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RECOGNITION OF TRADITIONAL KNOWLEDGE WITHIN THE PATENT SYSTEM:
INTERIM DRAFT

Document prepared by the Secretariat

I. OVERVIEW

1. The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“the Committee”) developed several defensive protection mechanisms that aim to enhance the recognition of traditional knowledge (TK) within the patent system, and thus to reduce the practical likelihood that patents will be allowed that incorrectly claim inventions that make use of TK and genetic resources. These are outlined fully in documents WIPO/GRTKF/IC/5/6 and WIPO/GRTKF/IC/6/8.
2. This document focuses on one aspect only of the defensive protection of TK, that of enhancing the examination of patent applications that are relevant to TK (including those that claim inventions that are based on, derived from, guided by or make use of TK). At its seventh session, the Committee approved an outline for recommendations on examination of TK related applications for patent authorities. It also requested the Secretariat to prepare a full draft set of recommendations, based on responses to a Questionnaire on Recognition of Traditional Knowledge and Genetic Resources in the Patent System (WIPO/GRTKF/IC/Q.5) that was circulated between the Committee’s sixth and seventh sessions. An initial draft of the recommendations was provided to the Committee at its eighth session as document WIPO/GRTKF/IC/8/8. The present document is a further draft, based on the evolving experience of patent authorities with the recognition of traditional knowledge, other reported

developments, and the views and comments of Committee participants. The draft also takes account of the responses to the questionnaire, compiled as WIPO/GRTKF/IC/9/INF/6.

3. Consistent with past discussion and past documents in this series, this draft is provided on the assumption that it is a background information resource, and should not prejudice to any legal issues at the national or international level, and should not prejudice negotiations or substantive outcomes and decisions in WIPO or in any other forum. A review and further drafting process is therefore suggested for the Committee to consider.

4. The Committee is invited to: (i) consider the further draft of recommendations for patent authorities contained in the Annex below; (ii) provide comments, suggestions, case studies and other input for the further elaboration of this draft, noting that this draft material is an information resource without prejudice to any legal issues and negotiations in WIPO or in other fora; and (iii) call for further responses to be submitted to WIPO/GRTKF/IC/Q.5 (Questionnaire on Recognition of Traditional Knowledge and Genetic Resources in the Patent System) prior to May 30, 2006, to enable the preparation of a final compilation of responses to that questionnaire.

[Annex follows]

ANNEX*

DRAFT RECOMMENDATIONS ON THE RECOGNITION OF TRADITIONAL
KNOWLEDGE IN THE PATENT SYSTEM

This interim draft has been prepared only to serve as a basis for ongoing discussion and consultation. It is in need of further development and consideration, including detailed factual material based on the diverse Member State input provided through WIPO/GRTKF/IC/Q.5 (Questionnaire on Recognition of Traditional Knowledge and Genetic Resources in the Patent System): see document WIPO/GRTKF/IC/9/INF/6.

I. OVERVIEW

1. A significant number of patent applications concern inventions which are in some way related to traditional knowledge (TK). For example, claimed inventions may be based on TK, may be derived from it, or may be guided by or make use of TK. The claims of some patent applications include TK directly within their scope. TK may, therefore, be potentially relevant to an invention's novelty or inventiveness (non-obviousness); to an applicant's declaration of identity of the true inventor(s); to an applicant's obligation to declare all known prior art relevant to an invention's patentability; or to the applicant's claim of entitlement to apply for an invention. In addition, some patent laws have a distinct disclosure obligation specially relating to TK or genetic resources, and there are several proposals to extend this practice or make it mandatory internationally.

2. TK is diverse in its nature, and is often an integral part of the life, laws, customs and culture of the communities that develop and maintain it. For some communities, illegitimate use of their TK is offensive or disturbing, and this includes the grant of patents that improperly include TK within their scope. TK is frequently the result of distinct and valuable knowledge systems and the intellectual development, often with a strong empirical and practical element, and is considered by many to have practical and technological value, as well as having broader cultural value and significance for the communities that develop, preserve and maintain TK through traditional mechanisms. TK has been an important component of many technological innovations which are considered part of the scientific or technical mainstream – historically, but also in the present day. The need for the patent system to understand and take full account of TK therefore has legal, ethical and practical aspects.

3. A wide range of possible linkages between a claimed invention and TK may arise when a patent application is examined. By and large, those working in patent offices and other authorities responsible for examining and determining the validity of patent applications have had little contact or experience with TK, and the diverse knowledge systems and traditional communities that develop and maintain TK. Yet TK can be closely relevant to the full and effective discharge of their responsibilities to ensure that patents are granted only on legitimate inventions. Greater understanding and awareness of TK and traditional knowledge systems can therefore emerge as an important legal and practical responsibility for patent authorities, but can also become a valuable aspect of professionalism and deeper understanding of the policy and cultural context of the patent system.

4. These draft recommendations have been developed to help patent authorities and patent professionals take account of TK, its technical content and its social and legal context, so that they can fulfil their responsibilities more effectively. At their core, these draft recommendations are intended to decrease the likelihood of the erroneous grant of patents which wrongly claim certain TK or genetic resources as inventions, and of patents on claimed inventions that are not novel or are obvious in the light of relevant TK.

II. BACKGROUND: TRADITIONAL KNOWLEDGE AND THE PATENT SYSTEM

Some perspectives on traditional knowledge

5. There are many diverse forms of traditional knowledge, and diverse perspectives on its characteristics. This section provides a range of perspectives, to illustrate its general nature.

