



CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW

**THE INTERNATIONAL DEBATE ON TRADITIONAL
KNOWLEDGE AS PRIOR ART IN THE PATENT SYSTEM:
ISSUES AND OPTIONS FOR DEVELOPING COUNTRIES**

BY

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EXECUTIVE SUMMARY

- i. Over the past few years, the patent system has come under considerable criticism for its failure to prevent the misappropriation of traditional knowledge. While there is wide agreement that positive protection of traditional knowledge can not be successively accomplished through the patent system, increasingly, consideration is being given to suggestions to use the patent system as a defensive measure against misappropriation of traditional knowledge. One option under discussion in both the WTO and at WIPO is to introduce changes in the system both in terms of rules and practices to ensure that prior art searches fully take into account existing traditional knowledge as part of the state of the art.
- ii. The concern is primarily that patents have been granted for inventions which did not meet fundamental requirements for patentability, when compared to traditional knowledge from which these inventions might have directly or indirectly been derived from. Had the relevant traditional knowledge been known to patent examiners at the time of examining the patent applications, it would have been considered as prior art and, subsequently, may have defeated the claims that the invention was new and involved an inventive step. In a nutshell, the problem that this paper seeks to address is the following: Although there is traditional knowledge being held and used by indigenous peoples and there are publications, databases, journals, periodicals and other means through which traditional knowledge is being disseminated and made public, rarely is traditional knowledge considered as part of the prior art during examination of patent applications.
- iii. This paper is aimed at examining some aspects of the debate on whether and how traditional knowledge could formally be considered as prior art during the examination of patent applications. It discusses the role of databases in making traditional knowledge accessible for purposes of prior art searches and makes recommendations on how best to ensure the patent system does not undermine efforts to protect traditional knowledge. The debate on mechanisms to protect traditional knowledge is no doubt a large and extremely complex one and this paper does not intend to be a comprehensive and detailed analysis of the different issues at stake. The intention is to highlight some salient features of the on-going debate on recognizing traditional knowledge as prior art in the patent system and the issues arising with regard to systemizing traditional knowledge in databases as a defensive measure to protect traditional knowledge.
- iv. The paper first looks at definitional issues regarding prior art and the importance of the concept within the patent system. Secondly, the paper examines the relevance of traditional knowledge as prior art in the patent system. Thirdly, the paper reviews the general problems related to traditional knowledge as prior art under the patent system. The paper then examines the definitions of prior art in Japan, the US and under the European Patent Convention, as well as current trends and practices in these systems and under the Patent Cooperation Treaty system. Sixth, the paper looks at progress in the discussions on traditional knowledge as prior art within WIPO and in the other fora in which the issue is

being discussed. Finally, the paper presents some specific recommendations on how to improve operational aspects of prior art searches to cover traditional knowledge.

- v. The recommendations underscore the need to ensure that the International Searching Authorities under the Patent Cooperation Treaty system and national patent offices, fully take into account relevant traditional knowledge when such knowledge constitutes prior art in relation to a claimed invention. At present, the International Search Guidelines under the Patent Cooperation Treaty and the practices of designated searching authorities do not include a specific requirement for the review of traditional knowledge during patent searches. In this context, the paper considers issues and suggests options regarding: a) how information relating to traditional knowledge which is in the public domain can be made available to patent offices through, for example, databases; b) developing appropriate information systems on traditional knowledge; and, c) formally recognizing traditional knowledge as prior art for purposes of examination of patent applications. Incorporating traditional knowledge into systematic and organized databases, however, raises questions regarding the impact of these organizational measures on indigenous people. Consequently, the paper also emphasizes the importance of taking into account the impact the codification of traditional knowledge might have on measures being put in place to positively protect traditional knowledge.
- vi. Apart from making recommendations for the improvement of the search procedures through mechanisms such as databases and traditional knowledge registers, another option explored in the paper is requiring patent applicants to disclose if any traditional knowledge forms part of the claimed invention. In cases where traditional knowledge forms part of the claimed invention, the paper recommends that patent applicants disclose the source of such traditional knowledge and provide evidence of prior informed consent and equitable benefit sharing with the source communities and/or countries.

I. INTRODUCTION

A. Brief Background

1. Over the past few years, the patent system (especially its operation in the United States - US) has come under considerable pressure and criticism for allowing the direct and indirect misappropriation of indigenous peoples and local communities traditional knowledge, particularly in technological fields where biological resources and traditional knowledge have been utilized as part of research and development processes and, ultimately, have become part of protected inventions.
2. The Turmeric Patent (US Patent No. 5,401,504), the “Neem” (*Azadirachta indica*) Patents (over 40 in the US alone and more than 150 throughout the world including Europe) and the “Ayahuasca” (*Banisteriopsis caapi*) Patent (US Plant Patent No. 5,751) are two of the most notorious cases where the system was stretched to its limits and failures in the prior art search and examination process paved the way to questionable patents being granted. Various claims in all of these “inventions” were based on biological resources and traditional knowledge and practices of indigenous communities in India and the Amazon respectively, which have been used for centuries in these parts of the world and which were obtained without any due respect to indigenous peoples’ rights over their resources, intellectual efforts and developments.
3. In this context, debates are extremely polarized between those who argue that the patent system is *inherently* harmful and unjust with regard to indigenous people and their traditional knowledge and those who maintain it is not. But, even the latter recognize that, in some cases, the patent system has been reinforcing negative perceptions world wide through the granting of very controversial patents.²
4. Paradoxically the same patent system is being considered by some as the source of solutions to overcome these perceptions and prevent and limit illegitimate access to and use of traditional knowledge or, at the very least, impede patents from being granted over dubiously or illegally obtained genetic resources and traditional knowledge. Undertaking good and more comprehensive prior art searches and fully complying with disclosure requirements, are useful tools and mechanisms through which “bio-piracy”³ can be effectively confronted.

² According to Dutfield “... the question to be asked, then, is whether perverse characteristics of the system are integral to IPRs or whether they could be mitigated by rigorous patent examinations or by careful drafting of IPR laws. A strong argument can be made that IPR systems should be made available to protect all useful knowledge whose dissemination is beneficial to the wider public. To the extent they cannot do this, they are inherently flawed. But, on the other hand, some defects could be corrected without having to make radical changes ...” Dutfield, Graham, 2000. *Intellectual Property Rights, Trade and Biodiversity*. World Conservation Union. Earthscan Publications Ltd. London, p.66

³ “Bio-piracy” is not so much a legal concept as a political tool to highlight situations where indigenous peoples traditional knowledge and their biological resources have been unlawfully or illegally utilized, usually by researchers and companies which thereafter claim intellectual property rights over products or processes which have been derived from these resources and knowledge. It is a useful concept to understand a situation where intellectual property instruments (i.e. patents and plant breeders’ rights) affect indigenous people’s interests over their rarely recognized intellectual efforts.

5. Creating international or linking existing national or regional databases containing information on disclosed indigenous people's and local communities' knowledge is a key option being considered. Complemented with enhanced and more rigorous patent examination procedures, an alternative to prevent misuse and abuse of the patent system is being analysed and discussed in academic circles and within policy making processes at the national and international level. Most of the debate and the search for solutions to the many problems posed are taking place at the *World Intellectual Property Organization (WIPO)*.

B. Objective

6. This paper seeks to briefly summarize certain aspects of the debate on traditional knowledge being considered as prior art, analyze the current limitations of prior art searches within the patent system, discuss the role and potential of databases as a source of traditional knowledge and make recommendations on how best to ensure the patent system, as it currently operates, does not undermine indigenous peoples and local communities interests related to the utilization of their traditional knowledge. The paper does not intend to be a comprehensive and detailed analysis of all of the different issues at stake, rather, it hopes to highlight some salient features of the ongoing debate with regards to traditional knowledge and assist in preventing biopiracy by suggesting ways to develop better practices within the operations of the patent system.

