

TRADITIONAL KNOWLEDGE AND PATENT PROTECTION: CONFLICTING VIEWS ON INTERNATIONAL PATENT STANDARDS*

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1 Introduction

In an era of diseases like cancer, diabetes, heart disease and HIV, pharmaceutical and biotech companies search for new and better drugs every day.¹ Most of these companies have realised that numerous useful compounds may lie in the natural resources that indigenous and local communities around the world have been using for centuries.² These remedies³ are part of traditional knowledge, regardless of whether or not sophisticated medical science embellishes them. Even though the importance of biological resources to human civilization is well recognised, the legal ownership and control of plant resources is still very controversial.⁴ The expansion of intellectual property rights laws⁵ into traditional knowledge areas, in turn, has received increasing international attention.⁶ The debate encompasses a diverse range of innovations in industrial, agricultural, environment and health matters developed from traditional products.⁷

Traditional knowledge is also very significant for the economy. The world market for herbal medicines has reached over forty-three billion US dollars, with annual growth rates of between five and fifteen percent.⁸ Plants are a very important source of medicine,⁹ and many pharmaceutical products are based on, or consist of, biological materials.¹⁰ The annual worldwide trade in plant-based medicine amounts to an

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¹ Kalb 2005 *Newsweek* 54.

² DeGeer 2003 *New Eng J Int'l & Comp L* 179.

³ Bender 2003 *Tulsa J Comp & Int'l L* 290.

⁴ Kloppenburg *First the Seed* xii and 49.

⁵ Cohen 1998 *Mich L Rev* 462.

⁶ WIPO 2009 www.wipo.int.

⁷ Mgbeoji *Global Biopiracy* 9.

⁸ For more on this topic see WHO *Strategy for Traditional Medicine*.

⁹ Lambert, Srivastava and Vietmeyer "Medical Plants" 1.

¹⁰ Ten Kate and Laird *Commercial Use of Biodiversity* 3.

estimated 500 billion US dollars.¹¹ Moreover, natural genetic resources play a significant role in research, the cosmetics industry, biotechnology and agriculture.¹² For example, Eli Lilly & Company isolated two extracts from Madagascar's rosy periwinkle (vinblastine and vincristine) that have since become powerful drugs — one to treat childhood leukaemia, and the other to treat Hodgkin's disease. Together, these drugs generate over 200 billion US dollars in revenue each year.¹³

Countries that are rich in traditional knowledge should take every possible action to protect their resources. As traditional knowledge is usually undocumented, it is far too easy, for example, for someone to "discover" a "new" plant and file a patent application. The novelty of traditional knowledge allows it to be patented with no compensation given to the actual inventors.¹⁴

This article undertakes a comparative analysis of American and European as well as international legal regulations on patent law and traditional knowledge. Part one introduces key definitions and examples of traditional knowledge. The second section provides an overview of the evolution of plant variety and plant genetic resources protection under patent law. Part three explores existing international patent standards while also taking patentable subject matter and its influence on traditional knowledge protection under deeper consideration. It also discusses those patent cases where traditional knowledge played a crucial role. The fourth section briefly examines additional problems in applying international patent law to traditional knowledge. And finally, emerging protection systems are also considered.

2 Defining indigenous people, traditional knowledge, patents and the concept of biopiracy

There are many, and often competing, definitions of indigenous peoples. The Martinez Cobo Report prepared by the United Nations defines indigenous peoples as "those which, having a historical continuity with pre-invasion and pre-colonial

¹¹ German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety 2008 www.bmu.de.

¹² German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety 2008 www.bmu.de.

¹³ Jiang 2008 *Harard Int Rev* 3; Torrance 2008 *Geo. Int'l Envtl L Re.* 242.

¹⁴ Kothari "Beyond the Biodiversity Convention" 67-68.

societies that developed on their territories, consider themselves distinct from other sectors of the societies now prevailing in those territories, or parts of them."¹⁵ Another definition is provided by the International Labour Organisation: "[indigenous people are] those, who have descended from populations that inhabited a country at the time of conquest, colonisation, or the establishment of present state boundaries, and who irrespective of their legal status, retain some or all of their own social, economic, cultural, and political institutions."¹⁶

Traditional knowledge is typically defined either as knowledge developed by indigenous communities¹⁷ or "tradition-based literary, artistic or scientific works, performances, inventions, scientific discoveries, designs, marks, names, symbols, undisclosed information and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, literary or artistic fields."¹⁸ Indigenous knowledge, on the other hand, is understood by the WIPO to be the traditional knowledge of indigenous peoples. Therefore, according to the WIPO "all indigenous knowledge is part of the traditional knowledge category but traditional knowledge is not necessarily indigenous."¹⁹ Traditional knowledge is a diverse and sophisticated entity.²⁰ The *Convention on Biological Diversity* characterises it as "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyle."²¹ Because, as Correa²² noted, there is no universal definition of traditional knowledge "different expressions of the information embraced by traditional knowledge can make it difficult to agree on a legally and scientifically acceptable definition."

Another important expression is "biopiracy," which may be defined as the misappropriation of traditional knowledge for the purpose of seeking exclusive patent ownership over that knowledge.²³ It could also be described as the process through

¹⁵ UN *Martinez Cobo Report* 1986.

¹⁶ ILO *Indigenous and Tribal Peoples Convention*, emphasis added.

