be used as a source for determining whether the claims of a patent application are novel and inventive (non-obvious).

#### Japanese comment

12. This database is intended to be used by patent examiners in each country to conduct prior art searches, in order to prevent erroneous granting of patents. In this database, prior art information including documentation on GR and TK associated with GR is stored. A patent examiner conducts a prior art search by using this database, when appropriate, to make use of relevant information so as to make a decision on patentability of applications, such as novelty and inventive step.

#### Norwegian comment

13. The Norwegian Industrial Property Office does not have its own national databases but have access to the European Patent Office databases that can route queries to *e.g.* India's TK database.

#### South African comment

14. The database is used for educational, public interest, research and bioprospecting. It is also used to investigate misappropriation to prevent the granting of patents for codified disclosed indigenous knowledge.

#### Republic of Korea comment

15. Anybody can have access to the database free of charge only if they sign up via traditional knowledge portal Internet service. KIPO and its related organizations support to enable users to get access to the database via Open API. KIPO would improve the function of Open API this year.

#### US comment

16. A database of traditional knowledge would be available for searching by potential patent applicants and patent examiners in making patentability decisions. In addition, the database could be available for researchers, so as to study the knowledge of indigenous people and local communities.

#### Are there enough GRTK databases already?

#### Canadian comment

17. It is difficult to answer this question without knowing the extent and breadth of existing GR and TK. The current database coverage that is in a format that is usable for patent examination could be more extensive. However, new databases may be redundant if the information overlaps with what is already publicly available elsewhere. While a consolidation of databases available may be useful, it is recognized that this may not be possible. In order for a database entry to be useful in determining whether a claimed invention is novel and inventive, a relevant database entry must pre-date the date of the patent claim in question, and it must be publically available to be cited in accordance with the Canadian *Patent Act*.

#### South African comment

18. No.

#### Republic of Korea comment

19. TK and GR related with TK has been focused on so far, however, information on genetic resource (GR) would be supplemented henceforward.

#### Would new databases be redundant?

South African comment

20. No.

## What is the value added? What is the feasibility of having a database of GRs and/or TK to demonstrate that an invention lacks novelty or does not have an inventive step?

#### Japanese comment

21. To date, a number of TK-related databases have been identified (see WIPO/GRTKF/IC/3/6 Annex II). Most notably, India and Republic of Korea are known to have established their own online TK digital libraries (TKDLs) designed to be used for prior art searches by IP offices. Considering that (1) in patent examination, it is necessary to search for prior art worldwide to ensure the principle of universal novelty, and (2) that TK associated with GR has been uniquely developing in each country/region, those databases which may be created by interested countries by collecting information on GR/TK in their countries and made available for examiners in and outside the countries, would improve efficiency and completeness of prior art searches. This enables examiners to make the right judgments in terms of determining whether or not an invention lacks novelty and inventive step with relevant prior art information at hand.

#### South African comment

22. Currently only one database exist, housing data which is in the public domain.

#### Republic of Korea comment

23. KIPO adds information on chemical compound on the database of medicinal herb so as to take its advantage in the research of medicine today.

#### US comment

24. Each WIPO Member has traditional knowledge associated with genetic resources, and genetic resources that are different from other WPO Members and the collection and compilation of such information would be beneficial and may not replicate information found elsewhere. These databases are feasible, but whether they are cost-effective will depend upon the WIPO Member and the number of databases that already exist to compile the information.

# Given that there are already many excellent databases of GR *per se* (e.g., Global Biodiversity Information Facility) as well as databases of scientific literature on GR and their molecular constituents that patent offices use already (e.g., Chemical Abstracts) – what contribution does/would a new database of GRs make?

#### Canadian comment

25. It is difficult to answer this question without knowing the extent and breadth of existing GR and TK. A new database of GRs would only be useful if it provided additional information to what is already publicly available.

#### Norwegian comment

26. It may simplify the search procedure by making it easier to conduct more systematic search that covers the content of several databases.

#### South African comment

27. These databases serve specific roles for example Global Biodiversity Information Facility focuses on making scientific data on <u>biodiversity</u> available via the <u>Internet</u> using <u>web services</u>.

The data are provided by many institutions from around the world. What is of primary concern for us that much data that was recorded in the absence of prior informed consent?

#### US comment

28. A database is the interface together with the content. Not all databases have the same content. Also, not all databases have the same search functionality. There may be value in creating additional databases that are more stable (have the same search results each time), which do not track the users or their search queries, that are more amenable to being linked with other databases, and which are available to not only patent examiners, but others, so that a prospective patent applicant can conduct a search and decide whether to file a patent application.

### How would/do national GR/TK databases relate to, or interact with, the CBD clearing house?

#### Canadian comment

29. GR/TK databases should be separate from the CBD clearing house.

#### Japanese comment

30. The CBD clearing house, which serves as a means for sharing information related to access and benefit-sharing; and the GR/TK databases that are used for searching prior art, have different purposes. It is assumed that, in principle, there is no relation or interaction between them. According to its own judgment of each country, however, the same information as that which is under the control of the CBD clearing house may be included in its own domestic GR/TK databases.

#### Norwegian comment

31. The various databases serve different purposes. Information could have a bearing in both and a possible link between databases would be beneficial during the search and examination of a patent application. The consequences must be assessed individually.

#### South African comment

32. There are two clearing house mechanisms envisaged by the CBD, namely clearing house mechanism and ABS clearing house mechanism.

#### US comment

33. Databases may have no linkage to the CBD clearinghouse.

#### What is/would be the legal effect of information being stored in the database?

#### Canadian comment

34. There is no legal effect to the information in the database. Information stored in a database can be used as prior art citable for novelty and/or inventiveness to prevent patents, based on claims to old and known GRs/TK, from being granted, provided that the relevant database entries are dated and publically available.

#### Japanese comment

35. Storing the information in a database would result in no change as to the legal effect of the information.

#### Norwegian comment

36. This depends on a range of factors and the legal effect in relation to patent processing would probably be that a listing would be an indication of certain facts.

#### South African comment

37. This would depend on the level of access. The NRS will be established under its own law, which would provide for a sui generis protection for indigenous knowledge. The legislation also provides for the establishment of registers, that record and registers local community knowledge and technologies.