C. Contents of the Paper

7. The main analysis in this paper under parts II and III is divided into seven sections. The first looks at definitional issues regarding prior art and the importance of the concept within the patent system. The second briefly examines the relevance of traditional knowledge as prior art in the patent system. The third section reviews the general problems related to traditional knowledge as prior art under the patent system. The fourth section looks at definitions of prior art in Japan, the US and under the European Patent Convention (EPC), as well as current trends and practices regarding prior art searches in these systems. The fifth focuses on the *Patent Cooperation Treaty (PCT)* procedures. The sixth section addresses institutional progress and discussions on traditional knowledge and prior art within WIPO and its different bodies. It also gives a brief overview of other fora in which the issue of traditional knowledge as prior art is being discussed. Finally, the seventh section presents specific recommendations on how to improve operational aspects of prior art searches and thus ensure more comprehensive patent application examinations. In this context, the paper is intended to provide an overall picture of the debate and, ultimately, contribute to: preventing the illegal or unlawful granting of rights over traditional knowledge.

II. TRADITIONAL KNOWLEDGE AS PRIOR ART AND THE USE OF THE PATENT SYSTEM AS A DEFENSIVE MEASURE AGAINST MISAPPROPRIATION.

A. Definition and the Importance of Traditional Knowledge

8. There is no agreed definition for “traditional knowledge”. WIPO, in its fact finding mission report, uses the term “traditional knowledge” to refer to “... *tradition based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields.*”⁴ WIPO also suggests that the terms “traditional knowledge” and “indigenous knowledge” could be interchangeable. The *Convention on Biological Diversity* (CBD) on the other hand, refers to indigenous people’s knowledge, *innovations and practices* to highlight the intellectual effort of indigenous and local communities⁵ as they relate to biodiversity conservation and sustainable use.
9. The term traditional knowledge is only one of various words used to address similar subject matter, namely the intellectual effort and its results, generated by indigenous peoples and local communities, which has enabled them to adapt to and live in relative harmony with their natural environments throughout the centuries and contribute to modern society with innumerable products.⁶

⁴ One important and widely acknowledged aspect about traditional knowledge is that it does not imply static nor necessarily old knowledge. Rather, traditional knowledge is often dynamic and adaptive to changing cultural patterns and a wide range of external influences, including occupation of indigenous people’s lands, market pressures over certain resources, re-settlement, etc. Traditional knowledge often flows in oral forms and is not codified in writing or in systematized forms (i.e. books or databases). For some a key feature is its *collective nature*: knowledge is generated collectively in complex communal manners where no one individual can be recognized as a “creator” (this is not an issue over which no consensus exists although most people tend to agree on the collective nature of traditional knowledge). For further details on terminology see: WIPO. *Intellectual Property Needs and Expectations of Traditional Knowledge Holders*. WIPO Report on Fact Finding Missions on Intellectual Property and Traditional Knowledge (1998 – 1999) Geneva, April, 2001.

⁵ Who *owns* traditional knowledge is possibly the hardest question which experts and indigenous communities themselves face when conceptualizing defensive or positive mechanisms to protect traditional knowledge. Except for limited cases, particular and specific indigenous traditional knowledge is usually shared among a wide range of communities within countries and even among them. Determining *who* has the right to decide about traditional knowledge and what exactly does this right entail poses critical concerns which go beyond the scope of this paper. For discussion of this issue see: Vogel, Joseph. *El Cartel de la Biodiversidad. Transformación de los Conocimientos Tradicionales en Secretos Comerciales*. SAN REM, Ecociencia, USAID, CARE. Quito, 2000

⁶ For the purpose of this paper and recognizing that there are differences between the concepts of “Indigenous communities” and “indigenous peoples”, both will be used indifferently throughout the text. A commonly used term is that of the *International Labor Convention 169 Concerning Indigenous and Tribal Peoples in Independent Countries* which refers to “indigenous peoples” as “...peoples in independent countries whose social, cultural and economic conditions distinguish them from other sections of the national community, and whose status is regulated wholly or partially by their own customs or traditions or by special laws or regulations” (article 1(b)). The CBD on the other hand refers to “indigenous and local communities”, thus also including local communities (i.e. small farmers) which might not necessary be indigenous as would a native community in the Amazon.

10. The importance of traditional knowledge can be perceived by looking at simple facts: 85 % to 90% of the basic livelihood needs of the worlds poor (more than half of the worlds population, including indigenous and local communities) are based on direct use of biological resources (and related traditional knowledge) for food, medicine, shelter, transport, etc.; over 1.4 billion poor farmers rely on farm saved seeds and local plant breeding techniques as their primary source of seed;⁷ 57 % of the top 150 brand name drugs prescribed during a six month period in 1993, contained at least one major active compound derived or patterned on compounds from biological diversity and of the 35 plant derived drugs included in the top 150 best selling drugs, 94% contained at least one compound with proven use in traditional medicinal practices by indigenous and local communities.⁸ . Areas of high concentration of biodiversity and the location of indigenous and local communities often coincide and evidence a pattern of close interrelation between nature, man and knowledge. Communities conserve, maintain, enhance and, in many instances, act as guardians of natural and biological resources.
11. On the other hand, the importance of traditional knowledge also reflects itself in other ways. Modern technologies, including biotechnology, which manipulate, use, adapt or transform biological resources often, use, either directly or indirectly, indigenous knowledge at some point during product research and development processes. Whether using ethnobotanical information found in scientific literature or databases or through direct consultation and interaction with indigenous peoples, traditional knowledge serves an important purpose as a valuable input directing and orienting research activities of universities and companies particularly during initial stages of research. Sectors which have benefited from these inputs include: food, beverages, pharmaceuticals, chemicals, horticulture, agriculture, construction materials and cosmetics.⁹

B. Patents and the Relevance of Prior Art in Relation to Traditional Knowledge

12. In broad terms, patents can be defined as exclusive rights granted for an invention - either a product or a process - that offers a new technical solution to a specific problem. A patent implies the grant of a “monopoly” to an inventor who has used his knowledge and skills to produce a product or process which is new, involves an inventive step and is capable of industrial application. This “monopoly” is limited in time and allows for the patent holder to exercise an exclusive right over the invention and benefit commercially from its exploitation.
13. The grant of a patent is conditioned upon the *full public disclosure* of the invention in order to enable others to improve on existing inventions and technology in general. Disclosure is key in order to help a) determine whether the claimed invention is in fact new (i.e. it does not form part of the state of the art) and not obvious to a person skilled

⁷ See: The Crucible II Group. *Seedling Solutions. Volume 1: Policy options for genetic resources. People, Plants and Patents revisited*. IDRC, IPGRI and Dag Hammarskjold Foundation. Italy, 2000, p.1

⁸ For further information see: Grifo, Francesca. *The Origins of Prescription Drugs*. In: Francesca Grifo and Joshua Rosenthal (eds.) *Biodiversity and Human Health*. Washington DC, Island Press, 1997.

⁹ See: Ten Kate, Kerry and Laird, Sarah. *The Commercial Use of Biodiversity. Access to Genetic Resources and Benefit Sharing*. Earthscan Publications Ltd. London, 1999.

in that particular technological field and b) to allow for other inventors to continue developing and improving technology based on the patented invention, thereby promoting the progress of science and technology. This is in principle, one of the most important counterweights for granting a patent holder exclusive rights in the marketplace. As a general rule, information which is in the public domain cannot be subject to patent claims.