¹⁷ Gervais 2005 *Mich St L Rev* 140.

¹⁸ WIPO "Intellectual Property Needs" 25.

¹⁹ WIPO "Intellectual Property Needs" 23.

²⁰ Oguamanam 2003 *St Thomas L Rev* 61.

²¹ A 8(j) of the *Convention on Biological Diversity* 1992.

²² Correa *Traditional Knowledge* 4.

²³ Stenton 2004 *Eur Intell Prop Rev* 17.

which the rights to genetic resources and knowledge are "erased and assumed by those who have exploited indigenous knowledge and biodiversity."²⁴

According to Matchup's definition, a patent is a discretionary grant of a state on an invention, which excludes unauthorised persons, for a specified number of years, from making commercial use of a clearly defined and specified invention.²⁵

3 The road to biotechnology patents in the United States and Europe

To analyse the influence of patent law on traditional knowledge, it is necessary to examine the conditions for patentability. To do this, it is worthwhile to take a brief look at some significant cases and legal regulations.

3.1 *The protection of plant varieties and plant genetic resources in the United States*

Patent law in the United States has been shifting and adapting itself to the evolution of technology and science, and to economic trends.²⁶ Initially, American patent law did not allow the patenting of natural products. In 1852 in *Le Roy v Tatham*,²⁷ the United States Supreme Court held that:

A principle, in the abstract, is a fundamental truth: an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right. Nor can an exclusive right exist to a new power, should one be discovered in addition to those already known.²⁸ Until 1930 there was no protection for plant varieties in the United States.²⁹

In 1930 Congress enacted the *Plant Patent Act*³⁰ in order to give the same opportunity "to participate in the benefits of the patent system as has been given industry."³¹ However, under the *Plant Patent Act*, patent rights were granted only to

²⁴ Shiva *et al* *Enclosure and Recovery* 31.

²⁵ *Attorney-General v Adelaide Steamship Co.* 1913 Appeal Cases 781.

²⁶ Sibley *Law and Strategy* 11-26.

²⁷ *Le Roy v Tatham* 55 US 156 (1852).

²⁸ *Le Roy v Tatham* 55 US 156 (1852) 175.

²⁹ Cantuária Marin *Providing Protection* 5.

³⁰ Para 161-164 of the *Plant Patent Act* 1930.

³¹ Statement of Allenby White (Chairman, Breeders' Rights Study Committee, American Seed Trade Association) held on 91st Congress 2d Session. 7 (1970).

asexually reproducing species.³² In another case - *Dennis v Pitner* - the United States Supreme Court challenged the principle that a discovery was not patentable. The Court held that the subject matter, an extract from the root of a plant found in South America, was patentable.³³ The patent was not granted in the end, however, because the Supreme Court concluded that Dennis was not the first one to discover this particular new insecticide.³⁴

Exactly fifty years after enacting the *Plant Patent Act*, in 1970, the *Plant Variety Protection Act*³⁵ afforded patent-like protection to novel varieties of sexually reproduced plants. The Act provided research and farmers' privilege exceptions from granted exclusive right.³⁶ The courts in their practice often expanded the boundaries of the patent system in favour of biotechnology's patentability.³⁷

Perhaps the most famous and crucial decision on life forms as patentable subject matter, however, is the majority decision of the US Supreme Court in *Diamond v Chakrabarty*.³⁸ The decision provided an innovative basis for future American patent law by making transgenic micro-organisms patentable. In their decision, which overturned the US Patent Office's original denial of the patent, the Supreme Court held that:

The Committee Report accompanying the 1952 Act informs us that the Congress intended statutory subject matter to "include anything under the sun that is made by man" ... and the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions.³⁹

Since 1980 then, living things can be considered statutory subject matter provided that they do not occur naturally. Presently in the United States it is possible to patent plant varieties,⁴⁰ genes developed through genetic engineering, or even substances

³² Para 163 of the *Plant Patent Act* 1930.

³³ *Dennis v Pitner* 106 F 2d 142 (7th Cir 1939) 308 US 606/1939.

³⁴ *Dennis v Pitner* 106 F 2d 142 (7th Cir 1939) 308 US 606/1939 150.

³⁵ Para 2321 *Plant Variety Protection Act* 1970.

³⁶ Para 2489, 2543 and 2544, *Plant Variety Protection Act* 1970.

³⁷ Golden 2001 *Emory L J* 126.

³⁸ *Diamond v Chakrabarty* 447 US 303 (1980).

³⁹ *Diamond v Chakrabarty* 447 US 303 (1980) 2207-2208 and 2210.

