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INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

Tenth Session

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RESPONSE TO THE QUESTIONNAIRE ON RECOGNITION OF TRADITIONAL KNOWLEDGE AND GENETIC RESOURCES IN THE PATENT SYSTEM

Document prepared by the Secretariat

1. The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee') decided at its sixth session to develop a questionnaire on prior art criteria and draft recommendations to authorities responsible for patent search and examination to take greater account of traditional knowledge (TK) systems (on the basis of document WIPO/GRTKF/IC/6/8 and the previous proposals set out in that document). Between the Committee's sixth and seventh sessions, a questionnaire on recognition of TK in the patent system (WIPO/GRTKF/IC/Q.5) was prepared and circulated to all WIPO Member States, as well as other stakeholders. The contents of this questionnaire were drawn from previous Committee work on these issues, including a series of Member State and regional group proposals (as outlined in WIPO/GRTKF/IC/6/8).
2. The questionnaire covered both legal and practical aspects of the recognition of prior art, including the legal characteristics of relevant prior art used in determinations of novelty and non-obviousness (inventive step), the actual sources of prior art that are used in search and examination, other aspects of search and examination procedures, and provisions or case studies specifically concerning the recognition of TK and genetic resources during search and examination.

3. Document WIPO/GRTKF/IC/9/INF/6 provided a collation of responses to the questionnaire received up to November 2005. It included responses from Argentina, Armenia, Australia, Austria, Azerbaijan, Bangladesh, Bolivia, Brazil, Bulgaria, Burundi, Chad, China, Colombia, Congo, Croatia, Czech Republic, Denmark, Egypt, , Fiji, Finland, France, Georgia, Germany, Ghana, Iceland, Ireland, Italy, Japan, Kenya, Lithuania, Malaysia, Mauritius, Mexico, Republic of Moldova, Monaco, Netherlands, Norway, Panama, Philippines, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Senegal, Singapore, Spain, Sweden, Thailand, Tonga, Trinidad and Tobago, Turkey, Ukraine, Venezuela, Viet Nam, Eurasian Patent Office and European Patent Office.

4. Since the ninth session of the Committee, a further response has been received and is annexed to the present document.

*5. The Committee is invited to take note of the contents of the Annex to this document in relation to documents
WIPO/GRTKF/IC/9/INF/6 and
WIPO/GRTKF/IC/9/8.*

[Annex follows]

ANNEX

Responses from the Government of Canada to:
Questionnaire: Patent procedures and traditional knowledge
(WIPO/GRTKF/IC/Q.5)

Submitted to the World Intellectual Property Organization (WIPO) Intergovernmental
Committee (IGC) on Intellectual Property
and Genetic Resources, Traditional Knowledge and Folklore

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PART I: ROLE OF THE OFFICE

The questions in part I seek to clarify the role of the patent authority in your jurisdiction, to give a basic context to the remainder of the questionnaire. If the patent authority does not conduct search and substantive examination, then you need only answer Parts I, II and V.

Q1. Prior art searching: In your jurisdiction, is a search conducted for relevant prior art during the prosecution of a patent application? If so, when is the search conducted? What triggers the search (e.g. a routine step during patent procedure, at the request of patent applicants, or at the request of third parties)?

Yes. The Canadian Intellectual Property Office's (CIPO) Patent Examiners conduct searches for relevant prior art during the prosecution of a patent application, and these searches are triggered after CIPO has received a formal request for examination, and all the necessary documentation and fees from the applicant pursuant to section 35 of Canada's Patent Act (PA).

Q2. Substantive examination: In your jurisdiction, are patent applications given substantive examination? If so, when is the examination conducted, and what triggers the examination (e.g. a routine step during patent procedure, at the request of patent applicants, or at the request of third parties)? Is examination conducted at the same time as searching, or separately? What procedures exist for third parties to challenge the validity of a patent application or a granted patent?

Yes. CIPO conducts substantive examinations upon request by a patent applicant pursuant to section 35 of the PA. A request for examination must be made within five years from the date of filing in Canada. Search and examinations of patent applications are conducted concurrently. Pursuant to s. 34.1, any person can submit prior art that has a bearing on patentability on any claim in an application for a patent. A re-examination procedure of any

claim of a patent is available under section 48.1 of the PA by filing prior art. Search and examinations of patent applications are conducted concurrently.

