

NORTH–SOUTH BENEFIT SHARING ARRANGEMENTS IN BIOPROSPECTING AND GENETIC RESEARCH: A CRITICAL ETHICAL AND LEGAL ANALYSIS

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ABSTRACT

Most pharmaceutical research carried out today is focused on the treatment and management of the lifestyle diseases of the developed world. Diseases that affect mainly poor people are neglected in research advancements in treatment because they cannot generate large financial returns on research and development costs. Benefit sharing arrangements for the use of indigenous resources and genetic research could only marginally address this gap in research and development in diseases that affect the poor. Benefit sharing as a strategy is conceptually problematic, even if one, as we do, agrees that impoverished indigenous communities should not be exploited and that they should be assisted in improving their living conditions. The accepted concept of intellectual property protection envisages clearly defined originators and owners of knowledge, whereas the concept of community membership is fluid and indigenous knowledge is, by its very nature, open, with the originator(s) lost in the mists of time. The delineation of ‘community’ presents serious conceptual and practical difficulties as few communities form discrete, easily discernable groups, and most have problematic leadership structures. Benefit sharing is no substitute for governments’ responsibility to uplift impoverished communities. Benefit sharing arrangements may be fraught with difficulties but considerations of respect and equity demand that prior informed consent and consultation around commercialisation of knowledge take place with the source community and their government.¹

¹ C. Weijer & E.J. Emanuel. Protecting Communities in Biomedical Research. *Science* 2000; 289: 1142.

Everyone has the right to participate freely in the cultural life of the community, to enjoy the arts, and to share in scientific advancement and its benefits.

Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he [*sic*] is the author.²

INTRODUCTION

According to the Global Forum for Health Research:

Every year more than US\$70 billion is spent on health research and development by the public and private sectors. An estimated 10% of this is used for research into 90% of the world's health problems. This is what is called the '10/90 gap'.³

The issue of neglected diseases research is obviously of central importance to people living in developing countries.⁴

However, even if the current commercial research agendas of the pharmaceutical industry were directed at diseases according to the world's disease burden, another problem would nearly inevitably arise. It was brought to the world's attention by Edwin Cameron, an HIV positive South African judge. In his address to the delegates attending the International AIDS Conference in Durban in 2000, he stated that:

Nearly 34 million people in our world are at this moment dying [of AIDS]. And they are dying

because they don't have the privilege that I have, of purchasing my health and life. . . . Now why should I have the privilege of purchasing my life and health when 34 million people in the resource poor world are falling ill, feeling sick to death, and are dying? That to me . . . seems a moral inequity of such fundamental proportions that no one can look at it and fail to be spurred to thought and action about it. That is something which we in Africa cannot accept. It is something that the developed world also cannot accept.⁵

People in developing countries face two major challenges in their attempts to access life-saving medication: the first challenge is that the medication in question might not exist because the necessary research was not considered commercially sufficiently attractive by pharmaceutical multinationals to justify substantial investment;⁶ the second challenge is that the medication available is usually too expensive to permit affordable access. A team of researchers from Médecins sans Frontières reviewed the situation in a 2002 *Lancet* publication and concluded that 'despite an ever-increasing need for safe, effective, and affordable medicines for the treatment of these [tropical] diseases, drug development has virtually stopped.'⁷ International discussions about how to address these challenges in a just manner have been going on for some time but without any satisfactory solutions at the time of writing.⁸ New trade frameworks for health care research and development (R&D) have, for instance, been proposed by the United States (US) based Consumer Project for Technology. Its Director, Jamie Love, argues that 'trade agreements should be reframed to focus on standards for sharing the costs of R&D' and that we 'need business models for financing R&D that do

² United Nations (UN). 1999. *Declaration of Human Rights*. First adopted and proclaimed in 1948. New York, NY: UN: Article 27. Available at: <http://www.un.org/Overview/rights.html> [Accessed 9 May 2006].

³ Global Forum for Health Research (GFHR). 2002. *The 10/90 Report on Health Research 2001–2002*. Geneva: GFHR: xv. Available at: http://www.globalforumhealth.org/filesupld/1090_report_01-02/01_02_front_matt.pdf [Accessed 9 May 2006].

⁴ Médecins Sans Frontières (MSF) Campaign for Access to Essential Medicines & Drugs for Neglected Diseases (DND) Working Group. 2001. *Fatal Imbalance: The Crisis in Research and Development for Drugs in Neglected Diseases*. Geneva: MSF & DND. Available at: http://www.accessmed-msf.org/documents/fatal_imbalance_2001.pdf [Accessed 8 May 2006].

⁵ E. Cameron. 2000. The XII International AIDS Conference. Durban, South Africa. Press Conference, 10 July.

⁶ U. Schuklenk & R.E. Ashcroft. Affordable Access to Essential Medication in Developing Countries: Conflicts between Ethical and Economic Imperatives. *J Med Philos* 2002; 27: 179–195.

⁷ P. Trouiller et al. Drug Development for Neglected Diseases: A Deficient Market and a Public-health Policy Failure. *Lancet* 2002; 360: 1102.

