

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

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

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I. OVERVIEW

1. This questionnaire aims to collect information on legal and practical issues concerning the recognition of traditional knowledge (TK) and genetic resources in the examination of patent applications. It advances the work of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee') on defensive protection measures aimed at pre-empting the erroneous grant of patents which wrongly claim certain TK or genetic resources as inventions. Responses are sought especially from patent search and examination authorities, preferably by September 30, 2004, so that they can be compiled and considered by the Committee at its next session (which meets from November 1 to 5, 2004).

II. BACKGROUND: TRADITIONAL KNOWLEDGE AS PRIOR ART

2. There is a wide-ranging debate about the relationship between patents and genetic resources and TK, covering such issues as the role of patents within regimes governing access to and benefit sharing from genetic resources and associated TK, as well as the legitimacy of patents on genetic materials. This questionnaire is intended only to have limited scope; it does not address these important broader issues: these are being debated in the Committee and in other fora within WIPO and other international organizations and processes.

3. This questionnaire concentrates on specific aspects of patent law and procedure that arise about the status of TK and associated genetic resources in relation to claimed inventions. TK about the beneficial properties of a genetic resource may help an inventor to derive an invention from that genetic resource. But there are also concerns that patent claims may be drafted to cover inventions that consist directly of existing TK or genetic resources, or that are obvious adaptations or applications of existing TK or genetic resources. Such patents may be invalid, in principle, due to lack of novelty or obviousness (or because the applicant does not derive the right to apply from the true inventor). But there may be practical obstacles that mean that relevant TK and genetic resources are not taken into account during examination.

What is defensive protection?

4. Various defensive protection strategies have been employed to prevent the acquisition of intellectual property rights over TK or genetic resources by parties other than the customary custodians of the knowledge or resources. The Committee has developed and

implemented several practical mechanisms for defensive protection. It has also referred proposals for improved defensive protection to other WIPO bodies for action. (A recent summary is provided in document WIPO/GRTKF/IC/6/8).

5. Defensive protection strategies focussed on the patent system have a legal and a practical aspect. The legal aspect entails ensuring that information is published or documented in such a way as to meet the legal criteria to be counted as prior art in the jurisdiction concerned (this may include, for instance, ensuring that there is a clear date of publication, and that the disclosure enables the reader to put the technology into effect). The practical aspect entails ensuring that the information is actually available to search authorities and patent examiners, and is effectively accessible to patent authorities (such as being indexed or classified), so that it is much more likely to be found in a search for relevant prior art. These two aspects were elaborated fully in document WIPO/GRTKF/IC/5/6. This questionnaire seeks information on both aspects.

Limitations of defensive protection

6. It is often stressed that protection of TK should be comprehensive, exploring both positive and defensive options. Defensive protection only aims to prevent other parties from gaining IP rights, and it does not in itself prevent others from using this material. Often, the active assertion of rights (positive protection) is necessary to prevent undesirable use of TK by third parties. In some scenarios, defensive protection may actually undermine the interests of TK holders, particularly when this involves giving the public access to TK which is otherwise undisclosed, secret or inaccessible. In the absence of positive rights, public disclosure of TK may actually facilitate the unauthorized use of TK which the community wishes to protect. Accordingly, no work on defensive protection (including this questionnaire) should be construed as encouraging TK holders to disclose, document or publish any element of their TK, or to give consent to their TK to be published or otherwise disseminated, unless they have had the opportunity to consider fully the consequences of doing so and have given their prior informed consent.

III. OVERVIEW OF THIS QUESTIONNAIRE

7. In March 2004, the Committee reviewed the work completed on defensive protection (WIPO/GRTKF/IC/5/6 and WIPO/GRTKF/IC/6/8) and commissioned a questionnaire to clarify the status of TK as prior art, and approved the development of draft recommendations to authorities responsible for patent search and examination to take greater account of TK systems (WIPO/GRTKF/IC/6/14, para. 110). The present document contains the questionnaire requested by the Committee.

What will the questionnaire be used for?

8. Responses to the questionnaire will help illustrate how TK and genetic resources may be taken into account during patent procedures. This information, once collated, may help improve the effectiveness of any defensive protection strategies that custodians of TK and genetic resources choose to use. It will also help inform and focus the proposed draft recommendations to patent authorities. It is not intended to have any legal implications, and any comments on applicable laws are not intended to be definitive or authoritative. It is,

rather, intended to promote the flow of practical information and the development of practical recommendations.

