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PROTECTION OF TRADITIONAL MEDICINE

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PROTECTION OF TRADITIONAL MEDICINE¹

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* The views expressed in the paper are solely of the author.

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Foreword

This paper by Richard Wilder, Partner, Powell, Goldstein, Frazer & Murphy LLP, Washington, D.C., United States of America, is part of a series of research papers prepared for the Working Group on Health and International Economy of the Commission on Macroeconomics and Health (CMH). The Commission was set up by the Director General, World Health Organisation, under the Chairmanship of Prof. Jeffrey Sachs. As a member of the CMH and Co-chairperson of this Working Group, I have had the privilege of commissioning research papers on issues of importance for health and the international economy.

I have no doubt that the analysis in this paper raises a number of significant issues which need to be debated and discussed at this crucial juncture when high prices of patented medicines are a source of major concern.

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Abstract

The importance of traditional medicine as a source of primary health care was first officially recognized by the World Health Organization (WHO) in the Primary Health Care Declaration of Alma Ata (1978) and has been globally addressed since 1976 by the Traditional Medicine Program of the WHO. The Member States of WHO have defined “traditional medicine” as having a long history and comprising

the sum total of the knowledge, skills, and practices based on the theories, beliefs and experiences, indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses. The terms complementary/alternative/non-conventional medicine are used interchangeably with traditional medicine in some countries.

The paper will discuss the role and importance of traditional medicine in health care with particular emphasis on the protection of traditional medicine. The paper will examine the work that has been done to date by non-governmental organizations, academics, governments, and by relevant intergovernmental organizations. In particular, it will cover:

- Definition of Subject Matter: A definition of traditional knowledge, with particular emphasis on traditional medicine;
- Role of Traditional Medicine: An indication of the role of traditional medicine – in particular in respect of products that may have applications in the treatment of disease outside of the local context in which the traditional medicines were developed;
- Concerns Regarding Protection: Concerns of holders of traditional knowledge have regarding the protection of that knowledge – in particular in the field of traditional medicine;
- Role of Intellectual Property Protection: The role of intellectual property in (a) protecting contributions made by holders of traditional medical knowledge, (b) preventing third parties from obtaining protection for such contributions not made by them, and (c) interfacing with customary law; and
- Problems Identified Regarding Intellectual Property Protection for Traditional Knowledge: Concerns have been expressed by holders of traditional medical knowledge and by some governments – in particular of developing countries – about the suitability of intellectual property protection for traditional knowledge, giving rise to calls for a *sui generis* system of protection.

1 INTRODUCTION

Traditional Medicine is a subset of traditional knowledge. Its protection and sharing of benefits has been under debate at both the international and domestic level for decades. The purpose of this paper is to provide an overview of both the subject of traditional medicine and the debate concerning its protection and to provide guidance as to the role that the protection of traditional medicine should play in the work of the WHO Commission on Macroeconomics and Health.¹

The present paper relies on the work of the World Intellectual Property Organization – in particular, the Global Intellectual Property Issues Division² of which the author was Director until September, 2000 – and the World Health Organization – in particular the Traditional Medicines Programme.³

2 JEEVANI: SETTING THE STAGE BY EXAMPLE

“Jeevani” is an herbal medicine developed by the scientists of the Tropical Botanic Garden and Research Institute (TBGRI) located in the State of Kerala, India.⁴ Jeevani is

¹ The Commission on Macroeconomics and Health (CMH) was established in January 2000 by the Director General of the WHO, Dr Gro Harlem Brundtland, in response to the need to place health at the centre of the development agenda. The CMH's chief task is to act as a source of advice and analyses for the broader development community and WHO on how health relates to macroeconomic and development issues. Working Group 4 (Health and the International Economy), for which this report has been drafted, will examine trade in health services, health commodities and health insurance, Trade-Related Intellectual Property Rights (TRIPs), international movements of risk factors, health conditions and health finance policies as rationales for protection, and other ways that trade may be impacting on the health sector.

² The work of WIPO's Global Intellectual Property Issues Division in the field of traditional knowledge, including traditional medicine, can be found at the web-site of WIPO at the following URL: <http://www.wipo.int/traditionalknowledge>.

³ Through its Traditional Medicine Programme, WHO supports Member States in their efforts to formulate national policies on traditional medicine, to study the potential usefulness of traditional medicine including evaluation of practices and examination of the safety and efficacy of remedies, to upgrade the knowledge of traditional and modern health practitioners, as well as to educate and inform the general public about proven traditional health practices. This work is undertaken through 20 Collaborating Centres. The work of WHO's Traditional Medicine Programme is managed under the Department of Essential Drugs and Medicine Policies, information about which may be found at the web-site of the WHO at the following URL: <http://www.who.int/medicines>.

⁴ This discussion of Jeevani is derived from a case study on the origins and development of that herbal medicine prepared by Dr. Anil Gupta for the World Intellectual Property Organization and the United National Environment Programme and submitted to the Fifth Conference of the Parties

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based on the traditional medicinal knowledge of the Kani tribe found in the Thiruvananthapuram district of the State of Kerala in South India. It derives from arogyapaacha plant (*trichopus zeylanicus*) – a small rhizomatous, perennial herb distributed in Sri Lanka, Southern India, and Malaysia. Jeevani is reported to have the following indications:

- Activates the body's natural defenses
- Activates delayed type hypersensitivity reactions and antibody synthesis
- Increases the number of polymorphonuclear granulocytes
- Activates the cellular immune system
- Exhibits hepato-protective and cholorectic activities
- Has adaptogenic properties as evidenced by anti-peptic ulcer and anti-fatigue effects

The fruit of the arogyapaacha plant was shared with members of an ethnobotanical expedition to the Western Ghats Kani tribals in 1987 who felt “charged and full of energy and vitality” following eating the fruit.⁵ The effects of Jeevani have been reported in the popular press.⁶ Further, Jeevani has apparently been included in Japanese herbal medicines.⁷

Investigations were undertaken to isolate the active elements in the arogyapaacha plant – followed by clinical trials to demonstrate the effect of arogyapaacha in improving athletic performance, mental alertness and work output. These investigations were conducted by

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of the Convention on Biological Diversity. See UNEP/CBD/COP/5/INF/26 (10 May 2000) (hereinafter “WIPO/UNEP Study”).

⁵ Pushpangadan, P., Rajasekhjran S., Ratheesh Kumar P.K., Velayudhan Nair V., Lakshmi N., and Sarad Amma L., “Arogyapacha (*Trichopus Zeylanicus*). The Ginseng of Kani Tribes of Agasthyar Hills (Kerala) for Evergreen Health and Vitality.” *Ancient Sciences of Life*, 7:13-16 (1988).

⁶ WIPO/UNEP Study, p.40.

⁷ Amagayha, S., and Ogihara, Y., *Journal of Ethnopharmacology*; 28:357 (1990).

researchers at TIBGRI who realized that “without intellectual property protection they would not be able to generate much revenue by licensing the drug they developed.”⁸ Three patents claiming processes for the preparation of herbal drugs based on arogyapaacha were filed in India (product patents for drugs not being available in that country) but not in other countries. TIBGRI negotiated agreements to transfer technology related to arogyapaacha to interested parties on payment of a license fee. With the assistance of TIBGRI, the Kani Samudaya Kshema Trust was created to promote both the welfare of the Kanis in Kerala, but also the sustainable use and conservation of biological resources. Monetary benefits, in the form of a percentage of the royalties received by TIBGRI for the use of its arogyapaacha-related technology, have been paid into this Trust.

A number of questions pertaining to intellectual property arose during the development work done in respect of the arogyapaacha plant and its commercialization:

- Who is entitled to apply for an receive patent protection, the Kanis (and, if so, only traditional healers, selected ones of traditional healers, or other persons) or the researchers at TIBGRI?;
- What is the proper proportion of the benefits to go to the Kanis (which husbanded the arogyapaacha plant and identified its medicinal value to researchers) versus TIBGRI (who undertook to identify compounds having medicinal value, conduct clinical trials, and file for and obtain patent protection on related processes)?;
- How can sustainable cultivation of the arogyapaacha be maintained in the face of increased commercial demand?;
- Should programs for the sharing of benefits be managed at the level of the individual, sub-clan, clan (Kanis), state (Kerala) or nation (India)?;

⁸ WIPO/UNEP Study, p. 42.

- Since arogyapaacha is native to India, Sri Lanka, and Malaysia, is there an obligation to share benefits with other nations or groups of indigenous peoples in those nations?; and
- Who is entitled to control use of the name “Jeevani” as applied to products or processes that make use of the arogyapaacha plant?

According to the WIPO-UNEP Study, these questions have either been answered in respect of Jeevani or are under study. Notwithstanding that some questions remain, the WIPO-UNEP study was able to conclude that:

[t]he effective protection of intellectual property is a necessary condition for generating benefits, which will be subject to benefit sharing, but it is not a sufficient condition. Several additional measures are needed to supplement the role of intellectual property rights in benefit sharing over biological resources and traditional knowledge.⁹

The example of Jeevani encapsulates many of the problems that arise in the protection of traditional medicine and will be referred to in the following sections of this paper.