#### Republic of Korea comment

38. The information does not have any legal effect. KIPO expects that information in the field of traditional knowledge is systematically organized, thus it being used for research and development in the related field, as well as for patent examination.

#### US comment

39. There would be no legal effect of information being included in the database.

## If information that was placed in the database was not intended to be in the public domain, what, if anything, can be done to ensure GRs and/or TK are not in the public domain once on the database?

#### Japanese Comment

40. If any information that was not intended to be in the public domain was stored in a database, only publicly available part of such information could, where applicable, be cited as prior art. It should be noted that the use of said information is limited to patent examination procedures only. In order to prevent unauthorized use of GR and/or TK stored in the database, it would be useful to add a note of caution indicating that the information is not in the public domain and belongs to its holder.

41. If any secret information was stored in a database, the search result for this type of information should indicate this. Therefore, some means of ensuring that the said information would not be cited as prior art by an examiner would need to be established. When an examiner searches the information concerned, for example, a warning should be given not to have the information be utilized as prior art.

#### Norwegian comment

42. If the information is already in the public domain, this cannot be altered and the information can be used.

#### South African comment

43. The information resides in a restricted level. Access to confidential level is subjected to the legal framework; PIC, NDA, M/ITA, BS etc.

#### Republic of Korea comment

44. As it is laid open to the public, we do not have to ensure knowledge is not in the public domain.

#### US comment

45. If the database is to be available to patent examiners, as well as to the public then it should only contain information that is eligible to be prior art. If trade secret or other secret information is included in the database, then there should be a mechanism to have the information be deleted, unless it is shown that the information was in fact separately published.

#### What is/would be the status of protection of GRs and TK when put on a database?

#### Canadian comment

46. The database would be used as a search tool and not as an indicator of the status of protection of the GRs and TK on the database.

#### Japanese Comment

47. By storing GRs and TK on a database, the status of protection of such GRs and TK concerned should not and must not be changed.

#### Norwegian comment

48. The inclusion of information in a database cannot predetermine possible protection of GR/TK.

#### Republic of Korea comment

49. The answer is the same as above.

#### US comment

50. The information in the database should not be secret information, and examiners relying upon the database should be able to use the inclusion in the database as proof that the information was made public and eligible to be used as prior art to reject a claim or claims of a patent application.

Does/Would the database contain only prior art? Information that is secret would only be prior art if it was known by the inventor. What would be the utility of including non-prior art information in the database? What is the date of publication if TK in a database is to be considered prior art?

#### Canadian comment

51. Secret information cannot be used as a bar to patentability in Canada. As such, the only potential value in including non-prior art or secret information in the database would be to

prompt a patent examiner to look elsewhere for a publically available version of the information, if available, that could then be cited for novelty and/or inventive step. If the database was the only source of information, it could not be used to prevent patenting of the GR/TK. In order for TK in a database to be considered prior art, the TK entry in the database must pre-date the date of the patent claim in question.

#### Japanese comment

52. It is a basic concept that a database should store only GR/TK that is accompanied by citable information as prior art. However, this should not necessarily prevent secret information from being stored in a database, because even this kind of information may be useful for patent examiners as reference materials. (For example, there may be cases where even though examiners may not be able to cite such secret information itself as prior art, they, bearing in mind that such information does in fact exist, may be able to find relevant, publicly known prior art by searching other databases). When secret information is stored on a database, this should be clearly indicated, and appropriate measures should be taken so that examiners do not cite the said information as prior art.

#### Norwegian comment

53. Databases should be a measure to avoid erroneous grant of patents. The databases should only contain information that can constitute prior art. Therefore information on secret TK should not be contained in databases

#### South African comment

54. No, the database would not only contain prior art. The NRS contains both codified and uncodified undisclosed African Traditional Medicines, offering primarily defensive protection, whilst on the other hand it supports exclusive positive rights. The database will provide an effective search tool to prevent the granting of patents for codified disclosed indigenous knowledge. The utility of including non-prior art information in the database would be preservation but more importantly disclosure of this information would destroy novelty and would render the holder incapable of obtaining intellectual property protection even if the knowledge fulfils the necessary criteria under applicable protection laws. Given the nature of indigenous knowledge, the date of disclosure cannot be clearly determined. As to the date of publication, the date of disclosure into the database will suffice as the publication date. This provides a source of legal certainty, since determination of relevant dates is paramount intellectual property examination. As to the legal test for asserting that a GR or TK is in the public domain and is, therefore, part of prior art, in the absence of a substantive search and examination system, there is no legal test for asserting that a GR or TK is in the public domain.

#### Republic of Korea comment

55. Among traditional knowledge resources, the database stores only the information containing technological factors.

#### US comment

56. Yes, the information in the database should be entitled to be considered as prior art. Of course, exceptions may apply where, for example, the database entry contains a disclosure of a local community, and within an applicable grace period, inventors within the community file a patent application on an improvement to the knowledge, genetic resource or expression disclosed in the database. In such an instance, the database entry may not be prior art to that applicant.

## What is prior art? What is the legal test for asserting that a GR or TK is in the public domain and is, therefore, part of prior art?

#### Canadian comment

57. In Canada, in accordance with sections 28.2(1) and 28.3 of the Canadian *Patent Act,* information must meet the following conditions in order for it to be considered as prior art:

- the information must have a verifiable date;
- the information must be generally available, without restriction, to members of the public; and
- the person or persons receiving the information, to be categorized as members of the public, must have no special relationship to the author of the document. (e.g. subcontractors).

58. For a database entry to be citable as prior art in Canada, it would have to be publically available, i.e. it cannot be "secret". An examiner must disclose the contents of the prior art in the examiner's report to explain why it is being applied against the patent application. An applicant must be able to review the cited prior art as well.

#### Norwegian comment

59. According to the European Patent Convention and the Norwegian Patent Act the prior art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the patent application. This legal test is applied to all forms of knowledge, including TK.

#### South African comment

60. As to what is prior art, whilst we take a dim view of traditional knowledge as prior art we hold that prior art generally refers to the entire body of knowledge which is available to the public before the filing date or, if priority is claimed, before the priority date, Information that is secret would only be prior art if it was known by the inventor. As to the legal test for asserting that a GR or TK is in the public domain and is, therefore, part of prior art, in the absence of a substantive search and examination system, there is no legal test for asserting that a GR or TK is in the public domain.

