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RECOGNITION OF TRADITIONAL KNOWLEDGE WITHIN THE PATENT SYSTEM

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) thatwas 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, and this was noted by the Committee. 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, as well as the

responses to the questionnaire, compiled as WIPO/GRTKF/IC/9/INF/6, a further draft was prepared as document WIPO/GRTKF/IC/9/8, and this was considered and noted by the Committee at its ninth and tenth sessions. A further response to the questionnaire was also circulated as WIPO/GRTKF/IC/10/INF/7.

3. As this draft material has been developed and considered by the Committee over seven sessions, it is proposed that it now be published as a resource for offices that may wish to use it.

4. The Committee is invited to note the further draft of recommendations for patent authorities contained in Annex 1 and to make any comments that it may wish on the draft.

[Annex follows]

ANNEX

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

CONSULTATION PAPER

This paper does not represent any official position. It is circulated as a background resource to facilitate discussion and consultation. Depending on the feedback received, further versions may be circulated before the recommendations are finalized. The recommendations are not normative in nature and do not have any legal effect, but are intended to promote awareness of the nature of traditional knowledge and traditional knowledge systems, to ensure traditional knowledge systems are appropriately recognized in the patent system, and to promote best practices in the practical operation of the patent system. Comments and feedback are welcome, and should be directed to grtkf@wipo.int.

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.

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 peoples' 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

[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')

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 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 ($C_{20}H_{24}N_2O_2$) 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

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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

> 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 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

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

procedure that arise about the status of TK and associated genetic resources in relation to claimed inventions.

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 entails 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.

<u>Some definitions</u>

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 worlds' 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 Treaty[7], 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

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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 sixteen 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 See document WIPO/GRTKF/IC/2/INF.2 and www.wipo.int/eng/meetings/2001/igc/doc/grtkfic2_inf2.doc

second parent field-bean plant, wherein the first or second field-bean plant is that of the invention.[8]

21. According to CGRFA documents[9], 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:

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

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.

(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 USA, and

(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

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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>.

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 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.

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.

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

I. Patent authorities should 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.

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

OUTLINE OF ISSUES

29. 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.

30. The issues considered 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.

31. 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?"

32. 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

III. Patent authorities should 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.

DESCRIPTION OF TRADITIONAL KNOWLEDGE

33. 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.

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

Draft recommendations

IV. Patent examiners who work in relevant technical fields such as life sciences and environmental technology should 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

V. Authorities should prepare analyses or issues papers discussing TK systems and TK that are relevant for patentability criteria in their national or regional systems, for the reference or general awareness-raising of examiners working in relevant technological fields.

LEGAL ISSUES RELEVANT TO TK AND NOVELTY

35. 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.

36. 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]

37. 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

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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

practical context should be enhanced by capacity-building programs along the lines requested 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]

38. 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

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

LEGAL ISSUES RELATING TO TK AND NON-OBVIOUSNESS

39. 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. Within WIPO, the Asian Group has proposed exploring "practical means of integrating into substantive patent examination procedures the teaching of TK systems in such a way that "the person with ordinary skill in

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[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

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

40. 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."

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[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. It 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

VII. 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.

VIII. 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.'

INVENTORSHIP AND ENTITLEMENT TO APPLY

41. Patent examination may need to look beyond the actual patentability of the invention as such, and consider other questions in patent law such as inventorship and the applicant's entitlement to apply for an invention; patent office practice differs between countries in this regard. The question of inventorship and entitlement to apply for a patent may be at issue in cases where the inventive concept has been derived in whole or in part from a TK holder, such as an individual TK practitioner, but that person is not recognized as the or a inventor of the invention as claimed. This question therefore have 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. Entitlement to apply for a patent, inventorship, rights to ownership, obligations arising from non-inventive contributions, enforcement of contractual obligations, and the formal recognition of ownership, licensing and security interests, are all legally significant issues in acquiring, holding and enforcing patent rights, and – and thus may play a role in access and benefit-sharing. They are typically considered distinctly from the patentability of the invention as such (a narrower concept, as contrasted with the validity of a patent on that invention, and the entitlement to own and exercise the patent right).

42. According to the Paris Convention, "[t]he inventor shall have the right to be mentioned as such in the patent,"[24] even though the inventor or joint inventor may not be entitled to the patent itself. The declaration of the identity of the inventor or inventors can involve a crucial assessment of which individuals substantially contributed to the claimed invention, and forms the basis of the legitimacy of the patent application and any patent right granted. Identifying the inventor or inventors is fundamental as the patent right is derived, directly or indirectly, from the act of invention. An applicant who does not have the required relationship with the actual inventor or inventors (e.g. as the inventor, as the inventor's relevant employer, or otherwise as successor in title) is not entitled to a patent right, even if the patent is otherwise fully valid on substantive grounds (novel, inventive, and industrially applicable) – so this apparent formality may also be a significant assertion of a legal entitlement, and failure to disclose an actual inventor (including one of the joint inventors) may prejudice the patent right. Otherwise, the origin or basis of the patent right may be required to be declared. The European Patent Convention (Article 81) states that "(t)he European patent application shall designate the inventor. If the applicant is not the inventor or is not the sole inventor, the designation shall contain a statement indicating the origin of the right to the European patent."