⁴⁰ Correa *Intellectual Property Rights* 180-183.

isolated from naturally occurring material, including genes and isolated DNA sequences.⁴¹

3.2 The protection of plant varieties and plant genetic resource protection in Europe

The most significant treaty for granting European patents at the regional and continental level is the *European Patent Convention* of 1973 (hereafter the EPC).⁴² In contrast to American patent law, the EPC does not allow the patenting of plant varieties. Article 53 (b) of the EPC states that patents shall not be granted:

For plants or animals varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.⁴³

In the *Ciba-Geigy* case, the European Patent Office Board of Appeals held that "no general exclusion of inventions in the sphere of animate nature can be inferred from the European Patent Convention."⁴⁴ In the analogous *Lubrizol* case, the Board of Appeals granted Lubrizol patent protection for the method of modifying plant cells.⁴⁵ The Board stressed that exclusions from patentability enclosed in Article 53 of the European Patent Convention were to be "construed narrowly."⁴⁶

The European Patent Office Plant Genetic Systems' decision⁴⁷ uniquely interpreted Article 53 of the EPC. In this case, a patent was granted for a transgenic plant having a foreign sequence in its genome. The Board concluded that the patent was not contrary to morality because Article 53(a) EPC should be interpreted as to exclude only "inventions the exploitation of which is likely to breach the public peace or social order (for example through acts of terrorism) or to seriously prejudice the environment."⁴⁸

⁴¹ The first patent application filed for the Cohen-Boyer technology for recombinant DNA resulted in three US patents granted in 1974; European Patent Office *Scenarios for the Future* 18.

⁴² *Convention on the Grant of the European Patents* 1973.

⁴³ A 53(b) EPC.

⁴⁴ *Propagatin material/Ciba-Geigy* OJ EPO 112 (1984).

⁴⁵ *Hybrid Plants/Lubrizol* OJ EPO 71 (1997).

⁴⁶ *Hybrid Plants/Lubrizol* OJ EPO 71 (1997).

⁴⁷ *Plant Cells/Plant Genetic Systems* OJ EPO 545 (1995).

⁴⁸ *Plant Cells/Plant Genetic Systems* OJ EPO 545 (1995) 557.

As was explained above, the EPC does not entirely exempt plant varieties from patentability. Before the above decision was taken, it was believed that Article 53(b) of the EPC limited the scope of patent protection for plants in Europe. But on the European Community level, the *Biotechnology Directive*⁴⁹ allows plants to be patented indirectly, when the biotechnological process that developed them is itself patented. According to Article 4(1) of the Directive, "plant and animal varieties and essentially biological processes for the production of plants or animals shall not be patentable."⁵⁰ On the other hand, according to Article 4(2) of the Directive, "inventions, which concern plants or animals, shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety."⁵¹

4 International patent standards

4.1 TRIPS standards

The internationalisation of patent systems has been enforced since 1883 by the *Paris Convention on the Protection of Industrial Property*.⁵² It created a union for the minimum protection of industrial property, especially the principles of "national treatment" and the "right of priority".⁵³ While this treaty established some global standards, patents under the *Paris Convention* were not protected internationally. According to Article 4bis of the *Paris Convention*, patents must still be applied for in the various countries.⁵⁴ Moreover, the *Paris Convention* reveals that there are different national patent laws, and states that:

Nationals of any country of the Union shall, as regards the protection of industrial property, enjoy in all other countries of the Union the advantages that their respective laws now grant, or may hereafter grant to nationals.⁵⁵

⁴⁹ Directive 98/44/EC 1998.

⁵⁰ A 4(1) Directive 98/44/EC 1998.

⁵¹ A 4(2) Directive 98/44/EC 1998.

⁵² *Paris Convention for the Protection of Industrial Property* 1883.

⁵³ For a detailed analysis of Arts. 2 and 4 of the *Paris Convention for the Protection of Industrial Property* 1883. see Wagner and Pachenberg 1974 IIC 361.

⁵⁴ A 4bis *Paris Convention for the Protection of Industrial Property* 1883 states the principle of the territoriality of patents.

⁵⁵ A 2(1) *Paris Convention for the Protection of Industrial Property* 1883.

The next crucial international step was the establishment of the World Intellectual Property Organisation in 1970.⁵⁶ *The Patent Cooperation Treaty* of 1970 was another step forward for achieving a unified procedure for filling patent applications in its Contracting States.⁵⁷ *The Patent Cooperation Treaty*, like the *Paris Convention*, is administrated by the WIPO. It establishes facilities for applicants wishing to obtain patent protection in more than one contracting state. According to the PCT, orally transmitted traditional knowledge can be used internationally only if the oral accounts are substantiated by a written description.⁵⁸

The *Agreement on Trade-Related Aspects of Intellectual Property (TRIPS)*, in turn,⁵⁹ sets the global minimum for patentability. It is a basic framework that protects the intellectual property rights of individuals and corporations across the member-states of the World Trade Organisation. TRIPS is recognised as an "impressive" agreement with "comprehensive scope and coverage," leading some to argue that it is the "most important multilateral instrument in this field."⁶⁰ According to Article 1 of TRIPS, members are not obliged to implement more extensive protection in their domestic law than that required by TRIPS.⁶¹ Rather, what is important is that TRIPS has established, for the first time in this era of patents, global minimum standards for patentability.⁶² These provisions provide that:

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or process, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.⁶³

According to paragraphs 2 and 3, members may exclude from patentability:

2. Inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion

⁵⁶ Convention Establishing the World Intellectual Property Organisation 1967 signed at Stockholm on July 14, 1967 and as amended on September 28, 1979.

⁵⁷ Patent Cooperation Treaty 1970.

⁵⁸ PCT Gazette International Search Guidelines, Chapter VI, paragraph 1.2.

⁵⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights 1994.

⁶⁰ Gervais TRIPS Agreement 220.

⁶¹ A 1(1) Agreement on Trade-Related Aspects of Intellectual Property Rights 1994.

⁶² See A 27 Agreement on Trade-Related Aspects of Intellectual Property Rights 1994.