#### Republic of Korea comment

61. It refers to centuries-old TK-related books, reports and papers, as well as the ones published in the public domain in the modern age, containing technological factors, such as raw materials and manufacturing method, and etc.

#### US comment

62. In the United States, prior art is defined by Title 35 of the United States Code, Section 102. It is noted that information can be in prior art, but not in the public domain (e.g., an earlier issued patent).

## Does/Would the database contain only prior art? What would be the utility of including non-prior art information in the database?

#### South African comment

63. No, a combination of both. The database will provide an effective search tool to prevent the granting of patents for codified disclosed indigenous knowledge by making the documentation data available to patent examiners as searchable prior art.

64. Non-prior art information should not be included in the database, as it would not be useful to examiners.

#### Method of use by Patent Examiners:

## Does/would a disclosure of source requirement in patent applications assist an examiner to use the database? If so, how?

#### Canadian comment

65. Disclosure of source may direct patent examiners to a database that has relevant prior art. However, examiners may find this database already based on the description in the patent application and their knowledge of the subject matter.

#### Japanese comment

66. Information on the source of GR does not include any technical information relevant to patentability. Therefore, disclosing the source of GR would not assist an examiner in terms of when to use what database for prior art searches. As clearly shown in the case of Turmeric, in which the patent at issue clearly described the source of turmeric, it is important to conduct a complete and effective prior art search in order to prevent erroneous granting of patents, whereas information on the source of GR does not contribute a thing in terms of judging whether or not an invention lacks novelty and inventive step.

#### Norwegian comment

67. The disclosure requirement would be an enabler for more specific and directed searches.

#### South African comment

68. Yes: it would give legitimacy of use and exploitation of the genetic resource and traditional knowledge. The legal basis for disclosure requirement may therefore have its roots in the laws and regulations of the source country.

#### Republic of Korea comment

69. There is no special requirement.

#### US comment

70. Disclosure of the source would not assist a patent examiner in patent examination or to use a database. Examiners need to conduct comprehensive searches, and should not be distracted by a suggestion that a resource comes from a certain part of the world to erroneously conclude that knowledge from that part of the world would be more useful than knowledge from other parts of the world.

If the database is used by a patent examiner, how does/could the examiner use the data in the database? If the examiner finds an entry in the database that contains published information that shows that a claimed invention is not novel, how does/would the examiner use the database entry to inform the applicant that the claim was rejected?

#### Canadian comment

71. If an examiner finds an entry in a database containing published information that shows that a claimed invention is not novel, the examiner cites the database entry as prior art in the examination report, and provides a detailed explanation of how the proposed invention shows lack of novelty for the given claim(s). The examination report is then available for public inspection the Canadian Intellectual Property Office. Such reports should eventually also be accessible via the internet. A copy of database entries cited in the examination report may be provided to the applicant, upon request.

#### Japanese comment

72. A patent examiner uses databases in order to conduct a prior art search for patent applications under examination. When finding such information that defeats the patentability of a patent application in question, as a result of having searched a database, the examiner notifies the applicant to that effect by citing publicly available information described in the database entry.

#### Norwegian comment

73. The Norwegian Industrial Property Office would cite the original publication/public demonstration of TK. If the database entry is the only written source we would cite the database entry.

#### South African comment

74. Since the information is already published, the database should demonstrate its source of the information and there is no problem to use such disclosed information. Request for information will be electronic- with the filling in of the appropriate pro-forma.

#### Republic of Korea comment

75. All the data provided are licensed, enabling to transmit them free of charge. Thus, it is permissible to transmit the information that examiners find to applicants by printing them in a PDF form. There is no problem unless information is intentionally downloaded in volume.

#### US comment

76. Examiners using the database would look for prior art to show that a claimed invention is not novel or lacks inventive step, or to make decisions related to whether the disclosure is sufficiently complete and utility/industrial applicability. When an examiner finds an entry in a database that is relevant to their decisions, the examiner would notify the applicant and cite the information from the database entry, and generally provide a copy of the database entry.

## Would an examiner cite the database entry, or the original publication/public demonstration of TK?

#### Canadian comment

77. The examiner could cite either of these, but generally the examiner would cite the database entry, unless the original publication/public demonstration of TK was available.

#### Japanese comment

78. A patent examiner does not cite a database entry itself, but cites the publicly available information on TK described in the database entry.

#### Norwegian comment

79. See answer above.

#### South African comment

80. Yes, both approaches would be acceptable.

#### US comment

81. An examiner could either cite the entry or, where there was a prior publication/public demonstration, cite the original document.

What controls are in place/would be placed on the information that is documented as part of the patent review process? E.g., oral information must be written down to be entered into the database and be searchable. If the entry in the database corresponding to the oral information is used by the examiner to reject a claim of a patent application, the information would be made public so that all reviewing the patent application can understand the proceedings. Thus, normally the information would not be controlled once used, it would be freely accessible even without reference to the database.

#### Canadian comment

82. In Canada, outside of an initial 18 month confidentiality period, all patents and patent applications are accessible to the public at the Canadian Intellectual Property Office. Eventually this information will also be accessible via the internet. As stated above, the examination report, which may contain citations to entries in a database are also available for public inspection at the Canadian Intellectual Property Office.

#### Japanese comment

83. An examiner does not cite a database entry itself but cites the publicly available information on TK described in database entries. The form of citation is generally based on WIPO Standard ST.14. For cases in Japan, as long as there are no contractual restrictions regarding copyright, a copy of the non-patent literature (NPL) cited in the notice of reasons for refusal of a patent application is sent to the applicant, limited to the scope that is necessary for conducting patent examination processes. However, making copies of such a NPL sent to the applicant is prohibited for any purposes other than those necessary for patent examination processes of that patent application in question. Note that anyone is allowed to browse such NPLs cited in patent examinations via dedicated terminals at JPO, but no third parties, i.e., persons who are not the actual, concerned applicants themselves, are allowed to request copies.

#### South African comment

84. This question is phrased in such a way as to place information in the so called public domain by virtue of being used to disqualify a patent. This implies that any information that is in database that has not been used in previous RDI and has not been disclosed and cannot be disclosed by virtue of being utilized to validate or invalidate an application for a patent.

