

Biopiracy within the Pharmaceutical Industry: A Stark Illustration of just how Abusive, Manipulative and Perverse the Patenting Process can be towards Countries of the South

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PART I

What is Biopiracy? – Examples from Four Continents

The definition of biopiracy advanced by The Action Group on Erosion, Technology and Concentration reads as “the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions seeking exclusive monopoly control over these resources and knowledge”¹. Biopiracy therefore represents the gratuitous extraction of the environmental heritage and cultural knowledge from regions of the Earth for economic exploitation and industrial monopolisation. The contemporary phenomenon of biopiracy continues to be justified through a variety of legally biased rules founded upon Western concepts and politico-economic objectives, which seek to enforce a worldwide high-level and non-discriminatory patent regime. This article reports on the emotive² social and legal issues surrounding biopiracy³ and proposes possible solutions to ensure that a fair and equitable set of standards is imposed upon Western pharmaceutical companies and governments when dealing with the biological resources and traditional knowledge (TK) of developing countries, to the benefit of all parties concerned⁴. We find that certain amicable initiatives (public and private) are already in practice but that they do not adequately meet the necessary standards of fairness and equality among nations.

With some 80% of the world's biological diversity⁵ lying in the tropical and sub-tropical regions of the South⁶, accompanied by the fact that 56% of the top 150 prescribed drugs in the United States (US) are based on chemicals derived from plants⁷, and the existence of a world market for herbal medicines estimated at \$43 billion with an annual growth rate of between 5% and 15%⁸, the potential economic rewards for the undeveloped world are enormous, as is the temptation for pharmaceutical companies to commit acts of biopiracy.

¹ *'Integrating Intellectual Property Rights and Development Policy'*, Report of the Commission on Intellectual Property Rights, London, September 2002.

² When reading the wealth of literature on the subject, one is often referred to the words of colonialist profiteers such as Christopher Columbus who in relation to the Native Americans remarked, “They ... brought us parrots and balls of cotton and spears and many other things ... They willingly traded everything they owned. ... They do not bear arms ... They would make fine servants ... With fifty men we could subjugate them all and make them do whatever we want”. For examples see Shiva, V., *Biopiracy: The Plunder of Nature and Knowledge*, Green Books, 1998.

³ Part II.

⁴ Part III.

⁵ Only 1% of 250,000 known species of tropical plant have been tested. Ann Fullick, *'The Spice of Life'*, New Scientist, 7 December 2002.

⁶ Velasquez G. and Boulet P, *'Essential drugs in the new international economic environment'*, Bulletin of the World Health Organisation, 1999, 77 (3).

⁷ 40% of Western pharmaceutical products are found to contain Asian plant extracts alone. (*'Biopirates patent traditional wisdom'*, Inter Press Service, 8 October 1998 – <http://www.ips.org>).

⁸ The Inter-Regional Workshop on Intellectual property Rights in the Context of Traditional Medicine (Bangkok, 6-8 December 2000).

The temptation to pillage this proverbial “Garden of Eden” is even greater when considering the current economic crisis⁹ and saturation¹⁰ of the pharmaceutical industry and its perennial quest for new materials and biological processes¹¹. The “worrying times”¹² resulting from the recent decline of the industry’s profits, returns¹³ and share value¹⁴ due to generic drug production¹⁵, increased competition resulting from patent expirations¹⁶, compulsory licensing and cases of breach of confidentiality have led to “sagging morale, departing scientists and dwindling pipelines”¹⁷. Indeed, the world’s second-largest drug firm, GlaxoSmithKline, faces several lean years with very few new drugs being launched before 2005¹⁸ as does the industry as a whole, with only 15 new drugs being approved by the US Food and Drug administration in 2002, compared with a five-year annual average of 31¹⁹. Firms such as Phytopharm, a specialist in biotechnology and the use of plants to develop medicines, have been forced to expand their market into the development of drugs for domestic animals in order to fund their pipeline of human products²⁰. Problems also arise because diseases are becoming harder to treat due to increased resistance. In South East Asia, multi-drug-resistant malaria is now so widespread that virtually no anti-malarial drug can be

⁹ Lehman Brothers expects global drug makers to have launched 47 new drugs in 2002, one third fewer than figures in 1997 with the leading 13 companies producing an expected 23 for 2003. (The Economist, 26 October 2002).

¹⁰ Market saturation is prevalent in the case of genes and gene-related molecules with more than 20,000 having been registered at the US Patent and Trademark Office (USPTO) since 1980 (Gary Stix, *Legal Circumvention: Molecular switches provide a route around existing gene patents*, Scientific American, July 2002). Between 1990 and 1995, around 25,000 biotechnological patents were granted worldwide, representing 1% of the total number of global patents. 37% of such patents originated from the US, another 37% were from Japan, with the EU having granted a total of 19%. With the exception of Australia, Canada, China, Israel and the Republic of Korea, the rest of the world accounted for a mere 0.7% of total global biotechnological patents (Correa, C.M., *Intellectual Property Rights, the WTO and Developing Countries (The TRIPS Agreement and Policy Options)*, Chapter VI, [Zed Books, 2000]). Such statistics underline the value of such resources and are also indicative of the huge imbalance in the number of patents issued in the North and South explaining the reinforcement of northern commercial domination through TRIPS, which favours a worldwide high-level and non-discriminatory patent system reflecting the policy agenda of Western technology exporters.

¹¹ The World Health Organisation’s recent statistics suggest that there is still no adequate therapy for three-quarters of the 2,500 medical conditions currently recognised.

¹² Roger Dobson, *Lack of new drugs is reaching crisis point, says review*, British Medical Journal, 18 January 2003.

¹³ Recent statistics indicate that the US pharmaceutical industry spent \$30.3 billion on research and development and \$19.1 billion on all promotional activities, including \$2.7 billion for consumer advertising. (Scott Gottlieb, *Congress criticises drugs industry for misleading advertising*, British Medical Journal, 14 December 2002).

¹⁴ GlaxoSmithKline’s share value has almost halved in the space of a year. (Nils Pratley, *Eight reasons why Garnier should not get any more*, The Sunday Times, 24 November 2002). Astra Zeneca, an Anglo-Swedish merger is 35% lower than its peak, Pfizer, the world’s largest drugs company is also down 35%, Eli Lilly has almost halved and Bristol-Meyers Squibb has fallen 68%. All these figures are from October 2002 so share prices are more than likely to have fallen to even lower levels at the time of writing. (Nils Pratley, *On the Sick List*, The Sunday Times, 27 October 2002).

¹⁵ GlaxoSmithKline is also under threat from generic drug producers such as Andrx who was recently held not to have infringed GlaxoSmithKline’s patent on Wellbutin and Zyban treatments. (Nick Hassel, *US generic drug court case worries hit GSK*, The Times, 29 November 2002).

¹⁶ GlaxoSmithKline’s sales of its best-selling antibiotic, Augmentin, have collapsed following the loss of its patent, due to increased competition from cheaper unbranded rivals and the company has set aside more than £100m to fight approaching patent disputes. (Paul Durman, *Glaxo running out of time and ideas*, The Sunday Times, 27 October 2002).

¹⁷ Roger Dobson, *Lack of new drugs is reaching crisis point, says review*, British Medical Journal, 18 January 2003.

¹⁸ The Economist, 30 November 2002. For further illustrations of GlaxoSmithKline’s malaise see: Nils Pratley, *On the Sick List*, The Sunday Times, 27 October 2002.

¹⁹ Roger Dobson, *Lack of new drugs is reaching crisis point, says review*, British Medical Journal, 18 January 2003.

²⁰ The particular financial context of the company is that it made a £3.84m loss, which reflected a 50% increase in R & D expenditure to a level of £6m. (Mark Court, *Animal drugs plan for Phytopharm*, The Times, 6 December 2002).

used alone reliably. It is primarily the investigation of older drugs used in novel combinations that has produced a temporary solution in this region of the world ²¹.

The global nature of Biopiracy: Illustrations of the “green rush” ²²

ASIA: India’s Neem Tree (*Azadiracta indica*).