14. Disclosing traditional knowledge which forms part of an invention and of the state of the art or prior art will promote the progress of science by creating an incentive for the maintenance of traditional knowledge systems. It will also create an incentive for indigenous peoples to continue traditional practices which have enabled them to maintain biodiversity *in situ*.¹⁰ This will elevate and promote the *status* of traditional knowledge. This will happen by traditional knowledge being widely and universally accepted within “western” or “modern” innovation protection systems and becoming a reference point within the regular operations of the international patent system.
15. This is also a relevant aspect recognized by article 8(j) of the CBD which calls upon parties to adopt measures to respect, preserve and maintain traditional knowledge, to promote its wider use (with the approval and involvement of indigenous peoples) and encourage the equitable sharing of benefits arising from the use of this knowledge.

C. Traditional Knowledge As Prior Art

16. There has been considerable concern that patents have been granted for inventions which did not meet fundamental requirements for patentability, specifically in relation to the requirements of novelty and inventiveness, when compared to traditional knowledge from which these inventions might have been directly or indirectly derived.
17. Had this traditional knowledge been known to patent authorities – examiners in particular – at the time of review of patent applications, it may have been considered as prior art and, subsequently, may have defeated the claims that the invention was new and involved an inventive step. This would have assisted in the prevention of “bio-piracy”.
18. Prior art or the state of the art usually refers to the complete body of knowledge which is available to the public before a patent application is filed or, if a priority date is claimed, before that priority date. Novelty is measured against the state of the art. The inventive step of an invention will be achieved when it is not obvious to a person skilled in the art, taking into account any matter which forms part of the state of the art. Patent authorities are responsible to ensure that these substantial requirements of patentability are met by the claimed invention before a patent is actually granted.¹¹
19. In simple terms, the problem relating prior art and traditional knowledge could be summarized as follows: although there is traditional knowledge being held and used by

¹⁰ See: CIEL. *Comments on Improving Identification of Prior Art. Recommendations on Traditional Knowledge Relating to Biological Diversity Submitted to the United States Patents and Trademark Office*. August, 1999, p. 3.

¹¹ See Holyoak, Jon and Torremans, Paul. *Intellectual Property Law*. Second Edition. Butterworths, London, 1998 (Chapter 3, Section B).

indigenous peoples (and researchers as well for their own academic and research purposes) and there are publications, databases, journals, periodicals and other means through which traditional knowledge is being disseminated and made public, traditional knowledge has rarely been recognized and considered as forming part of the state of the art for the purpose of the patent system in general. Seldom have patent examiners undertaken exhaustive searches and review of traditional knowledge sources. This has caused, especially in the United States, problems with patents such as those relating to Neem and Ayahuasca.

20. Reasons for this situation vary but include: not having access to traditional knowledge information in classified non-patent literature, not having adequate and effective search tools to retrieve this information and, in general, because this type of information is not systematically ordered and arranged to facilitate its use by patent examiners.¹² Curiously, the approach to this issue, particularly in the United States, is to grant patents and only when such patents are challenged, undertake comprehensive prior art searches. This situation is a major burden for indigenous communities which wish to nullify or invalidate patents over inventions or discoveries that have used or incorporated their traditional knowledge when a) this knowledge already exists in the public domain and b) when this knowledge has been obtained without prior informed consent.

D. Definitions of Prior Art and Search Practices in the US, Japan and under the European Patent Convention

21. Sub-sections 102(a) and (b) of the US Patent Act (35 U.S.C.) establish that a patent will not be granted if the invention was patented or described in a printed publication in the US or a foreign country, either before the date of the claimed invention or more than a year before the date of the patent application. A patent shall not be granted also if the invention was known or used by others in the foreign country. Unpublished or unpatented knowledge or use in a foreign country is not relevant to patentability under this sub-section.
22. Sub-section 102(f) is also relevant in that it determines that a patent will not be awarded when the applicant did not invent the actual subject matter to be patented. In this regard, any information – including traditional knowledge – published or unpublished, in the US or abroad, demonstrating that the applicant is not the actual inventor can be material to patentability. Therefore, patent claims that merely duplicate processes known to indigenous communities should be rejected.¹³ According to US law, patent authorities (in this case the *US Patent and Trademark Office - USPTO*) should carry out a thorough investigation of available prior art relating to the subject matter. The key consideration is to determine whether this information is available or not. Prior art will be available when an examiner can access this information through written texts, databases, published herbarium specimens (in the case of plant patents) or other sources, or when it is provided by the applicant as part of his disclosure obligation.¹⁴

¹² See document WIPO/GRTKF/IC/2/6, paragraph 5.

¹³ See CIEL. *Comments on Improving Identification of Prior Art: Recommendations on Traditional Knowledge Relating to Biodiversity Submitted to the United States Patents and Trade Office*. August 2, 1999.

¹⁴ See *Ibid.* p. 4

23. Recent cases of biopiracy (including the Turmeric and Ayahuasca cases) demonstrate the need for patent examiners in the United States to consistently access and adequately evaluate prior art to ensure patents are not awarded in cases where the subject matter is broader than what was actually invented.
24. Examiners should also review all known databases and registers of traditional knowledge in order to ensure that patents actually involve an inventive step and should additionally integrate existing rules, practices and guidelines governing international searches (i.e. PCT) into routine examination procedures.
25. In order to address these issues and avoid patenting of traditional knowledge, the USPTO has suggested the need to create more easily accessible non-patent literature databases that deal with traditional knowledge. Traditional knowledge could, in this way, be documented, captured electronically and placed under appropriate classification systems in order for it to be more easily searched and retrieved by patent examiners.¹⁵
26. On the other hand, Section 29 of the Japanese Patent Law provides that prior art entails:
a) inventions which were publicly known, b) inventions which were publicly worked and c) inventions which were described in a distributed publication or made available to the public through telecommunication lines in Japan or elsewhere, prior to the filing date or priority date.
27. Complimentary to the above criteria, the Japanese *Operational Guidelines on Treatment of Technical Information Disclosed on the Internet as Prior Art* (December, 1999), offer detailed guidance as to the treatment as prior art of inventions which became available to the general public through communication lines prior to the filing of the patent application. These “telecommunication lines”, as defined, would include websites and on line databases of traditional knowledge. Availability of the information - even if not effectively accessed - is therefore important. As long as access is not restricted to the websites or databases (even if a password or non discriminating procedure is required), these will be considered available to the general public and, therefore, be considered to contain information which could be considered prior art.¹⁶ The same principles would obviously apply to written documentation.
28. In the case of Europe, Article 54(2) of the EPC defines prior art (the state of the art) as comprising “...*everything made available to the public by means of a written or oral description, by use, or in any other way, before the filing of the European patent application*”. EPC jurisprudence has made it clear that the issue is not so much whether the general public are aware of the existence of the information but, rather, that the information is simply available and accessible to anyone at any given time (before the application is filed). This is particularly important with regards to traditional knowledge and information sources of which the general public might not be readily aware.¹⁷

¹⁵ See: Letter by Mr. Robert Saifer, Director, International Liaison Staff, *US Patent and Trademark Office*, addressed to Dr. R. A. Mashelkar, Director General, *Council of Scientific and Industrial Research*, Government of India (August 27, 1999). This proposal is for the purpose of ensuring preventive protection of traditional knowledge but poses important challenges and problems as well with regard to formally systematizing and openly disclosing traditional knowledge and integrating it into the public domain.