85. Data is documented in oral format and data fields on the information are extracted. Extracting the answers to the questions for the meta-data from the recorded material and entering it into database makes it searchable. Not all data whether it is rejected by a patent application is to be made publically available. Prior informed consent and non-disclosure agreements entered into between the IK holder and the project could place some restriction on whether the data is to be placed in the public domain. All data sourced from the database **must** acknowledge the source where it was mined or where it comes from.

#### Republic of Korea comment

86. As anybody can use the information on the database free of charge, applicants can use them freely just after signing up.

#### US comment

87. Information that is made available as part of the patent review process would be available to the public, if a copy of the complete file history is purchased. Access to non-patent literature would not be viewable through the electronic file history of the patent application (the USPTO Patent Application Information Retrieval System).

## Is/Would the information that is documented as part of the patent review process then be given to an applicant as due process requires?

#### Canadian comment

88. The applicant is provided with the examiner's report which may contain written citations to relevant database entries. If requested, a copy of the relevant database entries cited may be provided to the applicant.

#### Japanese comment

89. Same as above.

Norwegian comment

90. Yes

#### South African comment

91. Yes. Only if the information was already used and is in the so called public domain. Otherwise the information that is oral and undisclosed cannot be placed in the public domain. Just like all researchers who are given access to the information sign confidential agreements, information used from the NRS requires signing of confidential agreements as it is not in public domain. but based on authenticated access and use agreements

#### US comment

92. Yes, the applicant would be provided with a copy of the documentary evidence showing that the claimed invention was not novel/lacked inventive step.

## Would applicants have access to whatever information that would be used? Also where the office makes files available, then would the data from the database that was found by the examiner be available?

#### Canadian comment

93. As stated above, the applicant would have to be given access to the documented information as they need to be able to respond to the examiners citation of this prior art in the applicant's response to the examination report. This could be done by the applicant having access to the relevant database entry, or the office could provide a copy of the information to the applicant at the applicant's request. Also mentioned above, subject to the 18 month confidentiality period after filing of the patent application, information or documents in the patent office, including patents, applications, and examiner's reports, are generally open to public inspection.

#### Japanese comment

94. Same as above.

#### Norwegian comment

95. Yes.

#### South African comment

96. No. Only applicable information and subject to a high court ruling, or having met the access criteria set out by NRS

#### US comment

97. Yes, applicants would have access to the information that would be used. Third parties may not have access to the complete database entry, through the USPTO Patent Application Information Retrieval System, so as to reduce the risk of copyright infringement.

#### If the examiner finds an entry in the database that corresponds to the claimed invention, but there is no indication that the database entry was published or known to the inventor, what would the relevance of the entry to the patent application process?

#### Canadian comment

98. If the database entry was not publically available, it cannot be cited as evidence of lack of novelty or of inventive step. In Canada, such prior art must be publically available to be citable and secret, non-published information cannot be used as evidence to prevent the granting of a patent application. If there is information publicly available that constitutes prior art demonstrating that a claimed invention is not novel and/or inventive, it is not relevant whether the prior art was actually known to the inventor.

#### Japanese comment

99. Database entries not accompanied by publicly available information cannot be cited as prior art. These types of entries, which can be useful as reference materials for examiners conducting examination, cannot themselves become prior art.

#### Norwegian comment

100. The documentation would be used in the proceedings.

#### South African comment

101. All entries in the NRS are linked to holder/community, given that no entry is made in the absence of PIC. In any event, one of the conditions is an undertaking that access is in conformity with national laws, or in the absence of applicable law consistency with international treaties.

#### Republic of Korea comment

102. The data largely consist of papers, ancient documents and modern publication (books, reports, and etc.), and all the data contain publishing information on primary source documents.

#### US comment

103. A date that the entry would have been available as prior art will always be included in the database. There is no requirement in US patent law that an inventor have actually known of the information for the information to be prior art.

#### Should possible databases be part of the PCT minimum documentation?

#### Canadian comment

104. These databases, where available, could be part of the PCT minimum documentation, provided they are useful to determining patentability (i.e. are publically available, dated records).

#### Japanese comment

105. Possible databases would be able to be part of the PCT minimum documentation, if the Meeting of International Authorities under the PCT (PCT/MIA) so agreed taking into account a precedent of Republic of Korea Journal Traditional Knowledge (see PCT/MIA/15/4 and 13) and the six criteria agreed for the selection of TK-related periodicals (see, paragraph 12 in PCT/MIA/7/5, Annex I of PCT/MIA/10/4).

#### Norwegian comment

106. If the quality of the database is reliable and structured it would make sense to have it as a part of the PCT-minimum documentation.

#### South African comment

107. Yes, the database must allow for free text searching of the data by using the PCT search engine. However, the search and retrieval of indigenous knowledge within the NRS differs from the IPC- base prior art searches.

#### US comment

108. Whether a database becomes PCT minimum documentation should depend upon the usefulness of the database, and whether the database is actually available to all international searching authorities.

#### Access to and Use by Other than Patent Examiners:

## Does/would a database enable a GR or TK holder/provider to know if their GR or TK had been used to develop an invention claimed in a patent application?

#### Canadian comment

109. This is unlikely, unless patent information was also put into the database.

#### Norwegian comment

110. If the specification of a granted patent refers to GR/TK as the closest prior art the holder/provider could use this information to assess whether there is a connection.

#### South African comment

111. Yes, so long as the rules of engagement are set out property.

#### US comment

112. No. If a patent is granted, and an entry in the database was cited by the patent examiner during examination, then the entry will be printed as part of the "References Cited".

## Are/Would databases be available only to intellectual property offices? If yes, to whom and what are/should be the conditions of access and use and required security measures?

#### Canadian comment

113. While Canada does not have significant experience with the use of GR/TK databases, where Canada's Canadian Intellectual Property Office has used GR/TK databases, access and use to those databases has been governed by an agreement with the provider of the database. Such agreements include provisions regarding confidentiality and disclosure. However, conditions of access, use and security must permit the citation of a database entry, where it constitutes prior art, in the examination report and must allow for the applicant to have a copy of the relevant database entry(ies).

#### Japanese comment

114. Since databases are designed to prevent erroneous granting of patents, they basically should be accessible only by IP Offices, which conduct patent examinations. However, in terms of the importance of conducting prior art searches to applicants and licensees, Members may wish to consider the possibility of allowing public access to such databases in the future.

#### Norwegian comment

115. This is dependent on the content. If they only contains prior art they should be available for everyone. Others than intellectual property offices should though pay to obtain access.