43. If a patent is based on another person's knowledge (whether traditional or not), to the extent that this knowledge forms a substantive part (or all) of the invention, and that person is not identified as an inventor, this could have substantial legal implications. It could form the basis of a claim that this person is entitled to a partial or full share of ownership of the patent or form the basis of invalidation or revocation of the patent.[25] If the knowledge had been disclosed to the public (for instance by the TK holder) prior to the patent's priority date, then it could also invalidate the claimed invention owing to lack of novelty.

44. Requirements to disclose the inventor are directly relevant to the debate about misappropriation of TK, in view of the concerns expressed that some claimed inventions may incorporate TK without authorization of its provider. There is a great deal of case law in patent law concerning 'inventive contribution,' in other words, on how to determine what kind of contribution to the development of an invention amounts to substantial inventorship (including co-inventorship). According to one authority on United Kingdom patent law, "the generation of the idea or avenue for research, that is the formulation of the problem to be addressed, has also been treated as inventive" citing a case[26] in which "it was held that a person (A) was a joint inventor of a new method of securing electric cables, where it was unlikely that the main inventor (B) would have turned his mind to the question without having been prompted by (A) … [the tribunal] was influenced by the fact that the principal inventor, who did not work in the field, was only alerted to the possibility of the improvement by A."[27] On the other hand, "the decision to pursue a particular goal is unlikely to be treated as being sufficiently creative for it to be recognized as an inventive contribution."

45. Where the inventive activity of a patent applicant uses the TK as a lead or a hint, and the TK is not part of the inventive process as such, then TK holders or TK providers may not be considered a co-inventor as such. Outcomes in this area and the distinctions between

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[24] Article 4*ter*; cf PCT Article 4(1)(v).

[25] Attachment to the Australian response: grounds for revocation include "that the patentee is not entitled to the patent" and "that the patent was obtained by fraud, false suggestion or misrepresentation."

[26] *Staeng's Patent* [1996] RPC 183.

[27] L. Bently & B. Sherman, "Intellectual Property Law," Oxford, 2001, p. 476.

inventive and non-inventive contribution may also vary according to the way general principles are applied in respective national legal systems. Potentially, what is considered an inventive contribution in one jurisdiction may not be considered as such in another jurisdiction, meaning that the obligation to identify each inventor could in some borderline cases differ in different countries – cases in which TK provided a directly relevant lead or constituted the first step of the inventive process could figure among such borderline cases. This eventuality is illustrated by Rule 4.6 (c) of the Regulations under the PCT, which provides for the possible need for a request filed with an international application to "indicate different persons as inventors where, in this respect, the requirements of the national laws of the designated States are not the same."

46. Patent examination does not normally focus on the fundamental question of whether the applicant is entitled to apply for the patent (for example, there may be a documentary requirement to furnish a deed of assignment demonstrating the title has passed to the applicant from the inventor, but the examiner would not normally separately investigate the facts surrounding the validity of the assignment, or the exact factual circumstances of the invention, the contribution of various), but this does not mean that these issues are not weighed fully when contested (e.g. when a third party claims a share in ownership or inventorship). In some cases, it may not be the responsibility of the patent office to check on questions of ownership.[28] For instance, in Finnish law:

> "disputes regarding the ownership of an invention are decided in courts… if a person claims before the Patent Authority that he has proper title to the invention and if the circumstances are held to be uncertain, the Patent Authority may invite such person to institute proceedings before a court of law within a period of time to be laid down. If proceedings for proper title to an invention are pending before a court, the patent application may be suspended until a final decision is given by the court."

Accordingly, not all items of required information are necessarily checked and assessed during the patent examination process, even in those patent systems that have mandatory substantive examination of patent applications. It may only be when a patent is the subject of litigation that such fundamental issues as inventorship and entitlement to apply are fully assessed.

47. Nonetheless, where the patent examiner has the responsibility to verify the actual inventorship or the applicant's entitlement to applyfor or be granted a patent, it may be necessary to seek further information or verification . Consider the following practical scenario:

> A patent application claims a combination of known traditional ingredients, with the claim that it has a surprising therapeutic effect. This surprising effect may have been disclosed by a traditional medical practitioner, who had discovered it during the course

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[28] The Enlarged Board of Appeal described the situation concerning the EPO as follows: "[u]nder the European patent system, the EPO has no power to determine a dispute as to whether or not a particular applicant is legally entitled to apply for and be granted a European patent in respect of the subject-matter of a particular application… the "Protocol on Recognition"), which is an integral part of the EPC, … gives the courts of the Contracting States jurisdiction to decide claims to entitlement to the right to the grant of a European patent…," decision G 3/92 (Latchways Application), 13 June 1994.

of their own experimentation and adaptation of traditional healing methods. In this case, the traditional healer may be the actual inventor, and the title to apply for a patent may need to be legally derived from that person. If the effect, claimed to be surprising, apparently seems to be consistent with an established traditional medicine system then it may be necessary to consider whether it would be obvious to a person skilled in the art, a test which may include practitioners of this form of traditional medical knowledge.