Local villagers have regarded Neem as a free pharmacy – “the curer of all ailments” – for over 2000 years. In total, 23 parts of the tree are used in traditional medicinal remedies and practices ²³. Between 1994 and 1999 around 70 patents were granted to Western universities, drug and cosmetic companies, and genetic researchers regarding different properties and genes of the tree. In 1994 the European Patent Office (EPO) granted W.R.Grace EP 0436257 for a “method for controlling fungi on plants by the aid of a hydrophobic extracted neem oil”. The following year a group of international Non-Governmental Organisations (NGO) and representatives of Indian farmers filed legal opposition submitting evidence that the fungicidal effect of Neem seed extracts had been known and used for centuries thereby negating the novelty requirement for patentability. The debate reached a conclusion in 1999 when the EPO, revoking the patent, found that according to the evidence “all features of the present claim have been disclosed to the public prior to the patent application ... and [the patent] was considered not to involve an inventive step”.

It is important to underline that the patent was only **subsequently** revoked and that W.R.Grace was able to exploit its monopoly until 2000. Equally important is the fact that the patent was granted in Europe and was not subject to the lax perception of “prior art” applicable in the US ²⁴.

AUSTRALASIA: Samoan *Homolanthus acuminatus*.

The traditional healers of Samoa have for centuries ground up the stems of *Homolanthus acuminatus* and steeped it in hot water in order to treat yellow fever. This process recently caught the interest of the US National Cancer Institute (USNCI), which collected bulk samples of the plant to extract the prostratin that could potentially be used to treat HIV. Presently, the USNCI is developing a potential multi-million dollar drug for treating viral infections. There is no evidence of any prior agreement having been sought with the Samoan authorities, local communities or healers for the collection of the plants and subsequent use of the associated knowledge. Equally deplorable is the fact that no remuneration has been offered ²⁵.

Kava, found throughout the South-Sea Islands and cultivated for 3000 years for its medical properties, has been exploited in the same manner. With the upsurge in consumer demand for herbal medicines during the 1990s ²⁶, Kava generated \$30 million in 1997 on the US market alone, with projected sales of \$50 million for 1998. Again, little or no profit was returned to the islanders ²⁷.

²¹ British Medical Journal, 23 November 2002.

²² For further examples, visit <http://www.grain.org>.

²³ These include medicine for wounds, protection of teeth and gums, the accumulation of anti-bodies, detoxification, a cure for smallpox, hysteria, leprosy, AIDS, malaria and snake bites as well as numerous disinfectant and cosmetic uses. For more specific non-essential uses, such as a vaginal lubricant, see Andrew Purvis, ‘*Nature’s Pharmacy*’, <http://www.guardian.co.uk>, 30 May 2002.

²⁴ Section 102 of the US Patent Act. For further details, see below.

²⁵ Keith Perry, ‘*Getting fair price for indigenous remedies*’, <http://www.guardian.co.uk>, 21 December 2000.

²⁶ One particular example of the Kava shrub being patented is by L’Oreal, as a treatment for reducing hair loss. (Vidal, J., ‘*Can you really Patent a Tree?*’, The Guardian, 27 November 1999).

²⁷ Keith Perry, ‘*Getting fair price for indigenous remedies*’, The Guardian (electronic version), 21 December 2000.

SOUTH AMERICA: Ayahuasca from the Amazon Basin.

The bark of *Banisteriopsis caapi* has traditionally been used by indigenous shamans to diagnose and treat illnesses. A specimen was granted US Plant Patent 5,751 in 1986. The Coordinating Body of Indigenous Organisations of the Amazon Basin learnt of the patent in 1994 and a re-examination was requested on behalf of them by the Centre for International Environmental Law on grounds of prior art and also by suggesting that such a patent would be contrary to the public morality aspects of the US Patent Act due to the sacred nature of the plant throughout the Amazon Region. Despite such persuasive arguments, the USPTO ordered that the patent should stand²⁸. This example represents an “as is” form of biopiracy where the raw material has not undergone any further improvement and is therefore even more lamentable.

The Peruvian ‘miracle plant’, *Mirabilis jalapa*, is another such case of biopiracy from this region of the world which has recently been granted EP 576483²⁹.

AFRICA: The Hoodia gordonii Cactus.

One of Africa’s oldest tribes, the San, has also fallen victim to biopiracy. “Nature’s Prozac”, discovered and used by the tribe since prehistoric times, was patented in 1995. Hoodia, traditionally used to stave off thirst and hunger during long periods of time, has recently been translated into a blockbuster obesity cure, P57, with a market potential of \$6 billion. The particularly disconcerting aspect of this case is that it was a governmental organisation, the Council for Scientific and Industrial Research (CSIR)³⁰, that took and patented the knowledge before licensing it to Phytopharm who subsequently sub-licensed to Pfizer, with none of the projected royalties being earmarked for the San.

A claim was launched against the CSIR stating that it had failed to comply with the rules of the Convention on Biological Diversity 1992 (CBD), requiring prior informed consent. Consequently, a “Memorandum of Understanding” was reached between the parties in March 2002, whereby the San would receive a share of any future royalties from the CSIR³¹, along with offers of education programmes, computer training and employment cultivating the plant³².

Such an example represents a rare case where a bilateral agreement on access and benefit sharing has obviated the need for expensive and time-consuming litigation³³. A less encouraging case from the African continent concerns two drugs derived from the Rosy Periwinkle, which generate \$100 million annually for Eli Lilly. The plant is indigenous to the rainforest of Madagascar, and the country has received nothing in return.

Cases of biopiracy also extend to the subterranean world, possibly the most fertile and diverse region of the world, with one small bag of soil potentially containing more species than an

²⁸ The decision was made at the beginning of 2001. (*Integrating Intellectual Property Rights and Development Policy*’, Report of the Commission on Intellectual Property Rights, London, September 2002).

²⁹ The Ecologist, ‘*The top five patents on life*’, Volume 32 No. 5, June 2002.

³⁰ An organisation with a mandate to help and assist South African communities by developing natural resources into commercial products!

³¹ Although the drug is unlikely to reach the market before 2006, and still requires approval from the American Food and Drug Administration, the San can expect to receive £6.6 million per year that will be carefully audited to ensure that the communities, rather than a few individuals, will reap the benefits. (Gavin Evans, ‘*The Diet Secret of the Desert*’, The Times (T2 Supplement), 19 November 2002).

³² Money was also distributed to the government through a licensing system in relation to bio-prospecting.

³³ ‘*Integrating Intellectual Property Rights and Development Policy*’, Report of the Commission on Intellectual Property Rights, London, September 2002.

entire tropical rainforest. The United Nations has launched a worldwide programme to discover the micro-bacteria that dwell in the soils of such countries as Brazil, Kenya, Indonesia and India³⁴. The Chinese Academy of Sciences has also recently embarked on such a quest in neighbouring Tibet and Inner Mongolia to discover commercially useful microbes³⁵.

The potential scope of biopiracy is clearly not restricted to exotic vegetation and soils as it also encompasses rare and highly toxic animal species³⁶ and, even more alarmingly, indigenous peoples themselves. Tissue³⁷ and blood samples³⁸ are regularly exported from developing countries for research into a particular field, and are then often abused³⁹ when they are found to have properties that may prove useful in another field of medicine leading to a multi-million dollar pharmaceutical product. Such instances of abuse are even more prone to occur given the fact that much academic research in the US is sponsored by the pharmaceutical industry. The notion that the “partnership between industry and academia will lead to clinical advances only if academic freedom is preserved” is only very loosely applicable in the US⁴⁰. More alarming is the current tendency of pharmaceutical companies to exploit innocently collected material in gene banks⁴¹ and cell libraries, which has been collected over periods of time from indigenous communities and has been, until today, off bounds for conversion into patent rights⁴².

Such practices illustrate the absence of any moral considerations but, more fundamentally, do not recognise the energy and effort that certain indigenous communities have invested for

³⁴ Anthony Browne, ‘UN hopes answers may lie in the soil’, *The Times*, 29 November 2002.

³⁵ David Cyranoski, ‘Microbe hunt raises doubts over local benefits of bioprospecting’, *Nature*, 14 November 2002.