#### South African comment

116. No. It would be available to other institutions such as the competent authorities (CBD) and WHO platforms. Offices accessing the NRS will be subjected to the legal framework; namely MoU, NDAs etc.

#### Republic of Korea comment

117. The general public, as well as examiners of KIPO, can access the database.

#### US comment

118. No, any USPTO-owned database would be available to the public. Other national databases would be free to determine their own conditions for access.

Are the databases, or would they be, subject to disclosure under a country's freedom of information or access to information laws (.e.g., laws that provide that resources that have been developed using public funding shall be available to the public)?

#### Canadian comment

119. Canada's Access to Information Act (AIA) outlines that records under the control of a government institution are subject to public access. Therefore, a database in the Government's control could be subject to disclosure. However, the AIA also outlines several exceptions to the general rule of disclosure. One of the exceptions does not allow the information to be released so long as it was obtained in confidence from the government of a foreign state or institution thereof, from an international organization of states or an institution thereof, or from an aboriginal government.

#### Norwegian comment

120. If the databases only are available to intellectual property offices, the content of databases as such would not be subject to disclosure under Norway's freedom of information act or other laws. Extracts from a database that is used in proceedings and presented for the applicant and/or other parties would be subject to disclosure to the public according to provisions in the Norwegian Patent Act. If the databases are available for everyone, those who want access cannot use the freedom of information act but must comply with conditions for obtaining access to the database.

#### South African comment

121. Yes. The Promotion of Access to information Act, grounds refusal of access to records based on certain conditions. For example access may be refused if the record contains information which was obtained or is held by the Service for purposes of enforcing legislation concerning the collection of data if the record contains secrets of a third party, financial, commercial, scientific or technical information, other than trade secrets, of a third party, the disclosure of which would be likely to cause harm to commercial or financial interest of that third party; if information is supplied in confidence by a third party that puts the third party at a disadvantage in contractual or other negotiations. The Act gives effect to the constitutional right

of access. The State may refuse access to records of indigenous knowledge if refusal is based on a ground listed in section 34 of the PAI Act.

#### US comment

122. Any USPTO-owned database would be available to the public. The USPTO database of patents and patent application publications is available at the USPTO and at Patent and Trademark Depository Libraries, and any similar database of TKGR would be available to the same. As a result, FOIA would not apply.

123. As a general principle for legal certainty (and to avoid unnecessary legal costs at a later stage), a prospective patent applicant should be in a position to conduct a complete prior art search before filing for a patent and file a patent application so that the claims distinguish the invention from any prior art. Moreover in the case of an opposition and in the case of third party observations, a third party needs to be able to study prior art.

## How is the database intended to ensure that sufficient information could be available to third parties?

#### Norwegian comment

124. The database should be open to third parties.

#### Is the database a compilation of information obtainable from other sources?

#### Canadian comment

125. At a minimum, content could include:

- Name of the GR/TK
- Origin of the GR/TK
- Bibliographic details this must include a publication date to be used as prior art for the purposes of patent prosecution.
- Modern or scientific names to plants, diseases, or processes, and establishes relationship between traditional knowledge and modern knowledge

#### South African comment

126. This question is double barreled. Disclosure of knowledge/ prior art may be within the description itself, or by reference to relevant document:

- As to how is the database intended to ensure that sufficient information could be available to third parties? and/or;
- As long as the necessary legal documents are said, information will be available to the third party;
- As to is the database a compilation of information obtainable from other sources? Yes, its an add on but includes information collected for the first time and that will be protected

#### US comment

127. Prospective patent applicants would be able to search any USPTO TKGR database. The database would be collect information that is available through other sources.

#### Content:

#### What is/should be the content of the databases?

#### Japanese comment

128. The databases should at least include documentation on GR as well as traditional knowledge associated with GR. Furthermore, each Member State could include data other than GR or TK in the database at their discretion, if the data can be considered as prior art based on the Member State's laws and practices.

#### Norwegian comment

129. Information on genetic resources. Information on TK that not is secret, that is TK that could comprise prior art.

#### South African comment

130. This is a nonsensical question.

#### Republic of Korea comment

131. National academic papers selected as related to traditional knowledge (TK) among the ones in the fields of traditional medicine and food.

132. Record regarding traditional technologies, such as traditional medicine, traditional food, traditional crafts, agriculture and the art of living, and etc., extracted from ancient documents and its translation into modern language.

133. Modern research papers published based on TK

#### US comment

134. The database would contain information that would be important to patent examiners to understand the entry, and the date as of which the entry would be prior art. For example, for genetic resources, the entry would contain a description of a plant, pictures or drawings of the plant, known names and uses of the plants, as well as growing conditions for the plant.

## In some countries, oral disclosure is considered prior art, and a particularly crucial point of such disclosures are the fixation of a date and the origin of the information. How could oral information be provided in the database?

#### Canadian comment

135. A written, dated transcript of an oral disclosure could be provided in the database, and this written record could then be used as prior art for the purposes of patent prosecution.

#### South African comment

136. All data has extensive metadata that is linked, whether it is a video, a picture, a document, including the persons that are associated with creation of the dataset.

137. Perhaps important to note that whilst a fixation date is entered this does not translate to the date of existence (retrospective) of the oral nature of the TK. Of course oral information is

used by communities of practice who protect it and exercise the right of providing or denying access. This question is phrased mischievously.

#### US comment

138. Oral information could be included in a database by including a transcript of the information.

## What elements are/should be required for data in database? Should there be minimums, such as knowledge, and holder, if known, and if a holder is known, contact information for the holder and source, if source, if known?

#### Canadian comment

139. See above regarding content of the database. In terms of holder and contact information, this is not necessary or useful for the purposes of using the database as a source of information on prior art that may be used to determine whether a claimed invention is novel and inventive.

#### Japanese comment

140. Data that is useful for examiners in judging novelty or inventive step should be stored in the database. From that perspective, in addition to reference to documentation of GRTK which includes sufficient technical content so as to qualify as prior art including ability to ascertain prior art date, the name and a brief description of the GR is at least necessary. On the other hand, it should not be obligatory to store information on PIC or MAT, as such information does not contribute to decisions on patentability.

#### Norwegian comment

141. It should be a minimum in the way as indicated in the question.

#### South African comment

142. Yes. Some of the metadata standards followed at international level are extensive Dublin Core, International patent classification, International Classification of Diseases (depending on the subject matter of the database).