⁶³ A 27(1) Agreement on Trade-Related Aspects of Intellectual Property Rights 1994.

is not made merely because the exploitation is prohibited by their law.

3. Diagnostic, therapeutic and surgical methods for the treatment of humans or animals; plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.⁶⁴

However, while Article 27 establishes general global requirements for patentability, it does not provide a universal international definition for the terms "new," "inventive step" or "industrial application." Therefore member-states may apply different interpretations of these terms, which is problematic. TRIPS also does not provide an international standard for "inventive creativity." Thus many developing countries could be patenting the obvious without realising it. Indeed, from the traditional knowledge perspective, the most important aspect of patentability is this criterion of novelty.

4.2 *The criterion of novelty*

Since the TRIPS Agreement does not provide any definition of invention, member-states are relatively free to frame the policy options in the biological patents' field however they choose.⁶⁵ The patent system has thus far established the legal doctrine that only tangible inventions are protectable.⁶⁶ However, as stated previously, patents are granted now more and more to inventions that are discoveries of the laws of nature or isolates of natural chemical compounds.

According to Article 52(1) of the *European Patent Convention*, "patents should be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step."⁶⁷ In the United States, patents are granted for inventions that are novel and non-obvious, and if they serve a utilitarian

⁶⁴ A 27(2) and (3) *Agreement on Trade-Related Aspects of Intellectual Property Rights* 1994.

⁶⁵ UNCTAD *TRIPs Agreement* 34.

⁶⁶ Pott 1944 *Mod L Rev* 113.

⁶⁷ A 52(1) EPC.

purpose.⁶⁸ Indeed, at first glance the novelty standard looks the same in Europe as in the United States.

Under Section 102 of the US Patent Act, prior knowledge, usage, and/or invention in the United States can be used as evidence to invalidate an American patent for lacking novelty.⁶⁹ Novelty, in turn, is measured against the state of the art. It is generally met unless the invention is patented or described in a publication in the United States or a foreign country.⁷⁰ Further, patent examiners compare the invention with "prior art."⁷¹ If the purported invention is identical to any references establishing prior art, it lacks novelty and no patent will be granted.⁷²

The major criticism of American patent law on this point is its state-centric nature. The United States operates under a system of geographically specific notions of printed publications to determine prior art. Scholars argue that American patent law thus "waters down the novelty requirement by patenting inventions known or used in foreign countries as long as they have not been patented in a printed publication."⁷³ Developing countries which do not have strong systems of patent protection could therefore suffer, and traditional knowledge could be exploited in the United States. Indeed, the cultural and economic damage that this regime could cause to indigenous people is mammoth.

In European patent law, the novelty requirement is treated a bit differently. Under Article 54(2) of the EPC:

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 in any other way, before the date of filing of the European patent application.⁷⁴

So under European patent law it is not important whether or not the general public is aware of the existence of information stating prior art, but rather that the information

⁶⁸ Paras 101-103, 35 USC 271 Infringement of patent.

⁶⁹ Para 102, 35 USC 1994.

⁷⁰ Para 102(a), 35 USC 1994.

⁷¹ According to Correa *Traditional Knowledge 7*: "Prior art is all public knowledge before the priority date which could be relevant to the novelty or obviousness of an invention."

⁷² Schecter and Thomas *Principles of Patent Law* 74; von Hahn *Traditionelles Wissen* 164.

⁷³ DeGeer 2003 *New Eng J Int'l & Comp L* 364.

⁷⁴ A 54(2) EPC 42.

is available and accessible to anyone at any given time before an application is filed.⁷⁵

To illustrate the implications of these different interpretations of novelty for biopiracy in industrialised countries, it is worthwhile to consider the *Neem Tree* case.⁷⁶ The neem tree (*Azadirachta indica*) is a tree that is native to the Indian sub-continent but exists in Australia, Africa, Central and South America.⁷⁷ An extract from the tree has been used in pesticides, medicines, cosmetics, dental remedies, and contraceptives.⁷⁸ Indeed, Indian communities have known of these useful properties for ages. According to Ghosh, about 130 patents have been granted by the United States Patent Office on products and processes involving extracts from this Neem tree.⁷⁹ The most controversial ones are those patents granted to W.R. Grace, an American company in the chemical and pharmaceutical industries. The patent granted in 1990 was "for improving the storage stability of neem seed extracts containing azadirachtin"⁸⁰ and the patent granted in 1994 was "for storage of stable insecticidal composition comprising neem seed extract."⁸¹ The Indian government filed a complaint in the US patent office accusing W.R. Grace of copying an Indian invention but soon withdrew the complaint when it became clear that the invented process was not based on traditional knowledge in India.

The European Patent Office, after five years of legal battle, in 2000 withdrew the European patent grant to W.R. Grace and the US Department of Agriculture for a process to extract oil from the neem tree.⁸² After five more years of litigation, in 2005, the patent for the anti-fungal properties of neem was also finally revoked and invalidated.⁸³ The Opposition Board of the European Patent Office found that the

⁷⁵ Taubman and Leistner "Traditional Knowledge" 114-119.

⁷⁶ The similar *Turmeric* case shows that the definition of prior art defines the scope of the protection of intellectual property., (US Patent No 5, 401, 504; US Patent No 6, 048, 533; US Patent No 5, 897, 865) The *Basmati* case shows how patent law can permit the imitation of products. (US trademark application no 76, 081, 451)

⁷⁷ Anonymous www.en.wikipedia.org.