¹⁶ See WIPO/GRTKF/IC/2/6, paragraphs 56 - 59

¹⁷ See *Ibid.*, paragraphs 53 - 54

29. Patent searches in the European Patent Office (EPO), seek to discover the state of the art or prior art which is relevant for the purpose of determining whether an invention to which the patent application relates is new and involves an inventive step. This is basically a documentary search. The documentation includes patent documents, complemented by articles, periodicals and other non-patent literature. The search will be as comprehensive and exhaustive as possible, with limitations imposed by economic considerations. As an *International Searching Authority* under the PCT system, the EPO will carry out the search based on documentation specified in PCT Regulations.¹⁸
30. Due to economic considerations, a search examiner will use his discretion to end his search when the probability of discovering further relevant prior art becomes very low in relation to the effort needed. The search will also be stopped when the documents found clearly demonstrate a lack of novelty in the subject matter of the claimed invention and its elaboration in the description would not amount to an inventive step.¹⁹

¹⁸ See: Guidelines for Examination in the European Patent Office. EPO, June, 2000. p. 2

¹⁹ See Ibid., p. 17

E. The Patent Cooperation Treaty (PCT): Prior Art Definition and Disclosure Requirements²⁰

31. The PCT was concluded in Washington D.C in 1970 and to date there are over 100 countries which have ratified the Agreement. The PCT is only an international system for processing patent applications and formal granting of patents remains under national or regional jurisdiction.
32. The PCT process consists of two phases: an international phase and a national phase. The international phase is based upon: an international application, an international search, an international publication and an international preliminary examination. The national phase is made up of different procedures which an applicant needs to carry out with the designated office once the international phase is over.
33. It is the international phase procedures and institutional capacities of searching authorities, which make PCT an important instrument with which to promote alternatives for considering traditional knowledge either during the *International Search* or as part of an *International Preliminary Examination*.
34. Article 15(1) and (2) of the PCT establish that international applications will be subject to an international search. This search aims at discovering relevant prior art which, for the purposes of the PCT is defined by Rule 33.1 of the PCT Regulations as “ ... *everything which has been made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) and which is capable of being of assistance in determining that the claimed invention is or is not new and that it does or does not involve an inventive step (i.e. that it is or is not obvious) , provided that the making available to the public occurred prior to the international filing date*”.²¹
35. It seems clear that oral disclosure, use, exhibition or other means of disclosure will only be considered relevant during an international search if they are substantiated by *written* disclosure. Indeed, as important (and common) as oral traditions might be among indigenous communities, there are practical aspects of patent searching procedures which would make it necessary to evidence and substantiate traditional knowledge and practices in some written form.

²⁰ The PCT is particularly relevant to the traditional knowledge and prior art discussions because of the international nature of its prior art searching procedures and the advantages it offers. The international search - through an International Searching Authority – is carried out by national offices of Australia, Austria, China, Japan, the Republic of Korea, Russian Federation, Sweden, the US and the European Patent Office. High quality, although not binding, International Search Reports and International Preliminary Examinations provide patent applicants with an additional and considerable degree of certainty with regards to the patentability of their inventions, therefore its novelty, inventiveness and industrial application. Institutional capacities, human resources and financial resources available in these offices make them the ideal to ensure comprehensive and rigorous patent searches. For further details of the advantages of the PCT see: WIPO. *Basic Facts about the Patent Cooperation Treaty. The worldwide system for simplified multiple filing of patent applications*. WIPO. April, 2002.

²¹ See: Rule 33.1 (a) Regulations Under the PCT.

36. The international search²² will cover all technical fields which may contain material pertinent to the invention and involve subject matter that is usually recognized as equivalent to the subject matter of the claimed invention for all or certain of its features. The International Searching Authority will “...endeavor to discover as much of the relevant prior art as its facilities permit, and shall, in any case, consult the documentation specified in the Regulation”.²³ Furthermore, the international search “... in so far as possible and reasonable, will cover entire subject matter to which the claims are directed or to which they might *reasonably be expected to be directed after they have been amended*.”²⁴ An International Searching Authority should therefore endeavor to discover as much of the relevant prior art as its facilities permit. In any case, the authority must consult the so-called minimum documentation.²⁵
37. The current minimum documentation list was agreed upon during the Fourth Plenary Session of the *Standing Committee on Information Technology* (SCIT) (December 6 – 10, 1999) and came into effect in January, 2000. As a means to incorporate traditional knowledge into international searches, one option could be that periodicals, newsletters, gazettes and other publications which document traditional knowledge be integrated into the minimum documentation list.
38. Incorporating traditional knowledge sources in the *Journal of Patent Associated Literature* (JOPAL), a centralized database of bibliographic data used to aid patent offices in search of technical and scientific non-patent literature, could also play an important role in ensuring comprehensive prior art searches with regards to traditional knowledge.
39. The *Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (the “Intergovernmental Committee”)²⁶ under Task B.3, is assessing how best to ensure that the International Searching Authority can carry out international searches and discover pertinent traditional knowledge when it constitutes prior art in relation to the invention. At present, the *International Search Guidelines* of the PCT and overall practices of designated searching authorities do not

²² The International Search Report contains: citation of the documents considered relevant, classification of the subject matter (according to the International Patent Classification), an indication of the fields which have been searched and any electronic database searched. Citations of particular relevance must be especially indicated.

²³ See: Article 15(4) PCT.

²⁴ See: Rule 33.3 (b) Regulations under the PCT.

²⁵ Minimum documentation comprises: Patent documents issued by France after 1919; by Germany from 1920 to 1945 and by the Federal Republic of Germany since 1945; by Japan (for International searching Authorities other than the Japan Patent Office) only those documents for which English abstracts are available; by the former Soviet Union and now the Russian Federation (for International Searching Authorities other than the Russian Patent Office) only those documents for which English abstracts are available; by Switzerland (except documents in Italian); by the United Kingdom; by the United States of America; by the African Intellectual Property Organization; by the European Patent Office and by the Eurasian Patent Office. It also includes published international PCT applications and from various sources including 135 periodicals. If an International searching Authority has more documents available it is obliged to consult them to the extent permitted by its facilities. See: Chapter VII, Volume I of the PCT Applicants Guide.

²⁶ The Intergovernmental Committee was established by the WIPO General Assembly at its Twenty Sixth Session held in Geneva from September 26 to October 3, 2000. See document: WO/GA/26/6 at <http://www.wipo.int>

include a specific requirement for the review of traditional knowledge information or data.

40. PCT also offers, upon demand of the applicant, an *International Preliminary Examination*.²⁷ The preliminary examination which is carried out by an *International Preliminary Examining Authority*²⁸ is intended to provide a confidential non-binding report regarding novelty, inventiveness and industrial applicability. This report does not however address issues of patentability under any specific existing law or regulation. It merely states whether the claims appear to comply with the criteria of novelty, inventiveness and industrial application as defined in the PCT. Although there are no uniform approaches to these criteria in national laws, their application under the PCT during the international phase gives the applicant a good idea of the likely results during the national phase.
41. Finally, with regards to non-written disclosures, the PCT provides that “... *in cases where the making available to the public occurred by means of an oral disclosure, use, exhibition or other non-written means (non-written disclosure) before the relevant date as defined in Rule 64.1(b) and the date of such non-written disclosure is indicated in a written disclosure which has been made available to the public on a date which is the same as, or later than, the relevant date, the non-written disclosure shall not be considered part of the prior art for the purposes of article 33(2) and (3). Nevertheless, the international preliminary examination report shall call attention to such non-written disclosure in the manner provided for in Rule 70.9*”.