6. The following comment highlights the nature of the distinct systems within which traditional knowledge is developed and maintained:

“The most important thing to recognize is that indigenous knowledge is embedded in indigenous knowledge-systems which are very specific in each case. I therefore disagree to conceive intellectual property protection for indigenous knowledge as developing procedures for buying and selling indigenous knowledge as data. That already transforms indigenous knowledge into what it is not. The different indigenous knowledge systems can be described as ‘disciplines’, i.e., more than just a pile of data. They include ethical standards, standards of responsibility, standards for transmission and they form a system of rules and practices which are very specific. They include different practices of earning and sacrificing to gain knowledge. The knowledge may stay in a community for hundreds of years, but the process of learning it in each generation can be very different. If you are going to become a knowledgeable person, you have to work for it, but that is different from how you work for knowledge at a University; when you gain authorization (i.e., like a diploma from a University), you have different kinds of work that you had to do for this authorization. Each people’s indigenous knowledge system is a specific ‘discipline’, with its own protocol of how the knowledge can be learned.”¹

7. This comment underscores that TK systems are dynamic, not static or antique, and that they have scientific characteristics:

“Many indigenous people avoid the term ‘traditional knowledge’ because ‘traditional’ implies that the knowledge is old, static, and passed down from generation to generation without critical re-evaluation, change or further development. In other words, the implication is that TK is not ‘science’ in the formal sense of a systematic body of knowledge that is continually subject to empirical challenges and revision. Rather the

¹ Participant at the Roundtable on Traditional Knowledge and Intellectual Property Rights, Arctic Institute of North America, cited in Intellectual Property Needs and Expectations of Traditional Knowledge Holders, WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge (1998-1999), WIPO, Geneva, 2001 (‘Fact-Finding Report’)

term implies something ‘cultural’ and antique. [...] What ... the international community needs to protect is ‘indigenous science.’”²

8. A further perspective underscores that TK has a community basis, and its use and dissemination is often already governed by long-standing customary law:

“We have had songs, traditional knowledge and so on for hundreds of years. There was no doubt as to who originally owned them – they were originally owned by one person, who later passed them on to his or her clan. There were clear customary laws regarding the right to use the songs and the knowledge. There was no problem in the past. Why are there problems now? We should begin with communities, and see how they protected their cultural expressions and knowledge. Then we should use the same customary tools or tools adapted from them.”³

9. The legal status of TK has already arisen in the practice of patent law. In one leading case in the United Kingdom, when considering the status of TK as prior art relating to patentability, the court has phrased the general issues as follows:

“The Amazonian Indians have known for centuries that cinchona bark can be used to treat malarial and other fevers. They used it in the form of powdered bark. In 1820, French scientists discovered that the active ingredient, an alkaloid called quinine, could be extracted and used more effectively in the form of sulphate of quinine. In 1944, the structure of the alkaloid molecule (C₂₀ H₂₄ N₂ O₂) was discovered. This meant that the substance could be synthesised.”

“Imagine a scientist telling an Amazonian Indian about the discoveries of 1820 and 1944. He says: ‘We have found that the reason why the bark is good for fevers is that it contains an alkaloid with a rather complicated chemical structure which reacts with the red corpuscles in the bloodstream. It is called quinine.’ The Indian replies: ‘That is very interesting. In my tribe, we call it the magic spirit of the bark.’ Does the Indian know about quinine? My Lords, under the description of a quality of the bark which makes it useful for treating fevers, he obviously does. I do not think it matters that he chooses to label it in animistic rather than chemical terms. He knows that the bark has a quality which makes it good for fever and that is one description of quinine.”

“On the other hand, in a different context, the Amazonian Indian would not know about quinine. If shown pills of quinine sulphate, he would not associate them with the cinchona bark. He does not know quinine under the description of a substance in the form of pills and he certainly would not know about the artificially synthesised alkaloid...”

“The quinine example shows that there are descriptions under which something may in a relevant sense be known without anyone being aware of its chemical composition or even that it has an identifiable molecular structure. This proposition is unaffected by whether the substance is natural or artificial. So far I have been considering what it means to know about something in ordinary everyday life. Do the same principles

² Written comments from Prof. Russell Barsh, cited in Fact-Finding Report

³ Meeting with Dr. Jacob Simet, Executive Director, National Culture Commission, Papua New Guinea, cited in Fact-Finding Report

apply in the law of patents? Or does patent law have a specialised epistemology of its own?”⁴

Relevance for the patent system

10. As these perspectives illustrate, it can be a misconception to assume that TK is not innovative, that it has no scientific or technological component, or that it is necessarily public domain information that can be freely used without legal constraint. Its ‘traditional’ characteristics do not mean that TK is not relevant to determining questions of patentability. Indeed, TK holders who innovate within their knowledge systems have created inventions that are technically patentable (even if, for a range of reasons, they have not chosen to patent their inventions). TK systems are not static, and often respond to the changing needs and requirements of the communities that maintain them. Innovation therefore does continue within the traditional context, but often in a collective or cumulative way that may not correspond directly with the notions of inventorship and inventive step that are embedded in the patent system. Equally, TK is often viewed as being collectively held by communities, often through a form of custodianship (with responsibility for maintaining and passing on knowledge according to customary laws or practices), which contrasts with conventional forms of ownership of IP. Some TK holders have cited these differing notions of the innovative process and of ownership of knowledge as reasons for preferring not to use the patent system to protect their inventions. Some TK holders have used the patent system to protect innovations within traditional knowledge systems, but the majority have not used the patent system. Hence, much TK relevant to patentability of claimed inventions will not be disclosed in searches of patent literature.