PART II: LEGAL CHARACTERISTICS OF PRIOR ART

The questions in Part II concern the legal standards that define what material is eligible for consideration as prior art, and can therefore be considered when assessing the novelty and non-obviousness (inventive step) of a claimed invention. The sources of these standards may include legislation, regulations, judicial and administrative decisions, and office guidelines.

Q3 General scope of prior art relevant to novelty: What is defined in your jurisdiction as prior art that is relevant to the determination of an invention's novelty? Does it include:

- (i) information that is published in written form locally or in foreign countries?*
- (ii) information that is orally disclosed locally or in foreign countries?*
- (iii) other information, such as public working of invention, secret use of the invention? If so, please specify.*

Pursuant to section 28.2 of the PA, prior art is generally defined as everything disclosed in such a manner that it becomes available to the public in Canada or elsewhere before the "claim date", which is the day on which a patent application is filed in Canada. If the subject matter defined in an application is disclosed in a prior art reference, it is considered to be anticipated by the reference, and therefore lacks novelty. In Canada, prior art includes information that is published in written form locally or in foreign countries.

Q4: Nature of disclosure: Are there any established standards or criteria for determining the content that a prior art reference must disclose in order to be relevant (e.g. sufficient information to enable a person skilled in the art to carry out the claimed invention)?

If this entails reference to a person skilled in the art, how is that concept defined?

Pursuant to section 28.3 of the PA, the subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to

(a) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and

(b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere. Courts in Canada have defined "a person skilled in the art" as a hypothetical person possessing the ordinary skill and knowledge of the particular art to which the invention relates, and a mind willing to understand a specification that is addressed to him. This hypothetical person has sometimes been equated with the "reasonable man" used as a standard in negligence cases. He is assumed to be a man who is going to try to achieve success and not one who is looking for difficulties or seeking failure. While the hypothetical "ordinary worker" is deemed to be uninventive as part of his fictional personality, he or she is thought to be reasonably diligent in keeping up with advances in the field to which the patent relates. The "common knowledge" of skilled workers undergoes continuous evolution and growth.

Q5. Specific conditions for recognition of prior art: What other specific conditions apply in determining whether a certain piece of prior art has been sufficiently disclosed to be taken into account?

(i) Public availability: If the prior art must be available to the public to be relevant, how has the relevant public been defined - e.g. what is a public setting, and what form of disclosure amounts to availability? Alternatively, what kinds of semi-public disclosure or disclosure within a private setting have not been counted as relevant disclosure of prior art?

(ii) Languages: Is prior art counted if it is only available in foreign languages (including dead languages), or minority languages?

(iii) Publication: If prior art must be ‘published’ to be taken into account, what criteria apply for prior art to be an eligible form of publication?

(iv) Internet or electronic publication: What counts as publication or public availability on the internet or on other digital networks?

Is there a requirement for networks to be publicly accessible?

Is material on proprietary (pay for use) databases or digital networks included as potential prior art? Does this apply to databases or networks that are private, for example accessible only by members of a particular community, or employees of a particular company, university or research institute?

What conditions apply for material uploaded on the Internet to be taken into account as prior art?

(v) Other conditions: Are there any other conditions that can determine whether certain information can be taken into account as relevant prior art?

(i) Public availability: The PA does not define what “available to the public in Canada or elsewhere” means within section 28.2. Courts in Canada have looked to the common language meaning of this expression in their interpretations.

(ii) Languages: Prior art can be in any language.

(iii) Publication: The PA does not require “publication”. Prior art only needs to be “available to the public in Canada, or elsewhere”.

(iv) Internet or electronic publication: Materials available on the Internet may be considered publicly available.

(v) Other conditions: Pursuant to section 34.1 of the PA, any person can file prior art with the Commissioner of Patents that the person believes has a bearing on the patentability of any claim in an application for a patent.

Q6. Establishing the effective date of prior art: What determines the effective date for prior art to be cited against a patent application?

What standards of evidence are required to demonstrate that a written disclosure was published on or by a certain date?

What standards of evidence are required to demonstrate that an oral disclosure was made on or by a certain date?

What standards of evidence proof are required to demonstrate that material was published on-line?

For a patent document, is the effective date the priority date, filing date or publication date?

Pursuant to section 28.2, so long as a document is published or information is made publicly available before the priority date of the patent, it then becomes prior art. Respecting the sub-questions outlined above, neither the PA or PR set out exhaustive rules respecting standards of evidence. The validity of evidence is assessed on a case by case basis.