3 DEFINITION OF THE SUBJECT MATTER OF TRADITIONAL MEDICINE TO BE PROTECTED

No authoritative treaty-based definition exists for either “traditional knowledge” or its subset “traditional medicine” for the purposes of their protection. Article 8(j) of the Convention on Biological Diversity (“CBD”) makes reference to the “innovations and practices of indigenous and local communities.”¹⁰ But a definition of “traditional

⁹ WIPO/UNEP Study, p. 48. The other conditions beyond intellectual property protection that are necessary are: legal capacity to negotiate and manage contracts or agreements involving intellectual property, technical capacity to commercialize the traditional medicine (either through gathering and/or processing the relevant plants or other natural materials or by manufacturing the pharmaceutical or other product derived from such natural materials), and business acumen to maximize the dynamic efficiency of the transaction.

¹⁰ Article 8(j) of the Convention on Biological Diversity states that:

Each contracting Party shall, as far as possible and as 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

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knowledge” as such – let alone the conditions that must be satisfied for its protection – is not found in the CBD itself.

The importance of traditional medicine as a source of primary health care was first officially recognized by the World Health Organization (WHO) in the Primary Health Care Declaration of Alma Ata (1978) and has been globally addressed since 1976 by the Traditional Medicine Programme of the WHO. The WHO, through that Programme, defined “traditional medicine” as having a long history and comprising

the sum total of the knowledge, skills, and practices based on the theories, beliefs and experiences, indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses. The terms complementary/alternative/non-conventional medicine are used interchangeably with traditional medicine in some countries.¹¹

There are four aspects of traditional medicine and its use that should be considered in connection with questions about its protection:¹²

- (i) traditional medicine may be both ancient and contemporary,
- (ii) traditional medical knowledge may be codified (written) or non-codified (oral),
- (iii) traditional medicine may involve products or processes, and

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conservation and sustainable use of biodiversity and promote 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.

¹¹ *WHO General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine*, Geneva (WHO/EDM/TRM/2000).

¹² The present paper deals with the protection of traditional medicines only. Issues related to the exploitation of such protection – including benefit sharing – are not taken up.

- (iv) traditional medicinal products (in particular herbal remedies) are increasingly traded internationally and are, therefore, of increasing economic significance.

Given the breadth of the definition of traditional medicine, the fact that it is a manifestation of the many cultures that have given rise to it (rather than a global construct), and the vagaries inherent in its four aspects identified above, it is highly problematic to make clear, categorical statements about the protection of traditional knowledge. It is rendered even more problematic when considered at the international level. Indeed, I believe that is why the Government of India has recently said that

[t]he modalities for protecting TK are still emerging and evolving. The nature of entitlements and share in benefits is also a grey area. Even at the international level, clarity has as yet not emerged and countries are grappling to understand the issue.¹³

A Is Traditional Medicine Ancient or Contemporary?

A fundamental aspect of traditional knowledge – including traditional medicine – is that it is “traditional” only to the extent that its creation and use are part of the cultural traditions of communities. “Traditional,” therefore, does not necessarily mean that the knowledge is ancient – although the antiquity of some traditional knowledge makes its protection problematic as will be discussed below. “Traditional” knowledge is being created every day, it is evolving as a response of individuals and communities to the challenges posed by their social and natural environment. For example, in the case of Jeevani, the subject matter that is susceptible of protection includes that which is ancient – the arogyapaacha plant itself in its natural state and the information that it is useful for medicinal purposes. Contemporary subject matter includes the process and results of extraction of active compounds from the plant, the process and result of isolation of those compounds, the identification of the pharmacological effect of those compounds, and the identification of the doses and method of delivery that have a desired pharmacological

¹³ *Protection of Biodiversity and Traditional Knowledge – The Indian Experience*, Submission by India to the WTO, WT/CTE/W/156, IP/C/W/198, ¶ 12 (14 July 2000).

effect and are safe and efficacious. In the case of Jeevani, it was this contemporary subject matter for which protection was sought – including patent protection in India.

B Is Traditional Medicine Codified or Non-Codified?

Traditional medicine may be reduced to writing (codified) or transmitted orally (non-codified). In South Asia, for example, the codified knowledge systems include the Ayurvedic system of medicine, which is codified in the 54 authoritative books of the Ayurvedic System, the Siddha system, as codified in 29 authoritative books, and the Unani Tibb tradition, as codified in 13 authoritative books.¹⁴ As will be discussed below, this distinction may have implications in the intellectual property context – in particular whether given aspects of traditional medicine fall in the public domain. Moreover, certain disadvantages connected with non-codified traditional knowledge have been recognized and are being corrected through programs to document or codify traditional knowledge. This is discussed further below.

C Does the Traditional Medicine Relate to Products or Processes?

Thirdly, traditional medicine may involve the use of (i) products (including plants or parts of plants, animals or parts of animals, and minerals) or (ii) processes (including methods, procedures or ceremonies). Traditional medicine may include these two aspects, practiced alone or in combination. The present paper draws a distinction between products that exist *in situ* as genetic resources for which medical uses are not known and products for which a specific traditional medical use is known. The former products are outside the scope of this paper.¹⁵ Nonetheless, it should be noted that national laws governing such access might also address traditional knowledge concerning

¹⁴ In India the First Schedule of the Drugs and Cosmetics Act, No. 23 of 1940, as amended by the Drugs and Cosmetics (Amendment) Act No. 71 of 1986, specifies the authoritative books of the Ayurvedic, Siddha and Unani Tibb Systems.

¹⁵ The pharmacological value of such plants is identified not through reliance on traditional knowledge, but thorough mass collecting, emphasizing maximum taxonomic diversity, and the testing of everything collected. The protection of genetic resources as such raises unique intellectual property issues which are being studied by WIPO, UNEP, the WTO, and the Food and Agriculture Organization, *The International Undertaking on Plant Genetic Resources*, Resolution 8/83 (1983) (Since 1994, the Commission on Genetic Resources for Food and Agriculture of the FAO has been working on a revision of the International Undertaking).

the use of such resources.¹⁶ For the latter types of products, a selection is made based upon traditional knowledge of their use. It is this – the "ethnopharmacological" approach to the identification of uses of products – which is of interest in this paper. Examples of traditional medical processes include acupuncture and related techniques, manual therapies, qigong, tai ji, yoga, naturopathy, thermal therapy, aroma therapy (where a medicine is not administered to the patient), and other physical, mental, spiritual and mind-body therapies.¹⁷

D Is Traditional Medicine an Object of International Trade?

Lastly, trade in traditional medicinal products is growing. An increasingly important outlet or use for traditional medicine falls under the rubric of “complementary,” “alternative,” or “non-conventional” medicine. These refer to a broad set of health care practices that are not part of the country’s own tradition or are not integrated into the dominant health care system. These include both traditional medical products and processes as discussed above. For example, as reported in the WIPO/UNEP Report, Jeevani is increasingly being used in botanical remedies in Europe, North America, and Japan.

Reliable data on total expenditures on traditional medicine – including complementary or alternative medicine – is scarce. Estimates have been made, however, for sales of herbal products worldwide and in selected markets. The Secretariat of the CBD has estimated that the world market for herbal medicines has reached US\$ 43 billion, with annual national growth rates of between 5 and 15%.¹⁸ It further estimated that sales of herbal

¹⁶ See Andean Community (Bolivia, Colombia, Ecuador, Peru and Venezuela) *Common System on Access to Genetic Resources*, Decision 391 (1996) and the *Biodiversity Law of Costa Rica*, Law No. 7.788/98 (1998). Moreover, the draft *Biological Diversity Act* of India contains provisions that address the protection of traditional knowledge. To the extent these laws are relevant to a discussion of *sui generis* systems for the protection of traditional knowledge, they will be discussed below in section IV.D.

¹⁷ The protection of traditional medical processes through the patent system will, as discussed below, depend upon the definition of patentable subject matter under relevant national laws. Article 27(3)(a) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which is administered by the World Trade Organization allows, for example, WTO Members to exclude “therapeutic . . . method for the treatment of humans or animals.”

¹⁸ *Strategy for Traditional Medicine 2000-2003*, WHO, Geneva, p. vi. (September, 2000)

products increased by 101% in markets in the United States from 1996 to 1998.¹⁹ In the European Union, it has been estimated that annual sales for herbal medicinal products are in the range of US\$ 7 billion and in the United States, annual sales were estimated (in 1997) to have increased to US\$ 5.1 billion from US\$ 200 million in 1988.²⁰ For developing countries, traditional medicine forms the basis for an important domestic industry and for export. For example, it has been estimated that sales of traditional pharmaceutical products in China in 1996

consisted of 43.8% of the total medicine sales [in China]. 11,360 commercial enterprises and 35,339 business units have been set up. The output of [traditional Chinese pharmaceutical products] annually is 199 thousand tons, 5.8 billion dollars can be earned by the export of [traditional Chinese] pharmaceutical products.²¹

There is also a question as to the size of the overall market value of products – in particular, pharmaceutical products – that incorporate traditional medical knowledge. For example, the Secretariat of the United National Conference on Trade and Development recently examined the relevant literature but did not hazard an estimate as to market value of such products – instead citing to research from the mid-1980’s that was more anecdotal than analytical.²² Advancing technology and changing economic conditions

¹⁹ *Id.*, p. 5.