11. 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.

The subject of ongoing debate

12. A wide-ranging debate continues to probe the relationship between patents and genetic resources and TK. Several international fora are addressing 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. These draft recommendations have limited scope and do not seek directly to address these important broader issues: this is because they are the subject of active debate in several international organizations and processes. These draft recommendations therefore play a complementary and supplementary role only, and do not seek to preempt or predetermine the outcomes of these important debates. These draft recommendations concentrate on specific aspects of patent law and procedure that arise about the status of TK and associated genetic resources in relation to claimed inventions.

⁴ *Merrell Dow Pharmaceuticals Inc. v. H.N. Norton & Co. Ltd.*, [1996] RPC 76, at 88 (per Lord Hoffmann)

What is defensive protection?

13. ‘Defensive protection’ of TK refers to strategies 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. Defensive protection has both legal and practical aspects. The legal aspect concerns whether TK is recognized as relevant prior art under the patent law of the jurisdiction concerned. Legal questions may include, for instance, recognition of orally transmitted knowledge, establishing a clear date of public disclosure of written or oral knowledge, and determining whether the TK was disclosed in such a way as to enable the reader to put the technology into effect. The practical aspect includes ensuring that 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 are elaborated in document WIPO/GRTKF/IC/5/6. Several practical mechanisms for defensive protection have been implemented at the international level. (A recent summary is provided in document WIPO/GRTKF/IC/6/8).

Concerns about defensive protection alone

14. 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. For this reason, these recommendations do not encourage 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. For these reasons, discussed further below, TK should be handled carefully, if its legal status is unclear, so that there should be no risk that it is unwittingly disclosed to unauthorized parties or introduced to the public domain.

Some definitions

15. There is no formal international definition of TK, at least in the context of existing IP instruments. One working definition, which has no legal status, characterizes it as referring “to the content or substance of knowledge that is the result of intellectual activity and insight in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge that is embodied in the traditional lifestyle of a community or people, or is contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources.”

16. The Convention on Biological Diversity (CBD) is a key international instrument that deals with TK relating to biodiversity. It has specific obligations concerning respecting,

preserving and maintaining knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity. TK is often associated with genetic resources. The CBD defines genetic resources as “genetic material of actual or potential value.” Genetic material is in turn defined as “any material of plant, animal, microbial or other origin containing functional units of heredity.”

Some illustrative scenarios

17. The status of TK can be very diverse when considered from the perspective of standard patent principles. This paragraph helps to illustrate this diversity. As noted, TK need not be “old” or “ancient”, and may itself be novel or innovative. It may be held within a specific, localized community, or it may be a codified system of knowledge that is more extensively shared and practiced. It may be held confidentially within a community or a smaller group, it may be widely disseminated public knowledge, or it may have a status between these two extremes. Even where it is publicly disclosed, it may be covered by the customary laws and practices of traditional communities, and TK holders may therefore expect it to be used in line with these laws and practices. Certain TK may also be subject to an access and benefit-sharing law or agreement which imposes obligations on how the TK is used by the person gaining access to it. 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 and the diverse characteristics of TK. They help illustrate the kind of practical and legal questions that can arise as to the prior art status of TK, and the practicalities of locating it during the course of examination and other patent procedures:

- 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 in written form; 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; and
- a claimed invention concerns an innovation essentially within an established TK system in one country, which would be obvious to a practitioner working within that specific knowledge system, but may not be obvious to a researcher in the country where the patent is applied for.

Defensive protection of genetic resources

18. Genetic resources and traditional knowledge are often closely related. As noted above, genetic resources are defined in the CBD as “genetic material of actual or potential value.”

While genetic resources are physical resources, they are potentially relevant in the review of prior art and in determining the novelty and inventiveness of a claimed invention, such as where a claim is made out to a plant or other organism. This may be illustrated by a case that was recently considered by the Commission on Genetic Resources for Food and Agriculture (CGRFA) of the FAO, pursuant to a submission from the International Center for Tropical Agriculture (CIAT).⁵

An illustrative example: International Agricultural Research Centres

19. The International Agricultural Research Centres of the Consultative Group on International Agricultural Research (CGIAR) hold the world's most important *ex situ* collections of the germplasm of major food crops. In 1994, twelve CGIAR centres, CIAT included, concluded agreements with FAO in 1994,⁶ bringing their collections into the International Network of *Ex Situ* Collections under the Auspices of FAO, and recognising the "intergovernmental authority of FAO and its [CGRFA] in setting policies for the International Network." They agreed to hold the designated germplasm "in trust for the benefit of the international community", and "not to claim ownership, or seek intellectual property rights, over the designated germplasm and related information", and to lay this obligation on any subsequent recipients of material from their collections. This was recognized to be an interim solution, pending the completion of the negotiations for the International Treaty on Plant Genetic Resources for Food and Agriculture. The Treaty⁷, adopted on 3 November 2001, in Article 15, recognizes "the importance to this Treaty of the *ex situ* collections of plant genetic resources for food and agriculture held in trust by the IARCs of the CGIAR". It makes provisions for the IARCs of the CGIAR and other International Institutions holding *ex situ* collections of plant genetic resources for food and agriculture, bringing them under the terms of the Treaty.