³⁶ The salivary hormone of the ‘Gila Monster’ is under development to regulate insulin production in diabetes patients, the salivary substance of the ‘Vampire Bat’ may be used to treat blood clots in stroke victims, the protein found in the venom of the ‘Giant Scorpion’ could be utilised as a smart bomb that seeks out brain tumours, the poison of the ‘Puffer Fish’ (a marine organism) may ease the pain of heroine withdrawal and cancer, the molecules in the saliva of the ‘Medicinal Leech’ are known to reduce the risk of blood clotting in some surgeries and the poisonous skin secretions of the ‘Poison-Dart Frog’ may assist with pain management evading morphine’s addiction risk. (Arlene Weintraub, ‘*Medicine’s Wild Kingdom: Potent chemicals derived from exotic animals are yielding a range of treatments*’, *Business Week*, 3 February 2003).

³⁷ Peter Forster, ‘Indian objection to export of human tissue for research’, *British Medical Journal*, 25 January 2003.

³⁸ For blood samples taken from Amerindians on Vancouver Island in Canada see, Rex Dalton, ‘Tribe blasts exploitation of blood samples’, *Nature*, 14 November 2002.

³⁹ The Rural Advancement Foundation International (RAFI) remark that “Human genetic diversity (especially that of isolated indigenous communities) is a matter of increasing scientific, commercial and military interest. The flow of human genetic resources among military and civilian researchers across international borders is unmonitored and unrestricted despite its value and significance”. The US National Institute of Health (NIH) received the first known patent for an unmodified human cell line drawn from an indigenous person from Papua New Guinea devoid of any prior consent or consultation of the indigenous peoples or national government (U.S. 5,397,696) and has since accumulated human tissue samples from China, Colombia, the French West Indies, Haiti, Mauritania, Guinea-Bassau, Ivory Coast, Central African Republic, Zaire, French Guyana, Peru and the Solomon Islands for use in researching cures for Alzheimer’s, Parkinson’s, leukaemia, neurological diseases and cancer worth billions of dollars, but also, it is suggested, that they are being utilised to develop military capabilities. (‘*New questions about management and exchange of human tissues at NIH: Indigenous person’s cells patented*’, RAFI Communiqué (Mar/Apr 1996), <http://www.cptech.org/ip/rafi.html>). The American case of *John Moore*, a leukaemia patient, provides a domestic example where cells taken from his cancerous spleen were subsequently used without his permission to develop a useful and patentable cell-line. Alarmingly, the Supreme Court of California held that Moore was not able to claim ownership of the intellectual property in his own cell-line due to the trivial disparities between his actual cells and those that were patented. (Crespi, S., ‘*Biotechnology Patenting: The Wicked Animal Must Defend Itself*’, *European Intellectual Property Review* 431 [1995]).

⁴⁰ Janice Hopkins Tanne, ‘Better standards needed for industry sponsored clinical trials’, *British Medical Journal*, 2 November 2002.

⁴¹ The Human Genome Diversity Project is a prime example.

⁴² ‘*Conserving Indigenous Knowledge: Integrating two systems of innovation*’. An independent study by the Rural Advancement Foundation International. Commissioned by the United Nations Development Programme.

centuries in the cultivation and conservation of such valuable species of plant and organism upon which they remain dependent for food, security⁴³ and health⁴⁴. An analogy with sections 39-42 of the UK Patent Act 1977⁴⁵ can be drawn, as such materials and TK are clearly of “outstanding benefit” to the pharmaceutical industry with it being therefore “just” to furnish a financial reward for this invaluable contribution. The case for remuneration is even stronger, given the absence of any technological or financial assistance by the pharmaceutical companies in making the discovery of such knowledge. Despite the absence of any contractual lien, equity clearly demands that the custodians of TK and biological resources should receive fair compensation if such knowledge leads to commercial gain. One must, however, appreciate that the concept of wealth is not universal. For local communities, the imperative may be to ensure that the knowledge is preserved and respected rather than receive monetary compensation from its commercial exploitation. In applying a “but for” test, one remarks that, “but for the TK or raw material, the final pharmaceutical product would not have resulted”⁴⁶. Presently, not only is the pharmaceutical industry gaining an invaluable resource gratuitously but it is also gaining centuries-worth of free testing⁴⁷. Such compelling arguments evidently provide an undisputable justification for significant remuneration.

PART II

A Focus on the Legislative Disservices and Hypocrisies underpinning Biopiracy

1. Legally justified Biopiracy under Western Patent Laws

THE DISCOVERY v. INVENTION FALLACY

⁴³ Up to 1.3 million people worldwide are hunter-gatherers, and as a consequence, remain exclusively dependent on the “undomesticated bounty of nature” for survival (June 2003, *Hunter-gatherer distribution*, www.geographical.co.uk).

⁴⁴ Traditional medicines provide the only affordable form of treatment available to the poor. An estimated 80% of populations in the developing world depend on traditional medicines to meet their healthcare needs. (*Integrating Intellectual Property Rights and Development Policy*, Report of the Commission on Intellectual Property Rights, London, September 2002).

⁴⁵ Relating to the employee rights regarding inventions created in the course of employment. For Japanese examples of such a system see David Cyranoski, *Japan's innovators take patent deals to court*, *Nature*, 17 October 2002.

⁴⁶ As Vandana Shiva remarks, “The value of the product is dependent on the source ... not on how it is processed”. (Shiva, V., *Biopiracy: The Plunder of Nature and Knowledge*, Chapter 4 [Green Books, 1998]).

⁴⁷ “When we decide to develop a drug, it’s already been used in human beings for a long time, in some cases, hundreds of years or more. We have a reasonable assurance that there’s less liability as far as safety problems [are concerned] ... And when you’re working on small molecules, that’s always a very significant potential problem and an unknown until you get into some pretty expensive animal work or into humans themselves”. (G. Kirk Raab, board chairman and advisor to Shaman Pharmaceuticals: <http://archive.greenpeace.org/~geneng/reports/pat/intrapat4.htm>).

The capacity to patent nature necessarily blurs the distinction between discovery and invention and, by doing so, installs stagnancy in pharmaceutical advancement by encouraging the former rather than the latter. The landmark decision of *Diamond v. Chackrabarty*⁴⁸ opened the floodgates by holding that patents may be awarded to “anything under the sun that is made by man”. Only “the laws of nature, physical phenomena, and abstract ideas” are excluded from patentability. *Prima facie*, biological resources and processes extracted from traditional knowledge appear to be discoveries, within the meaning of section 1(2)(a) of the Patent Act 1977, rather than inventions, as they are purely uncovering something that already exists, devoid of any creative element. According to B.G.E. Tewolde⁴⁹, patenting is highly inappropriate in treating living things as biological processes for they are not invented and reproduce themselves, unlike mechanical things and processes⁵⁰.

The justification for patenting traditional medicines results from the glaring fallacy and inherently biased Western perception that, because significant financial resources have been invested in refining the original material, scientific trials and chemical analysis, the product has been improved and should be regarded as novel⁵¹. The hypocrisy of such an argument is particularly apparent when considering the attempts of some pharmaceutical companies to patent naturally occurring genes on the basis that they ‘discovered’ them.

Criticism of this prejudiced Western statutory interpretation is advanced by Carlos M. Correa who suggests that in reality, drug companies do not actually do that much in converting the raw material into the final product. In fact, “the genomics gold rush revolves around genes that have been isolated and purified outside an animal, plant or micro-organism”⁵². These simple processes of isolation and purification are sufficient, or sufficiently unnatural, to give the gene the necessary amount of novelty to be patentable⁵³. As Drahos remarks, “How many people would think that the rock they pick up in the park becomes an invention of theirs after they have washed and polished it?”⁵⁴. This critical point of view is shared by nations such as Mexico, Argentina and Brazil, which do not allow the patenting of naturally existing materials. Brazilian patent law in particular stipulates that no patent shall be granted to living

⁴⁸ 447 US 303 (1980).

⁴⁹ An African scientist and Chairperson of the African Group in the CBD,

⁵⁰ “Distorting the meaning of patenting in order to make it applicable to life only serves to attract rejection of the whole system ... Opposition is growing all the time, opposition not only to the legitimacy, but also to the legality of patenting” (Khor, M., *Rethinking IPRs and the TRIPS Agreement*, Oxfam International Seminar on Intellectual Property and Development, Brussels, March 2001). Such sentiments are echoed by R. Grunwald who argues that “Making something existing in nature visible, tangible, smellable, audible, testable, in short accessible for the human senses and understanding does not necessarily mean he can “own” it, exclude others from its use even for a limited time ...”. (Crespi, S., *Biotechnology Patenting: The Wicked Animal Must Defend Itself*, European Intellectual Property Review 431 [1995]).