²⁰ Mahady, Gail, *International Collaboration in Traditional Medicine and Medicinal Plant Research: A World Health Perspective*, p. 1, (available at web site of University of Illinois at Chicago: www.uic.edu) (2000).

²¹ Dr. Liu Bao-Yan, Deputy Director, Department of Science, Technology and Education, State Administration of Traditional Chinese Medicine, Beijing, *The Role of Traditional Medicines and Practices in the National Health Care System*, Paper presented at WIPO Asian Regional Seminar on Intellectual Property Issues in the Field of Traditional Medicine, New Delhi, India, October 7 to 9, 1998.

²² *See Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices (Background note by the UNCTAD secretariat)*, TD/B/COM.1/EM/13/2, ¶ (22 August 2000) (“There have been some attempts to estimate the contribution of TK, particularly biodiversity-related TK, to modern industry and agriculture. For pharmaceuticals, the estimated market value of plant-based medicines sold in OECD countries in 1985 was US\$ 43 billion That many of these would have used TK-leads in their product development is borne out by biochemist Norman Farnsworth’s (1988) estimation that of the 119 plant-based compounds used

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should cause any such estimates to be viewed skeptically. For example, recent economic research shows that “the value of biodiversity for use in pharmaceutical research may be as low as a few cents per hectare even in the world’s biodiversity ‘hotspots’ . . .”²³ The same may be true for traditional knowledge concerning diagnosis and cure of human diseases – in particular if advances in chemistry and genomics make the identification of the cause of and the cure for given diseases more accurate and effective.²⁴

Rather than focussing attention and effort on estimating the market value of pharmaceutical products that incorporate traditional knowledge, it is recommended that effort be focussed on protecting traditional medical knowledge for prospective purposes.²⁵ Such purposes include protecting the economic and cultural value of traditional medical knowledge and guarding against others obtaining protection for subject matter in which they have no rights. These purposes will be discussed in some detail in the following sections.

These four elements of traditional medicine must be understood in order to conceive of strategies for its protection. For example, traditional medicine that is of contemporary origin may be easier to protect through patents or trade secrets than that of ancient origin. That which is codified may present problems for its protection (loss of novelty for patent

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in medicine worldwide, 74 per cent had the same or related uses as the medicinal plants from which they were derived.”) (citation omitted).

²³ Watal, J., *Intellectual Property and Biotechnology: Trade Interests of Developing Countries*, Int. J. Biotechnology, Vol. 2, Nos. 1/2/3, p. 50 (2000).

²⁴ See Barsh, Russel, *Who Steals Indigenous Knowledge?*, p. 4 (hereinafter “Barsh”) (paper reporting on research funded by the Rockefeller Foundation through First Peoples Worldwide in possession of author) (“The interest of Big Pharma in ethnomedical field research is declining, moreover, as a result of recent developments in random high-speed synthesis and screening of novel molecules and the potential for using human genome maps in designing highly selective drugs. These developments have led at least one longtime proponent of ethnomedically-guided drug discovery to editorialize about the loss to humanity if so many large research organizations simply withdraw from the world’s culturally diverse indigenous frontiers.” (citations omitted))

²⁵ Strong opposition to this suggestion can be anticipated – particularly by those who wish to raise the political heat on the issue of the protection of traditional knowledge. There is a limited role for a retrospective look at cases and problems that have arisen, however. In my view it is limited to identifying problems to be fixed, which is the sense in which I have examined specific cases in the present paper.

protection, for example) but may also prove more difficult for others to appropriate without permission. Protection for medicinal, or product-based, traditional medicine will likely need a different strategy for protection than traditional medicine based on ceremony or process. Increased trade in complementary or alternative medicinal products – in particular herbal remedies or botanicals – increases both the urgency as well as potential for the protection of traditional medicine. Lastly, traditional medical knowledge may lead to laboratory work to identify a compound in a plant having pharmacological value that leads to clinical trials that leads to a product having an international market. Protecting the knowledge at the start of that chain of events – as identified in the Jeevani example – is a necessary, though not sufficient condition for the chain to be complete.

4 ROLE OF INTELLECTUAL PROPERTY PROTECTION

Practitioners of traditional medicine or holders of traditional medicinal knowledge have expressed a wide range of views and needs in relation to the protection of such medicine or knowledge. This section will review those needs and the applicability of the principal intellectual property instruments proposed for the protection of traditional medicine and traditional medicinal knowledge. Finally, this section will review discussions on the development of *sui generis* protection system for such medicine or knowledge.

A Overview of Intellectual Property Protection

Even though intellectual property has, potentially, a very wide meaning,²⁶ the intellectual property instruments reviewed in the present paper shall be limited to: patents, trade secrets, trade marks, and geographical indications.

²⁶ The term “intellectual property” is defined in Article 2(viii) of the WIPO Convention to include rights relating to:

- literary, artistic and scientific works;
- performances of performing artists, sound recordings, and broadcasts;
- inventions in all fields of human endeavor;
- scientific discoveries;
- industrial designs;
- trademarks, service marks, and commercial names and designations;
- protection against unfair competition; and,

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a) Patent Protection

Broadly, countries are obliged to provide patent protection “for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”²⁷ There is variation at the national level among WTO Members as to what they consider to be an invention that is “new” or that involves an “inventive step” for the purpose of granting patent protection.²⁸

A patent is granted by a national office (or regional office for a group of countries where applicable) upon filing and a formalities check or substantive examination. That is to say, there is no international patent. Rather, patent protection must be sought in each country or region (where a regional patent office²⁹ exists) where patent protection is desired. The substantive requirements for patent protection, as indicated above, are that an invention be new, involve an inventive step and be capable of industrial application. To determine whether an invention is “new” or “involves an inventive step” a comparison is made between that invention and the “prior art;” prior art being technical

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- all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

²⁷ TRIPS Agreement, Article 27.1.

²⁸ Such variations are, of course, bounded by the basic rule of treaty interpretation that a given provision be interpreted reasonably. Moreover, provisions of the TRIPS Agreement should be interpreted so as to be consistent with other obligations – for example, that found in Article 27.1 to provide patent protection in all fields of technology. Put another way, implementation of the requirements that an invention be new or involve an inventive step to be patentable cannot be used as a disguised mechanism to exclude certain subject matter from patentability. Further, the practice of other WTO Members in implementing these obligations will be relevant to their interpretation. *See Vienna Convention on the Law of Treaties*, Article 31.3(b) (“There shall be taken into account [for the purpose of interpretation of treaties], together with the context . . . any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation.”). This is relevant because WTO Panels and the Appellate Body, in interpreting provisions of the WTO Agreements, have adopted Article 31 of the Vienna Convention on the Law of Treaties. *See, e.g., United States – Standards for Reformulated Gasoline*, WT/DS2/AB/R (29 April 1996), p. 17. It should be noted that an international process has recently been launched by WIPO to harmonize substantive certain aspects of patent law – including what is contained in the “prior art” and what is meant by “new,” “inventive step,” and “industrially applicable.” *See Suggestions for Further Development of International Patent Law*, WIPO, SCP/4/2 (September 25, 2000).

²⁹ Examples of regional patent offices include the European Patent Organization, the African Industrial Property Office, the African Organization for Intellectual Property, and the Eurasian Patent Office.

disclosures that predate the patent application or invention.³⁰ Such technical disclosures may include patent literature – patent applications or patents published by national patent offices – or non-patent literature, including scientific and technical journals or periodicals. Because a patent application must disclose the invention so that others skilled in the relevant technical area may practice it and because it must claim the invention with specificity, it must be drafted with great care. A patent grant is a “negative” right – it allows the patent holder to prevent others from making, using, selling, offering for sale, or importing the patented invention. Other laws – including those for the protection of human or animal health or the environment – must be complied with. The protection is granted for a limited period, generally 20 years from the date the patent application is filed. After that time, the invention disclosed and claimed in the patent becomes part of the public domain for all to use.

b) Trade Secret Protection

Trade secret protection is another mechanism for the protection of intellectual property rights in traditional medicine. The requirements for the protection of confidential information – or trade secrets – at the international level are summarized in Article 39.2 of the TRIPS Agreement, which reads as follows:

Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:

³⁰ This is a vastly simplified description of what constitutes the “prior art.” The scope of the prior art depends on national law. For example, most countries follow a so-called first-to-file system for patent applications. In such systems the scope of the prior art is comprised of disclosures made prior to the filing date of the patent application being examined. In the United States of America, however, a first-to-invent system is followed whereby the right to a patent may turn on a determination of who was the first to invent a particular invention, rather than who was the first to file for patent protection. Moreover, patent laws exhibit differences in the treatment of oral prior art. Some national or regional patent laws recognize oral disclosures made anywhere in the world as forming part of the prior art. Other laws extend such recognition only to oral disclosures made within their own national borders.