Draft recommendations

IX. Where patent authorities have the legal competence to consider questions either of inventorship or of entitlement to apply during examination of the patent, they should 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.

PRACTICAL ISSUES RELATING TO SEARCHING FOR TK AS PRIOR ART

48. There is a relative paucity of information on traditional knowledge within the existing patent system – with some exceptions, such as the coverage of innovations within the field of Traditional Chinese Medicine which are available in the Chinese patent literature. Nonetheless, a wide range of information resources concerning TK are already available for searching (see the surveys in the Appendix, drawn from documents WIPO/GRTKF/IC/2/6, WIPO/GRTKF/IC/3/5 and WIPO/GRTKF/IC/3/6), and similar materials are available concerning genetic resources (for example, the System-wide Information Network for Genetic Resources (SINGER), reported in WIPO/GRTKF/IC/5/6, Annex II).

49. To illustrate the recent efforts made by patent authorities working in cooperation to improve the practical focus of searches relating to traditional knowledge subject matter, consider the following examples:

The broadening of the ‘minimum documentation’ under the PCT to cover a wide array of TK-related publications: these now include the *Journal of Ethnopharmacology; Journal of Chinese Medicine; Economic Botany, Journal of the Society of Economic Botany; Pharmaceutical Biology; Acta Pharmaceutica*; *Planta Medica; Phytochemistry; Journal of Nutrition; Journal of Natural Products; Fitoterapia; Phytotherapy Research; Indian Journal of Traditional Knowledge (IJTK) and the abstracting journal Medicinal and Aromatic Plants Abstracts (MAPA).* These were selected by the cooperating offices (the International Authorities under the PCT system) on the basis of six criteria: *(i) sufficient description of technical content so as to qualify as prior art, including ability to ascertain prior art date; (ii) practicable access to periodicals, including their availability in electronic form; (iii) availability of an English text of articles or, at least, of English language abstracts; (iv) the range of fields of technology covered by periodicals; (v) geographical context of periodicals; and (vi) access conditions applicable to periodicals, including cost and text searchability.*

– The revision of the International Patent Classification to create greater recognition of the nature and diversity of traditional innovative activities, particularly in the field of plant-based medicines. A WIPO Task Force on Classification of Traditional Knowledge developed a new main group for the IPC, designated A61K 36/00, with approximately 200 subgroups, in the field of medicinal preparations containing plants. This should increase the likelihood that patent examiners will locate already published TK that is relevant to claimed inventions in patent applications, without adversely affecting the legal status of TK from the point of view of TK holders.

Some practical challenges in considering documented TK in patent procedures

50. One important practical question is how to enhance the scope of TK that is actually searched and taken into account during the processing of patent applications, and how to focus the search most effectively onto relevant prior art. Unlike other areas of technology, much of the prior art relevant to examination of TK-related patents is rarely found in patent documentation and is often absent from the general scientific literature routeinly search by patent authorities. The disclosure of TK in general scientific literature may also lack the detailed 'teaching' and the overall context that is integral to traditional knowledge systems, thus making it more difficult to assess the true novelty and inventive step of a claimed invention that is derived from TK. With some notable exceptions, most collections of TK have not been developed with the principal aim of defensive publication, and serving as discloses prior art for patent purposes.

51. Equally, difficulties and concerns 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, 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.

52. The practical considerations in the defensive protection of TK, through defensive publication, including the following:

(a) *Prior informed consent and clarity of objectives:* because defensive protection will often entail either the first publication of TK or information about genetic resources, this may have significant implications for the rights of the TK holders and custodians of genetic resources. For instance, it would mean that TK holders may forego patent rights over any innovations thus disclosed, and it would effectively end the protection of such material under laws concerning trade secrets and confidentiality. For material already publicly available in principle, but in fact obscure and difficult to access, a defensive protection strategy may entail making this material much more readily available – in turn, this may increase the possibility of third parties gaining access to and using this information, potentially in ways that would run counter to the interests and concerns of TK holders. For this reason, it is essential to consider carefully whether defensive protection is really what is intended, and whether the community or institution concerned would actually prefer to pursue a positive protection strategy or a combined positive and defensive approach. It would be important to secure the prior informed consent of any party providing information or material that would be disclosed in a defensive protection mechanism: this consent may need to be based on a full description of the implications of disclosure. WIPO is developing a practical toolkit that helps strengthen

the capacity of TK holders to identify and defend their interests during the documentation of their TK.