⁵¹ Correa, C.M., *Intellectual Property Rights, the WTO and Developing Countries (The TRIPS Agreement and Policy Options)*, Chapter VI [Zed Books, 2000].

⁵² Gary Stix, *Legal Circumvention: Molecular switches provide a route around existing gene patents*, Scientific American, July 2002. This article also explores the use of “zinc finger proteins” to switch genes on and off, which are perceived as sufficiently novel for a new patent.

⁵³ As the proposed European Directive on the matter suggests under article 3.2, “Biological material which is isolated from its natural environment or processed by means of a technical process may be the subject of an invention even if it already occurred in nature”. Such a position is adopted throughout developed countries including the US and Japan. (Correa, C.M., *Intellectual Property Rights, the WTO and Developing Countries (The TRIPS Agreement and Policy Options)*, Chapter VI [Zed Books, 2000]).

⁵⁴ Drahos also comments, “One suspects that, if Mother Nature had a patent on a particular naturally occurring gene sequence, she would almost always win a patent suit brought against the alleged inventor, since typically all that happens in non-natural gene sequences is the removal of redundant codons. In essence the sequences are the same”. (Drahos, P., *Biotechnology Patents, Market and Morality*, European Intellectual Property Review 441 [1999]).

beings or “biological materials found in nature”, even if isolated, including the “genome or germplasm” of any living being⁵⁵.

The fact that discoveries are theoretically excluded from patentability is paradoxical in the sense that it licences the exploitation of developing countries as they are deemed never to have invented anything and legitimises the gratuitous expatriation of their TK and resources, which are subsequently, in a pharmaceutical context, afforded monopolistic patent protection following minor superficial modifications in Western laboratories. By coming to such a conclusion, the West’s misconception that inventions are not possible in the absence of a patent infrastructure is highlighted – as the resource or process has not been patented, it is capable of being invented. As a consequence, it is the “first-to-file” who receives the monopolistic protection rather than the “first-to-invent”, who may face infringement proceedings if he/she chooses to reproduce what they have veritably invented.

In relation to TK, a unique form of intangible intellectual property, one is left asking the question: is patentability actually an issue? What is important is identifying the original owner(s) of the knowledge – an evidential issue – rather than seeking to overlook this factor in order to sustain a biased Western patenting regime. Such evidence could be obtained from anthropological sources and would contest the West’s current social and cultural conservatism regarding potential forms of intellectual property.

PRIOR ART, TERRITORIALITY AND MORALITY

In the United Kingdom⁵⁶ and Europe⁵⁷, the issue of prior art is considered on a **global** scale, however, the US considers prior knowledge or use in **domestic** terms⁵⁸, whereby only if the knowledge or use is located within the US is the novelty element unfulfilled⁵⁹. This undoubtedly facilitates the theft and patenting of TK from all other nations and carries the consequence that countries that do not permit the patenting of plants and animals can provide no bar to a patent being obtained in the US.

Additionally, although territoriality of patent rights precludes patent holders from exercising their rights outside the registered jurisdiction, the patent holder retains the right to prevent the importation of products made elsewhere containing the “invention”. Consequently, holders of US patents can deny the native communities from where the bio-resources originate, access to the lucrative US market.

The US tradition of ignoring issues of morality and equity has proved equally problematic⁶⁰ and has led to a blinkered approach whereby US patent applications are **presumptively** valid on grounds of public policy and can only be declared invalid **subsequently** through purely domestic political action⁶¹. Indigenous tribes are left without recourse to challenge the system and the financial implications of litigation remain beyond their minor financial means. Such a predicament produces a dangerous scenario where the scope of patentability is expanding while the role of moral standards and legal challenges becomes increasingly limited⁶².

⁵⁵ Correa, C.M., *Intellectual Property Rights, the WTO and Developing Countries (The TRIPS Agreement and Policy Options)*, Chapter VI (Zed Books, 2000).

⁵⁶ Section 2(2) of the Patent Act 1977.

⁵⁷ Articles 54 and 55 of the European Patent Convention.

⁵⁸ Such an unsatisfactory state of affairs is also present in Japan.

⁵⁹ Section 102 of the US Patent Act.

⁶⁰ See the example of biopiracy from the Amazon Basin above.

⁶¹ Hearings of the US Congress have come to the conclusion that “patent law is not the place to exercise moral judgements about scientific activity”. (Drahos, P., ‘*Biotechnology Patents, Market and Morality*’, European Intellectual Property Review 441 [1999]).

⁶² Such an approach is also being adopted by the legislative and judicial interpretations of article 53(a) of the European Patent Convention regarding the test of morality, which depends on the patent being “abhorrent to the

SECTION 27(3)(b) OF TRIPS

Currently, great pressure surrounds this controversial provision, with Europe and the US seeking to extend the range of patentability by either removing or tightening this express exemption⁶³. Under this article, members of the World Trade Organisation (WTO) are entitled to exclude “animals and plants, **other than** micro-organisms, and essentially biological processes for the production of plants and animals **other than** non-biological and microbiological processes” from patentability. It is therefore apparent that WTO members have to allow patents for certain types of life form and living processes due to the provision’s under-inclusive nature. No scientific basis exists for this facile demarcation, which undermines the position of many nations’ approach to the patentability of plants and animals pre-TRIPS⁶⁴.

Should such a provision be eroded, and developing countries comply with TRIPS there is a danger that when they actually come to patenting their own biological wealth they will find that the patents have already been taken out by Western drugs companies and would therefore be subject to invalidity or infringement proceedings. Given the over-protectionism of patents in the US and the tradition of over-compensating for patent infringement, the inequalities in financial capacity to litigate and experience of the litigation system are once again highlighted⁶⁵.

Additionally, under TRIPS, if the plants and processes procured from the developing world acquire greater value or further uses through advanced biotechnology research, no provision requires that such patents should be made available for use in the original developing country. Equally absent is a provision necessitating a local working requirement of patents. A patent can therefore be registered in a developing country with no obligation to produce it there.

2. Inherent hypocrisies underpinning Biopiracy

Developed countries have historically exploited the absence of patents and the free exchange of information to acquire valuable knowledge in order for socio-economic progression. As Drahos remarks, “Property rights were part of that crucial infrastructure of organisation that enabled Western states to achieve economic take-off and stability ... Property rights, in other words, pattern economic growth”⁶⁶. The US for instance in 1866 refused to sign the Berne Convention on the grounds that, as a developing country, it had a right to the “heritage of mankind” to assist its development⁶⁷. *The Economist* highlights this flagrant hypocrisy in its

overwhelming majority of the public”. The *Red Dove* case decided by the Federal Supreme Court of Germany can be regarded as a landmark case, equivalent to the US case of *Diamond v. Chakrabarty*, in extending patent protection to biotechnological inventions. Although the approaches in the US and Europe are not absolutely uniform, the much publicised *Onco-mouse* case led to exactly the same outcome in both jurisdictions. (Drahos, P., ‘*Biotechnology Patents, Market and Morality*’, European Intellectual Property Review 441 [1999]). There is therefore no reason to suggest that such a narrow interpretation will be applied to article 27(2) of TRIPS regarding *ordre public*, although certain authors suggest that avoiding serious prejudice to the environment may fall within the ambit. (Daniel J. Gervais, ‘*The TRIPS Agreement – Interpretation and Implementation*’, European Intellectual Property Review 156 [1999]). What is particularly important to recognise in relation to article 27(2) is that its application is limited to specific inventions rather than categories of patent.

⁶³ Vidal, J., ‘*Can you really Patent a Tree?*’, The Guardian, 27 November 1999.

⁶⁴ See the examples of Brazil, Mexico and Argentina above.

⁶⁵ Marc Galanter, ‘*Why the ‘Haves’ Come Out Ahead: Speculations on the Limits of Legal Change*’, 1974 Law Society 9(1): 95-160.

⁶⁶ Drahos, P., ‘*Biotechnology Patents, Market and Morality*’, European Intellectual Property Review 441 (1999).