F. The Current Discussions in WIPO on Traditional Knowledge as Prior Art

42. During the first session of the Intergovernmental Committee²⁹ held from April 30 to May 3, 2001, Member States agreed upon an agenda of work and items to be prioritized by the Intergovernmental Committee. Under Agenda Item 5.2 (Protection of Traditional Knowledge) a series of tasks were proposed; Tasks B.1 to B.4. In terms of Task B.3³⁰ Member States expressed their wish to consider and examine existing criteria and the need for possible new criteria to allow for more effective integration of traditional knowledge documentation into searchable prior art.³¹
43. At its Second Session, held on December 10 – 14, 2001, the Intergovernmental Committee considered the *Progress Report on the Status of Traditional Knowledge as Prior Art*³² and debated extensively on implementation of Task B.3. Five overall activities were considered in order to implement Task B.3. These included : compiling an inventory of existing traditional knowledge periodicals in order to discuss whether they might be considered by the PCT International Searching Authorities as part of their

²⁷ See: Article 31(1) of the PCT.

²⁸ These are generally the same as International Searching Authorities.

²⁹ See: WO/GA/26/6 at <http://www.wipo.int>

³⁰ See: WIPO/GRTKF/IC/1/3

³¹ See: WIPO/GRTKF/IC/2/6

³² WIPO/GRTKF/IC/2/6

minimum documentation requirements (Possible Activity 1); as a result of Possible Activity 1, assess whether prioritized periodicals might be incorporated into JOPAL project (Possible Activity 2); discuss possible recommendations to consider traditional knowledge as prior art in amendments to guidelines for patent searches and examinations (Possible Activity 3); assess the feasibility of the electronic exchange of public domain traditional knowledge documentation data, including through the creation of a database and digital library (Possible Activity 4); examine applicability of existing intellectual property documentation standards to traditional knowledge related subject matter (Possible Activity 5); and discuss means of assisting indigenous peoples and traditional knowledge documentation initiatives (Possible Activity 6).

44. One key issue is how to ensure prior art searches carried out by patent authorities take adequate consideration of traditional knowledge. Even though throughout the world there is a large amount of documented traditional knowledge, there are current limitations as to how patent procedures can include broader and more comprehensive searches for prior art and thereby prevent misappropriation of traditional knowledge. These limitations however, seem to stem from regular practices rather than from fundamental difficulties (or even legal restrictions) which patent authorities face.
45. Additionally, the analysis would also have to extend to how traditional knowledge might be positively protected.³³ It is not enough to focus on defensive protection although it can be supported as an initial step towards overall protection of traditional knowledge.³⁴
46. Addressing these concerns will necessarily require: a) assessing how public domain information relating to traditional knowledge can be made available for patent offices³⁵, b) allowing patent offices to formally integrate the analysis of this information into their procedures for examining and granting patents and c) developing appropriate information systems (including databases) on traditional knowledge. The development of such information systems would have to take into account whether centralized information systems are needed or whether decentralized but interconnected systems might be a better option. Most importantly, due consideration would have to be given to

³³ Negative or preventive protection of traditional knowledge refers to the use of mechanisms to impede traditional knowledge from being misappropriated. For example, the prior art search (for traditional knowledge) during patent procedures and ensuring non-obviousness of an invention are two ways through which negative protection can be ensured. It is a *preventive* measure and a reaction to an action (filing of a patent). Positive protection refers to mechanisms which ensure rights are actually provided and conferred to indigenous peoples with regards to their traditional knowledge.

³⁴ For a review of policy and legal advances in regimes for the protection of traditional knowledge in Suriname, Guyana, Brazil, Colombia, Venezuela, Ecuador, Peru and Bolivia see: Ruiz, Manuel. *Protección sui generis de conocimientos indígenas en la Amazonía*. Corporación Andina de Fomento, Parlamento Andino y Sociedad Peruana de Derecho Ambiental. Lima, 2002.

³⁵ Discussions are still ongoing as to circumstances where traditional knowledge can be or not be considered as being in the public domain. For example, it is not the same to have traditional knowledge recorded and codified in a widely available database as to have traditional knowledge available within indigenous peoples' contexts alone (i.e. available within a few organized communities). The question to ask is whether it could be argued that in the latter case, traditional knowledge is in fact in the public domain. In any case it should be assumed that the information and data which could eventually be incorporated into publicly available databases will be information and data, which is at least accessible, and, therefore, *in* the public domain. For further discussion see: WIPO/GRTKF/IC/2/6.

the impact which codifying traditional knowledge might have on traditional knowledge cultures and livelihoods.³⁶

47. The following few paragraphs describe past and present work within WIPO bodies in relation to the issue of traditional knowledge and prior art debates.

◆ *WIPO Standing Committee on Information Technology (SCIT).*

48. During its Third Plenary Session, (June 14 – 15, 1999), the SCIT adopted a *Strategic Information Technology Plan into the 21st Century* which includes references to the need to create traditional knowledge databases for traditional knowledge in the public domain. At its Fourth Plenary Session (December 6 - 10, 1999) the SCIT considered an *Approach Paper for Establishing Traditional Knowledge Digital Libraries (TKDL)* which, in turn, is part of *WIPO Intellectual Property Digital Libraries (IPDL)*. The IPDL initiative seeks to identify and develop data exchange standards to be used by WIPO Member States offices and the IPDL system implemented by the International Bureau and to provide maximum level of integrated access to WIPO IP data collections. Although the SCIT decided not to pursue the TKDL within its Program, it did recognize the need to consider the exchange of traditional knowledge within the overall approach of WIPO to the issue of traditional knowledge.³⁷

◆ *WIPO Committee of Experts of the Special Union for International Patent Classification Union (IPC Union).*

49. At its Thirtieth Session, the Committee of Experts of the IPC Union (February, 2002), agreed that a Task Force (made up of representatives from China, India, Japan, United States and the European Patent Office) be created in order to study the *Traditional Knowledge Resources Classification (TKRC)* of the TKDL as presented by India and assess its information aspects and relation to the IPC. The IPC Committee noted that: a) the most efficient way of developing classification tools for traditional knowledge would be their integration into the IPC, b) the IPC could be used for classifying non-patent, traditional knowledge information, c) work of the Task Force should be carried out with a view of an IPC revision proposal, and d) the Task Force should look at ways in which a revised IPC could be linked to traditional knowledge classifications.³⁸

◆ *WIPO Standing Committee on the Law of Patents (SCP).*

³⁶ Laird, Alexaidés, Bannister and Posey argue that “... knowledge within communities is not equally distributed; rather it is distributed and exchanged according to particular norms and criteria, all of which may be disrupted by the publication process”. Furthermore, they also suggest that due to the very complex ways in which knowledge is generated and flows within indigenous communities “... removal or transfer of information from the group through publication can threaten internal and external stability”. Knowledge will be misrepresented, weakened and misused. Finally, these authors recognize that there is an international trend – probably fuelled in part by the CBD – towards greater consultation with groups regarding publication of their knowledge. See: Laird, S., Alexaidés, M., Bannister, K., Posey, D. Publication of Biodiversity Research Results and the Flow of Knowledge. In: Laird, Sarah (ed). 2002. *Biodiversity and Traditional Knowledge. Equitable Partnerships in Practice*. WWF, RBGKew and UNESCO. Earthscan Publications Ltd. London, p. 82.