Example of a field bean cultivar

20. The present case is cited merely to illustrate the practical questions that may arise in relation to patent examination and grant in relation to inventions making use of genetic resources. The question of whether an individual patent is valid or not is entirely a question of national law (or regional law where applicable), to be determined by the appropriate national or regional authorities. This case concerns United States patent 5,894,079, issued on April 13, 1999, entitled "Field bean cultivar named enola." This patent was granted for a new cultivar of field bean (*Phaseolus vulgaris* L.) which produces a distinctly yellow seed with a yellow hilum that remains relatively unchanged over time. The invention also relates to a method of producing a field-bean cultivar by crossing a first parent field-bean plant with a second parent field-bean plant, wherein the first or second field-bean plant is that of the invention.⁸

⁵ The International Center for Tropical Agriculture (CIAT) is a non-profit, nongovernmental research organization dedicated to alleviating hunger and conserving natural resources in developing countries. It is one of 16 international agricultural research centers which form part of the Consultative Group on International Agricultural Research (CGIAR). See: <http://www.ciat.cgiar.org/>

⁶ Available at <ftp://ext-ftp.fao.org/ag/cgrfa/GS/cgtexte.pdf>.

⁷ The text of the Treaty was made available to the Second Session of the Inter-governmental Committee as document WIPO/GRTKF/IC/2/INF.2, and is at http://www.wipo.int/eng/meetings/2001/igc/doc/grtkfic2_inf2.doc

⁸ See document CGRFA-9/02/Inf.7, page 1.

21. According to CGRFA documents⁹, questions were raised about the validity of this patent, which “restricts the use of designated bean germplasm with yellow seeds for purposes of agronomy and breeding in the USA, even though the FAO-CGIAR Agreements expressly prohibit the claiming of intellectual property rights on designated germplasm, even for accessions distributed before their designation [...]. In addition, the patent does not fulfill two basic requisites: newness, and non-obviousness”.¹⁰ The question of the terms of access to CGIAR collections are not dealt with at all in this example, and indeed, as noted below, it has been pointed out by some FAO Members that “the material had not in fact come from the in-trust collections”. This example addresses only the novelty and non-obviousness requirements, which ultimately are specific legal questions considered by national authorities who apply national patent law on the basis of the patent claims considered in the light of any relevant prior art that has been identified. However, there is also the practical question of how to locate and identify relevant prior art and to make this information available in a form that can be used for patent procedures. Various legal processes are available under national or regional patent laws for the validity of a patent to be reviewed, including in the light of prior art newly brought to the attention of patent or judicial authorities. Re-examination by the United States Patent and Trademark Office (USPTO) is one such national procedure.

22. In 2000 the Director General of CIAT indicated that “the ‘Enola’ bean is close to several yellow-seeded bean varieties deposited in the trust collection held at the Centre”, and that CIAT “will continue to distribute freely such germplasm accessions in the framework of the FAO-CGIAR Agreement”.¹¹ CIAT-BRU used microsatellites (a form of molecular marker) to survey 21 bean lines from the CIAT collections with yellow seeds and hilum. “Enola” was discovered to be genetically very close to the CIAT accessions G22227 and G14024. G22227 is a breeding line from northwestern Mexico and G14024, also known as “Peruano”, is a bean line that CIAT obtained from Mexico, but which is originally from Peru. CIAT-GRU also showed that “Enola” has “T” phaseolin, a marker that is common among wild forms and landraces of the Central Andes of Peru.¹²

23. In March 2000 the Director General of CIAT issued a letter indicating that the “Enola” bean is substantially identical in all important respects to a number of accessions held by CIAT in its genebank. In May 2000, the FAO Legal Office sent a letter to the Director General of CIAT supporting the latter’s intention to bring the matter to the attention of the USPTO. On December 20, 2000, CIAT requested re-examination of the patent. The reasons for the request for re-examination were:

(a) that the use of bean designated germplasm with seed of yellow color might be restricted by the patent for agronomy and other breeding purposes in the United States of America, and

⁹ Document CGRFA-9/02/11, Report on the International network of Ex Situ Collections under the Auspices of FAO, paragraphs 23-26 <<ftp://ext-ftp.fao.org/ag/cgrfa/cgrfa9/r9w13e.pdf>> and document CGRFA-9/02/Inf.7, Report on the International Network of *Ex Situ* Collections under the Auspices of FAO: further information provided by the International Centre for Tropical Agriculture (CIAT), regarding its request for a re-examination of U.S. patent No.5,894,079 <<ftp://ext-ftp.fao.org/ag/cgrfa/cgrfa9/r9i7e.pdf>>.

¹⁰ CGRFA-9/02/Inf.7, page 2.

¹¹ See document CGRFA-9/02/Inf.7, page 2.

¹² See document CGRFA-9/02/Inf.7, page 3.

(b) that two basic requisites for granting the patent (namely novelty and non-obviousness) were not fulfilled.

On February 8, 2001, the USPTO indicated that it would re-examine the patent.