Q7. Continuity of publication: Does material have to be continuously available to be relevant as prior art, or does it remain valid even if it has been withdrawn from circulation or made inaccessible to the public for a certain period?

Does a published disclosure have to be continuously publicly available to be counted as prior art?

Does material published on the Internet or other publication have to be demonstrated to be continuously available to be counted as prior art?

Materials respecting prior art do not have to be continuously available, whether it is disseminated via the Internet or by other media.

Q8. Specific decisions or guidelines: In your jurisdiction, have there been any specific judicial or administrative decisions, or examination guidelines, that refer to the status of TK or genetic resources as prior art for the determination of novelty? If so, please give details.

Inventions are not patentable if they are found to lacking in novelty. Genetic resources and traditional knowledge may both be considered in an examination of a patent.

Q9. Prior art base for non-obviousness: Please describe in general terms the prior art that may be taken into account when determining whether an invention is non-obvious (or involves an inventive step).

in what respects does it differ from the standard that applies to prior art for the assessment of novelty (with reference to the issues raised in questions 3 to 6)?

Pursuant to section 28.3 of the PA, the subject matter of an invention claimed in a patent application must not have been obvious to a person skilled in the art on the claim date. When determining what is obvious to a person skilled in the art, the section directs the Courts to take into account information disclosed more than one year before the filing date by the applicant, and all information disclosed by persons other than the applicant before the claim date.

Q10. Person skilled in the art: What standards apply to determining the person skilled in the art (or equivalent test) when assessing non-obviousness (inventive step) in your jurisdiction? - If an element of TK (including TK associated with certain genetic resources) is considered available to or accessible by the public outside the original community that holds the TK, but the skills to interpret or practice the art of TK are limited to the community only, how would the person skilled in the art be assessed for the determination of inventive step?

In Canada, Courts have interpreted “a person skilled in the art” to mean a hypothetical person possessing the ordinary skill and knowledge of the particular art to which the invention relates, and a mind willing to understand a specification that is addressed to him. This hypothetical person has sometimes been equated with the “reasonable man” used as a standard in negligence cases. He is assumed to be a man who is going to try to achieve success and not one who is looking for difficulties or seeking failure. While the hypothetical “ordinary worker” is deemed to be uninventive as part of his fictional personality, he or she is

thought to be reasonably diligent in keeping up with advances in the field to which the patent relates. The “common knowledge” of skilled workers undergoes continuous evolution and growth.

Q11. Specific decisions or guidelines: In your jurisdiction, have there been any specific judicial or administrative decisions, or examination guidelines, that refer to the status of TK as prior art for the determination of non-obviousness (inventive step), or concerning practitioners of TK as persons skilled in the art? If so, please give details.

No. There have been no judicial or administrative decisions, or examination guidelines that refer to the status of TK.

PART III: SOURCES OF PRIOR ART IN PATENT PROCEDURES

The questions in Part III concern the actual mechanisms that are used during patent procedures to locate potentially relevant prior art.

Q12. General sources of prior art: What are the sources of prior art that are considered during patent procedures:

- (i) Voluntary disclosure by applicants within patent specifications?*
- (ii) Mandatory disclosure by applicants? If so, how is the obligation defined?*
 - disclosure must be within the patent specification?*
 - disclosure must be separately submitted to the patent authorities?*
- (iii) Searching within your office?*
- (iv) International searches (under the PCT)?*
- (v) Searches from other sources (such as from other patent offices)?*

Sources of prior art that are considered during patent procedures in Canada include

- (i) voluntary disclosure by applicants within patent specifications
- (ii) mandatory disclosure by applicants
- (iii) searches by CIPO Patent Examiners
- (iv) international searches under the PCT
- (v) searches from other sources including those conducted by other patent offices

Q13. In-house searching: If searching is undertaken in your office during patent procedures, what are the sources searched:

patent documents?

non-patent literature (printed)?

non-patent information (electronic/on-line)?

Do searches regularly make use of any sources (databases, journals, textbooks, etc) that relate specifically to TK (e.g. the TK Digital Library) or genetic resources (e.g. the IPGRA Singer database)?

Prior art searches conducted by CIPO during patent procedures consider the following sources: patent and non-patent literature mainly in electronic format. Specifically, these sources include the Canadian Patent Database (Canadian patent documents from 1920 to the present); GeneSeq (Patent literature relating to genetic sequences); publically available sequence databases such as GenBank and Swiss-Prot; IEL Xplore; Medline/PUBMED (1965 to the present); Nature Biotechnology (Full text from 1995 onwards); STN (chemical abstracts and sequence searches), KNOVEL; and Scopus.