³⁷ For further information on this see documents: SCIT/3/2 Item 7.2; SCIT/4/2 Annex II; SCIT/4/8

³⁸ For details see: WIPO/GRTKF/IGC/3/5

50. The SCP is at present discussing the definition of “prior art” in the context of the development of the draft *Substantive Patent Law Treaty* (SPLT). As part of its information gathering activities, the SCP has received a series of responses from countries with regard to the prior art effect on patentability of information disclosed on the Internet. As a general rule, some national patent authorities limit the use of the Internet for the purpose of prior art searches to websites and databases of high credibility. Others categorize websites according to their credibility.
51. One key problem regarding websites is timing and contents of Internet databases and overall information. Suggestions for a “certification service” to certify timing of disclosure and content of websites received mixed reactions. Many countries, however, expressed their concerns regarding the cost and effectiveness of such a mechanism and there is probably a considerable need to assess the feasibility and desirability of such a certification scheme.³⁹
52. During the Seventh Session of the SCP (May 6 – 10, 2002) the draft article 8 of the SPLT on the definition of prior art was discussed. The draft provisions basically provide that prior art refers to any information made available to the public, *anywhere* in the world in any form as prescribed in the Regulations, before the relevant claim. Under Rule 8 of the draft Regulations it is provided that information made available to the public in any form, such as written form, by oral communication, by display, or through use, shall qualify as prior art under Article 8(1).

◆ *The Intergovernmental Committee.*

53. The Intergovernmental Committee was established in the year 2000 after extensive discussion within WIPO and its Member States on intellectual property and genetic resources issues. The Intergovernmental Committee was established to provide a forum for discussion among Member States on intellectual property issues that arise in the context of: a) access to genetic resources and benefit sharing, b) protection of traditional knowledge, and c) protection of expressions of folklore. These are cross-cutting issues which affect conventional intellectual property branches but do not fit into existing bodies such as the SCP or the SCIT. Work within the Intergovernmental Committee was expected to complement and be consistent with advances in the CBD process and the *Commission on Genetic Resources for Food and Agriculture* (CGRFA) of the *Food and Agriculture Organization* (FAO).
54. During its Third Session (June 13 – 21, 2002) the Intergovernmental Committee discussed among other issues, the inventory of traditional knowledge-related periodicals, existing intellectual property protection of traditional knowledge and elements of a *sui generis* system for the protection of traditional knowledge.

◆ *Other forums working on traditional knowledge.*

³⁹ Information on the Internet, particularly with regards to traditional knowledge, presents a challenge regarding *when* exactly the information was incorporated into the Internet. This relates to the issue of *filing* and *priority* dates of a patent application. Personal conversation with: Mrs. Begoña Venero, Member of the Intellectual Property Tribunal of INDECOPI (the Peruvian National Institute for the Defense of Competition and Intellectual Property). See also: SCP/4/5.

55. There are numerous other forums and institutions working on different aspects of traditional knowledge. Some of the main forums and institutions that deal with the issue of traditional knowledge, prior art and databases include, the CBD, the World Health Organization (WHO) and the WTO in its Committee on Trade and Environment (CTE) and in the TRIPS Council.
56. *The Convention on Biological Diversity*: Within the work of the *Ad Hoc Working Group on Article 8(j) and Related Provisions*, activities have been proposed to develop guidelines and standards to prevent misappropriation of traditional knowledge in general. The Fifth Conference of the Parties (COP) called upon Parties to support the development of national registers of traditional knowledge, innovations and practices.⁴⁰ The Panel of Experts on Access to Genetic Resources also agreed that developing registers could assist in identifying and promoting recognition of traditional knowledge as prior art.⁴¹
57. *World Health Organization*: The WHO coordinates a *Traditional Medicine Team* set up to support countries in developing national strategies on traditional medicine and upgrading the knowledge of traditional medicine practitioners. During an inter regional *Workshop on Intellectual Property Rights in the Context of Traditional Medicine* (Bangkok, December, 2000) it was recommended that traditional knowledge in the public domain should be documented in the form of digital libraries and exchanged and disseminated through mechanisms related to intellectual property rights. Work in this regard should be coordinated with WIPO.⁴²
58. *WTO's Committee on Trade and the Environment and the TRIPs Council*: Work and discussions have progressed mainly in the area of traditional knowledge and databases, and how these might serve as defensive mechanisms against "bio-piracy". Under the review of article 27.3(b) of the TRIPs Agreement one proposal is that features and main characteristics of an international database on traditional knowledge could include: the need for this database to be international in scope; the need for the database to act as a gateway to existing regional and national databases (not a *centralized* database per se); the need for this mechanism to be administered by WIPO.⁴³
59. Still other forums and institutions working on different aspects of traditional knowledge and indigenous and local peoples in general include: the World Bank, the United Nations Conference on Trade and Environment (UNCTAD), the Andean Community of Nations, the Inter-American Development Bank and the African Union, to name a few.

⁴⁰ See Decision V/16 of COP V, Annex IV

⁴¹ See document UNEP/CBD/COP/5/8 paragraphs 136 - 138

⁴² See <http://www.who.org>

⁴³ See document IP/C/W/284, paragraph 17

III. KEY ISSUES AND OPTIONS TO CONSIDER IN DEVELOPING MECHANISMS UNDER THE PATENT SYSTEM TO IMPEDE OR LIMIT MISAPPROPRIATION OF TRADITIONAL KNOWLEDGE

60. It is useful to highlight some basic considerations regarding traditional knowledge, prior art, disclosure and patentability discussion in order to propose practical recommendations to address the problems which the linkages between these elements bring about. Some of the main considerations include the fact that:

- there is abundant information on codified traditional knowledge in existing publications, databases, periodicals, journals, etc.,
- much of this information could be considered to be in the public domain,
- some of this information has been collected without prior informed consent from indigenous and local communities,
- most of this information is not organized nor classified in a systematic manner and is only exceptionally used by the patent system in order to evaluate prior art and determine novelty and inventiveness; more often, it is has been used to challenge patents *already* granted,
- using databases for protecting defensively and positively traditional knowledge is not mutually exclusive,
- some indigenous peoples are using databases to document and protect their rights, for example, the Tulatip tribes in the United States⁴⁴,
- incorporating traditional knowledge into systematic and organized databases⁴⁵, even when already in the public domain, raises questions regarding the impact of these organizational measures on indigenous peoples cultures and also calls for an assessment of the potential effects of this organized informational system on *positive* protection of traditional knowledge⁴⁶,
- although *negative* or *defensive* protection – preventing bio-piracy through patents – goes one step forward in ensuring the patent system operates appropriately, it is only a measure out of a series of potentially useful

⁴⁴ See, Tulatip Natural Resources. Cultural Stories. ICONS CD ROM, 2002.

⁴⁵ Another issue for consideration is the possibility of developing registers (databases) with differentiated levels of accessibility, depending on the purpose of accessing the pertinent information. This could enable the register to serve a two tier purpose: on one hand it can act as a defensive protection measure but also have a positive protection feature in the case of certain traditional knowledge which is kept under greater restrictions. For further discussion see: WIPO/GRTKF/IC/3/6, paragraph 55.

⁴⁶ A good example here might be the *International Cooperative Biodiversity Group* project in Peru. Indigenous communities managed to negotiate contractual conditions for the use of their knowledge which was in the public domain, although limited to a geographical ambit where the public domain was, in practice, limited to the communities which shared this knowledge. Knowledge had not flowed outside their communities. If this knowledge had been recorded and organized in a functional, publicly available database it would have been harder if not impossible for communities to argue the need to negotiate over now codified and recorded traditional knowledge. The fact that knowledge is not recorded nor codified (even if in the public domain) provides indigenous communities with an opportunity to negotiate over its use. For an analysis of this case see: Tobin, B. Chapter 9. *Biodiversity prospecting contracts: the search for equitable agreements*. In: Laird, Sarah (ed). 2002. *Biodiversity and Traditional Knowledge. Equitable Partnerships in Practice*. WWF, RBGKew and UNESCO. Earthscan Publications Ltd. London, p.287 – 309.

approaches to ensure protection of traditional knowledge which is, ultimately, the main challenge.