24. At the ninth session of the CGRFA, held from October 14 to 18, 2002, CIAT provided updated information on CIAT's request for re-examination of the patent.¹³ Additionally, this specific patent case and the question of "intellectual property rights ... being sought by third parties over designated germplasm provided by the CGIAR Centres" were brought to the CGRFA's attention in the "Report on the International Network of *Ex Situ* Collections under the Auspices of the FAO".¹⁴ The deliberations of the Commission are summarized in the Report of the ninth session as follows:

"A number of countries expressed concern over cases involving the inappropriate granting of intellectual property rights over materials from the International Network, noting, however, that such cases had all been attended to. The Commission was informed of ongoing litigation by the International Centre for Tropical Agriculture (CIAT) ... Some members of the Commission expressed concern that inappropriate granting of intellectual property rights could jeopardize public confidence in the in-trust collections held by the Centres within the International Network, and requested the Director General of FAO to bring the matter to the attention of the United Nations General Assembly and the World Trade Organization, and to forward the documents, *Report on the International Network of Ex Situ Collections under the Auspices of the FAO*, and *Report on the International Network of Ex Situ Collections under the Auspices of the FAO: Further Information Provided by the International Centre for Tropical Agriculture (CIAT), Regarding its Request for Re-examination of U.S. Patent No. 5,894,079*, to the World Intellectual Property Organization (WIPO) and its various Committees, with a request that WIPO cooperate with FAO in preparing a study on how intellectual property rights may affect the availability and use of material from the International Network and the International Treaty. Other Members noted that the material had not in fact come from the in-trust collections, and that the FAO had already supported CIAT's claim against the Patent."¹⁵

25. Such discussions in genetic resource policy fora on individual patent cases may raise broader policy or legal issues, which are not touched on in the present document. However, this case also illustrates the practical context of defensive protection strategies in the field of genetic resources. Put simply, the question is one of how to increase the likelihood that relevant information about genetic resources is available to patent-granting authorities, that this information is available at an early stage in patent processing, and that this information will in fact be located and assessed during the initial examination of the patent application. The development of extensive information tools and data collections in the field of genetic resources makes this an increasing practical possibility. This information becomes especially important when it relates to public domain or open access international collections of germplasm. It also brings into focus the substantial procedural costs which a national public

¹³ See document CGRFA-9/02/Inf.7.

¹⁴ See document CGRFA-9/02/11, paragraphs 23 to 26.

¹⁵ See document CGRFA-9/02/REP Report of the Commission on Genetic Resources for Food and Agriculture, paragraphs 31 available at: <<ftp://ext-ftp.fao.org/ag/cgrfa9/r9repe.pdf>>.

or international institution may have to shoulder in challenging a patent, an important matter to take into account in considering defensive protection strategies, particularly when there is no possible financial benefit for the institution if its challenge succeeds.

IV. PRACTICAL CONTEXT OF THESE DRAFT RECOMMENDATIONS

26. These draft recommendations stem from a series of case studies and proposals developed by various WIPO Member States and regional groups which have called for patent search and examination authorities to take greater account of TK and genetic resources in the course of assessing the validity of patent applications.

These recommendations may be relevant to a wider range of contexts. They may have a role in:

- (i) assisting patent authorities to review and develop procedures that ensure relevant TK is taken account of during patent procedures, thus potentially improving the likelihood of validity of granted patents;
- (ii) providing a training and awareness tool for patent examiners, patent practitioners, researchers and innovative enterprises, community representatives, civil society representatives and other third parties concerned in with the validity of granted patents;
- (iii) provide specific practical guidance in the event that certain TK holders take an informed decision to document certain elements of their TK for the purpose of defensive publication (supplementing the toolkit for safeguarding TK holders' interests during the documentation of TK);
- (iv) providing an informal platform for cooperation between offices, for instance in recognizing concentrations of expertise in specific TK systems (as discussed in WIPO/GRTKF/IC/6/8, paragraph 22); and
- (v) providing background guidance to or possible directions for policymakers and legislators during review and development of national and regional patent systems.

27. The following sections of the draft recommendations will comprise an explanatory passage, aimed at promoting awareness and setting the recommendations in context, followed by specific recommendations concerning the operations of patent authorities. These recommendations are intended to promote greater and more effective attention to TK during patent search and examination within the bounds of the existing legal framework, as a practical means of promoting the realization of existing patent principles from a broader base of prior art and a wider understanding of the context of traditional knowledge.

V. OBJECTIVE

28. These draft recommendations aim to provide a platform for practical cooperation and policy development to improve the likelihood that granted patents are valid in the light of traditional knowledge and genetic resources, and with respect to relevant traditional knowledge systems. They are without prejudice to further legal, practical and policy initiatives to achieve this objective at the national, regional and international level, and aim to supplement or complement initiatives elsewhere.

Draft recommendations

29. It could be recommended that:

(i) patent authorities undertake specific and systemic initiatives to ensure that granted patents are valid in the light of traditional knowledge and genetic resources, and with respect to relevant traditional knowledge systems; and

(ii) Patent authorities make use of the following recommendations and guidelines in their search and examination processes to achieve this end.

VI. OUTLINE OF ISSUES

30. This section outlines the issues, both legal and practical, that affect the recognition of TK as prior art in the determination of validity of patents and patent applications, especially with reference to novelty and obviousness. It then illustrates the nature of the problems through a series of illustrative scenarios.

31. The issues to be discussed include:

(i) The prior art status of TK;

(ii) The practical accessibility of TK; and

(iii) Assessing inventive step for innovations within or drawing on TK.

32. Peru has pointed to the “need to evaluate how it would be possible to organize and systematize much of this information [on genetic resources and TK] and the role that could be played by a national database in that regard. In summary, how is it possible to articulate this database and information with the search procedures and examinations of the main patent offices throughout the world in order to avoid patents being granted on the basis of partial and limited examinations of novelty and inventive step?”