(b) *Unambiguous publication date*: prior art will only be considered relevant to the substantive examination of a patent if it has been made available to the public before the filing date or priority date of the patent application. Therefore, an unambigous publication date is critical for effective defensive protection. This is particularly relevant for Internet-based publication strategies, where the content of webpages is often changed without clearly dating the amendments. The important date is the date on which the material has been made available to the public, not necessarily the date on which it was first written down (for instance, in the situation where information was kept confidential and only subsequently published). Another important factor is that a patent application with an earlier priority date may be counted as relevant prior art: for instance, even if the earlier application was not published as at the priority date of the later application, it may still be counted as relevant in determining the novelty of the later application. Prior secret commercial use may also be relevant in some countries and in some circumstances. Details of the legal situation in these areas vary considerably between jurisdictions.

(c) *Language and medium of publication:* the cost/effectiveness ratio for defensive publication may vary significantly between various paper-based, print and electronic media. Often governments, organizations or communities seeking defensive protection for their resources and innovations are constrained by cost considerations and must take into account the costs of translation. Stakeholders will probably also have their own preferences as regards the medium of publication, based on their existing publication instruments.[29] If an Internet-based publication medium is chosen, it is crucial, however, that it be possible to verify that the disclosure has remained consistently available in the same form since its publication. It is also important (as noted in paragraph (b) above) that the date of publication be clearly established, a point which is not always clear for internet materials.

(d) *Content of the disclosure:* it is critical for the defensive strategy that the disclosure should contain a complete and comprehensive description of the entire technological concept concerned. If the description covers only certain aspects of the concept, it will be less effective in preventing subsequent patent claims on other aspects of the technological concept. The defensive publication should therefore include descriptions of the use of the technological concept, both the uses which have been shown within TK systems and speculation about other possible uses or applications of the disclosed innovation. The description of a technological concept should also aim at meeting the requirement to enable a person skilled in the art to perform it in practice. If defensive publications include statements indicating that certain innovations, technical approaches or ideas will not work, it may actually strengthen a claim as to non-obviousness for a related patent claim that concerns a way of making this technology workable: such statements should therefore be made with caution.

(e) *Availability to the public:* the critical requirement for a specific teaching to form part of the state-of-the-art, is that it must be available to the public. There is considerable case

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[29] For example, the Gulf Cooperation Council Folklore Center already publishes a Quarterly Review of Folklore in paper form, which includes traditional medicine. In such a case, it would probably be most efficient and cost-effective to build the defensive strategy upon the existing publications.

law on what constitutes "availability" and "the public." Generally, information which is held confidential is not considered prior art. In the case of TK the term "the public" has been particularly scrutinized with respect to the question whether a teaching has been disclosed to "the public" when it has been used in a traditional community, but not outside. The term "availability" becomes important in the genetic resources and TK context with regard to the use of databases and their making available to patent offices exclusively under non-disclosure agreements. Generally speaking, to be counted as prior art, information must have been available to the public: in some cases, this can be as simple as disclosure to one other person, without placing that person under an obligation of confidentiality. In practice, to ensure that it is taken into account during routein search and examination, it is advantageous (from the point of view of defensive protection) if the disclosed information can easily be found by people doing research in the field and especially by patent examiners. On the other hand, making information readily available may well undermine other protection interests (see the extensive discussion in documents WIPO/GRTKF/IC/5/5 and WIPO/GRTKF/IC/5/12).

(f) M*anagement of rights arising from defensive publication:* while defensive publication is intended to waive any possibility of acquisition of patent rights for the disclosed invention, the defensive publication may itself give rise to other intellectual property rights such as copyright or *sui generis* rights in non-original databases. These rights should be proactively managed by the disclosing stakeholders. Additionally, there are some forms of defensive publication which may allow the publishing stakeholder to retain certain rights or to defer the surrender of the rights.

53. The Appendix to these draft recommendations will contain further details on the nature of available databases as well as information on their specific restrictions and other issues relating to the recognition of traditional knowledge. It is essential to understand that databases have a wide range of objectives and functionalities, as is illustrated by this comparative survey of the objectives, functionalities and technical specifications of databases and registries of TK and genetic/biological resources that was set out in the WIPO standards developed by the Asian Group of countries and adopted by the WIPO IGC:

Objective	Functionalities	Technical Specifications	Example Databases
1. Conservation and preservation	1.1 Culturally appropriate recording, compilation and exchange of data	1.1.1 agreed and culturally appropriate Data Specification for databases and registries	People's Biodiversity Registers (PBR), Farmers' Rights Information System (FRIS), Health Heritage Database, TKDL, FRLHT Ayurvedic Materia Medica (India)
2. Defensive protection	2.1 Data search and retrieval integrated with other forms of non-patent literature	2.1.1 IPC-based classification systems for traditional knowledge	TCM Patent Database (China)