⁷⁸ Shiva www.twinside.org.sg.

⁷⁹ Ghosh 2003 *Colum J Asian L* 106.

⁸⁰ US Patent No 4, 949, 681.

⁸¹ US Patent No 5, 124, 349 patented the method for controlling fungi on plants using a hydrophobic oil extracted from the seeds of the Neem tree.

⁸² The patent was for a method of controlling fungi on plants with the aid of hydrophobic oil extracted from the Neem plant. (Patent No EP0436257)

⁸³ Sheridan 2005 *Nature Biotechnology* 5.

patent granted lacked novelty. This shows that the European Patent Office does not give a patent for an invention which has been known anywhere else.⁸⁴ The fact that the European Patent Office challenged this patent on the grounds that the process was based on traditional knowledge is interesting for other reasons as well.⁸⁵ The European Patent Office usually prefers to rely on the technicalities of an inventive step rather than on the *ordre public* and morality.⁸⁶ Moreover, the European Patent Office often tries to take into consideration the prior art that published in printed form in scientific journals. Traditional knowledge therefore faces obstacles if it has not been documented in printed form. Further, if the traditional knowledge under consideration has not been published anywhere, the patent office requires detailed information on "what was made available to the public, where, when, how, and by whom."⁸⁷

If the traditional knowledge were published, however, defensive protection could be exercised. Indeed, some countries are developing databases of traditional knowledge that may be used as evidence of prior art. For example, the government of India has granted the European Patent Office access to its Traditional Knowledge Digital Library, which is a thirty-million-page searchable database translated from Hindi, Sanskrit, Arabic, Persian, Urdu and Tamil into English, German, French, Spanish and Japanese.⁸⁸ The European Patent Office began using the database on February 2, 2009.⁸⁹ The database is unique in those technical fields that are concerned with questions of traditional knowledge. It is estimated that around 2,000 patents based on Indian traditional knowledge are incorrectly granted every year.⁹⁰ On the other hand, as Basheer rightly pointed out, "it [traditional knowledge] is of no value if you just hide it away and keep it for patent offices."⁹¹

⁸⁴ Pandeya and Koshy 2009 www.livemint.com.

⁸⁵ Observations made on the *Neem* and *Hoodia* cases, *Hoodia* case: EP Application 98917372, EP Publication 0973534, Board of Appeal T 0543/04.

⁸⁶ The reason for this is that the rules for assessing an inventive step are well established, and there are no rules for assessing *ordre public* and morality. For more on this topic see Barton *Der "Ordre public"* 217-407.

⁸⁷ Dolder 2007 *Biotechnology Law Report* 589.

⁸⁸ Pandeya and Koshy 2009 www.livemint.com.

⁸⁹ Oller "EPO accepts traditional knowledge database".

⁹⁰ Oller "EPO accepts traditional knowledge database".

⁹¹ Oller "EPO accepts traditional knowledge database", emphasis added.

The *Neem Tree* case shows just how differently various countries interpret the requirements of intellectual property, such as the novelty requirement for patents. Indeed, we can distinguish between standards of absolute novelty and relative novelty.⁹² The TRIPS Agreement therefore fails to protect traditional knowledge because it does not provide an international rule of novelty and gives too much discretion to states in shaping their own domestic patent law.⁹³

4.3 TRIPS and the Convention on Biological Diversity

The *Convention on Biological Diversity*⁹⁴ (the CBD) was presented at the United Nations Conference on Environment and Development in Rio de Janeiro in 1992.⁹⁵ It came into force in 1993 and has 192 contracting states.⁹⁶ The CBD attempts to recognise and formalise the value of traditional knowledge and to ensure that holders of traditional knowledge are compensated accordingly. The aims of the CBD are "the conservation of biological diversity, the suitable use of its components, and the fair and equitable sharing of the benefits from the use of genetic resources."⁹⁷ Since many developing countries are dependent on biological resources, they support the CBD to prevent the unauthorised appropriation of traditional knowledge and to ensure benefit sharing, rather than to establish a system of positive protection.⁹⁸ Article 8(j) of the CBD provides as follows:

Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.⁹⁹

⁹² An absolute novelty standard in Europe and a relative novelty standard in the United States.

⁹³ Gervais *TRIPS Agreement* 220-221.

⁹⁴ A 8(j) of the *Convention on Biological Diversity* 1992 (the CBD). The CBD is signed but not yet ratified by the United States.

⁹⁵ Carroll 2005 *Am U L Rev* 2446-2447.

⁹⁶ Dutfield *Intellectual Property Rights* 212.

⁹⁷ As 1 and 8(j) of the *Convention on Biological Diversity* 1992.

⁹⁸ Correa *Traditional Knowledge* 22.

⁹⁹ A 8(j) CBD.