33. Further material for this section could draw on earlier material put to the Committee, in particular proposals and discussion by the Group of Latin American and Caribbean Countries (WIPO/GRTKF/IC/1/5), Asian Group (WIPO/GRTKF/IC/4/14), and the Delegation of Peru (WIPO/GRTKF/IC/5/13 and WIPO/GRTKF/IC/8/12), as well as Secretariat papers on the subject (WIPO/GRTKF/IC/2/6, WIPO/GRTKF/IC/5/6 and WIPO/GRTKF/IC/6/8). This would also clarify the tension between the objective of disclosure for defensive purposes, and protecting TK against unauthorized disclosure and unauthorized use and misappropriation by third parties.

Draft recommendations

34. It could be recommended that:

(i) patent authorities be encouraged to give appropriate priority to recognizing relevant TK and to the practical implications of such recognition in policy development,

resource deployment and strategic planning of their operations; to consider the practical implications of TK for search and examination; and to explore practical solutions to enhancing the validity of patents in the light of TK and TK systems.

VII. DESCRIPTION OF TRADITIONAL KNOWLEDGE

35. This section describes the nature of traditional knowledge and TK systems, acknowledging the diversity of such knowledge systems and dealing with such aspects as its informal nature, traditional forms of preservation and transmission, the communal qualities of the ownership, development and transmission of TK, and the role of customary law and practices in governing traditional use and dissemination of TK. It demonstrates how, while it may be developed in a traditional context, much TK has a technical component, and can include empirically-based information of direct relevance to the technical patentability of claimed inventions in a wide range of technological fields.

36. This section would include illustrative examples of TK, drawn from already published material concerning case studies, national laws, and community experiences.

Draft recommendations

37. It could be recommended that:

(i) patent examiners be given training and awareness in TK and TK systems; where possible this should include direct training by TK holders working within a traditional context in the patent authority's country; and

(ii) authorities prepare an analysis or issues paper discussing TK systems and TK that are relevant for patentability criteria, for the reference or general awareness-raising of examiners working in relevant technological fields.

VIII. LEGAL ISSUES RELEVANT TO TK AND NOVELTY

38. This section describes in more detail the technical issues concerning the recognition of TK in the patent system. It sets out, in particular the general scope of prior art relevant to novelty (such as foreign or local disclosure), the nature of disclosure required to defeat novelty, specific conditions for recognition of prior art (public availability, languages, publication, including aspects of internet or electronic publication), requirements to establishing the effective date of prior art, and the need for continuity of publication or public availability.

39. Regarding novelty in relation to TK, the Group of Countries of Latin America and the Caribbean (GRULAC) commented as follows:

Patent laws generally require an invention to be universally novel if it is to qualify for a patent. Where a product or process already forms part of the state of art at the time of the filing of the first patent application, a patent may not be granted as the subject matter lacks the required novelty. That principle is difficult to apply in practice, as the standard of what should be considered part of the state of the art for that purpose varies between the laws of the various countries and regions. In some cases, the only

information regarded as being within the state of the art is that contained and disclosed in written or printed documentation accessible by certain media (printed matter, public access data bases, etc). On the other hand, what is not regarded as forming part of the state of the art is all material existing in nature that is not documented, and also undocumented traditional products, processes and knowledge that communities and peoples from various regions of the world have known and used for many years or even centuries. The shortcomings of the system for publicizing what is regarded as being within the state of the art has the practical effect allowing a third party to claim in a patent application products and processes that are already known and being used in various parts of the world. This may bring with it economic and commercial consequences for the traditional users of the subject matter, who might see themselves prevented from continuing or engaging in their industrial and commercial activities. The Committee could look into ways of devising a means of settling this problem at the international level in such a way as to include within the state of the art also that which has become known through use, traditional marketing, oral disclosure or any other means whereby a product or process has been made known to the public.¹⁶

40. One particular issue concerns the recognition of orally disclosed information. Much TK is customarily transmitted orally, and is not normally reduced to a written or fixed form. This has led to concerns that, to the extent that any patent law system specifically recognizes documented or written knowledge when determining the validity of patent claims, there is the possibility of claimed inventions being deemed valid, even when they may involve the appropriation of orally disclosed TK. The concern is that this would prejudice the interests of those communities with a stronger oral tradition. From the legal perspective, it is possible to recognize orally disclosed material as being relevant prior art, and this recognition may be universal, in the sense that knowledge disclosed by any means, in any geographical location, may be considered as prior art relevant to the novelty of a claimed invention.¹⁷ Recognizing its legal status as relevant to the determination of validity of patent claims would clearly increase the legal basis for defensive protection, without necessarily requiring TK holders to disclose or publish their TK in violation of the principle of prior informed consent. In practice, taking account of orally disclosed TK, including that which is disclosed in foreign jurisdictions, would create some evidentiary issues, precisely because of the lack of documentation.¹⁸ On the other hand, there is concern that documentation of oral TK, including for the sake of patent procedures, can accelerate or facilitate its misappropriation, including its commercial use by third parties without the prior informed consent of the holders of TK.¹⁹ The need to respect the wishes, interests and concerns of TK holders suggests that legal recognition of orally disclosed TK as relevant prior art would enhance the impact of defensive strategies, while leaving clearly open the choice to TK holders in practice as to whether, how, and under what conditions they choose to disclose, publish or otherwise make available their TK. The prospects for TK holders to identify and promote their interests in a practical context should be enhanced by capacity-building programs along the lines requested

¹⁶ WIPO/GRTKF/IC/1/5, Annex II, page 7.

¹⁷ See, for example, the proposal under consideration by the Standing Committee on the Law of Patents, document SCP/9/2, p. 21.