- (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
- (b) has commercial value because it is secret; and
- (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

There are two important differences between patent and trade secret protection. First, there is no requirement that a trade secret be new or involve an inventive step as required for patent protection. Certainly, if a trade secret is not “new” it may not be a secret and, therefore, not protectable. But a trade secret need not meet the more formal, rigorous standards for patent protection of novelty and inventive step. Second, a trade secret can, if kept secret, last in perpetuity. In contrast, as noted above, patent protection generally lasts for only 20 years after the filing date of the patent application.

c) Trade Mark Protection

Trademarks are signs or combinations of signs used to identify the origin or source of a good or service. Trademarks come in a variety of shapes (two and three dimensional) and forms. A trademark may be a simple word or phrase, a company’s name, a number, letters, (combinations of) colors, or an image. In some countries, sounds and smells are afforded protection as trademarks. In addition to general trademarks for goods or services, some national (or where appropriate regional) systems provide for specialized trademarks called certification or classification marks. Because of their relevance to the protection of traditional knowledge, certification and classification marks will be explained in some detail. Trademark protection is, generally, accorded only after an application is filed, which is examined and granted by a competent national authority.

Certification marks are trademarks used to identify a product which meets certain standards established, managed and enforced by an organization “competent to certify” the products concerned. The organization applies for the registration of the mark and if

successful, becomes the trademark owner. Only manufacturers who offer products for sale made in accordance with the standards established by the relevant organization are licensed by the organization to use the mark. Consumers thus benefit from knowing that the products concerned meet the required standards.

Collective marks are trademarks which serve to distinguish the geographical origin or other common characteristics of goods or services of different enterprises which use the collective mark under the control of the owner. Collective marks are usually owned by associations of enterprises which offer the goods or services offered under the mark. The regulations governing the use of the collective mark have to be included in the application for registration of the mark. In general terms, the difference between collective marks and certification marks is that the former may only be used by members of the organization, while certification marks may be used by anyone who complies with the relevant standards. Thus, the use of a collective mark may not in and of itself be considered as a guarantee of quality, but merely an indication of association.

d) Protection of Geographical Indications³¹

A geographical indication is a sign used on goods that have a specific geographical origin and possess qualities or a reputation that are due to that place of origin.³² Most commonly, a geographical indication consists of the name of the place of origin of the goods. Agricultural products typically have qualities that derive from their place of production and are influenced by specific local factors, such as climate and soil. Whether a sign functions as a geographical indication is a matter of national law and consumer perception.

³¹ The general discussion on the protection of geographical indications is derived from that found on the web-site of WIPO at the following URL: http://www.wipo.int/about-ip/en/index.html?wipo_content_frame=/about-ip/en/geographical_ind.html.

³² The TRIPS Agreement, in Article 22.1 defines a geographical indication to be:
indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.

A geographical indication points to a specific place or region of production that determines the characteristic qualities of the product that originates therein. It is important that the product derives its qualities and reputation from that place. Since those qualities depend on the place of production, a specific "link" exists between the products and their original place of production. Geographical indications are understood by consumers to denote the origin and the quality of products. False use of geographical indications by unauthorized parties is detrimental to consumers and legitimate producers. The former are deceived and led into believing to buy a genuine product with specific qualities and characteristics, while they in fact get a worthless imitation. The latter suffer damage because valuable business is taken away from them and the established reputation for their products is damaged.

B The Applicability of Intellectual Property Protection to Traditional Medicine

Far from starting from a clean slate, there has been a great deal of discussion about the protection of traditional knowledge, including traditional medicine, through the intellectual property system. The protection of traditional knowledge, including traditional medical knowledge, arises under Article 8(j) of the Convention on Biological Diversity.³³ The issues surrounding the protection of traditional knowledge generally, and the implementation of Article 8(j) of the CBD specifically, have been extensively discussed in WIPO,³⁴ in the context of the Convention on Biological Diversity,³⁵ by the

³³ Article 8(j) of the CBD, which applies to *in situ* conservation of biological diversity, establishes that Contracting Parties “shall, as far as possible and as appropriate [...] [s]ubject to [their] 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 the benefits arising from the utilization of such knowledge, innovations and practices.”

³⁴ See “Protection of Traditional Knowledge: A Global Intellectual Property Issue” (WIPO/RT/LDC/1/4), “Protection of Traditional Knowledge: A Global Intellectual Property Issue” (WIPO/IP/TK/RT/99/2), and “Intellectual Property and Genetic Resources – An Overview” (WIPO/IP/GR/00/2). Further work by WIPO on the protection of traditional knowledge may be found at its website: www.wipo.int/traditionalknowledge.

³⁵ See “Farmers’ Rights and Rights of Similar Groups – The Rights of indigenous and local communities embodying traditional lifestyles: experience and potential for implementation of Article 8(j) of the Convention on Biological Diversity” (UNEP/CBD/IC/2/14), “Knowledge, Innovations and Practices of Indigenous and Local Communities: Implementation of Article 8(j)”

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Secretariat of the WTO,³⁶ and by the United Nations Conference on Trade and Development.³⁷ The discussion continues in WIPO through the newly established Intergovernmental Committee on Intellectual Property and Traditional Knowledge, Genetic Resources, and Folklore, which meets for the first time April 30-May 2, 2001.³⁸ Moreover, several WTO Members have submitted documents to the Committee on Trade and Environment and/or the Council for Trade-Related Aspects of Intellectual Property Rights relating to the protection of traditional knowledge.³⁹ Further, some of the communications received by the General Council of the WTO from WTO Members in connection with preparations for the 1999 WTO Seattle Ministerial Conference dealt with the protection of traditional knowledge.⁴⁰

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(UNEP/CBD/COP/3/19), “The Relationship Between Intellectual property Rights and the Relevant Provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Convention on Biological Diversity” (UNEP/CBD/ISOC/5), “Legal and Other Appropriate Forms of Protection for the Knowledge, Innovations and Practices of Indigenous and Local Communities Embodying Traditional Lifestyles Relevant for the Conservation and Sustainable Use of Biological Diversity” (UNEP/CBD/WG8J/1/2). Further, at the Fourth Conference of the Parties (COP) of the Convention on Biological Diversity in April 1998 established an *ad hoc* Open-ended Inter-Sessional Working Group on Article 8(j) to, *inter alia*, develop a program of work for the implementation of Article 8(j) and related provisions and to provide advice on the development of legal and other appropriate forms of protection for subject matter covered by Article 8(j). COP Decision IV/9, ¶ 1(a) and (b).

³⁶ See “Environment and TRIPS” (WT/CTE/W/8 and W/8/Corr.1), “The Convention on Biological Diversity and the Agreement on Trade-Related Aspects of Intellectual Property Rights” (WT/CTE/W/50), “The Relationship Between the Convention on Biological Diversity (CBD) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); with a Focus on Article 27.3(b)” (WT/CTE/W/125).

³⁷ See Systems and National Experiences for protecting Traditional Knowledge, Innovations and Practices, TD/B/COM.1/EM.13/2 (22 August 2000).

³⁸ The documents for this first meeting have yet to be published by WIPO. A preview of the issues for discussion may be found in WO/GA/26/6 (August 25, 2000).

³⁹ See Protection of Biodiversity and Traditional Knowledge – The Indian Experience, WT/CTE/W/156, IP/C/W/198 (14 July 2000); Review of Article 27.3(b), Submission of Brazil [add doc. Number], Communication from Bulgaria, the Czech Republic, Egypt, Iceland, India, Kenya, Liechtenstein, Pakistan, Slovenia, Sri Lanka, Switzerland and Turkey, IP/C/W/204/REV. 1 (2 October 2000); Review of the Provisions of Article 27.3(b): Further Views of the United States, IP/C/W/209 (3 October 2000).

⁴⁰ The Government of Venezuela stated, in a communication to the WTO General Council, that the TRIPs Agreement should be reviewed and possibly renegotiated to “[e]stablish on a mandatory basis within the TRIPS Agreement a system for the protection of intellectual property, with an ethical and economic content, applicable to the traditional knowledge of local and indigenous

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a) Patent Protection

The concerns of holders of traditional medical knowledge in respect of patent protection are two-fold. Both concerns involve the patentability standards of “novelty” or “inventive step.” First, for those seeking protection, certain aspects of traditional medicine may be known and are, therefore, not “new” or do not involve an “inventive step” and are, therefore, not patentable.⁴¹ Second, for those seeking to prevent others from obtaining patent protection,⁴² the concern is the opposite: how to publicize certain aspects of traditional medicine such that others are prevented from obtaining patent protection because, due to its publicity, that aspect of traditional medicine is not “new” or does not involve an “inventive step.”

As to the former concern – seeking protection – holders of knowledge of traditional medicine will seek to avoid the disclosure of their innovations, because such disclosure destroys the novelty of the innovation and makes it impossible for the invention to

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communities, together with recognition of the need to define the rights of collective holders.” (WTO Document WT/GC/W/282).