Many countries have therefore instituted legal regimes to restrict access to their biological resources.¹⁰⁰ The access agreements require bioprospectors to share any profits that may arise from patented inventions based on natural products.¹⁰¹

Since there is no link between the TRIPS Agreement and the CBD, discussion about the relationship between the two has come to the fore recently.¹⁰² In particular, many arguments about the implementation of the TRIPS Agreement and the CBD together were raised in the Doha Ministerial Declaration in 2001.¹⁰³ Proponents of patent protection for plant varieties and animal invention asked if adequate international protection was necessary to facilitate the transfer of technology. Opponents countered that broad patent protection would facilitate biopiracy.¹⁰⁴ Some countries currently argue that there is inherent conflict between TRIPS and CBD. Developing countries have suggested that the patentability of genetic resources under TRIPS leads to the appropriation of those resources by private parties and is inconsistent with the sovereign rights¹⁰⁵ of countries supported by the CBD.¹⁰⁶ On the other hand, developed countries have argued that TRIPS did not prevent member-states from protecting farmers' rights within their national *sui generis* systems of protection.¹⁰⁷ They also take the stand that there is no conflict between TRIPS and CBD because the objectives and purposes of both agreements are different. Granting exclusive rights over natural material and respecting the sovereign rights of countries over their genetic material are also reconcilable in their view.¹⁰⁸

However, poor countries and communities still complain of "biopiracy" because access to biodiversity is difficult to restrict and control and there is a structural imbalance between countries rich in biological diversity and those strong in

¹⁰⁰ Kate and Laird *Commercial Use* 16. For more on the access to genetic resources see Wolfrum "Convention on Biological Diversity" 383.

¹⁰¹ Wilson *Diversity of Life* 342. For more on the links between rights over access regulation (A 15 of the CBD) and patent rights over biotechnological products (A 27(3)(b) TRIPS, see Sampath *Regulating Bioprospecting* 105-107.

¹⁰² European Patent Office *Scenarios for the Future* 59; see Lochen *Die völkerrechtlichen Regelungen* 171-174.

¹⁰³ Gervais *TRIPS Agreement* 217-218.

¹⁰⁴ Gervais *TRIPS Agreement* 228.

¹⁰⁵ A 15(1) of the *Convention on Biological Diversity* 1992: "Recognising the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation".

¹⁰⁶ Stoianoff "International Perspective" 46-47.

¹⁰⁷ Gervais *TRIPS Agreement* 229.

¹⁰⁸ Gervais *TRIPS Agreement* 231.

technological and legal instruments. There is no mechanism and legal system to guarantee benefit sharing between a patent and a material holder.¹⁰⁹

5 Obstacles to patenting traditional knowledge

Under current international patent standards, traditional knowledge faces many obstacles. According to Subbiah, we can distinguish between substantive, evidentiary, and administrative difficulties.¹¹⁰

From the substantive perspective, inventiveness is treated as an "isolated, individualised achievement of an identifiable inventor," as against traditional knowledge, which is generally collectively owned by the local communities in one or more countries and continents.¹¹¹ Intellectual property law exists to create incentives for creation, but traditional knowledge needs no incentives for development – it is developed as a response to the necessity of the natives.¹¹² Moreover, identifying individual inventors may be contradictory to the community's beliefs and internal values. Some cultures regard their knowledge as "deeply personal and spiritual" and therefore not subject to ownership.¹¹³ Additionally, some indigenous people believe all life has spirit and is equal to human life, making any claim of private ownership of biodiversity an absurdity.¹¹⁴

Evidentiary obstacles arise during the application process for a patent. Today's high patent standards require an applicant to separate the moment when the invention emerged, from the process of invention. For traditional knowledge holders it is very difficult to point to the particular moment of innovation.¹¹⁵ This is because traditional knowledge has been developed for ages and no one can determine an exact date of origin.¹¹⁶ It is also difficult for traditional knowledge holders to determine which elements are self-evident and which are non-obvious creations, because they have

¹⁰⁹ Staffler *Towards a Reconciliation* 23.

¹¹⁰ Subbiah 2004 *BC Int'l & Comp L Rev* 543-546.

¹¹¹ Subbiah 2004 *BC Int'l & Comp L Rev* 543-546 543.

¹¹² WIPO *Survey on Existing Forms*.

¹¹³ Conway-Jones 2005 *How L J* 745-746; Nijar *In Defense of Local Community* 24.

¹¹⁴ Bender 2003 *Tulsa J Comp & Int'l L* 294.

¹¹⁵ Ragavan 2001 *Minn Intell Prop Rev* 13.

¹¹⁶ Ragavan 2001 *Minn Intell Prop Rev* 13.

transmitted the knowledge from generation to generation.¹¹⁷ As stated previously, most traditional knowledge is undocumented. In the United States, for example, only documented knowledge that appears in a printed publication is beyond patentability. It therefore fails to be recognised as prior art, and thus cannot be protected from being patented by another party. Finally, even if traditional knowledge in some regions is common knowledge, as it was in the *NeemTree* or *Turmeric* case, it may still be patented in some jurisdictions. The reasons are not only that there are very limited prior art searches in the United States, but also that there is no requirement for patent applicants to conduct their own prior art searches before lodging an application.¹¹⁸

Administrative barriers arise in the process of granting patents. It is obvious that indigenous peoples do not possess the appropriate financial resources to fill out a patent application themselves.¹¹⁹ Moreover, not only administrative but also judicial procedures are often long and costly. According to economists, it would cost a poor country more than two million US dollars to set up the basic infrastructure for administering intellectual property rights.¹²⁰ In addition, patent applications also must be written using technical chemical and/or biotechnological terms.