#### Republic of Korea comment

143. Publication information of primary source documents, such as the publication date and the title.

#### US comment

144. The minimum for an entry would be a description of the GR, and a date.

## Does/Should the database have information that could not be used by a patent examiner to show that an invention does not have novelty or lacks inventive step because the information was secret and thus would not be evidence to defeat patentability?

#### Canadian comment

145. From a Canadian perspective, what is most useful is information that could be used to show whether an invention is novel and inventive. Other information could help a patent examiner find an alternate source of the information to cite. However, if the patent examiner

cannot find such a source, there would be nothing to refute the novelty and/or inventive step of the claim(s) in question.

#### Japanese comment

146. In principle, information that is not assumed to be used as prior art by examiners should not be included in the database. Secret TK, which might be useful as information for examiners, may be included in the database depending on the discretion of each country.

#### Norwegian comment

147. No, it should not have such information.

#### South African comment

148. The definition of what is secret varies according to who is looking at it. There is difference between the sacred and secret and communities deal with such differently. The question is posed within the paradigm of convention IP. The answers to the question posed would only produce a narrow handling of the concept secret.

149. The NRS has a list of data fields organised in categories to facilitate grouping of related data which includes inter alia biographical information, date of entry; technical information, data on the GR and TK local and scientific names, taxonomic data on collected species, satellite localisation of areas and communities where materials have been collected, identification of parties, agreements etc.

#### US comment

150. No, information that is not able to be cited as prior art should not be included in the database.

## Does/Would the database contain oral information? If yes, what method would be used for capturing this in the database?

#### Canadian comment

151. See above regarding recording oral disclosures.

#### Japanese comment

152. The format for data, which is to be stored in the database, will be dependent upon the formats that are acceptable as prior art under the laws and practices at each Member State. If a Member State considers oral information to be a prior art, then it should be possible for this type of information to be included in the database. In such a case, however, the Member State is encouraged to convert the oral information into a format such as text that can be searched on the database by examiners.

#### Norwegian comment

153. In that case it must be written down. We are though skeptical to gather oral information in the databases because it will require a lot of resources.

#### South African comment

154. Yes. Audio recording, video recording.

#### Republic of Korea comment

155. As all the information is collected from books published in the public domain, even if the database contains oral information, the database would not be the first public medium.

#### US comment

156. The database could contain oral information, but it would need to be able to be searched electronically. If the technology permits oral information to be searched, then a transcription would not be required.

## How does/would the database address issue of language and translation in order to be accessible by all Member States?

#### Canadian comment

157. Database providers should make their databases available in the official languages of WIPO to make them accessible for WIPO Member States' patent offices. It would need to be considered whether WIPO could play a role to assist database providers in this regard.

#### Japanese comment

158. It would be a good idea for each Member State to translate into English the names of GRs and related keywords that they store in their own languages in their own respective databases. In addition, if the Member States cooperate in creating a list of technical terms in multiple languages for the technical terms on GR, this would streamline the work of translating the data on GR into English. Another means for overcoming the language barrier would be to create a classification for GR, and search for prior arts using the classification. However, this method will take a long time. As for language issues, it would be beneficial if we could share experiences and practices of Member States that have existing database on TK, such as India and Republic of Korea.

#### Norwegian comment

159. Latin names on plants and other biological resources.

#### South African comment

160. Catalogue information can be converted into text in the six UN languages. Furthermore, the NRS has technology capabilities of allowing knowledge base conversions of indigenous names into scientific names. The knowledge collected will all be kept in indigenous languages of the knowledge holders.

#### Republic of Korea comment

161. Papers include English abstract. Information on traditional medicine is provided in English, as well as in Republic of Korea. Other information may gradually be translated into English.

#### US comment

162. Information is entitled to be considered as prior art, no matter what language the information is conveyed in. That said, for plants, there may be no dictionary that translates a local plant name to other languages. As a result, it would be helpful if databases include any

known alternative names of a plant. In addition, it would be helpful for the database to itself include an English translation of the entire entry so as to facilitate its use.

#### Structure and Guidelines:

#### Are there/Should there be minimum standards to harmonize structure and content?

#### Canadian comment

163. Ideally there would be a standardized structure and content to facilitate the searching of the database by patent examiners and to have the content easily understood by all users.

#### Japanese comment

164. Minimum standards to harmonize the structure and content of the databases is necessary so as to enable examiners in each country to search databases of other countries in a seamless manner, that is, in the same way as they search the database in their own countries.

#### Norwegian comment

165. That would be helpful.

#### South African comment

166. Yes. These should include data format standards preferably define rules for encoding documents in a <u>format</u> that is readable both by a user and <u>machine</u> this would preferably be XML. In addition there should be both transmission and security standards.

#### Republic of Korea comment

167. Information on primary source documents should be included. Reference should be added to promote its use among users. IPC classification should be assigned.

#### US comment

168. Yes, minimum standards would facilitate interoperability.

#### In what form is/should the content be expressed?

#### Japanese comment

169. The content should be in formats such as text, drawings, or images that can be searched by examiners on the database.

#### South African comment

170. Content is expressed in oral format (in the vernacular), sound (vernacular), written (in vernacular). The NRS expresses content in different forms depending on its intended use.

#### Republic of Korea comment

171. Title, the original, modern interpretation, source, and the IPC.

#### US comment

172. The form of the content will depend upon the nature of the entry, but generally images and text would be included. In addition, where a genetic resource is an animal, a sound file may be appropriate.

## Are there/Should there be more than one database, e.g., a public database, a confidential database, and private databases? If yes, what kind of information should be contained in each type of database?

#### Canadian comment

173. For patent prosecution, the database must be publicly available. Consequently, a confidential and/or private database would not be useful in preventing a patent from being granted to old and known subject matter.

#### Japanese comment

174. Since any or all of these databases would be intended to be used for patent examinations, we should first attempt to set up a database accessible only from IP offices. We should subsequently consider the possibility of providing the same kinds of databases for applicants to use, by taking into account the function, efficiency, and security of the database as well as the needs of applicants.

#### South African comment

175. Given the technology there is no need to have several databases for the same objective as these could be linked.

176. Of particular concern is the US position on-non patent literature databases that deal with traditional knowledge. We would prefer each member state develops its own classified non-patent literature database.