		2.1.2 Integration of traditional knowledge data with existing databases and services used in prior art searches;	Health Heritage Test Database integrated with WIPO IPDLs and PCT Search Engine, FRLHT Ayurvedic Materia Medica, Ayuta Index, (India)
		2.1.3 Text-based search and retrieval	Health Heritage Test Database (India) Biozulua (Venezuela)
	2.2 Addressing differing vocabularies	2.2.1 Thesauri, dictionaries and controlled vocabularies	TCM Patent Database (China)
	2.3 Translation to and from local languages	2.3.1 Automated translation	TKDLs (India)
	2.4 Bibliographic references	2.1.4 Data fields and standards for bibliographic references	TKDL (India) and Health Heritage Test Database (India)
3. Positive protection	3.1. Information exchange on intellectual property titles granted for TK and genetic resources – or other intellectual property-related mechanisms.	3.1.1 Data fields and standards for: - right holder - knowledge holder - claims or other definition the protected subject matter; - date of application and of grant; - information on maintenance and use of rights, etc.	- TCM Patent Database (China)
		3.1.2 Agreed data standards for rights information	None for traditional knowledge specifically
4. Full stakeholder involvement	4.1 Capacity building and financial, legal and technical assistance	4.1.1 "Toolkit" on the intellectual property aspects of documentation and database projects;	None
		4.1.2 Accessibility and affordability of hardware and software (both operating systems (e.g. Linux) and database software)	ICONS (United States of America)
	4.2 Stakeholder-identification and -participation in database and policy development	4.2.2 Consultations with indigenous and local communities	National Innovation Foundation (NIF) (India), "StoryBase" (United States of America)
5. National and local control of databases	5.1 Decentralized	5.1.1 Distributed database software	ICONS (United States of America)

	functioning and architecture of information networks	5.1.2 Access control software	"StoryBase" (United States of America)
		5.1.3 Security protocols (e.g. firewalls, using SSL, if the database is accessible through Internet websites…)	TKDL (India)
6. International recognition of defensive and positive protection of traditional knowledge	6.1 International information exchange systems	6.1.1 Networked environment for traditional knowledge databases	None
		6.1.2 Data standards for data exchange (eg XML interfaces)	None

What the search may need to disclose.

54. Patent practice requires consideration of certain practical and legal questions once records of relevant TK have been disclosed, and the immediate database used may serve as a signpost for further investigation if some of the following elements have not been fully recorded in the database as such:

(i) *What is the effective date of the TK as a printed publication:* Patent examiners must identify the date that a written reference was "publically" available or publically used to fix the date from which inventions may be anticipated (and patentability precluded) by that reference. The date a TK database is available as prior art may be quite recent. If the database translates other publically available documents, the publication date of those documents may be relevant dates of prior art that is different from the date the database was made available.

(ii) *Where and when was the TK publically used:* When TK is cited as a public use rather than as a publication, the location of that use may affect its availability as prior art. The data upon which such public use occurred will also be relevant.

(iii) *How does the TK relate to standards of inventive step or obviousness:* To evaluate inventive step or obviousness, an examiner would consider whether the disclosed TK would have made the claimed invention obvious to a person of ordinary skill in the art at the time the claimed invention was made. TK holders should consider how their disclosed TK might be used in such an analysis.

(iv) *Who has access to the TK database and the underlying TK:* Examiners must ordinarily provide copies to applicants of prior art on which they rely to reject a claimed invention. When a TK database and the TK itself are the same in terms of disclosure content, the database provides a transparent portal to the TK. The disclosure in searchable databases, however, could be different in scope than the TK. Would examiners need to send copies of the database information to the applicants? Would the database information and the underlying TK uses or publications be available to applicants? Could those writing patent applications obtain access to the database to search for prior art before filing their patent applications?

(v) *Is the disclosure content sufficient to teach or suggest the claimed invention:* Prior art disclosures must usually be sufficiently detailed and understandable to "enable" a person of ordinary skill in the claimed technology to practice the claimed invention.

(vi) *Could a TK database have inventorship implications:* Patent examiners are required to assume that inventorship has been correctly identified. They can challenge inventorship only if they have some tangible information that would suggest an error was made. Use of a TK database to raise an inventorship issue may be affected by its availability to applicants.

The problem of orally disclosed traditional knowledge

55. A further legal means of enhancing defensive strategies especially relevant to TK is 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.[30] 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.[31] 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.[32]

Draft recommendations

X Patent authorities are 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.

XI. Patent authorities are encouraged to train search and examination staff on the context of TK and sensitivities about its use and handling, so as to ensure that

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

31 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.

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

patent procedures do not contribute to the unauthorized dissemination and use of TK.

XII. Patent authorities are encouraged to promote awareness and sharing of information amongst each other regarding useful sources of traditional knowledge for the purposes of patent procedure, to the extent this can be done in line with the express needs and interests of traditional knowledge holders concerned.

COORDINATION, CONSULTATION AND COOPERATION

56. Coordination, consultation and cooperation between patent offices and with other stakeholders – at a formal or informal level – will be helpful in ensuring that patents are not illegitimately granted on claimed TK-related inventions. Consultation processes in particular could firstly include indigenous communities and representatives of TK holders, to draw on their specific expertise, and secondly other patent authorities, so as to promote the comprehensiveness and inclusiveness of search and examination.