Who should answer this questionnaire?

9. To give a comprehensive picture of the current situation, input is sought from patent authorities responsible for search and substantive examination of patent applications. Other participants in the Committee's work are also invited to answer on the basis of their experience.

What sources are relevant?

10. As this questionnaire has a practical focus, responses should draw on as wide a range of sources as possible to document the actual practice of patent authorities. Relevant sources may include national or regional laws and regulations, office practice guidelines and examination manuals, office determinations and policy statements, and specific judicial or administrative decisions.

Responding to the questionnaire

11. Please submit responses to the questionnaire, if possible, before September 30, 2004. This deadline is set so that a collation and initial summary of responses can be circulated at the seventh session of the Committee, which meets between November 1 to 5, 2004. Later submissions of the questionnaire may possibly be considered in subsequent meetings of the Committee, depending on decisions taken concerning its work.

12. If possible, responses should preferably be in electronic form, to be sent by email to WIPO at grtkf@wipo.int (with the heading "Q5 response"). Responses may otherwise be sent by fax or regular mail to WIPO, 34 chemin des Colombettes, 1211 Geneva 20 (Switzerland), Fax 41 22 338 8120. Any queries about the questionnaire can be directed to the Traditional Knowledge Division at the same email or fax address, or by telephone at 41 22 338 9111.

Scope and definitions

13. While there is no formal international definition, TK can be characterized in general as knowledge which is:

- generated, preserved and transmitted in a traditional context;
- distinctively associated with the traditional or Indigenous culture or community which preserves and transmits it between generations;
- linked to a local or Indigenous community through a sense of custodianship, guardianship or cultural responsibility, such as a sense of obligation to preserve the knowledge or a sense that to permit misappropriation or demeaning usage would be harmful or offensive; this relationship may be expressed formally or informally by customary law or practices;
- 'knowledge' in the sense that it originates from intellectual activity in a wide range of social, cultural, environmental and technological contexts; and
- identified by the source community as being TK (see WIPO/GRTKF/IC/6/4, paragraph 58).

Genetic resources are defined in the Convention on Biological Diversity as “genetic material of actual or potential value;” and genetic material is in turn defined as “any material of plant, animal, microbial or other origin containing functional units of heredity.

Some illustrative scenarios

14. The status of TK can be very diverse when considered from the perspective of standard patent principles. TK need not be ‘old’ or ‘ancient,’ and may itself be novel or innovative. It may be held confidentially within a community or a smaller group, or it may be public knowledge. A TK holder may be the actual inventor (or one of several inventors) of a claimed invention. The following imaginary scenarios should help illustrate the context for this work. They refer to the kind of practical situation in which questions can arise as to the prior art status of TK, and the practicalities of locating it during the course of examination:

- TK has been openly used, non-commercially, within a remote, relatively small traditional community in a foreign country; it has been extensively used in that community, but has never been fully documented; there is no indication it has been known or used outside the community;
- TK has been used secretly within a traditional community, in part to produce a medical cure, and some products of this use have been sold beyond the community; the users are under an obligation through customary law to limit the dissemination of the knowledge as such to certain authorized members of the community;
- TK has been recorded in an ancient language on a fragile and valuable parchment, which is now in a public collection; this parchment is cited in a public catalogue but can only be accessed by bona fide historical scholars upon request;
- a claimed invention concerns an innovation essentially within an established TK system in one country, which would be obvious to a practitioner in that system, but may not be obvious to a researcher in the country where the patent is applied for.

[Questionnaire follows]

Questionnaire: Patent procedures and traditional knowledgeContact details

Please provide the following details:

- Name, Title and Organization
- Country this response refers to.
- Address (postal, email)
- Telephone and Facsimile

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)?

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?

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.

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?

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?

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?

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?

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.

Prior art relevant for non-obviousness

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)?

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?

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.

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)?

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)?

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?

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?

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?

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?

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?

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)?

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.

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?

Thank you for the valuable time and consideration you have given to this questionnaire. Your response will help to advance policy debate and practical understanding in this important area.

[End of questionnaire and of document]