#### Republic of Korea comment

177. Public database only.

#### US comment

178. Any USPTO database would be public, there would be no confidential or private database at the national level. Groups within the US may decide to establish separate databases with confidentiality.

#### Should the content be classified according to the International Patent Classification?

#### Canadian comment

179. Having the content classified according to the International Patent Classification would further assist patent examiners in finding any database records relevant to the patent claims they are examining.

#### Japanese comment

180. Based on the perspective of streamlining prior art searches, we support the concept of assigning classification to the contents. On the other hand, it would be necessary to verify whether GR/TK uniquely developed in each country can be effectively classified using the existing IPC. It would be practical to first enable text searches and subsequently consider the possibility of assigning classification such as the IPC, in the process of developing the database.

#### Norwegian comment

181. The content should have some form of patent classification.

#### South African comment

182. Not necessarily, given that TK is not aligned to the IPC.

183. The NRS will adopt similar appropriate classification tools as the TKDL, namely the Traditional Knowledge Resources Classification as presented to the Special Union for the IPC. We support harmonisation of existing IP documentation standards and traditional knowledge documentation standards, and their consistent application, would be important for IP Offices to enable them to integrate standardized traditional knowledge documentation data into their existing procedures for filing, examining, publishing and granting IP titles. Such a system would be likely to enhance the system of search and examination of TK in prior art searches. However, the NRS is not being developed for the patent offices; they will be one of the many users of the system.

#### US comment

184. Yes, providing the ability to search according to the IPC would be useful, but is not absolutely necessary, especially if there would be a significant cost to doing so.

#### Are there/Should there be accompanying guidelines?

#### Canadian comment

It would be helpful to have a manual of how to use the database, and what types of data are recorded and how each entry is presented.

#### Japanese comment

185. Guidelines on maintenance and utilization of the database should be created in order to enable patent examiners to efficiently conduct prior art searches when using the database, as well as ensure the confidentiality of data on the GR stored on the database.

#### South African comment

186. Not necessarily as the IPC is adequate, however there needs to be a revision of the IPC to include a new sub-class covering traditional knowledge subject matter. In reference to guidelines we are wary of the Operational Guidelines on Treatment of Technical Information Disclosed on the Internet as Prior Art released by the Japanese Patent Office.

#### US comment

187. Yes, guidelines on the maintenance and utilization on databases would be useful for their creation and maintenance.

#### Responsibility and Cost:

#### Who is/should be responsible for compiling and maintaining the database?

#### Japanese comment

188. The types and formats of the data that is to be stored on any database depend on the domestic laws and practices in each Member State, so each Member State should be responsible for compiling and maintaining the database.

#### Norwegian comment

189. WIPO in cooperation with the member states.

#### South African comment

190. In view of the exorbitant costs, the state usually bears this responsibility. There are however, examples were private business developed their own database.

191. Given that the state has sovereignty of its resources database containing information of the resource must be the responsibility of the state.

192. Finally, a mandatory disclosure requirement within an international Treaty should be provided for.

#### Republic of Korea comment

193. The Republic of Korea Intellectual Property Office (KIPO) is responsible for the works, however, specialized research institutes by each field collect, translate and add information on publication on a regular basis.

#### US comment

194. Who is responsible for compiling and maintaining the database should depend upon the WIPO Member. In the United States, some information may be compiled in a database, but indigenous and local communities may decide to create their own databases as well.

How can we/should we ensure that universities or others which have information about traditional knowledge and genetic resources share that information with the country from which they obtained the information so that the information can be included in a database?

#### South African comment

195. Information in most universities 'libraries, archives and special collections were not obtained with permission from local and indigenous communities and hence their rights to that information is suspect. Wholesale dumping of such information in prior art database is problematic.

196. Universities receiving public funds are subjected to the South African Publically Financed Research Act of 52, which obliges researchers to benefit share.

#### US comment

197. Third parties who have previously collected information about traditional knowledge could be encouraged to help populate a database, but if the indigenous peoples provided the information to the university or museum no longer exist or have a different view on the information being made public, it may be overly complicated to compile the information.

## Who provides/would provide the data to be entered into the database? Could information be added to the database without prior informed consent of the holder of the information?

#### Japanese comment

198. The data to be stored in a database would be provided by stakeholders. Member States should consult with their respective stakeholders on what type of data should be stored in the database.

#### Norwegian comment

199. This will depend on whether the information is protected according to the legislation in the jurisdiction from where the information is collected. For example, if information is to be collected from existing databases consent from the owner would generally be required.

#### South African comment

200. Holders and indigenous and local communities, the researchers who also collect such information legally would be encouraged to deposit the information in the NRS. No.

#### Are/Should national authorities be compelled to develop TK databases? If not, why not?

#### Canadian comment

201. No. National authorities should be encouraged to do so only where relevant TK holders have an interest in and want such databases and where it would be useful to and mutually supportive of the existing intellectual property regime. There may be other non-intellectual property public policy reasons for having TK databases that go beyond the objective and scope of this exercise.

#### Japanese comment

202. As TK has been uniquely developed by each country, it is desirable for each country to create its own database. On the other hand, since technical difficulties are involved in creating databases, WIPO should provide the States the necessary technical support and sufficient time that will enable them to develop their databases.

#### Norwegian comment

203. No. This will not be relevant for all national authorities. Development of databases is mainly in the interest of holders of TK. If the holders not wish databases to be established there is not desirable to require that national authorities nevertheless should do so.

#### South African comment

204. No. Databases are only one form of protection, there are others. Secondly, the development of soft and hardware is a costly affair, as the management of the database. Thirdly, Anglo and Francophone African member countries are parties of regional intellectual property institutions which could develop these databases.

#### Republic of Korea comment

205. KIPO has annually added information by gathering related information and has requested other branches having related information to register to promote the use of the information.

#### US comment

206. No, national authorities should not be compelled to create a database.

### If the responsibility and costs for setting up of these databases rests at the respective country/IP-office:

What measures can be made to motivate countries to set up these databases, in particular in developing countries rich in GR and associated TK?

#### Japanese comment

207. WIPO should hold a seminar for developing countries on the necessity of creating a GR/TK database for patent examinations. We hope that the Member states, including the Republic of Korea and India, which already have their own databases, would participate in the seminar and talk about their experiences to the developing countries.