⁴¹ Some have recommended narrowly defining “novelty” for patent purposes so as to limit the applicability of the patent system in respect of health-related inventions. Such a narrow definition is a two-edged sword, however, if it restricts the patentability of traditional medicine. See Correa, Carlos, *Integrating Public Health Concerns Into Patent Legislation in Developing Countries*, South Centre (2000), p. 28 (“[P]olicy choices made to increase access to medicines – including a limitative approach towards the patentability of naturally occurring products and uses of existing products, as well as strict patentability requirements . . . – may lead to the exclusion of protection for most traditional medicinal products.”)

⁴² This is sometimes referred to as “biopiracy” – a term that is politically charged but that has no defined meaning in the context of property law. For some it means simply misappropriation of property or breach of contract regarding access to and use of traditional knowledge. For others, it means any access to and use of traditional knowledge to be biopiracy. For example, the Rural Advancement Foundation International (RAFI) has stated its belief

That exclusive monopoly intellectual property over products and processes constrain innovation and disenfranchise society. In the absence of adequate regulatory mechanisms including the Convention on Biological Diversity to safeguard the rights and interests of local communities, *RAFI regards all bioprospecting agreements to be biopiracy*. However, we acknowledge the right of indigenous and local communities to reach their own conclusions on these issues. (emphasis added).

(RAFI Web Site, *'Stop Biopiracy in Mexico! Indigenous Peoples' Organizations in Chiapas Demand Immediate Moratorium Mexican Government Says No to Bioprospecting Permits'*, <http://www.rafi.org/web/allnews-one.shtml?dfi=allnews.db&tfl=allnews-one-frag.ptml&operation=display&ro1=recNo&rf1=119&rt1=119&usebrs=true>)

qualify for patent protection anywhere in the world. As to the latter concern – preventing others from obtaining patents on traditional medicine – traditional healers may choose to publicize traditional knowledge as a strategy to make it part of recognized “prior art.” By making traditional knowledge part of the “prior art” it destroys its “novelty” so that others may not obtain patent protection.

Seeking Protection for Traditional Medical Knowledge

Holders of traditional knowledge may follow the procedures described above and draft and file patent applications for the purpose of seeking patent protection for inventions. Three constraints may be identified in this respect. First, most traditional knowledge – including traditional medical knowledge – is ancient and does not meet the requirements of novelty and inventive step. Second, traditional knowledge is held collectively – there is not a single individual or discrete group of individuals that can be identified as an “inventor” in whose name the application may be filed. Some thought has been given to customary law – which is discussed further, below – could interface with patent laws to influence a determination of “inventorship.” Third, the complexity and cost of drafting and prosecuting patent applications is outside that which holders of traditional knowledge can manage and afford. Each of these constraints was identified by WIPO in fact-finding missions conducted in 1998 and 1999 on the intellectual property needs and expectations of holders of traditional knowledge.⁴³

⁴³ In 1998 and 1999, WIPO conducted nine fact-finding missions to the South Pacific, Southern and Eastern Africa, South Asia, North America, Central America, West Africa, the Arab Countries, South America and the Caribbean on the intellectual property needs and expectations of holders of traditional knowledge. The report on these fact-finding missions may be found at the WIPO web site: www.wipo.int/traditional_knowledge. Moreover, UNCTAD also identified these three constraints and described them in the following terms:

While individual TK holders could in theory acquire a patent, it is generally the case that TK is passed on orally from generation to generation and evolves incrementally. Thus, it would be difficult to meet the criteria of novelty and inventive step. Second, TK tends to be generated collectively to the extent that no inventors are identifiable. Indeed the source of much TK cannot be traced to a specific community or even to a geographical region. Even if these obstacles were somehow overcome, most traditional communities do not have the resources to file patent applications or to take legal action to prevent patent infringement. TD/B/COM.1/EM.13/2, ¶35 (22 August 2000).

National and regional patent systems can be unforgiving – if the requirement of novelty or inventive step is not met, a patent shall not be granted.⁴⁴ Thus, if the invention for which protection is sought has been previously disclosed, the invention lacks “novelty” and a patent shall not be granted. Concerns in this respect have been raised about the publication of results of academic research in respect of traditional phytomedicines and the effect of such publication on the ability of holders of traditional knowledge to seek and obtain patent protection.⁴⁵

As mentioned above, the definition of “novelty” for patent purposes depends on the national or regional law under which a patent is granted. Thus, some national laws define oral disclosures as part of the “prior art” which will defeat “novelty” only if they are made within their national borders.⁴⁶ Other patent laws define oral disclosures made

⁴⁴ It has been suggested that holders of traditional medical knowledge could seek protection through petty patent systems. *See* Submission by India, ¶ 24. (“For novel and useful innovations, some kind of petty patent giving protection for a limited duration may be worked out.”) In some countries, protection may be obtained for “utility models” or “petty patents” which refer to titles of protection distinct from patent protection. Utility models generally protect the external configuration of mechanical devices and are generally subject to lower novelty and inventive step criteria. There are exceptions, however, to the limited subject matter for which “utility model” protection is typically available. For example, Kenya’s Industrial Property Act of 1989 is reported to provide utility model protection for traditional medicinal knowledge in the form of “herbal as well as nutritional formulations which give new effects.” *UNCTAD Background Note*, ¶ 36. Moreover, the term of protection is generally shorter than for patents. Utility models are not discussed further, however, as the discussion on patents raises the necessary issues regarding the protection of inventions in the field of traditional medicine. “Petty patents” may be available for all subject matter or a limited range – but typically more than just the external configuration of mechanical devices as in the case of “utility models.” “Petty patents” may have different standards for protection than patents (narrower novelty and inventive step requirements) and, typically have a shorter term. Moreover, while a regular patent may be subject to a substantive examination prior to grant, “petty patents” typically are not. Neither “petty patents” or “utility model” protection is referred to in the TRIPS Agreement, nor are standards regarding requirements for such protection or its scope established in the Paris Convention for the Protection of Industrial Property. Because of the lack of international standards for utility models and the great variation at the national level, they are not discussed further.

⁴⁵ *See* Barsh at p. 4 (Stating that publication by academics of information on specific traditional phytomedicines together with data on *in vitro* or clinical tests of their biological activity and efficacy “suggests that academic career activity poses a much greater immediate threat to indigenous knowledge systems than the patent system.”)

⁴⁶ *See* U.S. Patent Law, 35 U.S.C. § 102. *But see, Issues Proposed for WIPO Workprogram on Biotechnology*, WIPO Working Group on Biotechnology recommendation of reexamining this issue WIPO/BIOT/WG/99/1, ¶49 (October 28, 1999) (“The definition of “prior art” varies among most patent systems, often to a significant degree. One area where this is the case involves situations where the “prior art” is not documented in a formal sense (e.g., through publication in a scientific journal or published in a patent). Notwithstanding the variation in standards, most

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anywhere in the world as forming part of the prior art.⁴⁷ National and regional patent systems can be made less unforgiving. For example, some national systems provide for a so-called “grace period” during which disclosures – in particular disclosures by the applicant – will not be taken into considerations for the purpose of determining if the novelty of an invention has been defeated. The introduction of a “grace period” would adjust the definition of prior art to exclude from consideration any premature disclosure – whether made as part of a documentation project or made for the purpose of seeking to commercialize the invention – if that disclosure was made within a specified period before the filing of the application.⁴⁸

Again, a characteristic of traditional knowledge is that it is typically developed and held collectively. In contrast, inventions for which patent protection is sought are made by one or a small, discrete number of inventors. First, the concept of inventorship may be broad enough such that for a given claimed invention, inventorship should include not only those working in a lab who isolate and purify an active ingredient from a plant, but the traditional healer who identified that ingredient in the first place. A determination of

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patent systems prior public use or disclosure of an invention will normally have some capacity to defeat the novelty of an invention.”)