⁶⁷ Elisabeth Uphoff, *Intellectual Property and US relations with Indonesia, Malaysia, Singapore, and Thailand* (Ithaca, N.Y. SEAP, Cornell University 1991).

article ‘*Patently Problematic*’⁶⁸. The combination of TRIPS⁶⁹ coming into effect in 2006, or 2016⁷⁰ for certain least developed countries benefiting from a “stay of execution”⁷¹ regarding pharmaceutical patents, and biopiracy, will leave developing countries of this epoch who find themselves in a “knowledge economy”, with no gratuitous knowledge upon which to base economic and technological advancement, not even that of their indigenous ancestors⁷².

Ironically, the primary motivation behind TRIPS is the avoidance of piracy, underlining the hypocritical nature of biopiracy relating to knowledge and practices that do not benefit or fit conveniently within the patenting regime. Developed countries’ claims that patents ensure protection from piracy are contradicted by the commission of biopiracy⁷³. Although TRIPS affords excessive patent protection to **prevent** piratical practices, biopiracy represents a reversal of this objective, with legitimised exploitation being **initiated** by the West⁷⁴.

Developed countries have for centuries under colonialism exploited the natural resources of developing countries for financial reward and in the process have caused significant environmental destruction. In return, such natural resources have been sold back to the developing world as finished pharmaceutical products, often at unaffordable prices⁷⁵. The

⁶⁸ 14 September 2002. “There was a time when countries could go their own way on intellectual property rights, and introduce legal protection for creators whenever they thought it appropriate. For most of the 19th century, America provided no copyright protection for foreign authors, arguing that it needed the freedom to copy in order to educate the new nation. Similarly, parts of Europe built their industrial bases by copying the inventions of others, a model which was followed after the Second World War by both South Korea and Taiwan. Today, however, developing countries do not have the luxury to take their time over IPR”. Such sentiments are echoed by Velasquez and Boulet who remark “During their industrial development, many industrialised countries had weak patent protection in vital sectors, such as pharmaceuticals, in order to strengthen their industrial and technological capabilities. It was only after they attained sufficient technological development in certain areas that they considered strengthening their patent laws ... It seems fair that developing countries should have the same flexibility on intellectual property rules while they are improving their technological capacity”. (Velasquez G. and Boulet P, ‘*Essential drugs in the new international economic environment*’, Bulletin of the World Health Organisation, 1999, 77 (3)).

⁶⁹ Regarded by some as “the imposition of values and interests by Western transnational corporations on the diverse societies and cultures of the world”. (Shiva, V., *Biopiracy: The Plunder of Nature and Knowledge*, Chapter 4 [Green Books, 1998]). In terms of employment, the West wishes to avoid universal employment laws on the grounds that they would be economically and culturally inappropriate but in relation to a universal patenting regime under TRIPS they are avid proponents despite the fact that it is equally objectionable in economic and cultural terms.

⁷⁰ Paragraph 7 of The 13 November 2001 Declaration of the Fourth Ministerial Conference in Doha, Qatar. The declaration is regarded by some as an “outstanding example of the untransparent, discriminatory, biased and manipulative process of decision-making at the WTO, that favours a few major developed countries at the expense of the many developing countries”. (*Joint NGO Statement on the Untransparent and Manipulative Process Leading to the Draft WTO Doha Ministerial Declaration*, 7 November 2001, <http://www.cptech.org/ip/wto/doha/ngos11072001.html>).

⁷¹ The Economist, ‘*Imitation v. inspiration*’, 14 September 2002.

⁷² Developing countries wishing to become members of the WTO must sign up to TRIPS, which means that failure to comply will result in legitimised trade sanctions that could have a devastating economic impact. The US-Europe Banana War of the late 1990s is a prime example.

⁷³ As Richard Sykes, non-executive chairman, GlaxoSmithKline, piously predicates, “Companies that make generic copies are like pirates on the high seas. We don’t believe in piracy. We tried to stamp it out in the seventeenth and eighteenth centuries”. (Legrain, P., *Open World: The Truth about Globalisation*, Chapter 10 [Abacus, 2002]).

⁷⁴ “The big concern is that the commercial benefits that would accrue from the plant or herbal remedy would only go to the drug company and you end up with the product being licensed back to the countries from where it originates”. Keith Perry, ‘*Getting fair price for indigenous remedies*’, <http://www.guardian.co.uk>, 21 December 2000.

⁷⁵ As The Environment Minister for Indonesia recognises, “It is ridiculous if we have to pay to use herbs growing in our land which we’ve used since ancient times”, especially given the fact that such resources are considered public property and are not viewed as being capable of private appropriation. One particular example, specific to Indonesia, is that of a Japanese cosmetic company that has patented several traditional Indonesian formulas of

recent crisis of over-priced AIDS drugs⁷⁶ provides an excellent illustration of Western attitudes⁷⁷. Developed countries are more than happy to exploit developing countries as a cheap and diverse source of raw pharmaceutical materials but remain reluctant to reduce prices or to tackle neglected diseases⁷⁸. In general, there is no volition to cross-subsidise funding drugs for treating neglected diseases from the profits generated from more lucrative products⁷⁹, although some notable exceptions do exist⁸⁰.

Ironically, through such enterprises as the Kyoto Agreement and the World Summit on Sustainable Development⁸¹, developed countries are seeking to undo the harm they themselves have caused, by preventing developing countries from exploiting their own natural resources because of the environmental implications surrounding industrialisation. Notably, however, the US, the “environmental renegade”, continues to demonstrate its lack of consideration of environmental welfare having not signed the Kyoto Agreement and being a

herbs and spices in order to produce anti-ageing and hair tonics. (Butt, S., *Intellectual Property in Indonesia: A Problematic Legal Transplant*, European Intellectual Property Review 429 [2002]).

⁷⁶ Recent figures indicate that at the end of 2002 a suspected 42 million people worldwide will be living with HIV or AIDS, 29.4 million of whom are located in sub-Saharan Africa. (Zosia Kmiotowicz, *Failure to tackle AIDS puts millions at risk of starvation*, British Medical Journal, 30 November 2002). More than 2.4 million people in sub-Saharan Africa die from AIDS every year. (Mark Henderson, *Young women are new face of AIDS*, The Times, 27 November 2002). Approximately 70,000 HIV-positive children are born in South Africa every year. (*Hand out AIDS drug says SA judge*, BBC News, 27 November 2001).

⁷⁷ Indeed, one-third of the world's population continues to lack regular access to essential drugs. In the poorest parts of Africa and Asia, this figure rises to over 50%. (<http://www.who.int/medicines/strategy/access/stacstrat.shtml>). As the medical humanitarian organisation, Médecins sans Frontières, proclaims, “Medicines aren't Barbie dolls or CDs – they are a matter of life and death for millions of people” (*A matter of Life and Death: the Role of Patents in Access to Essential Medicines*, <http://www.accessmed-msf.org>).

⁷⁸ Médecins sans Frontières asserts that “We are getting more and more drugs of less and less use, while many killer diseases like TB, malaria, and sleeping sickness are ignored because they only affect poor people. 68% of new drugs represent little or no therapeutic advance; and less than 1% of new drugs are developed for tropical diseases that represent over 10% of the global disease burden” (*MSF calls on governments to act upon recommendations of the Commission for Intellectual Property Rights*, <http://www.accessmed-msf.org>).

⁷⁹ Eli Lilly for instance is known to focus its R & D budget of \$2 billion on a few diseases promising potentially huge financial rewards in such areas as diabetes, osteoporosis, cancer and depression. (The Economist, 26 October 2002). Only 8% of pharmaceutical expenditure is devoted to developing countries, which account for 75% of the global population (*Campagne Médicaments – s'informez*, <http://www.paris.msf.org>). Malaria is an excellent example of a Southern disease, which is simply ignored by the major pharmaceutical companies in search of more lucrative investments. More than 1 million people die from the disease every year

(<http://www.who.int/medicines/strategy/access/stacstrat.shtml>). Sub-Saharan Africa accounts for 90% of the world's malaria deaths. (Declan Butler, *Malaria initiative cries out for action in Africa*, Nature, 28 November 2002). In 1998, of some 11 million deaths in childhood from infection, nearly 5 million were due to diseases for which an effective method of protection exists. Of the total expenditure on health research among nations of the world, less than 10% is directed at 90% of the total disease burden, the bulk of which is restricted to developing countries. (Professor Sir David Weatherall, *Health for all?*, Oxford Today, Michaelmas Issue 2002).