#### South African comment

208. Measures that aim at stopping Bio-piracy and misappropriation of its GR associated with TK, Preservation of its IK/TCEs and attribution of ownership of the TK and TCEs to local and indigenous communities and holders.

#### US comment

209. WIPO Members should decide for themselves whether to establish a database, and should be free to decide that a national database is not in their interest.

## What mechanisms for cooperation between countries setting up databases, as well as with WIPO, could be foreseen to make the establishment of databases cost-effective and to provide solutions to common obstacles/problems?

#### Japanese comment

210. WIPO should hold symposiums on the GR/TK databases at regular intervals. At the symposiums, Member States will share their experiences and discuss ways for creating a more cost-effective database.

#### South African comment

211. The development of regional databases

#### US comment

212. WIPO should organize meetings of those authorities who have created or are creating databases.

### What technical assistance will WIPO be able to provide to member states (developed, developing and least developed) to establish national databases?

#### South African comment

213. Technical and capacity building: Assisting developed countries to replicate the NRS as it makes provision for both codified and uncodified systems of knowledge. Member states having publically available traditional knowledge the TKDDL is the answer.

#### US comment

214. WIPO should attempt to meet the needs of WIPO Members.

#### Security Concerns:

#### Are security measures necessary?

#### Republic of Korea comment

215. KIPO prepares systematic security measures against information systems hacking attacks, and all the information on the database has publishing information on primary source documents. Thus, it cannot be said that simple manipulation of database has a decisive effect on matters of rights.

## If security measures are necessary, because the database contains information that is not public, what security measures are used/could be used to protect data in the database?

#### Japanese comment

216. Security measures are certainly necessary. In order to protect data in the database, a password (PIN) should be created, which must be used to access the database and which would be shared by the examiners.

#### South African comment

217. Yes. Security measures are definitely necessary. The database caters for positive and defensive protection. Security measures such as encryption, access tagging is important.

218. Data encryption, access tagging, access and security policies (operational), Authenticated access to information

#### US comment

219. In general, security measures should not be necessary, as the information in the database should only be public information. The search queries, and information about who is searching the database should not be viewed by others, and if a search query is to be saved by the person conducting the search, it should not be available by third parties and there should be security measures in place to ensure that searches are not monitored.

## Has your database(s) ever been subject to a security risk or breach? If yes, what was the nature of the risk/breach and how, if at all, was it resolved/addressed?

#### US comment

220. The US does not have a TKGR database, so this question is not applicable.

## How can holders of TK (especially secret and/or sensitive TK) be confident that their TK will be only included in the database with their consent?

#### Canadian comment

221. Those establishing and maintaining databases should take steps to ensure that holders of TK are consulted and understand the implication of and support the publication of their TK on a database.

#### South African comment

222. Legal agreements to be signed by IK coordinators (i.e. Non disclosure agreements), Legal agreements to be signed by IK recorders (i.e. Non disclosure agreements), And Prior Informed Consent signed with IK holder,

#### US comment

223. Holders of TK should only permit their information to be placed in a USPTO database if it is intended to be used as prior art.

#### **International Portal Site**

## What should the structure be? How could the international portal site best interlink Member State databases?

#### Republic of Korea comment

224. KIPO provides Open API as well as Internet portal service for examiners, so they can take advantage of the services by adding its functions to an examination system. The function of Open API would be strengthened this year.

## How could we ensure no hacking or other security breaches occur affecting other linked Member State databases?

#### Japanese comment

225. It is important to establish ways to ensure that hacking and other malicious actions will not affect linked databases. In this respect, we hope that the knowledge possessed by the WIPO, which coordinates various initiatives with the Member States, could be put to use. Moreover, it would be useful for any Member States that have worked in cooperation with other States and created databases among themselves to share their experiences.

#### South African comment

226. We are very wary of an international portal site, as the African group previous indicated it would be become very complex as the site diversifies be becoming larger. The fear of its inoperability.

#### Republic of Korea comment

227. KIPO prepares systematic security measures against information systems hacking attacks, and all the information on the database has publishing information on primary source documents. Thus, it cannot be said that simple manipulation of database has a decisive effect on matters of rights.

## How would one click database make prior art search effective without mandatory disclosure requirement, as examiners already have access to other countries' databases such as in India and Korea?

#### Japanese comment

228. Although examiners already have access to existing databases, it cannot be said that they are utilizing those databases effectively. At present, they have to independently access each database in order to conduct prior art searches. Furthermore, the ways to search the databases vary from database to database. Creating an international portal site will enable one-stop searches on all the databases in the world. This would be possible by entering keywords on the site, which will significantly improve the efficiency of conducting prior art searches.

#### South African comment

229. No one would want to place their knowledge into databases which have no mandatory disclosure to track the use of its knowledge assets.

230. We are of the view that Examiners should also review all known databases and registers of traditional knowledge in order to ensure that patents actually involve an inventive step.

231. India and Korea are poor examples as both their traditional knowledge is codified and publically available.

#### Republic of Korea comment

232. As Korea and India each have the original culture, the database of each country is largely different from each other. Thus, it depends on users what to search first between the databases.

#### US comment

233. A one-click database would operate independently of any mandatory disclosure requirement. Such a database, or search interface, would allow an examiner to quickly search a number of databases.

## Would it help examiners know which database should be searched first, if the patent application discloses the source of GR?

#### Japanese comment

234. No, it wouldn't. Information on the sources of GR does not affect decisions as to patentability, so the efficiency of prior art searches by examiners will not be improved even when information on the source of GR is disclosed in a patent application. If it becomes possible to search each country's database through a single portal site, examiners will not be burdened with the need to choose which countries' databases they should use to conduct searches.

#### South African comment

235. The portal site would never provide an integrated tool for prior art search for legally protected IK

#### US comment

236. A mandatory or even optional disclosure requirement would not be useful to patent examiners.

How would WIPO ensure that all databases in the portal meet agreed/common standards on the information e.g., so that the information is reliable, specific, indicates a clear origin of the information, a clear date of fixation and is easily retrievable in a standardized manner?

#### Canadian comment

237. This may raise issues for existing databases.

#### South African comment

238. There should be a universal functionality and technical specification put in place

#### US comment

239. WIPO could establish standards for databases that would permit their interoperability.

[End of Annex and of document]