A. Disclosure Requirements

61. As a general rule, patent applicants should disclose to the patent authority all information known to be material to patentability. Such information could include description of traditional knowledge utilized in the invention.
62. For this purpose, patent authorities could require that applicants:
 - conduct their own prior art searches of traditional knowledge and include that information in the application,
 - disclose source country (or traditional knowledge holder communities), and
 - ensure that use of traditional knowledge complies with national laws⁴⁷ (i.e. on access to and use of genetic resources and traditional knowledge)⁴⁸ and international principles regarding prior informed consent and benefit sharing under the CBD.⁴⁹

⁴⁷ An example is provided by *Decision 486 of the Andean Community of Nations on a Common Regime on Industrial Property*. As part of the initial patent application procedure, the patent examiner, when provided with evidence that traditional knowledge or genetic resources of which the five Member States of the Andean Community of Nations are source countries or countries of origin respectively, has the right to require from the applicant evidence that traditional knowledge or resources used in his invention have been legally obtained. This mechanism leaves a degree of discretion to the examiner in order to demand these in cases where sufficient evidence is at hand to suggest traditional knowledge has been utilized. This is *not* considered a patentability requirement but a formal procedural condition as part of the administrative application process. For further analysis of this particular mechanism and regime see respectively: Pires de Carvalho, Nuno. *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPs Agreement: The Problem and the Solution*. In: Washington University Journal of Law and Policy. Vol 2, 2000 and Ruiz, Manuel. *Análisis de la Decisión 486 de la Comunidad Andina: Su Legalidad y Aplicabilidad en Cuanto a sus Exigencias sobre Origen de Recursos Genéticos y Conocimientos Tradicionales*. Documento preparado para la *Corporación Andina de Fomento* (versión en borrador). Lima, 2002.

⁴⁸ Countries such as Panama, Costa Rica, Brazil and the *Andean Community of Nations* (Venezuela, Colombia, Ecuador, Peru and Bolivia) have laws in place which establish basic requirements to access and use traditional knowledge. These laws however, generally refer to cases where knowledge is sought directly, *in situ*, for indigenous communities. They do not address the issue of knowledge kept in publicly available databases or in the public domain in general.

⁴⁹ International law should, generally, form a coherent system of principles and norms which complement each other or, at least, do not conflict among each other. In this sense, complying with these requirements enables the patent system to support the realization of the CBD objectives, particularly with regards to benefit sharing. Relevant articles linking the CBD to the intellectual property regime include:

Article 8(j) Each Contracting Party shall as far as possible and appropriate : *Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices.*

Article 10(c) Each Contracting Party shall as far and as possible: *Protect and encourage customary use of biological resources in accordance with traditional practices that are compatible with conservation and sustainable use requirements.*

Article 16(5) : *The Contracting Parties, recognizing that patent and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to*

B. Search Procedures

63. As has already been pointed out, many of the shortcomings and limitations of the patent system to deal with misappropriation stem from the fact that procedures for actually examining patent applications have, in broad terms, not been designed to consider traditional knowledge in the search of prior art even if in principle there is no reason why this should not be so.
64. In this regard, possible options to ensure traditional knowledge is not misappropriated through the patent system could include:
- ensuring that the patent application examination procedure (at the national level and particularly with regards to PCT) reviews and takes into account all accessible and available information contained in databases (particularly through the World Wide Web), publications and other sources of traditional knowledge.⁵⁰

C. The Relationship between the TRIPS Agreement and the CBD

65. Ways need to be devised to ensure that the TRIPs Agreement and the CBD are mutually supportive, even if their objectives point to different overall goals. With regards to patents in particular, the TRIPs Agreement should be amended to, at the very least, ensure that when patents are granted over biologically derived inventions which might incorporate traditional knowledge, the granting procedures require applicants to provide evidence showing that:
- the materials were accessed legally,⁵¹
 - traditional knowledge when, and if used, was obtained, used or incorporated into the invention with the consent of the corresponding knowledge holders,⁵²

national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

⁵⁰Implementation of the CBD in the area of conserving, maintaining and promoting wider application of traditional knowledge (article 8(j)) is paving the way for the development of mechanisms and instruments devised in order to confer positive and defensive protection of traditional knowledge. Most of these are related to the development of registers of traditional knowledge (databases). As databases become more widely available, this will enable patent examiners to conduct more precise and comprehensive prior art searches in the field of traditional knowledge. The CBD *Clearing House Mechanism* could become an alternative to provide a single and centralized entry point to worldwide databases on traditional knowledge.

⁵¹ This requirement was in fact first put into practice as part of the Peruvian regulation on plant breeders' rights where an applicant is required to provide legal evidence of the origin of genetic material contained in the plant variety and of the knowledge (including traditional knowledge) which was used in the variety (Supreme Decree 008-96-INDECOPI, 1996). Subsequently, Decision 391 of the Andean Community on a *Common Regime on Access to Genetic Resources* also included this same requirement as does the recent *Decision 486 on a Common Regime on Industrial Property* (2001). Countries like Brazil, Costa Rica, Denmark, India and others are also including these types of provisions into their access laws or intellectual property regulations.

⁵² If in the case of the *Budapest Treaty on the International Recognition of the Deposit of Microorganisms*, disclosure of biotechnological inventions is complemented by a voluntary deposit of the pertinent microorganism - for an effective full disclosure of the invention - and, furthermore, this does not run counter to the TRIPs Agreement nor article 29.1, it is possible to argue that the additional requirements suggested (i.e.

- there exist mutually agreed terms for benefit sharing.

66. In this regard, article 29.1 of the TRIPs Agreement, which provides that the applicant “... shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor ...” could be amended to include these requirements as part of the patent application procedure⁵³ and especially the disclosure of the origin of the genetic resources and traditional knowledge.

D. Access to Genetic resources (Traditional Knowledge) and Patent Authorities

67. Most biodiversity rich countries in the world have either developed or will soon have in place national legislation regulating access to genetic resources and, in some cases, provisions regulating access to and use of traditional knowledge. Whereas the problems presented above will be dealt with in areas where patents and biotechnology are mostly involved it is important that:

- national (and international) patent authorities maintain close communication and exchange information regarding specific instances where genetic resources have been accessed and traditional knowledge is being used for commercial or industrial purposes and b) applications which might involve use of these resources and knowledge.⁵⁴

E. Review of the Patent Classification System

68. Due to regular and internalized practices of national and international authorities in the use of the *International Patent Classification* system:

- a review of or amendment to the IPC could prove extremely useful in assisting patent examination authorities with a widely utilized tool for the patent examination process.

F. Additional Minimum Documentation

69. Due to the importance of indigenous knowledge and its use in research and development processes in a series of industries and its incorporation into patents:

disclosure of origin of the material and prior informed consent) could also be part of an adequate and full disclosure of the invention.

⁵⁴ What exactly is the nature of these linkages remains to be discussed. One example is provided by the Complementary Disposition of Decision 391 of the Andean Community on a Common Regime on Access to Genetic Resources which establishes that “...National (Access) Authorities and National Authorities of Intellectual Property will establish information exchange systems regarding access to genetic resources contracts and intellectual property rights granted”. This could not only help in initiating legal actions if resources have been obtained illegally but also assist searches during the patent application procedure in general.

- the minimum documentation list of the PCT system should include traditional knowledge related materials (books, gazettes, periodicals and databases).