⁸⁰ Over the past 15 years, Merck has donated \$1 billion to curing river blindness, a disease that affects 30m people every year in sub-Saharan Africa. The company has also donated \$100m worth of vaccines against such diseases as hepatitis to the Global Alliance for Vaccines and Immunisation and has adopted a differential pricing strategy for certain drugs such as Crixian, an AIDS drug, which sells at 85% less in the poorest countries in relation to the US. Merck is one of the few drug giants to display such “corporate social responsibility” following on from its original founder's view that “medicine is for people. It is not for profits. The profits follow.” but, continues to be perceived as commercially naive by its competitors and Wall Street. (The Economist, 14 December 2002). Perhaps stung by criticisms of its excessive pay deals, GlaxoSmithKline has pledged to spend at least \$1 billion to eradicate elephantiasis, a disease transmitted by mosquitoes that is prevalent in developing countries. (Mark Court, *Industry has key role over credibility*, The Times, 19 November 2002).

⁸¹ It is widely accepted that such summits are only ‘talking shops’ and as Paul Ladd, head of policy at Christian Aid, remarks, “A poor person in a poor country has very little to celebrate after this meeting of world leaders”. Indeed, in relation to maintaining bio-diversity, the 2002 summit in fact takes a step back from the 1992 Rio Earth Summit: there participants promised to ‘stop’ the loss of bio-diversity by 2010, but in 2002 they only promised to ‘slow it down’ by then. It goes without saying that such objectives are utterly devoid of any legally enforceable obligations. (Anthony Browne, *Lip service to a plan that won't hold water*, The Times, 4 September 2002).

passive bystander at the World Summit in Johannesburg⁸². As Jonathan A. Patz and R. Sari Kovats remark, “wealthy energy consuming nations are most responsible for the emissions that cause global warming, yet poor countries are most at risk ... The US contains 5% of the total population of the world yet produces 25% of total annual emissions of green house gas ... A country’s ability to cope with the impacts of climate change depends on its wealth, technology, and general infrastructure⁸³. Impoverished populations in the developing world do not have the industry, transportation, or intensive agriculture that cause global warming, yet they have limited capacity to protect themselves against the adverse consequences”⁸⁴.

Biopiracy undoubtedly threatens biological diversity⁸⁵, particularly in terms of monocultures in global agriculture⁸⁶, but also in generating risks of biological pollution from genetically engineered organisms. According to the Overseas Development Institute, “The existence of more extensive intellectual property protection for plant genetic resources could in the long run have a substantial impact on global biological diversity...”⁸⁷. An anomaly therefore exists in the environmental benevolence of the West as, through practising acts of biopiracy they continue to jeopardise the achievement of environmental conservation, bio-diversity and sustainable agricultural practices. Further, the traditional rights of local communities to bio-diversity are threatened, which weakens their capacity to conserve the remaining bio-diversity and undermines the general ethics of conservation. The absence of financial remuneration and a financial incentive to promote bio-diversity also discourages developing countries to refrain from attacking rainforests and other valuable bio-resources⁸⁸.

PART III

Possible Ways Forward to assure Just and Equitable Treatment of Countries of the South for the Benefit of all

It can be noted that three categories of biopiracy exist, ranging in the extent to which they are piratical:

1. Bio-prospecting, whereby one discovers a plant or an organism which is completely unknown to anyone. This represents the least piratical category as nothing is being abstracted from another, but paradoxically no patent protection is offered, as discoveries remain excluded from patentability.

⁸² Steven Shrybman, author of *The World Trade Organisation: A Citizen's Guide*, 2nd Edition.

⁸³ As Vandana Shiva forcefully puts it, “In a world of globalised, deregulated commerce in which everything is tradeable and economic strength is the only determinant of power and control, resources move from the poor to the rich, and pollution moves from the rich to the poor. The result is a global environmental apartheid”. (Vandana Shiva, *The World on the Edge, Living with Global Capitalism*, eds. Will Hutton and Anthony Giddens).

⁸⁴ Jonathan A. Patz and R. Sari Kovats, *Hotspots in climate change and human health*, British Medical Journal, 9 November 2002.

⁸⁵ “Genetic engineering, even while preying on the world’s biological diversity, threatens to aggravate the ecological crisis through the expansion of monocultures and monopolies”. (Shiva, V., *Biopiracy: The Plunder of Nature and Knowledge*, Chapter 5 [Green Books, 1998]).

⁸⁶ Such a spread of monocultures will result through corporations with patents attempting to maximise returns on investments by increasing market shares.

⁸⁷ *Patenting Plants – the Implications for Developing Countries*, Briefing Paper, November 1993, Overseas development Institute, London.

⁸⁸ It is estimated that 25% of the World’s plant species are at risk of extinction in the next half-century. For instance, in South Africa’s Western Cape, 6,000 out of 8,000 plant species are endemic meaning that they do not exist anywhere else. The potential medicinal use of such plants is therefore extremely precarious. (Peter Martin, *Save the last plants for me*, The Sunday Times, 9 March 2003).

2. The discovery of unknown properties in an already known plant or organism. This demonstrates some progression from a mere raw material although the steps involved are usually not profound but nevertheless, are subject to patentability⁸⁹.
3. The final category, which is both the cheapest and therefore most piratical, is the exploitation of traditional knowledge.

1. Fair and Equitable Solutions for Categories 1 and 2

One possible solution is the use of bio-prospecting permits to generate revenue and ensure the obtainment of prior informed consent from the developing country but, alone, this would not suffice. In addition, technology transfer and development accompanied by local involvement would be desirable and would benefit both parties. The pharmaceutical company would gain a motivated partner whilst the economic rewards would be advantageous for the local community.

The problem with employing this system in isolation is that the value of the bio-prospecting is exceedingly difficult to anticipate, with a risk of over or under-charging depending on what is uncovered. Additionally, a fairly negotiated contractual relationship with the local community or government would be attractive, reserving a right to a certain percentage of the profits resulting from the final pharmaceutical product. The adoption of a scheme similar to the Indian government's registration programme relating to the results of bio-prospecting would furnish evidence of such a monetary right. Such a system would allow the developing country involved to avoid the patenting regime, as the contractual format would circumvent the need to obtain a patent and then licence it out to interested parties. Instead, the patent would be granted to the pharmaceutical company under the proviso that a certain return should be distributed to the co-contracting party. The patenting regime remains unadulterated as discoveries remain excluded and the developing country maintains its freedom from a biased Western patent system.

The 'model' example of such an initiative is that of the major pharmaceutical company, Merck. In 1991, a year in which the firm made profits of \$8.6 billion, a contract was signed with Costa Rica, home to between 5% and 7% of all the world's species. In exchange for exclusive rights to screen, develop and patent new products from plants, micro-organisms and animals, a total of \$1.1 million was paid to a local bio-diversity programme and the National Environment Ministry. With an estimated 500,000 species this represents a fee of \$2 per species and on a global scale means that at such a rate of exchange the world's genetic resources could be purchased for \$20 million!

The contract also contained a clause to return an unspecified percentage⁹⁰ of the royalties earned from the resulting products. The US government and World Bank have heralded such a scheme as a model of fairness, failing to recognise the maintenance of a neo-colonialist imbalance between rich and poor. In such exceptional circumstances where a sum of compensation is furnished, the sum is grossly inadequate and insulting when considering the salaries of pharmaceutical chief executives⁹¹ and the industry's spending figures for R & D

⁸⁹ See the comments of Carlos M. Correa above.

⁹⁰ Estimated to be between 1% and 3%.

⁹¹ The recent controversy surrounding Jean-Pierre Garnier's (chief executive of GlaxoSmithKline) \$18m proposed pay package, although it was eventually rejected by the shareholders, provides an excellent illustration. (Mark Court, '*GSK withdraws Garnier's \$18m*', *The Times*, 27 November 2002). Admittedly, due to growing public frustration at the cost of drugs in the US and developing countries, some company executives have been more sensitive as in the case of Sidney Taurel of Eli Lilly who reduced his base salary to \$1m for 2002. (*The Economist*, 30 November 2002).

and advertising⁹². A report commissioned by Christian Aid estimates that biopiracy is cheating third world countries out of \$4.5 billion per annum⁹³. A report of the United Nations Development Programme (UNDP) suggests a figure of \$5.4 billion⁹⁴. One is left asking whether the benevolent initiatives of certain pharmaceutical organisations are genuine or simply Public Relations exercises.