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See European Patent Convention, Article 54(1) and (2) which reads as follows:

(1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

⁴⁸

Some national patent systems already provide for a “grace period” for such disclosures. For example, U.S. patent law provides for a one-year grace period. 35 U.S.C. § 102. In Japan a six-month grace period for certain limited types of disclosures may be claimed pursuant to Article 30 of the Japanese Patent Law. From 1984 to 1991, negotiations proceeded under the auspices of WIPO towards completing a treaty on the harmonization of certain substantive provisions in laws for the protection of inventions. Those negotiations culminated in the *Draft Treaty Supplementing the Paris Convention for the Protection of Industrial Property as Far as Patents are Concerned (Patent Law Treaty)* which was considered at the first part of a Diplomatic Conference July 12 to 30, 1991. The second part of the Diplomatic Conference was never convened. Hence the Draft Treaty was never concluded. Article 12 of the Draft Treaty would have provided for a 12 month grace period in respect of disclosures by the inventor. Negotiations to revive the substantive patent harmonization effort have begun under the auspices of WIPO. See *Suggestions for the Further Development of International Patent Law*, SCP/4/2, ¶13 (September 25, 2000) (Among the issues proposed for discussion is the definition of “prior art” including a general grace period).

inventorship is very fact-intensive and must be determined in accordance with the relevant national or regional law.⁴⁹ There have also been suggestions to explore the collective management of industrial property rights. Such an exploration of collective management of industrial property rights would build upon existing models of collective management of copyright and neighboring rights as well as on experiences of associations like the Society for Research and Initiatives for Sustainable Technologies (SRISTI) in Ahmedabad, India with the acquisition and management of patent rights on behalf of informal innovators.⁵⁰

Traditional medical practitioners have identified the high costs of filing patent applications as the biggest obstacle to the acquisition of patents by practitioners of traditional medicine. Concerns about costs, however, are not unique to holders of traditional knowledge.⁵¹ Suggestions have been made, however, that are specific to

⁴⁹ See Huft, Michael J., *Indigenous Peoples and Drug Discovery Research: A Question of Intellectual Property Rights*, 89 *Nw. U.L. Rev.* 1678 (1995) (“The cases dealing with joint inventions [in the United States] teach that the requirements for joint inventorship, although specific, are quite broadly stated. Joint inventors must have collaborated, but their collaboration need not be contemporaneous and may be minimal. Although they cannot have worked completely independently of each other, so that neither knew of the other’s work [case law] suggests that it is sufficient that only one knew of, and relied upon, the work of the other. Joint inventors must each have contributed to the final conception, but each need not be responsible for the entire conception. The cases suggest that any contribution, however small, that is essential in distinguishing the invention from the prior art, that is, in making it a patentable item, will be sufficient for joint inventorship. Any contribution, however large, that does not provide an essential element of the conception, but merely aids the inventive process of another, will be insufficient for joint inventorship.”) (citations omitted).

⁵⁰ See also Drahos, P., *Indigenous Knowledge, Intellectual Property and Biopiracy: Is a Global Bio-Collecting Society the Answer?*, *European Intellectual Property Review*, Issue 6 pp. 245-250 (2000) (Professor Drahos proposes a Global Bio-Collecting Society to (i) act as the repository for community registers of indigenous knowledge, (ii) upon request, provide assistance with any contractual negotiation, (iii) provide a monitoring service for the use of indigenous knowledge, and (iv) have a dispute resolution function.)

⁵¹ The high costs associated with intellectual property protection has is not just a concern of holders of traditional knowledge. The WIPO Industry Advisory Commission at its meeting May 4 and 5, 2000 adopted the following resolution:

Recognizing that the effectiveness of intellectual property as a stimulant to social and economic development is dependent upon the availability of protection at reasonable cost, the Industry Advisory Commission of the World Intellectual Property Organization (WIPO)

URGES the Member States of WIPO to adopt a work program for the development of a more comprehensive approach to the reduction of the costs of obtaining and maintaining intellectual property protection in multiple countries . . .

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holders of traditional knowledge, including requests for financial and legal assistance to traditional healers' organizations for the filing of patent applications and suggestions of collective filing of patent applications by traditional healers' associations on behalf of individuals or groups of informal innovators. This would allow holders of traditional knowledge to share transaction costs for acquiring and exercising patent rights.

Preventing the Grant of Patent Protection on Traditional Medical Knowledge Not Authorized by the Holder of Such Knowledge

Some organizations are systematically disclosing the innovations compiled in their TK-databases in order to prevent possible future patents based on the innovations. An example of an institution that engages in systematic, intentional disclosure is the *Farm Rights Information System (FRIS)* maintained by the M.S. Swaminathan Foundation in India.⁵² An example of an organization in the process of compiling a data base was given by the Government of India – the “HoneyBee data base” established by SRISTI - which explained it in the following terms:

the HoneyBee database, established ten years ago in India, is a facility for registration of innovations by innovators. The database can be accessed for adding value to these innovations and sharing benefits with the knowledge providers and innovators. Thus, the HoneyBee Network involves documentation, experimentation and dissemination of indigenous knowledge. The network has probably the world's largest database on grassroot innovations, having now about 10,000 innovations, with names and addresses of the innovators (individuals or communities).⁵³

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(WO/GA/26/4, Annex II, page 2 (August 18, 2000).

Further, the prohibitive costs involved in registering and maintaining patent protection has been identified as a potential violation Article 15(1)(c) of the International Convention on Economic, Social, and Cultural Rights. Hansen, Stephen A., *Thesaurus of Economic, Social, & Cultural Rights*, American Association for the Advancement of Science, p. 196 (2000).

⁵² Private communication from Mr. Shakeel Bhatti, World Intellectual Property Organization.

⁵³ *Protection of Biodiversity and Traditional Knowledge – The Indian Experience*, Submission of India, Committee on Trade and Environment and Council for Trade-Related Aspects of

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Holders of traditional knowledge have identified patents that had been granted for inventions that did not satisfy the test of “novelty” because of prior traditional knowledge-related disclosures.⁵⁴ Some of the patents were later invalidated due to the traditional knowledge-related disclosures that were cited against the patent. The most efficient use of such traditional knowledge-related disclosures and the patent system is to make such disclosures available to patent examiners so as to prevent such patents from issuing in the first place. Indeed, as the Government of India has said,

documentation has one clear benefit. It would check patents based on TK in the public domain that are today difficult to prevent due to lack of availability of information with patent examiners.⁵⁵

The need to improve documentation of traditional knowledge for use by patent offices as part of the “prior art” upon which their examination of patent applications is based is widely accepted. Indeed, in a recent paper to the WTO TRIPS Council, the Government of Brazil stated that it

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Intellectual Property Rights, WT/CTE/W/156, IP/C/W/198, ¶ 25 (14 July 2000) (hereinafter, “Indian Government WTO Submission”). Another example is a data base being developed by the Government of Venezuela under the auspices of the Fundación para el Desarrollo de las Ciencias Físicas, Matemáticas y Naturales.

⁵⁴ On March 28, 1995, the U.S. Patent and Trademark Office granted U.S. Patent No. 5,401,504 entitled “Use of Turmeric in Wound Healing” to Suman Das and Hari Har Cohly. The patent was assigned to the University of Mississippi Medical Center. A reexamination of the ‘504 patent was requested by the Government of India, acting through the Council of Scientific & Industrial Research, India (CSIR). The ‘504 patent, on the basis of “prior art” documents submitted by CSIR, all claims in the patent were rejected, in essence invalidating the patent.

⁵⁵ Indian Government WTO Submission, ¶ 17. Further, the WIPO Standing Committee on Information Technology has agreed to incorporate traditional knowledge in a digital form in the intellectual property digital library. Merely making such information available in a digital form is not sufficient to ensure that it is regularly used by patent-examining authorities. Technical standards will have to be agreed upon regarding international exchange of traditional medicine documentation within existing international intellectual property information systems for the search of prior art. Moreover, thought will have to be given to inclusion into the International Patent Classification of classes, subclasses, groups or subgroups for traditional medicine, so that traditional medicine-based patents can be systematically searched. Classification is indispensable for the retrieval of patent documents in the search for prior art. Such retrieval is needed by the

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considers that documentation of traditional knowledge would have the clear benefit of providing documentation for patent offices to determine prior art and check against patent claims that are filed without the consent of the holders of traditional knowledge. It should be noted that different Members [of the WTO] – such as Switzerland (IP/C/M/25, paragraph 81), India (IP/C/W/198, paragraphs 16 to 23) and the United States (IP/C/W/209, paragraph 3 of item 4) – have already agreed on the usefulness of documenting traditional knowledge.⁵⁶

Consistent with this approach, WIPO is taking steps to facilitate improved availability of traditional medicine documentation data for patent examiners at patent-granting authorities. For example, the Committee of Experts of the International Patent Classification Union has just created a Task force to study the relation and possible integration into the IPC of a Traditional Knowledge Resource Classification (TKRC). The Committee established a traditional knowledge task force comprising representatives of intellectual property offices of China, India, The United States of America, and the European Patent Office.

b) Trade Secret Protection of Traditional Medicine

Trade secret protection has some application to traditional medicinals – such as plant or animal matter used by traditional healers – but is of greatest applicability to non-medicinals (including ceremonies, methods or processes) practiced by traditional healers. This is because information that certain plants, animals or minerals have medicinal value may be more difficult to retain in confidence than ceremonies practiced by a traditional healer. Moreover, if traditional medicinal knowledge is ancient, the prospect of its being secret and, therefore, protectable as a trade secret is diminished. That is because over the years, a particular item of traditional medical knowledge may have become generally known. In cases where traditional knowledge is known among only a small, closed circle

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patent-issuing authorities, potential inventors, research and development institutions, and potentially by association of holders of traditional knowledge.

⁵⁶ *Review of Article 27.3(b) – Submission by Brazil*, IP/C/W/228, ¶ 40 (24 November 2000).

of traditional healers, however, or is passed down generation-to-generation within a family, the knowledge may not be generally known and may, therefore, be protectable as a trade secret.

Clearly, making such a determination must be made on a case-by-case basis because the question of the applicability of trade secret protection is very much fact dependent. Thus, the holder of traditional medical knowledge will have to consider – and be advised on – the elements identified above for the protection of trade secrets. A decision will have to be made, then, whether the elements for protection have been satisfied in a particular case. In addition, questions of ownership – individual or collective – as discussed above in reference to patent protection will also have to be resolved.

c) Traditional Medicine and Protection of Signs: Trademarks and Geographical Indications

As discussed above, trademarks – in particular certification and collective marks – and geographical indications may have some relevance to the protection of traditional medical knowledge.