¹⁸ Similar considerations have led in the copyright domain, for example, for some jurisdictions to require fixation of works as a prerequisite for their protection; but as discussed in document WIPO/GRTKF/IC/6/3, many jurisdictions do nonetheless protect unfixed literary and artistic works.

¹⁹ See document WIPO/GRTKF/IC/5/5 and WIPO/GRTKF/IC/5/6

by TK holders during the WIPO Fact-finding Missions,²⁰ such as the such as the toolkit to identify and protect TK holders' interests during any documentation process.²¹

41. Most responses to WIPO/GRTKF/IC/Q.5 advised that there are no 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. Some referred to specific guidelines under development. Australia reported on two cases: "TK was potential prior art in two administrative decisions issued by the Australian Patent Office — *Vincent Joseph Collins and Maryann Collins v William Robert McGilvray* [2002] APO 23 (see Annex 1) and *Frank D'Amelio and Graeme A. Close v Australian All Natural Pty Ltd* [2003] APO 25 (see Annex 2). The first application concerned a method for producing a blue colored oil from a mixture of the bark and wood from the Australian native Northern Cypress Pine, (*Callitris intratropica*). The second application involved a topical composition comprising an aqueous alcoholic extract from the plant *Centipeda cunninghamii* (commonly known as old man weed). While both administrative decisions actually relied on conventionally published documents for the purposes of novelty and inventive step, TK was clearly important background prior art. In the first decision, one of the documents in the former case referring to the traditional use of the bark resins of the native pine by the native Tiwi people of Northern Australia. In the second decision, the specification itself acknowledged the traditional medicinal use of old man weed. Note that both applications were found to be novel and inventive in light of the prior art provided at the hearing."²²

Draft recommendations

42. It could be recommended that:

(i) call for patent authorities to take full account of diverse contexts when assessing patent validity, including interpreting documents and publications from the point of view of the relevant traditional context and the teaching that would be apparent to a relevant TK holder; and

(ii) set out specific, illustrative means of achieving this, noting that this approach should be undertaken within the existing bounds of the applicable patent law.

IX. LEGAL ISSUES RELATING TO TK AND NON-OBVIOUSNESS

43. The standard of inventiveness or non-obviousness typically hinges on what would appear obvious to the 'person skilled in the art.' If a claimed invention is to some extent a hybrid, drawing in part on a TK system and in part on a separate scientific and technological discipline, this raises a question of whether the test for non-obviousness could consider the person skilled in the relevant background of TK. The Asian Group has proposed that: "The Intergovernmental Committee should explore practical means of integrating into substantive patent examination procedures the teaching of TK systems in such a way that "the person

²⁰ See "Intellectual Property Needs and Expectations of Traditional Knowledge Holders: WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge (1998-1999), publication 768 (E/F/S)

²¹ WIPO/GRTKF/IC/6/8, paragraph 19.

²² Questionnaire response by Australia, WIPO/GRTKF/IC/9/INF/6

with ordinary skill in the art” who is referenced in the determination of inventive step includes a person with ordinary skill in the relevant TK systems.”²³

44. WIPO/GRTKF/IC/Q.5 posed the question: “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?” The following sample of answers to the question gives a general sense of the range of possible approaches.

China: 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, i.e., shall be considered as prior art, but the skills to interpret or practice the art of TK are limited to the community only, our practice now is: if the relevant TK is systemic, e.g., our Zang Medicine, then the person skilled in the art shall have the basic idea of that TK, which means that the examiner shall learn some basic knowledge of that TK system; if the relevant TK is scattered and the examiner feels it difficult to learn, the examiner may ask the applicant to supply background information to make the application sufficiently clear. However, we feel this question shall be discussed further.

EPO: 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, the person skilled in the art would probably be considered as having the knowledge of one or several members of the community holding the TK.

Azerbaijan: If an element of TK (including TK associated with certain genetic resources) is considered available to 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, the person skilled in the art is assessed similarly.

Australia: In Australia there are no specific rules which apply regarding the assessment of the person skilled in the art for the determination of inventive step when an element of TK is involved. An objection of lack of inventive step only arises where it can be shown that a person skilled in the art would, in solving the problem, have taken the necessary steps to reach the claimed invention. In addition, problems may arise in the circumstances set out above, as the only common general knowledge that can be used in objections of lack of inventive step is the common general knowledge in Australia. Thus if the situation described in the question arises and the TK is TK in a community of indigenous Australians, then that common general knowledge will be common general knowledge in Australia and is potentially accessible to the relevant person skilled in the art. However, if the community which holds the TK is not in Australia, then this may cause a problem as the common general knowledge available to the relevant person skilled in the art is not going to be the common general knowledge in Australia. Consequently an examiner may have difficulties in identifying the relevant person skilled in the art and taking inventive step objections in these circumstances. ... If the knowledge is confidential to the community, especially the elders, then it does not form part of the common general knowledge and so is not available to be used in any assessment of inventiveness.”

²³ Document WIPO/GRTKF/IC/4/14, Annex, p. 4.

Finland: The person skilled in the art would be assessed as being a person having common knowledge in the art but no special knowledge like knowledge in the TK. The skills available only in the original community that holds the TK would not be counted in the skills of the person skilled in the art.