57. Some initiatives have been taken, including through specific legislative proposals, to consult directly with representatives of relevant communities. For instance, New Zealand described such a proposal in WIPO/GRTKF/IC/5/INF/2 (Annex I, p 13-14) and subsequently circulated a draft Patents Bill (www.med.govt.nz/upload/3358/draftbill.pdf) proposing that the patent procedure include consultation with a Māori advisory committee whose members are familiar with mātauranga Māori (Māori traditional knowledge) and tikanga Māori (Māori protocol and culture). The function of the Māori advisory committee would be "to advise the Commissioner (on request) on whether (a) an invention claimed in a patent application is derived from Māori traditional knowledge or from indigenous plants and animals; and (b) if so, whether the commercial exploitation of that invention is likely to be contrary to Māori values."

58. One particular benefit of consultation between authorities is the possibility of drawing on the considerable experience with the development of specific search and examination units that concentrate on certain areas of TK-related patent applications, and sharing any search and examination guidelines that have been developed to deal with TK-related patent applications. Where there are avenues or established mechanisms for work –sharing or pooling of expertise between patent offices, specific areas of expertise in certain systems of traditional knowledge may be taken into account in putting these into operation, so that other patent granting authorities could benefit from this specific expertise, which may be effectively uniquely held in one country.

59. For example, the New Zealand Intellectual Property Office reportedly" developed guidelines for patent examiners concerning patent applications of significance to Maori. The guidelines target inventions relating to, using or derived from indigenous flora and fauna, Maori individuals or groups, indigenous micro-organisms (including viruses, bacteria, fungi, algae where any line of research resulted from any traditional or local knowledge), and indigenous material derived from an inorganic source where research resulted from any traditional or local knowledge."

60. There is an increasing amount of practical experience in certain patent offices in considering the patentability of TK-based inventions from the specific point of view of the TK systems in which they have been developed. For instance, it is reported that the State

Intellectual Property Office (SIPO) of China received 20,864 patent applications in the field of traditional Chinese medicine (TCM) up to 2002, and that SIPO has a team of specialist patent examiners with expertise in the field of TCM. In general, those countries with rich backgrounds in traditional knowledge are likely to develop a strong basis of practical understanding in making judgements about whether claimed inventions are truly novel or inventive, having regard to the standards and conceptual framework of the TK holders and traditional communities themselves. This experience would illustrate how the conceptions of novelty, inventive step, and person skilled in the relevant art, may be adapted and applied most appropriately to innovations based on TK, so as to deal with concerns such as those noted above. This could in time lead to the recognition of certain regional or national patent offices in countries which are the source of certain TK systems as having specific expertise in providing at least an initial judgement on the validity of patent claims directed to material using such TK systems.

Draft recommendations

XIII Advisory or consultative mechanismsmay be developed to provide systematic advice to patent authorities on TK and TK systems that are relevant to their operations.

XIV Patent authorities should 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.

XV No procedures should be undertaken that would accelerate or facilitate the public dissemination of TK that is not disclosed with the consent of TK holders.

XVI Formal or informal cooperation should 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.

EXAMINING SPECIFIC DISCLOSURE REQUIREMENTS FOR GBMR/TK

61. In addition to general patentability criteria, a number of national laws now contain specific provisions requiring the applicant to make specific disclosures relating to genetic or biological materials or resources, and traditional knowledge (GBMR/TK) used in developing the claimed invention. In addition, international proposals have been made to introduce such a requirement into international law, in particular the WTO TRIPS Agreement. For some patent examiners, specifically those working in countries which have such requirements in their national laws, such disclosure requirements may become a specific part of their operations relevant to patent applications relevant to GBMR/TK.

62. However, this is an area of continuing policy debate and negotiation in other international forums. In recognition of the requirement in its mandate that the Committee’s work should not prejudice the work of other fourms, these strictly practical guidelines do not

directly deal with the question, but a brief summary of some of the issues is set out below, drawn from an examination of the issues prepared under the guidance of WIPO's Member States at the request of the CBD Conference of Parties; the full examination is also widely available.[33] The general aspects and character of such requirements are therefore described below without advocating any particular approach.

(i) trigger for the disclosure requirement

63. Three broad functions have been considered for disclosure methods relating to GBMR/TK:

(a) to disclose any GBMR/TK actually used in the course of developing the invention (a descriptive, enabling or transparency function, pertaining to the GBMR/TK itself and its relationship with the invention); in the case of biological resources, this may extend to actual deposit of samples as part of the essential patent disclosure obligation;

(b) to disclose the actual source or origin of the GBMR/TK (a disclosure of provenance function, relating to where the GBMR/TK was obtained, geographically and in what jurisdiction) – this may concern the country of origin (to clarify under which jurisdiction the source material was obtained), or a more specific location (for instance, to ensure that genetic resources can be accessed, so as to ensure the invention can be duplicated or reproduced, or so they can be traced to a specific community or custodian); and

(c) to provide an undertaking or evidence of prior informed consent and/or of equitable benefit-sharing (a compliance function, relating to the legitimacy of the acts of access to GBMR/TK source material and demonstration of the legitimacy of legal provenance) – this may entail showing that GBMR/TK used in the invention was obtained and used in compliance with applicable laws in the country of origin or in compliance with the terms of any specific agreement recording prior informed consent; that lawful arrangements have been established for equitable benefit-sharing; or that the act of applying for a patent was in itself undertaken in accordance with prior informed consent.