Certification marks may be useful in the protection of traditional medicine in the event an organization is established to “certify” that medicinal products are made in accordance with established standards. This may be useful, for example, where botanicals are gathered, processed, or purified in accordance with defined standards prior to shipping to foreign markets. Buyers in those foreign markets would be inclined to purchase products that are so-certified to ensure the botanicals they purchase meet consistent high standards or quality or potency. This is also of more general applicability where a given traditional community wishes to ensure that use of the name of the community it represents is used only in the way it directs.⁵⁷ A certification mark may be applicable to the case of “Jeevani.” As indicated in the WIPO/UNEP Report, a question was raised as to who was

⁵⁷ See UNCTAD Background Note, ¶ 41 (“In the United States, the Intertribal Agriculture Council licenses use of its annually-renewable ‘Made by American Indians’ mark for the promotion of agricultural or other Indian-made products that have been produced and/or processed by enrolled members of recognized Tribes.”).

entitled to control use of the name “Jeevani” as applied to products or processes that make use of the arogyapaacha plant. If those processes can be defined with sufficient specificity, the name “Jeevani” could be reserved for use on products made in accordance with those processes.

Collective marks may be useful for the protection of traditional medicine to indicate that a particular product – a botanical for example – complies with the rules of the collective. For example, that it originates from a given defined area. In a similar fashion, geographical indications may also be of use – in particular where characteristics of the goods (such as botanicals) are attributable to the geographic origin of the goods.

C Customary Protection of Traditional Medicinal Knowledge

A related aspect of traditional knowledge is the method of its regulation established within the community. This is regulation that arose outside of intellectual property protection and which depends for its force, vitality, and continuation on the community of which it is a part. Customary systems are as varied as are the traditional peoples who use them. They may be unique to a given culture and may also bear remarkable similarity to formal intellectual property systems. WIPO has done extensive work in this regard – as have a number of governments⁵⁸ and other inter-governmental organizations⁵⁹ – which will not be repeated here. Rather than trying to inventory and categorize the myriad customary systems for the protection of traditional knowledge, I will look at two – secrecy and ritual regimes.

Customary *secrecy regimes* operate independently of governmental regulation or even community support. The secrecy regime rests on the inventor’s ability to prevent the public disclosure of his innovation. Under a secrecy regime, innovative healers employ their inventions only themselves, and benefits arise for the healer only as long as the

⁵⁸ See Australian Copyright Council (ACC). *Protecting Indigenous Intellectual Property. A Discussion Paper*. Redfern: ACC, p. 11 (September 1998) (The recognition of customary IP law is recommended as a third way, besides the “preservationist approach” and the “nationalist approach” to the protection of traditional knowledge, which are both considered “problematic”).

⁵⁹ See UNCTAD *Background Note*, ¶¶ 33.

medicinal knowledge remains hidden. It is difficult to maintain secrecy within small communities, however, where close-range interaction and collaboration constrains the informal innovator's ability to conceal his innovation. Since informal innovators often rely on modifications of traditional techniques, that have been passed down in the community, would-be "infringers" may be able to imitate the innovation even after minimal observation. Accordingly, protection for such traditional techniques under principles of trade secrecy law may be problematic.

In the absence of trade secret protection, therefore, practitioners of traditional medicine may maintain a monopoly position on ritual or magical components which form part of informal innovations often allow traditional healers to monopolize and claim their innovations in spite of full disclosure of their techniques within the local context. The following example was identified during the WIPO fact-finding mission to South Asia:

The FFM to South Asia was given the case of a traditional healer who practices in the Tumkur district of Karnataka. For more than 20 years, he has treated 50 to 60 patients per day and has developed a specialization on skin diseases. He uses about 40 medicinal plants for oral and external application and produces each application individually for each patient. He only applies his formulations personally and, performs elaborate rituals during the treatment to obtain support from Laxmi, the goddess of wealth. His medicines are effective *only* in association with the appropriate ritual components. The only other practitioners who are authorized to use his relationship with Laxmi are his daughter and his son-in-law. The intangible property consisting of the rituals associated with his practices makes the healer's personal involvement mandatory in each use of his medical technology, even though the technology is fully disclosed. FFM findings suggest that in many traditional societies such ritual and magical powers are part

of informal regimes which protect traditional medicinal know how from unauthorized use by third parties.⁶⁰

Ritual regimes – as the example illustrates – can create exclusive rights approximating those of patents “to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product” or process, respectively.⁶¹ Contrary to a commonly held view, exclusive rights in respect of informal innovations are not uncommon within indigenous and local communities. Rituals may require physical objects which the inventor can easily maintain exclusive rights to or elaborate rituals that are hard to copy without selective initiation. Thus the sale of ritualized medical services often represents an inverted form of the modern patent-exploitation strategy of "tying". In a tying arrangement, the patent holder makes access to his intangible property dependent on the purchase of tangible commodities that s/he could not otherwise monopolize. TK holders use an inverted strategy in the local context. Under a ritual regime, an informal innovator makes access to his innovation conditional on the purchase or involvement of a tangible object or condition which he can monopolize (since he cannot obtain governmentally granted monopolies over his intangible possessions). For example, the WIPO fact-finding mission to North America found that

the inheritance and transfer of “medicine bundles” within or between families is accompanied by the transmission of traditional medicinal knowledge and certain rights to practice, transmit and apply that knowledge. The ownership of the physical bundle is often attached to exclusive rights to exploit the products and processes associated with the TMK that the bundle signifies. Informants pointed out that under certain circumstances, such bundles can be licensed to

⁶⁰ Wilder, R., *International Symposium on Protecting Intellectual Property in China: Challenges & Opportunities in the 21st Century*, Intellectual Property Rights and Traditional Knowledge (Including Traditional Medicine), p. 28 (July 25 and 26, 2000) (hereinafter, “Wilder Paper”).

⁶¹ Articles 28.1(a) and (b), TRIPS Agreement.

apprentices.⁶²

The foregoing descriptions of secrecy and ritual regimes are examples of customary ways in which traditional medical knowledge may be protected and transmitted and from which value to the holder may be obtained. This is by no means an exhaustive list. The role of customary law for the protection of traditional medical knowledge must be appreciated in the context of the culture that manifests it. Further, the role of cultural systems for the protection of traditional medical knowledge and the interaction (if any) with intellectual property protection must also be dealt with on a case-by-case basis. That is, on a region-by-region, country-by-country, culture-by-culture basis – a study clearly beyond the scope of the present paper.

D *Sui Generis* Systems of Protection

Because of the difficulties identified above in the application of intellectual property to traditional knowledge – including traditional medicine – there have been calls for the establishment of a *sui generis* system⁶³ for the protection of traditional knowledge. Given the present state of understanding of traditional knowledge and the applicability of intellectual property to its protection, it is premature to suggest proceeding with negotiations on an international *sui generis* system for the protection of traditional knowledge. In this respect, I agree with the statement by the Government of India that

Some experts suggested that a *sui generis* system separate from the existing IPR system should be designed to protect knowledge, innovations and practices

⁶² Wilder Paper, pp. 29-30.

⁶³ This is separate from a *sui generis* system for the protection of plant varieties called for in Article 27(3)(b) of the TRIPS Agreement, which is not further addressed here. As to calls for the establishment of a *sui generis* system for the protection of traditional knowledge, see *Review of Article 27.3(b) – Submission by Brazil*, IP/C/W/228, ¶ 36 (24 November 2000) (“Protection provided by the conventional IPR regime is limited by operation factors – lack of adequate education, awareness and resources, for example – and, most importantly, by conceptual factors, since certain aspects of the knowledge produced in most traditional communities are not necessarily within the scope of the TRIPS Agreement. Traditional knowledge is often held collectively, which makes it difficult to determine its title holders. It may also be intergenerational, which may not fit adequately the requirement of novelty. Dissemination of traditional knowledge is often made orally, which makes it difficult to constitute documented prior art.”)

associated with biological resources. However, the parameters, elements and modalities of a *sui generis* system are still being worked out.⁶⁴

In the first instance, not only the applicability of intellectual property protection, but also the “parameters, elements and modalities” referred to by the Government of India in respect of *sui generis* protection systems are being worked out at the national level. Some countries have introduced specialized legislation that seeks to protect the rights of holders of traditional knowledge – including traditional medicine. Examples of countries or interdraft legislation or laws include Brazil,⁶⁵ Panama,⁶⁶ Thailand,⁶⁷ the Philippines,⁶⁸ and the Organization of African Unity (OAU).⁶⁹ Intergovernmental organizations have taken up the question of *sui generis* protection for traditional knowledge.⁷⁰ Non-Governmental Organizations have also made proposals for model legislation in the field, including the Community Intellectual Rights Act proposed by the Third World Network

⁶⁴ Submission of India, WT/CTE/W/156, IP/C/W/198, ¶ 26. The Conference of the Parties to the Convention on Biological Diversity, May 15-26, 2000 in Nairobi, Kenya have taken a similar approach. On the one hand they emphasized the need for case studies “to enable a meaningful assessment of the effectiveness of existing legal and other appropriate forms of protection for the knowledge, innovations and practices of indigenous and local communities.” CBD COP V, Decision V/16, ¶ 13. On the other hand, they recognized “the potential importance of *sui generis* and other appropriate systems for the protection of traditional knowledge of indigenous and local communities and the equitable sharing of benefits arising from its use to meet the provisions of the Convention on Biological Diversity.” *Id.*, ¶ 14.