6 The different strategies for the protection of traditional knowledge

As discussed above, traditional knowledge may be protected under patents. However, the patent protection of traditional knowledge faces many difficulties. It is therefore worthwhile to briefly consider alternative protection strategies and options.

6.1 Models of intellectual property rights

New plant products and varieties of all species of plants may be protected under plant breeders' rights. The protection of plant varieties under the *International*

¹¹⁷ Dutfield 2003 *Case W Res J Int'l L* 247-248.

¹¹⁸ *American Hoist & Derrick Co v Sowa & Sons Inc* 725 F.2d 1350, 1362 (Fed Cir) 469 US 821 (1984).

¹¹⁹ DeGeer 2003 *New Eng J Int'l & Comp L* 179 181.

¹²⁰ Jiang 2008 *Harard Int Rev* 3; Torrance 2008 *Geo Int'l Env'tl L Rev* 242.

*Convention for the Protection of New Varieties of Plants*¹²¹ requires a more flexible novelty requirement than patent protection. Article 6(1) of the UPOV provides the following criteria for establishing novelty:

The variety shall be deemed to be new if, at the date of filing of the application for a breeder's right, propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for the purposes of exploitation of the variety

- (i) in the territory of the Contracting Party in which the application has been filed earlier than one year before that date and
- (ii) in a territory other than that of the Contracting Party in which the application has been filed earlier than four years or, in the case of trees or of vines, earlier than six years before the said date.¹²²

Traditional knowledge used in agricultural production may be protected under the protection of geographical indications. Many products that come from various regions are the result of traditional processes and knowledge implemented by communities in a given region.¹²³ Proposals relating to the expansion of the products enclosed in Article 23(1) of the TRIPS Agreement¹²⁴ have been supported by developing countries in relation to international flora.¹²⁵

All kinds of products, such as furniture, articles of ceramics, and leather and wood products may qualify for the protection of industrial designs.¹²⁶ Copyright, in turn, can be used to protect artistic manifestations of holders of traditional knowledge, and could also include literary works like legends, myths, and poems, theatrical works, musical works, and textile compositions.

However, a system based on intellectual property rights at the national level creates only territorial rights, which means that the rights cannot be enforced in an outside, third country. The existence of such a regime therefore does not solve the problem of "biopiracy," as in most cases the appropriation of traditional knowledge is made by foreign entities.

¹²¹ *International Convention for the Protection of New Varieties of Plants* 1961, commonly known by its French acronym UPOV (Union pour la Protection des Obtentions Végétales).

¹²² A 6(1) of the *International Convention for the Protection of New Varieties of Plants* 1961.

¹²³ GRULAC Traditional Knowledge.

¹²⁴ A 23(1) TRIPS enclosed additional protection for wine and spirits.

¹²⁵ Eg India, see WT/GC/W/147.

¹²⁶ For more on the protection of folklore see WIPO *Matters Concerning Intellectual Property*.

6.2 A *sui generis* regime of intellectual property rights

Another possible option, which may protect traditional knowledge, is a *sui generis* system of intellectual property rights.¹²⁷ There are several models of possible *sui generis* legislation. One such model was developed by the Third World Network in the 1994 discussion paper, *Community Intellectual Rights Act*.¹²⁸ Another one, for example, is provided by the Organisation of African Unity.¹²⁹ In practice, this kind of protection has not been systematically implemented, but it is strongly supported by many scholars and non-governmental organisations.

As Correa rightly pointed out, when creating a *sui generis* system it is always a matter of debate if the protection of traditional knowledge should be subsumed under a single and comprehensive regime covering all manifestations of traditional knowledge, or a set of specific regimes adapted to the nature of the subject matter to be protected.¹³⁰ A single regime requires the determination of different subject matters, which might be hard to find and which may prove difficult when trying to define common legal rules.¹³¹ Alternatively, a more specific system could, for example, be divided into three parts: artistic creations including folklore, plant genetic resources for food and agriculture, and traditional medicine.¹³² So far, only a few countries have incorporated *sui generis* systems into their national constitutions or national laws.¹³³

7 Conclusions

In recent decades, as biotechnology has developed, patentability has expanded in parallel. The expansion and globalisation of international trade has, in turn, further implicated intellectual property rights. With respect to biodiversity in particular,

¹²⁷ 'Sui generis' means "of one's or its own kind." See the Oxford English Dictionary. In law this is a term of art to identify a legal classification that exists independently of other categorisations because of its uniqueness. See *Dunway v New York*, 442 US 200 (1979).

¹²⁸ Nijar "A Conceptual Framework".

¹²⁹ Ekpere OAU's Model Law 20.

¹³⁰ Correa Traditional Knowledge 14.

¹³¹ Correa Traditional Knowledge 14.

¹³² Correa Traditional Knowledge 14. For more on this topic see European Commission *Report on the International Protection*.

¹³³ Countries like Costa Rica, Brazil, Panama, Thailand or Philippines. For more on this topic see Correa Traditional Knowledge 12.