Q14. Scope of search and search strategies: What is the scope of the regular search for prior art (e.g. in terms of classification of subject matter)? What are the standard search strategies or guidelines that are employed? Under what conditions are searches broadened or extended beyond the standard procedures?

Canada uses the IPC as a primary tool to determine the scope of searches, key words. Search strategies depend on the nature of the claim(s) (the number of claims, scope, etc)

Q15. Work-sharing and technological focus: Due to resource constraints or other practical limitations, does search or examination in your office concentrate on any specific areas of technology? Does your office make use of external search or examination results in any areas of technology, either as informal background information or through formally recognition?

No. In Canada, Patent Examiners do not concentrate or restrict their searches to particular areas of technology. Yes. CIPO uses external search/examination results as informal background information.

PART IV: OTHER ISSUES CONCERNING PATENT PROCEDURE

The questions in Part IV concern other procedural and practical issues that have arisen in discussion on improved search and examination procedures relating to TK and genetic resources.

Q16. Inventorship and entitlement to apply: Is inventorship or the applicant's entitlement to apply substantively considered during patent examination, either routinely or exceptionally? If it is done exceptionally, what triggers this consideration?

- (i) *If a prior art publication, document (such as a legal agreement) or other information is available to your office which appears to provide evidence that a patent application:*
- *incorrectly names the inventor(s); or*
 - *is submitted by an applicant who is not entitled to apply for or be granted a patent; is this an adequate basis for your office to reject the application?*
- (ii) *Would your answer differ if the information is publicly available or not?*
- (iii) *If there is substantive consideration of inventorship and entitlement to apply, and there are grounds to believe that a person other than the applicant would be entitled to receive a patent (or a share of a patent), is it possible for the patent to be issued in the name of that party, or to be transferred to that party?*

No. Pursuant to sections 49 and 50 of the PA, and section 37 and 38 of the Patent Rules, an applicant's entitlement to apply is not considered during patent examination. If it comes to CIPO's attention that a patent application incorrectly names the inventor or is submitted by an applicant who is not entitled to apply for or be granted a patent, the application is not automatically rejected. CIPO would contact the applicant, bring the defect to his or her attention, and then provide the applicant with an opportunity to respond.

Q17. Supply of prior art citation to applicant: When prior art information is relied upon to reject a patent application is a copy of this information supplied to the applicant?

In Canada, information relied on to reject a patent application is supplied when cited for the first time or is not easily available to the applicant.

Q18. Information not available to applicant: Can information available to an examiner but not necessarily available to an applicant (e.g. in a restricted database) be relied upon to reject a patent application?

Only information that is available to the public, and consequently the applicant, can be relied upon to reject a patent application.

PART V: INVENTIONS BASED ON TK AND GENETIC RESOURCES

The questions in Part V concern specific guidelines or mechanisms that are used during patent procedures; for example, one patent office has a division of specialists working on examination of patents concerning traditional medicine.

Q19. Specialization on TK and genetic resources: To what extent is a distinct or specialized approach taken for search and examination of inventions which are based on any area of TK or use certain genetic resources? In particular:

(i) Are there any specific search guidelines or regular search strategies that are required or are employed for patent applications that include subject matter relating to or based upon TK or genetic resources? If so, please provide details.

(ii) Are there specialist searchers or examiners, or search and examination groups, that concentrate on certain areas of TK (e.g. traditional medicine systems) or technologies based on or making use of genetic resources in a specific area (e.g. agricultural biotechnology)?

In Canada, there are no distinct or specialized approaches taken for search and examination of inventions which are based on TK or GRs.

Q20. Practical lessons: Can you supply details of any cases in your jurisdiction that have illustrated:

(i) significant legal issues concerning the status of certain TK as prior art; or

(ii) problems concerning the practical availability for search and examination purposes of potentially relevant TK?

Please advise of any practical lessons or insights that can be derived from these cases.

No such illustrative examples exist in Canada.

Q21. Suggestions for guidelines: Based on the practical experience of your office, or based on other experiences and cases, do you have any suggestions for possible guidelines or practical recommendations for search and examination procedures concerning inventions based on or derived from TK or genetic resources?

Based on CIPO's experience, we do not have any suggestions for possible guidelines or recommendations for search and examination procedures concerning inventions based on or derived from TK or genetic resources.