⁶⁵ *See Provisional Measure No. 2.052/00* (2000)..

⁶⁶ *See Ley del régimen especial de propiedad intelectual sobre los derechos colectivos de los pueblos indígenas, para la protección y defensa de su identidad cultural y de sus conocimientos tradicionales, y se dictan otras disposiciones*, Law No. 20/00 (2000).

⁶⁷ The *Traditional Medicine Bill* would, if enacted, protect traditional knowledge related to medical uses of plants.

⁶⁸ *See Indigenous Peoples Rights Act 1997* (Republic Act 8371) of the Philippines. Executive Order 247 of the Philippines provides a regulatory framework that governs access to biological resources.

⁶⁹ *See African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources*. This Model Legislation has been reproduced on the web-site of the Third World Network and may be found at the following URL: <http://www.twinside.org.sg./title/oau-cn.htm>.

⁷⁰ UN ECOSOC Subcommission on Prevention of Discrimination and Protection of Minorities, Ms Erica-Irene Daes, Chairperson of the Working Group and Special Rapporteur, *Study on the Protection of the Cultural and Intellectual Property of Indigenous Peoples* (ECOSOC 1993).

in 1996⁷¹ and the concept of “traditional resource rights” raised by Posey and Dutfield.⁷² The subject matter protectable under these laws varies – from artistic designs, to traditional knowledge associated with biodiversity, to only traditional knowledge of indigenous peoples that is *not* associated with biodiversity.⁷³ In addition, the method for obtaining rights varies under these laws – from those requiring no formalities to those requiring an application and examination. Moreover, some laws provide for an independent right of action to enforce rights in traditional knowledge, others simply provide that rights in traditional knowledge may be exercised to prevent others from obtaining industrial property (in particular, patent) rights. There is also variation as to the term of protection.

Given the preliminary and unsettled nature of the discussions on the need for and contours of *sui generis* protection for traditional knowledge, it is not discussed further in this paper. That is to say, I do not believe that the WHO Commission is the place to discuss these issues. To be clear, however, I do not believe that this is the end of the discussion. Indeed, the member states of WIPO have established a new Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (hereinafter, “IGC”). The first session of the IGC was held in Geneva April 30 to May 3, 2001. In that first session, the States members of WIPO or the Paris Convention discussed a number of matters relevant to traditional knowledge.⁷⁴ In particular, the IGC considered the following possible tasks to take up in this regard:

Possible Task B.1: Based on the current use of relevant terms . . . , the [IGC] may

⁷¹ See *The Main Elements of a Community Rights Act*, Web Site of Third World Network, <http://www.twinside.org.sg/title/comm-cn.htm>.

⁷² Posey, D.A. and Dutfield, G., *Beyond Intellectual Property: Towards Traditional Resource Rights for Indigenous Peoples and Local Communities* (IDRC 1996).

⁷³ For a discussion on the protection of traditional knowledge and a suggestion on how to protect it by means of a *sui generis* data base mechanism, see Carvalho, N., *From the Shaman’s Hut to the Patent Office: How Long and Winding is the Road?*, 40, 41, *Rev. ABPI* 3 (1999).

⁷⁴ See *Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore – An Overview*, document prepared by the WIPO Secretariat, WIPO/GRTKF/IC/1/3, March 16, 2001.

wish to delineate the scope of subject matter in respect of which the Member States wish to discuss the application of intellectual property protection for the purpose of having a definition of the term “traditional knowledge.”

Possible Task B.2: The Member States may wish to compile, compare and assess information on the availability and scope of intellectual property protection for traditional knowledge within the scope of subject matter which was delimited under Task B.1 and identify any elements of the agreed subject matter which require additional protection.

Possible Task B.3: The Member States may wish to consider revising existing criteria and developing new criteria which would allow the effective integration of traditional knowledge documentation into searchable prior art.

Possible Task B.4: The Member States may wish to consider ways of assisting traditional knowledge holders in relation to the enforcement of intellectual property rights, in particular by assisting them to strengthen their capacity to enforce their rights.⁷⁵

The IGC, at its first session, expressed support for each of the foregoing Tasks B.1 through B.4.⁷⁶ This work by WIPO, under the auspices of the IGC – as well as parallel efforts by WHO, UNCTAD, UNEP, the CBD Secretariat, and FAO – should be taken note of and supported by the Commission.

5 CONCLUSION

As stated by the Government of India, “[t]he modalities for protecting [traditional knowledge] are still emerging and evolving. . . . Even at the international level, clarity has as yet not emerged and countries are grappling to understand the issue.”⁷⁷ I agree with this assessment. Given this level of uncertainty – and the highly political nature of

⁷⁵ Id, ¶¶ 71, 77, 80, and 86.

⁷⁶ See, *Report of First Session*, WIPO/GRTKF/IC/1/13, ¶ 156, May 3, 2001.

⁷⁷ Submission of India, WT/CTE/W/156, IP/C/W/198, ¶ 12.

the debate – is recommend that the WHO Commission on Macroeconomics and Health refrain from making any statements about modalities for the protection of traditional medical knowledge.

That is not to say that the Commission should be silent on the topic of traditional medical knowledge. Traditional medical knowledge has played a role in identifying substances having pharmacological value useful in “western” medicine. Products used in traditional medical knowledge – in particular botanicals – have an important and growing role to play in international trade involving medical products. Finally, traditional knowledge has proven to be a source of “leads” to identify products that can, with further work, find wide-spread application in the treatment of disease. There is a chain that extends from the traditional knowledge through to the pharmaceutical product that has wide-spread applicability. Each link in that chain demands and warrants protection.⁷⁸

While protection of links in a chain leading from traditional knowledge to a widely marketed product may provide some benefits to the original holders of that knowledge – such benefits are unlikely to be large enough or sufficiently focussed to solve the health needs of traditional peoples. Many Traditional – in particular indigenous – peoples tend to differ from surrounding populations with respect to basic health factors such as congenital conditions, dietary requirements and sensitivities, and resistance or susceptibility to particular contagious diseases. A well-studied example is the very high incidence of type II (non-insulin-dependent) diabetes mellitus amongst the indigenous peoples of North America, parts of South America, Australia, and the South Pacific.⁷⁹ In addition, indigenous peoples are most heavily concentrated in developing countries, where they suffer from most of the same diseases of extreme poverty as their neighbors including heavy parasite loads, protein-calorie malnutrition and micronutrient deficiencies, and potentially lethal persistent gastro-intestinal infections among children. Further, indigenous peoples tend to be geographically or socially isolated from medical

⁷⁸ As noted above, in the case of traditional knowledge, in addition to modalities for protection, modalities to prevent unauthorized persons from obtaining protection is also essential.

⁷⁹ See Barsh, R.L., *Chronic Health Effects of Dispossession and Dietary Change: Lessons from North American Hunter-Gatherers*, Medical Anthropology, Vol. 18, pp. 145-150 (1999).

facilities to an even greater extent. Many indigenous peoples are experiencing increased incidence of malnutrition, overcrowding and increased contagion in resettlement areas, profound stress, and the loss of many of their traditional healers and medical practices.

The present paper has raised a number of issues surrounding the protection of traditional knowledge but, necessarily due to its limited focus, misses a larger issue affecting traditional – in particular indigenous – peoples. A majority of indigenous communities are in urgent need of more technical and financial resources to improve their own health status, including affordable access to drugs already available to others, as well as research aimed at understanding and ameliorating population-specific health concerns and priorities of indigenous communities for which no effective remedies have yet been developed. Mobilizing international public and private resources to meet these needs, in co-operation as far as possible with indigenous communities, is an appropriate task for with international public health community to address and an appropriate matter for the CMH to call attention to.

In conclusion, it is recommended that the Commission, consistent with its mission to act as a source of advice and analyses for the broader development community and WHO on how health relates to macroeconomic and development issues to:

- recognize the importance of traditional medicine in the communities in which such medicine originates and, increasingly, in international trade and
- recognize the importance of the protection of traditional medicine; and
- recognize the work at the international level – in particular by WHO, WIPO, WTO, UNCTAD, UNEP, and the CBD Secretariat – in identifying the needs and expectations of holders of traditional knowledge and the modalities for the protection of such knowledge and encourage the continuation of that work.

- recommend that work by WIPO – in particular under the auspices of the IGC – focus on the particular needs for protection in the area of traditional medical knowledge.
- recommend that attention be paid to the urgent and unique health-care needs of traditional – in particular, indigenous – peoples.