Diamond v Chakrabarty made it clear that life forms could be patented.¹³⁴ Subsequent decisions have confirmed the *Chakrabarty* ruling.¹³⁵

Biodiversity possesses significant economic value. ,For this reason it has raised complex and controversial issues about who gets what, at what cost to the parties involved, and the environmental implications.¹³⁶ According to Ghosh, "patent law increasingly is becoming a locus for battles over scientific validity and access to technology."¹³⁷

Although indigenous people possess the resources and the traditional knowledge to produce a unique set of biological materials, the global community is not only often depriving them to do so but is also devastating biodiversity at a rapid rate.¹³⁸ Often indigenous communities are seen simply as the passive guardians of their knowledge instead of its productive and innovative authors, but traditional knowledge is not a passive knowledge. It has been modified and improved for over a thousand years. Effective legal instruments are therefore needed to prevent the loss of this traditional knowledge, not least because the protection of traditional knowledge is crucial to the economic well-being of less-developed countries.¹³⁹

The debate about the protection of traditional knowledge is complex, ideological, and highlights an inherent incompatibility between the patent systems of industrialised countries and non-Western jurisprudence on property.¹⁴⁰ Intellectual property rights may be one of the possible strategies to protect traditional knowledge.¹⁴¹ However, the implications for the beneficiaries should be carefully considered. Within patent protection policies, there are also serious issues around the definitions of the subject matter, the rationale behind certain types of protection, and the means for achieving the policy goals. Collective ownership of traditional knowledge also creates additional difficulties for its protection.

¹³⁴ *Diamond v Chakrabarty* 447 US 303 (1980).

¹³⁵ See eg *Neem* and *Hoodia* cases, EP Application 98917372, EP Publication 0973534, Board of Appeal T 0543/04.

¹³⁶ Mgbeoji "Patents and Plant Resources-Related Knowledge" 81.

¹³⁷ Ghosh 2003 *Colum J Asian L* 120.

¹³⁸ Torrance 2008 *Geo Int'l Envtl L Rev* 270.

¹³⁹ Garcia 2007 *Berkeley La Raza L J* 27.

¹⁴⁰ Mgbeoji "Patents and Plant Resources-Related Knowledge" 82.

¹⁴¹ Correa *Traditional Knowledge* 27.

Many questions about the establishment of legal systems to protect traditional knowledge remain open. The most general, but at the same time the most important, is whether these legal regimes should be founded at the national level or begin at international level and then trickle down into national regulations. Although TRIPS establishes international standards of intellectual property rights protection, concerns about the relationship between TRIPS and the CBD remain. Therefore, decision makers should balance the possible benefits and costs of establishing legal systems and evaluate what other policies would be needed in order to effectively protect traditional knowledge from erosion and ensure its continuous development and wider use. Additionally, indigenous people should have more pro-active means by which to protect and promote their traditional knowledge, instead of having to rely on defensive protection.

With enough political solidarity and enough careful consideration from both the industrialised and the developing countries, a new structure for international intellectual property rights law could be implemented.¹⁴² Recognising the rights of indigenous peoples within this new structure would be a significant step forward in the economic development of the poor, while also granting the global community access to valuable natural resources in the third world.¹⁴³

¹⁴² Jiang 2008 *Harvard Int Rev* 3.

¹⁴³ Jiang 2008 *Harvard Int Rev* 3.

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List of abbreviations

Berkeley La Raza L J	Berkeley La Raza Law Journal
BC Int'l & Comp L Rev	Boston College International and Comparative Law Review
Case W Res J Int'l L	Case Western Reserve Journal of International Law
CBD	Convention on Biological Diversity
Colum J Asian L	Columbia Journal of Asian Law
Emory L J	Emory Law Journal
EPC	European Patent Convention
Eur Intell Prop Rev	European Intellectual Property Review
Geo Int'l Envtl L Rev	Georgetown International Environmental Law Review
GRULAC	Group of Countries of Latin America and the Caribbean
Harvard Int Rev	Harvard International Review
How L J	Howard Law Journal
IIC	International Review of Industrial Property and Copyright Law
ILO	International Labour Organisation
Mich L Rev	Michigan Law Review
Mich St L Rev	Michigan State Law Review
Minn Intell Prop Rev	Minnesota Intellectual Property Review
Mod L Rev	Modern Law Review
New Eng J Int'l & Comp L	New England Journal of International and Comparative Law

OJ EPO	Official Journal European Patent Office
PCT	Patent Cooperation Treaty
St Thomas L Rev	St Thomas Law Review
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property
Tulsa J Comp & Int'l L	Tulsa Journal of Comparative and International Law
UNCTAD	United Nations Conference on Trade and Development
UPOV	Union pour la Protection des Obtentions Végétales (International Union for the Protection of New Varieties of Plants)
WHO	World Health Organisation of the United Nations
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

TRADITIONAL KNOWLEDGE AND PATENT PROTECTION: CONFLICTING VIEWS ON INTERNATIONAL PATENT STANDARDS*

A Andrzejewski**

Summary

As diseases continue to spread around the globe, pharmaceutical and biotech companies continue to search for new and better drugs to treat them. Most of these companies have realised that useful compounds for these purposes may be found in the natural resources that indigenous and local communities use. And yet, even though the importance of these biological resources to global health and economic livelihood is well recognised, the legal ownership and control of this traditional knowledge is still very controversial. This article undertakes a comparative analysis of American and European, as well as international legal regulations on patent law and traditional knowledge. Key questions include: What is traditional knowledge? How have the national patent laws of these countries treated the protection of plant variety and plant genetic resources? What are the existing international standards for patents, and what implications do they have for protecting traditional knowledge? And finally, what protection systems are emerging for the future?

Keywords:

Traditional knowledge; patent protection; international patent standards.

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