Trinidad and Tobago: a person with average skill in the art is specified. The skills to interpret or practice the art of TK could only be considered limited to a community only if the knowledge remains tacit i.e. not disclosed in detail to external society. Once the knowledge becomes explicit it can be assumed that any person with average skill in the art with access to the explicit knowledge can utilize the art. If the knowledge remains tacit i.e., limited to a community, the knowledge is still considered public domain even if within a more limited public. It most likely cannot be considered secret. The persons within the community with the knowledge can also be assumed to have access to other explicit knowledge revealed outside of their community thereby adding another dimension to non-obviousness, which is often viewed as relative to an external person with average skill in the art.

Draft recommendations

45. It could be recommended that:

(i) patent authorities and patent examiners should give appropriate consideration to the traditional context when considering the non-obviousness of (or the existence of an inventive step in) subject inventions; and

(ii) patent authorities consider the implications of the practical context of traditional knowledge and the practitioners and holders of TK for the test of the “person skilled in the art”.

X. OTHER POTENTIAL LEGAL ISSUES

46. This section discusses other legal issues that may be relevant to the recognition of traditional knowledge, such as inventorship and entitlement to apply for a patent. It illustrates their potential relevance to traditional knowledge systems, and their potential relevance to patents for inventions that are TK, that use TK or that are otherwise based on TK.

47. This discussion would provide a range of illustrative scenarios as a way of drawing attention to the possible questions that could arise. It would also draw on the discussion of these issues in the “WIPO Technical Study on Disclosure Requirements concerning Genetic Resources and Traditional Knowledge”.

Draft recommendations

48. It could be recommended that:

(i) where patent authorities have the legal competence to consider questions either of inventorship or of entitlement to apply during examination of the patent, they be encouraged to consider the implications of *prima facie* evidence that a TK holder may be an unacknowledged inventor, that applicant did not derive the entitlement from a TK holder who

was the source of the invention, or that the applicant was otherwise not entitled to apply for or be granted a patent on a TK-based invention.

XI. PRACTICAL ISSUES RELATING TO SEARCHING FOR TK AS PRIOR ART

49. This section sets out practical possibilities for enhancing the scope of TK that is actually searched and taken into account during the processing of patent applications. In particular, it draws attention to the range of resources concerning TK that may be already available for searching, such as the TK Digital Library and the Honey Bee Network (drawing on documents WIPO/GRTKF/IC/2/6, WIPO/GRTKF/IC/3/5 and WIPO/GRTKF/IC/3/6), and similar materials concerning genetic resources (for example, the System-wide Information Network for Genetic Resources (SINGER), reported in WIPO/GRTKF/IC/5/6, Annex II). It would describe in detail the recent revisions of the International Patent Classification and the minimum documentation of the Patent Cooperation Treaty system.

50. It could also underscore the difficulties and concerns that can arise from the further dissemination of some TK, including some TK that is already published or otherwise publicly available. Consistent with the general principle of prior informed consent, it could underscore that where there is doubt about the status of TK and a possibility of remaining concerns on the part of the originating community, its further distribution or dissemination should be limited appropriately.

Possible recommendations

51. It could be recommended that:

(i) patent authorities be encouraged to incorporate into standard office procedures the systematic search of existing public domain sources of TK and information on genetic resources, including the databases and journals notified to the Committee; and

(ii) patent authorities be encouraged to train search and examination staff on the context of TK and sensitivities about its use and handling.

XII. COORDINATION, CONSULTATION AND COOPERATION

52. This section sets out possible forms of coordination, consultation and cooperation, with a view to ensuring that patents are not illegitimately granted on claimed TK-related inventions. It could consider consultation firstly with indigenous communities and representatives of TK holders, and secondly with other patent authorities, so as to promote the comprehensiveness and inclusiveness of search and examination. It would describe existing mechanisms that have been established in some countries, such as an advisory committee or consultative committee (WIPO/GRTKF/IC/5/INF/2, Annex I, 13 and 14), established to guide IP offices dealing with applications relating to TK, and experience with the development of specific search and examination units that concentrate on certain areas of TK-related patent applications.

53. This section then sets these developments in the context of the broader trend towards work-sharing, and the development of specific areas of expertise in individual offices (in this case, concerning specific TK systems) that could facilitate the work of other offices, and ensure that patent applications relating to TK are given as effective a search and examination

as is feasible. (This would build on the approach outlined in WIPO/GRTKF/IC/6/8, paragraph 22).

Possible recommendations

54. It could be recommended that:

(i) advisory or consultative mechanisms be developed to provide systematic advice to patent authorities on TK and TK systems that are relevant to their operations;

(ii) patent authorities share information on useful sources of public domain TK and information on GR that are relevant to specific areas of technology (e.g., medical, agricultural, ecological management), with due regard to concerns that this should not facilitate illegitimate access to or use of TK;

(iii) no procedures be undertaken that would accelerate or facilitate the public dissemination of TK that is not disclosed with the consent of TK holders; and

(iv) formal or informal cooperation be undertaken to seek opinions, search or examination reports, or background information concerning specific TK-related applications from those offices with a recognized expertise in specific knowledge systems or traditions, from offices which have established a search or examination unit concentrating on a particular TK system or sector of TK, and from relevant consultative or advisory committees.

[End of Annex and of document]

* An Annex to the recommendations would provide supplementary material for background, training and awareness-raising, such as case studies, illustrative provisions from existing office guidelines and examination manuals, and references to useful sources of public domain information on TK and genetic resources, based on the past work of the Committee and drawing extensively on the responses to questionnaire WIPO/GRTKF/IC/Q.5 contained in document WIPO/GRTKF/IC/9/INF/6.