64. Possible linkages that may trigger disclosure requirements include:

- access to GBMR is necessary to carry out or replicate the invention as claimed;
- access to GBMR is necessary to implement the preferred embodiment of the invention or other example given in the description of the patent;
- the TK is prior art, known to the applicant, which is relevant to the assessment of whether the invention as claimed is novel and not obvious;
- TK was provided by a TK holder and is directly used in developing the invention, to the extent that the TK holder is a potential co-inventor;
- the GBMR or TK were used in the course of research that led to the invention, and were essential to deriving the invention;
- the GBMR or TK were used in the course of research leading to the invention, but were only incidental to the attainment of the invention;
- the research leading to the invention, the attainment of the invention itself, or the act of filing the patent application, falls within the scope of an obligation incurred under an access agreement or access legislation.

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[33] See, for example, WO/GA/32/8

(ii) The legal principle forming the basis of the requirement

65. A disclosure requirement may be derived from existing patent law, or may be based in other legal systems. In the first category, the possibilities include:

(a) The obligation to disclose the invention sufficiently for it to be carried out by a person skilled in the art, and where appropriate to disclose the best mode for carrying out the invention known to the inventor;

(b) The requirement that patent claims be supported sufficiently by the technical disclosure in the patent;

(c) The requirement to provide information concerning known prior art relevant to the assessment of the patent claims;

(d) The requirement to establish entitlement to apply for or be granted a patent;

(e) Requirements concerning the registration of licenses and security interests; and

(f) A requirement derived from the interaction between patent law and principles of *ordre public* and morality.

66. Non-patent law principles underpinning a disclosure obligation could be drawn from laws concerning access to GBMR/TK, and related benefit-sharing obligations, including:

(a) international standards, notably the CBD and the FAO ITPGR;

(b) applicable national laws in the country of origin, the country of research/invention, or the country where the patent application is lodged, especially concerning access to and use of GBMR and related TK and laws giving domestic legal effect to the CBD; and

(c) contract law may provide the legal basis, in its own right or when contracts or licenses are used as a legal mechanism for implementing access and benefit-sharing regulations.

(iii) The nature of the obligation placed on the applicant

67. The obligation placed on the applicant can range from an exhortation or encouragement to a potential ground of refusal or revocation of a patent. Disclosure requirements concerning GBMR/TK have formal or procedural aspects (such as format and documentation requirements, and deadlines for compliance), as well as meeting substantive tests (for instance, in disclosing enough about genetic resources used in the invention to ensure a skilled person can replicate the invention). Therefore a disclosure requirement may be analyzed as having both aspects, and both may be significant.

68. While the impact of a disclosure obligation may best be determined with reference to the consequences of failure to comply, it is equally important to clarify what it means to comply: for instance, should the applicant go beyond information that is readily available, and should the applicant actively trace the origins of GBMR/TK and investigate the circumstances of its acquisition. The intent of the applicant may also be considered: was a failure to provide relevant information in good faith, or fraudulent in intent? And where should the burden of proof lie: is the applicant is obliged positively to prove that access to GBMR/TK met a certain standard, or can legitimacy of access be assumed in absence of evidence to the contrary?

(iv) The consequences of failure to comply

69. Since disclosure requirements generally have both formal and substantive aspects, the consequences of failure to comply with either aspect may differ. Failure to comply in formal

terms may not necessarily have serious consequences, provided it is not fraudulent and is remedied in a timely manner. Failure to comply in substantive terms (such as requirement to disclose sufficient material to sustain patent claims) may have major consequences for the fate of a patent application or granted patent. The consequences of failure to comply with a particular disclosure obligation may, in principle, flow from the reason for the imposition of the requirement. A failure to disclose genetic resources necessary to carry out the invention may lead to the refusal, narrowing or invalidation of claims that would depend for their legitimacy on that disclosure. A failure to provide adequate information to substantiate entitlement to apply for or be granted a patent may lead to the loss of the patent.

70. Certain disclosure requirements are not derived from substantive requirements relating to patentability of the invention as such, but relate more to broader questions of the entitlement of the applicant to receive a patent, to maintain ownership of a patent, or to exercise a patent right. In this regard, some proposals and commentary relate to a linkage between the manner of access of genetic resources, and the equitable basis of a patent on an invention derived from that access. Some disclosure requirements may therefore be linked to distinct legal mechanisms, including in foreign jurisdictions, such as when a requirement extends to submitting information or documentation about compliance with access and benefit-sharing and may be aimed at monitoring or enforcement of regulations or specific contracts. One way of characterizing the relationship may be to draw a link between inequitable behavior in one context or jurisdiction, and entitlement to exercise patent rights in another, where the patented invention is in some way a consequence of the inequitable behavior. Another way of defining the link would be to view the denial or invalidation of a patent right in one jurisdiction as a form of sanction for non-compliance with other laws, and linking this non-compliance to the entitlement to receive or hold a patent. International policy debate may clarify the relationship between the legal basis for obtaining and holding a patent in one country, and compliance with access and benefit-sharing in another country (that is, the source of genetic resources and associated TK).