Contingently related is the issue of how the revenue (if it exists) should be distributed. The United Nations' recent legal initiatives recognising the special identities and independent status of tribal peoples give such communities entitlement to the revenue generated by national government⁹⁵. Such protection of indigenous peoples is essential in the context of "relocation" schemes, which deprive such peoples of their ancestral lands in order for such land to be financially exploited for its natural resources through governmental or private enterprise initiatives⁹⁶. However, the benefits of a centralised state in relation to education and medicine, in particular, must not become overshadowed. This emphasises the need for a coherent distribution strategy between central government and the indigenous population regarding the revenue generated from the biological resources and TK.

2. Fair and Equitable Solutions for Category 3

Categories 1 and 2 concern tangible forms of intellectual property and access issues rather than the intangible format that applies to TK and are, *prima facie*, less problematic. TK does not fit within the patenting model⁹⁷ as it is a communal right rather than an individual one, the date of creation is uncertain and it is, in the vast majority of cases, unrecorded due to its oral transmission⁹⁸. It is therefore appropriate that the traditional users should be provided with some other method of maintaining their guardianship over their TK.

The use of confidentiality agreements or trade secrets could prove effective in enabling developing countries to licence out their knowledge to the highest or most suitable bidder. This could also be achieved through the creation of TK databases, which would provide a more appropriate and efficacious alternative to the patent system and would generate direct revenue should the pharmaceutical industry wish to experiment with the documented knowledge. The social, political and financial implications that creating a patenting regime

⁹² Recent statistics indicate that the US pharmaceutical industry spent \$30.3 billion on research and development and \$19.1 billion on all promotional activities, including \$2.7 billion for consumer advertising. (Scott Gottlieb, 'Congress criticises drugs industry for misleading advertising', British Medical Journal, 14 December 2002).

⁹³ 'Patents on life: 4. Fair Trade?', <http://archive.greenpeace.org/~geneng/reports/pat/intrapat4.htm>.

⁹⁴ 'Conserving Indigenous Knowledge: Integrating two systems of innovation'. An independent study by the Rural Advancement Foundation International. Commissioned by the United Nations Development Programme.

⁹⁵ The example of the San above is apposite.

⁹⁶ A recent case of such exploitation is found in the context of diamond mining, where De Beers in collaboration with the government of Botswana embarked upon forcing the removal of Gana and Gwi bushmen from their ancestral lands in the Kalahari desert. (Xan Rice, 'Rock solid against the activists', The Times, 21 November 2002).

⁹⁷ As the CIPR states, "IP rights, especially those requiring some form of novelty or those with fairly limited periods of protection (ie. patents), seem less appropriate for protecting traditional knowledge". ('Integrating Intellectual Property Rights and Development Policy', Report of the Commission on Intellectual Property Rights, London, September 2002).

⁹⁸ This generates great problems in relation to the granting patents as, in the absence of any accessible written record, a patent examiner in another country is unable to access documentation that would challenge the novelty or inventiveness of an application based on traditional knowledge. The additional problem associated with such a lack of documentation and preservation is that "Every time a shaman dies, it is as if a library burned down". (Mark J. Plotkin, vice president of Washington-based Conservation International and former director of the plant program at the Worldwide Fund for Nature, author of *Tales of a Shaman's Apprentice: An Ethnobotanist Searches for New Medicines in the Amazon Rain Forest*). The death of a TK holder can therefore result in the demise of an entire tradition and knowledge system.

entails would also be evaded, as would the costs of applying and registering patents worldwide⁹⁹.

India and China have adopted such an approach through the creation of TK Digital Libraries¹⁰⁰ in order for the data, expressed in several international languages, to be easily accessible to patent examiners. Indeed, a Commission on Intellectual Property Rights (CIPR) convened by Britain's Department for International Development urges that such information should be made available to national patent offices forming a mandatory part of patent examinations on a global scale¹⁰¹. On a local scale, certain native communities, notably native North Americans and Aborigines, have adopted similar programmes¹⁰² having chosen to do so on their own initiative¹⁰³. Such a process has the benefit of contributing to the preservation, promotion and possible exploitation of TK¹⁰⁴.

Perhaps of even greater significance would be the fact that the USPTO would no longer be entitled to wilfully disregard such knowledge under s102 due to the fact that such knowledge, expressed in the form of databases, would qualify as a foreign publication and must therefore be considered as prior art in patent applications. One potential means of reinforcing this desirable position would be through the mandatory disclosure of the geographical origin of the genetic resources or TK used, in the patent application. Such schemes have already been introduced in India¹⁰⁵ and Costa Rica¹⁰⁶ where failure to make such a disclosure could lead to the failure of the application or revocation of the patent. This method would also overcome the non-retroactive effect of the Convention on Biological Diversity 1992, as materials obtained from gene banks created prior to 1992 would have to be disclosed resurrecting issues of financial compensation. The chances of the US creating such a provision remain unlikely though.

Alternatively, defensive *sui generis* initiatives could provide an efficacious solution. The Philippines, for instance, has enacted legislation¹⁰⁷ giving indigenous communities rights over their TK which extend to controlling access to ancestral lands, access to biological and genetic resources and to indigenous knowledge related to these resources. Under such a system, access by interested foreign parties is based on prior informed consent of the community in accordance with customary laws, applying the rule "no permit, no collection" with heavy fines for those in breach. Any benefits arising from the genetic resources or TK will be shared, and the indigenous communities are entitled to participate at all levels of decision-making¹⁰⁸. Similar provisions are made in Guatemala, where expressions of national

⁹⁹ Merely securing a patent from America's patent office costs at least \$4000. (The Economist, 'Patently Problematic', 14 September 2002).

¹⁰⁰ To date, the Indian Traditional Knowledge Digital Library contains more than 4,500 entries.

¹⁰¹ The Economist, 'Patently Problematic', 14 September 2002.

¹⁰² A model law was recently unveiled on the South Pacific island of New Caledonia which requires companies seeking to exploit TK to obtain the permission of the group that first developed it. Applications would be made via regional cultural authorities who would adopt the role of identifying and alerting the traditional owners. The owners would then have the right to reject the application or to negotiate an authorisation agreement.

¹⁰³ Recently, delegates at the World's Indigenous Peoples conference, held on 16-19 October 2002 in Kelowna, British Columbia, have expressed concern at WIPO's involvement in such a process, as they believe that such databases could be used by Western companies and scientists to exploit their cultural heritage. (Rex Dalton, 'Tribes query motives of knowledge databases', Nature, 31 October 2002).

¹⁰⁴ 'Integrating Intellectual Property Rights and Development Policy', Report of the Commission on Intellectual Property Rights, London, September 2002.

¹⁰⁵ Section 10 of the Patents Act 1970 and section 25 which allows opposition to be filed on the grounds that "the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention".

¹⁰⁶ Article 80 of the Biodiversity Law 7788.

¹⁰⁷ The Indigenous Peoples Rights Act 1997, Republican Act No. 8371.

¹⁰⁸ 'Integrating Intellectual Property Rights and Development Policy', Report of the Commission on Intellectual Property Rights, London, September 2002.

culture, including medicinal knowledge, fall under State protection and cannot be sold or be subject to any form of remuneration¹⁰⁹. Thailand has also made legislative efforts to protect TK¹¹⁰, as have many other third-world nations¹¹¹. Trans-national alliances such as The South Asia Association for Regional Cooperation (SAARC)¹¹² and The Association of South East Asian Nations (ASEAN)¹¹³ have also adopted framework agreements regarding access to TK, biological and genetic resources.

It remains to be seen whether sufficiently common characteristics are present among the different national schemes in order to achieve an **international sui generis** system, which remains the objective of the G15 Group of developing countries¹¹⁴, but as we will now consider, the Convention on Biological Diversity 1992 could potentially achieve this.