68. In addition, JOPAL could also add traditional knowledge documentation sources into its bibliographic references.

G. Prior Informed Consent and Awareness Raising

71. Although there is an increased level of participation of indigenous people representatives in international forums (including the Intergovernmental Committee) and an awareness raising process has in practice begun on these issues, it could prove useful:

- For WIPO to support national consultative processes where indigenous communities are informed and asked about the possibility of codifying, centralizing or simply systematizing traditional knowledge in databases.

68. This process could help - to a certain extent and certainly not fully - to legitimize certain efforts and initiatives which are being undertaken to create traditional knowledge databases at the national and international level. Extreme care should be taken in order to ensure that traditional knowledge recorded is traditional knowledge which is in the public domain⁵⁵.

H. Operations of Databases

73. When developing and designing databases for prior art purposes (either at the local, national or international level), the following considerations should be taken into account:

- all information collected, even if already in the public domain, should, as far as possible, be collected by or with the full informed consent of communities,
- the database could have levels of confidentiality and restricted access depending on user of information and purposes of use,
- representatives of indigenous and local communities should be involved in managing the database,
- rather than designing mega databases, countries should develop official databases which link up - through a clearing house - to an international database which could be the gateway for patent examining authorities worldwide,
- the structure of databases, organization of information, timing, certification, language used should be standardized,
- information which is clearly not in the public domain (i.e. remains in oral form and has not left the ambit of specific indigenous communities or groups) should not be recorded,

⁵⁵ This is a particularly relevant activity in the light of experiences where traditional knowledge databases have been developed and widely made known to the public but where there have also been claims from indigenous communities themselves in the sense that the information contained in these databases was not obtained with the full informed consent of communities.

- inclusion of traditional knowledge in databases should not, as far as legally and practically possible, restrict the rights which indigenous peoples might have over the information,
- no intellectual property rights should be claimed over these national or international databases.

74. Databases could be an important tool in as much as they can be utilized in a practical and efficient manner, by communities and, especially, by patent searching authorities. Although communities, countries, institutions and even regions may be developing their own particular databases, according to specific realities and unique sets of criteria and considerations, there needs to be *some degree* of standardization if this mechanism is to be effective at the international level. However, this leads to a critical issue which will have to be further discussed with communities themselves: consolidating a tool which, in essence, will make traditional knowledge much more easily and readily accessible throughout the world for a wide ranging set of possible uses.
75. Traditional knowledge which is in the public domain - especially when the knowledge has surpassed the physical and geographical boundaries of communities - could be hard, but not impossible to protect in positive terms. However, focusing all efforts in positively protecting this type of knowledge will almost surely imply very high transaction costs which make the effort costly and even ineffective. It might be useful to suggest appealing to “good corporate practices” or institutional codes of conduct which, recognizing the vulnerability of traditional knowledge systems and the fact that knowledge has left communities often without them knowing so or not being fully informed. The draft regulation in Peru, for example, incorporates this approach and seeks to create an incentive so that a potential user of traditional knowledge in the public domain, at least considers the possibility of negotiating with communities over this knowledge.

ANNEX

The following are non-exhaustive lists of traditional knowledge sources.⁵⁶ It only serves to show the existence of a great amount of documented traditional knowledge related information.

For further and more detailed information see:

- ◇ Annex II of Document WIPO/GRTKF/IC/2/6 which contains a list of over 100 online databases which include traditional knowledge in areas of agriculture, herbal medicine, etc. The list includes a summary of the contents of each database.
- ◇ Annex I of WIPO/GRTKF/IC/3/5 which includes references to more than 100 traditional knowledge related periodicals and journals.

Brief List of Additional Existing Online Databases Containing Traditional Knowledge Documentation

Examples of important databases which incorporate traditional knowledge include:

- ◇ Dr. Duke's Phytochemical and Ethnobotanical Databases, www.ars-grin.gov/duke
- ◇ Farmers' Rights Information Service, <http://www.mssrf.org.sg/Fris9809/index.html>
- ◇ NAPRALERT (Natural Products Alert), <http://www.cas.org/ONLINE/DBSS/napralertss.html/>
- ◇ Nuffic/CIRAN International Indigenous Knowledge (IK) Network, www.nuffic.nl/ciran/ik.html
- ◇ Nunavut Environmental Database, <http://136.159.147.171/ned/>
- ◇ Phytochemical Society of North America's "Links to Phytochemical Resources on the Web", www.fin.edu/orgs/psna/links.html
- ◇ "Prelude" database of traditional veterinary medicine, Tropical Diseases Webring, http://pc4.sisc.ucl.ac.be/prelude/prelude_HomePage.html
- ◇ Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI), <http://csf.Colorado.EDU/sristi/>
- ◇ World Bank, "Database of Indigenous Knowledge and Practices" in Sub-Saharan Africa, www.worldbank.org/afr/iok/datab.htm
- ◇ List of traditional knowledge related periodicals, gazettes and journals (complete list extracted from WIPO/GRTKF/IC/2/6).
- ◇ Al Ma'thurat Al Sha'biyyah. A Quarterly Review of Folklore. (Gulf Cooperation Council Folklore Center).
- ◇ Indigenous Knowledge and Development Monitor: Newsletter of the Global Network of Indigenous Knowledge Resource Centers (Nuffic Center for International Research and Advisory Networks).

⁵⁶ The short lists are based mostly on WIPO compiled lists and a few other sources. Initial searches have shown abundant information on traditional knowledge. Equally relevant in the context of prior art (and even more abundant) are academic and research publications which actually record use of agriculture and medicinal plants and associated traditional knowledge

- ◇ Indigenous Knowledge Notes (World Bank, Africa Region's Knowledge and Learning Center).
- ◇ Honeybee Newsletter: Newsletter for Documentation and Experimentation of Local Innovations Developed by Farmers, Pastoralists, Artisans, and Horticulturalists. (Society for Research into Sustainable Technologies and Institutions).
- ◇ Journal of Ethnobiology (Society of Ethnobiology).
- ◇ Partners (Global Knowledge Partnership Secretariat, World Bank).
- ◇ Biodiversity Conservation Strategy Update (World Resources Institute).
- ◇ CIKARD News (Center for Indigenous Knowledge for Agriculture and Rural Development).
- ◇ IFFP Newsletter (Indigenous Food Plants Programme).
- ◇ ILEIA Newsletter (Information Centre for Low-External-Input Agriculture).
- ◇ International Traditional Medicine Newsletter (Program for Collaborative Research in the Pharmaceutical Sciences, University of Illinois).
- ◇ IWGIA Newsletter (International Work Group for Indigenous Affairs).

List of comprehensive publications on medicinal plants and traditional knowledge and use in the Amazon region.

- ◇ Taken together these four publications include information on traditional knowledge related to at least 1000 plant species in Amazonia.
- ◇ Instituto Interamericano de Cooperación para la Agricultura. *Promoción y Comercio de Plantas Promisorias con Principios Activos Especiales de la Selva del Perú*. Memorias. Lima. Abril de 1999.
- ◇ Instituto Interamericano de Cooperación para la Agricultura. *Plantas Medicinales en Atención Primaria de Salud, Agroindustria, Fitoquímica y Ecoturismo: Perspectivas de Desarrollo*. ACT, IICA, GTZ. Lima. Junio de 1999.
- ◇ Tratado de Cooperación Amazónica. *Biodiversidad y Salud en las Poblaciones Indígenas en la Amazonía*. Tratado de Cooperación Amazónica. Lima, Agosto de 1995.
- ◇ Tratado de Cooperación Amazónica. *Plantas Medicinales Amazónicas. Realidades y Perspectivas*. Lima. Febrero de 1995.