General issues

71. The essence of the patent system is transparency and disclosure (the concept of laying open for public inspection is the source of the English word ‘patent’.) Patent law has developed a set of exacting standards for information disclosure which have deep policy and legal foundations within the patent system. The grant of a patent, and the effective exercise of patent rights, are founded on the principle of sufficient disclosure. The very operation of the patent system involves making publicly available a great detail of legal, administrative and technological information, in a harmonized and accessible format. Some patent applications do, as a matter of existing practice, disclose significant information concerning GBMR and TK. Disclosures even in existing patent applications are currently used by concerned parties to monitor the use (and potential misappropriation) of GBMR or TK. This monitoring function of the international patent system has been enhanced by the increasing searchability and availability on-line of patent information.

72. The Technical Study suggests an underlying, key issue is how to characterize the necessary relationship between GBMR and TK on the one hand, and the claimed invention on the other. Discussion of possible disclosure requirements has already covered many ways of expressing this linkage. Better characterizing this linkage should also clarify the range and duration of obligations that may attach to such resources and knowledge, within the source country and in foreign jurisdictions, and how far these obligations ‘reach through’ subsequent

inventive activities and ensuing patent applications. General patent law principles provide more specific ways of expressing this relationship, even if the objective of the requirement is not conceived in traditional patent terms. Patent law may also be drawn on to clarify or implement more generally stated disclosure requirements: for example, a general requirement to disclose genetic resources used in the invention may be difficult to define in practice, and may implemented through a more precise test that requires disclosure only when access to the resources would be necessary to reproduce the invention.

73. Another key issue is the legal basis of the disclosure requirement in question, and its relationship with the processing of patent applications, the grant of patents and the exercise of patent rights. This raises also the legal and practical interaction of the disclosure requirement with other areas of law beyond the patent system, including the law of other jurisdictions.

74. Some of the legal and policy questions identified in the Technical Study were:

(a) the potential role of the patent system in one country in monitoring and giving effect to contracts, licenses, and regulations in other areas of law and in other jurisdictions, and the resolution of private international law or 'choice of law' issues that arise in interpreting and applying across jurisdictions contract obligations and laws determining legitimacy of access and downstream use of GBMR/TK;

(b) the nature of the disclosure obligation, in particular whether it is essentially a transparency mechanism to assist with the monitoring of compliance with non-patent laws and regulations, or whether it incorporates compliance mechanisms;

(c) the ways in which patent law and procedure can take account of the circumstances and context of inventive activity that are unrelated to the assessment of the invention itself and the eligibility of the applicant to be granted a patent;

(d) the situations in which national authorities can impose additional administrative, procedural or substantive legal requirements on patent applicants, within existing international legal standards applying to patent procedures, and the role of non-IP international law and legal principles in this regard;

(e) the legal and operational distinction (to the extent one can be drawn) between patent formalities or procedural requirements, and substantive criteria for patentability, and ways of characterizing the legal implications of such distinctions;

(f) clarification of the implications of issues such as the concept of 'country of origin' in relation to genetic resources covered by multilateral access and benefit-sharing systems, differing approaches to setting and enforcing conditions for access and benefit sharing in the context of patent disclosure requirements, and coherence between mechanisms for recording or certifying conditions of access and the patent system.

75. A further area for clarification is what actions of the inventor or patent applicant are to be monitored or regulated through a disclosure requirement – the actual use of the GBMR/TK (including its use in inventive activities), or the act of filing a patent application as such. The policy concern may relate to the legitimacy of the research or commercial behavior that makes use of the GBMR/TK (including prior informed consent of TK or GBMR holders). In this case, the patent application provides evidence of such behavior, where it may be of concern. Such concern may relate to the very filing a patent application or holding a patent (for instance, where prior informed consent is given to research but not seeking IP, or prior

informed consent includes agreement on assignment, co-ownership or similar disposition of ensuing IP).[34]

Draft recommendations

XVII Without prejudice to the work of international forums on such issues, and without prejudging policy choices in this area, attention may be given to sharing experience with (i) specific search and examination guidelines relevant to GBMR/TK inventioned, and (ii) practical implementation of specific disclosure measures, from the point of view of search and examination.

[Appendix follows]

[34] Clarified in response to comments of Brazil on WIPO/IP/GR/05/1.

APPENDIX

SUPPLEMENTARY MATERIAL

- case studies
- illustrative provisions from existing office guidelines and examination manuals
- useful sources of public domain information on TK and genetic resources
- details of IPC classes relevant to TK searches
- inventories of TK collated by the Committee
- responses to questionnaire WIPO/GRTKF/IC/Q.5.

[End of Appendix and of document]