3. The Convention on Biological Diversity 1992 (CBD) – An International Solution?

The CBD focuses on “fair and equitable benefit sharing”, ensuring that conservation of biodiversity and the sustainable use of its components are considered when ensuring an equitable and fair balance between North and South in the market of biological commodities¹¹⁵. The Convention recognises that conservation must be balanced with development in developing countries and that access to genetic resources should be on the basis of prior informed consent, and on mutually agreed terms between the parties, with fair and equitable benefit sharing of the profits derived from the use of TK¹¹⁶. Should nations ignore such fundamental principles access to the resources may be illegitimate and the dispute resolution mechanism provided by article 27 may be applied¹¹⁷.

Under article 15(1), state sovereignty is acknowledged regarding access to biological sources. The CBD additionally provides that in return for providing such access, a donor country should benefit through any of three mechanisms: participation in the research¹¹⁸; access to and transfer of derived technology¹¹⁹; and sharing in the results of research and proceeds of commercial exploitation¹²⁰. Such reciprocity is to be instituted “on mutually agreed terms” and “subject to prior informed consent”¹²¹. The CBD encouragingly makes provisions for exchange of information¹²² and, in particular, technology transfer under article 16¹²³. In order to achieve such a goal article 16(3) requires the signatories to “take legislative, administrative, or policy measures”, where the biological resources are being extracted from developing countries¹²⁴.

¹⁰⁹ Cultural Heritage Protection National Law (No. 26-97, as amended in 1998).

¹¹⁰ The Protection and promotion of Thai Traditional Medicines Intelligence Act 1999 and The Plant protection Act 1999. (The Inter-Regional Workshop on Intellectual property Rights in the Context of Traditional Medicine [Bangkok, 6-8 December 2000]).

¹¹¹ For further examples of legislative initiatives visit <http://www.grain.org/brl/tk-brl-en.cfm>.

¹¹² http://www.wipo.int/eng/meetings/2001/igc/doc/grtkfic1_13.doc

¹¹³ <http://www.grain.org/brl/asean-access-2000.cfm>

¹¹⁴ ‘Sustainable Use of Biodiversity, Traditional Knowledge and Protection Systems’, Joint Declaration G-15 Experts Meeting on Science and Technology, Caracas, 3-5 April 2002.

¹¹⁵ Article 1 “The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding”.

¹¹⁶ Article 8(j).

¹¹⁷ This could potentially involve the International Court of Justice.

¹¹⁸ Article 15(6).

¹¹⁹ Article 15(1).

¹²⁰ Article 15(7).

¹²¹ Articles 15(4), (5) and (7).

¹²² Article 17.

¹²³ Article 9(b) also makes provision for technology transfer in relation to conservation and research.

¹²⁴ A similar provision exists in article 19(2).

Numerous conflicts are, however, apparent between the CBD and TRIPS, which imposes much shorter-term objectives and could see article 27(3)(b) revoked if the West gets its way. However, somewhat paradoxically, in assuring a market of shared benefits emanating from natural resources, the CBD legitimises a market for bio-resources and TK, thereby accommodating the West's reductionist stance vis-à-vis article 27(3)(b) of TRIPS. Before 1992, living resources were regarded as honoured fellow members of a greater ecosystem and not potential private monopolies, whereas now they are reduced to commodities that are owned, priced and sold. There remain countless stories of the evasion of equitable benefit-sharing, of attempts to access and patent material that resides in public gene banks or botanical gardens¹²⁵ collected before the CBD came into force, of companies engaged in bio-prospecting while offering inadequate bilateral agreements to the communities in which they search¹²⁶, of companies freely bio-prospecting national parks and making huge profits from the search, and of companies asking employees to bring back a spoonful of soil while on vacation.

There are currently 168 signatories to the CBD, including the US, who signed up on the 4th of June 1993 with numerous reservations, but has to date failed to ratify¹²⁷. Although, the overwhelming majority of world nations, including all members of the European Union, have ratified the CBD, the Convention continues to have a minor impact on international trade relating to bio-diversity and TK, with these valuable resources remaining unprotected in international terms. The aim of using bio-prospecting as a tool for generating funds for nature conservation and improvement of the livelihoods of indigenous and local communities consequently remains unfulfilled.

4. Conclusion

The adoption of an equitable approach is paramount in implementing the proposed solutions discussed above. Exploitation will be avoided whilst medical advancement and progressive research can be achieved for the benefit of all. Given the huge importance of such resources to the pharmaceutical industry, with only 1% of 250,000 known species of tropical plant having been tested¹²⁸, whilst there is still no adequate therapy¹²⁹ for three-quarters of the 2,500 medical conditions currently recognised¹³⁰, the potential is enormous and essential.

The benefits of cooperation and reciprocity are fundamental. Maintaining the exploitation of developing countries creates a risk that such countries could adopt an over-defensive approach to bio-resources and TK through denial of access not only to the West but also to other developing regions of the World¹³¹, which will ultimately benefit nobody. An equitable solution to biopiracy involving financial rewards, technology transfer and dissemination,

¹²⁵ Kew Garden's £80m Millennium Seed Bank Project provides a rare but encouraging example of adherence to the spirit of the CBD, where partnerships have been forged with local communities ensuring technology transfer, training opportunities and the many benefits, for both parties, resulting from cooperation, notably biodiversity coupled with sustainable exploitation. (Peter Martin, 'Save the last plants for me', The Sunday Times, 9 March 2003).

¹²⁶ Please refer to the Merck example in Costa Rica above.

¹²⁷ This should come as no surprise given the generous contributions of the pharmaceutical industry to US national election campaigns: in 1999 Merck donated \$526,534 to the Republican Party and incurred lobbying expenditures of \$5,320,000; Eli Lilly contributed \$1,636,995 during the 2000 election cycle and lobbying expenditures of \$4,000,000 in 1999; PhRMA gave \$454,332 during the 2000 elections and incurred lobbying expenditures of \$5,020,000 in 1999. (Adbusters, May/June 2002). Additionally, one must not overlook the fact that Pfizer, Bristol-Myers Squibb and Merck all form part of the Intellectual Property Committee which shaped the TRIPS agreement. (Shiva, V., *Biopiracy: The Plunder of Nature and Knowledge*, Chapter 4 [Green Books, 1998]).

¹²⁸ Ann Fullick, 'The Spice of Life', New Scientist, 7 December 2002.

¹²⁹ Pharmaceuticals remain the most cost-effective means of treating patients and are the only option where no other treatment exists or clinical alternatives are too expensive. (<http://www.ifpma.org>).

¹³⁰ World Health Organisation.

¹³¹ <http://www.unesco.org/most/bpik18.htm>

training, education and subsequent employment leading to national prosperity would give teeth to the CBD and overcome some of the fundamental shortcomings of Doha and TRIPS, neither of which provides any concrete proposals of such valuable and fundamental schemes¹³². Through such initiatives, the pharmaceutical industry would avoid the stigma of neo-colonialism that it currently incurs.

Equally imperative is the avoidance of damaging competition between members of the developing world¹³³, who often share the same or similar biological resources, through uniformity in legislation¹³⁴, pricing and the services provided, although certain weight must be attached to the bio-diversity of each individual country. Instead of merely donating \$53 billion¹³⁵ to the third world every year, the world's richer nations should offer the developing world respect and dignity by engaging in bilaterally negotiated commercial agreements ensuring fair and equitable financial consideration and other benefits for the vital biological resources procured.

¹³² Such an imperative is only viewed by TRIPS under articles 7 and 8 as an "objective" devoid of any subsequent mention or legal enforceability, whilst article 66(2) in relation to least developed countries does not appear to have been taken into consideration by firms and institutions situated in developed countries. (*Integrating Intellectual Property Rights and Development Policy*, Report of the Commission on Intellectual Property Rights, London, September 2002). Paragraph 7 of the Doha Declaration on the TRIPS Agreement and public health merely "reaffirms" such a "commitment".

¹³³ Such a system would provide a refreshing change from the strings attached pledges of the US in relation to the extra \$5 billion pledged annually by President Bush under the "Millennium Challenge Account", which will inevitably lead to relentless competition between the countries competing for a slab of extra funding. (Elaine Monaghan, *Bush puts strings on \$5bn extra aid*, The Times, 27 November 2002).

¹³⁴ For instance, India's strict patent policy means that drugs are far cheaper in India than in neighbouring countries such as Sri Lanka (Health Action International, 1998, HAI News, No.100, April 1998).

¹³⁵ The Economist, *Aid Policy: Short Change*, 2 November 2002.