⁸ T. Hubbard & J.A. Love. A New Trade Framework for Global Healthcare R&D. *PloS Biol* 2004; 2: 147–150.

not depend on marketing monopolies for approved products.⁹

One of the responses to the problem of how the world's poor can be ensured access to essential drugs at least, has been the idea of benefit sharing. It applies both to clinical research as well as to bioprospecting. The widely internationally accepted idea, basically, is that if you use people in developing countries for clinical research purposes, there must be some appreciable benefit flowing back to them.¹⁰ Similarly, the United Nations (UN) Convention on Biological Diversity (CBD) requires that the benefits of non-human genetic resources be shared. The Secretariat of the CBD explains the ethical rationale behind this:

An important part of the biodiversity debate involves access to and sharing of the benefits arising out of the commercial and other utilization of genetic material, such as pharmaceutical products. Most of the world's biodiversity is found in developing countries, which consider it a resource for fueling their economic and social development. Historically, plant genetic resources were collected for commercial use outside their region of origin or as inputs in plant breeding. Foreign bioprospectors have searched for natural substances to develop new commercial products, such as drugs. Often, the products would be sold and protected by patents or other intellectual property rights, without fair benefits to the source countries. The treaty recognizes national sovereignty over all genetic resources, and provides that access to valuable biological resources be carried out on 'mutually agreed terms', and subject to 'prior informed consent' of the country of origin.¹¹

There is some (albeit weak) evidence that this benefit sharing strategy works by way of delivering benefits to poor people in developing countries. For instance, since 1995 regulation in the Philippines has meant that bioprospectors must acquire prior informed consent (PIC) not only from the government but also from local communities. Countries of the Andean Pact regulated specifically to ensure that financial benefits accrue. The University of California at Davis has set up a Genetic Resources Recognition Fund which pays benefits into a trust for postgraduate studies for students from source countries, should commercially viable products be licensed.

The CBD also recognises traditional/indigenous knowledge and the need to ensure the equitable sharing of benefits derived from the commercial exploitation of such knowledge. This view has become acceptable to the extent that a number of international policy-making bodies have issued guidelines, and even the Trade Related aspects of Intellectual Property Rights (TRIPS) Council of the World Trade Organisation (WTO) has been asked to review Article 27.3(b) which deals with patentability of biotechnological inventions and protection of plant varieties.¹²

As far as clinical research involving human participants, and also as far as research involving non-human genetic materials, is concerned, the idea that the benefits of any commercial products reaching the markets should be shared with poor communities in developing countries that assisted in bringing such products about is internationally widely supported. It is also accepted that ethical research conduct demands that respect be shown to the communities from which genetic tissue or remedies is garnered, even if no benefits materialise from the research.¹³

In this context, the UN CBD has become the most significant international regulatory framework addressing the issue of benefit sharing. Perhaps worth noting at the outset, is that the CBD is

⁹ J. Love. 2003. *A New Trade Framework for Global Healthcare R&D*. Columbia University, New York, NY. Seminar Paper, 4 December. Available at: http://www.earthinstitute.columbia.edu/cgsd/documents/love_000.pdf [Accessed 8 May 2006].

¹⁰ R. Lie, E. Emanuel & C. Grady. The Standard of Care Debate: The Declaration of Helsinki versus the International Consensus Opinion. *J Med Ethics* 2004; 30: 190–193.

¹¹ Convention on Biological Diversity. 2000. *Sustaining Life on Earth: How the Convention on Biological Diversity Promotes Nature and Human Well-being*. Montreal: UNEP/CBD. Available at: <https://www.biodiv.org/doc/publications/guide.asp?id=action-int> [Accessed 9 May 2006].

¹² World Trade Organization (WTO). 2005. *TRIPS: Part II – Standards Concerning the Availability, Scope and Use of Intellectual Property Rights*. Geneva: WTO: Article 27: Patentable Subject Matter. Available at: http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm [Accessed 8 May 2006].

¹³ Weijer & Emanuel, *op. cit.* note 1.

concerned with research on non-human biological material. (In the context of genetic research on humans, the Human Genome Organisation (HUGO) has proposed broad guidelines on benefit-sharing, recommending that 1–3% of annual profits be given ‘to healthcare infrastructure or humanitarian efforts’.¹⁴)

The CBD is an international instrument that is founded upon the recognition of the importance of biodiversity and measures to halt biodiversity erosion. It recognises:

... the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components.¹⁵

In terms of Article 1, Parties to the CBD undertake to identify important components of biological diversity, monitor them, and maintain and organise these data. It also acknowledges that ‘substantial investments are required to conserve biological diversity.’¹⁶ The rationale here is that benefit sharing brings financial returns to communities. These should, at least partially, finance conservation of biodiversity and so would act as an incentive to sustainable use.

Article 15 of the CBD sets out the conditions for access to genetic resources.¹⁷ These involve recognition of state sovereignty, facilitation of access by other states, prior informed consent of the state of origin of the genetic material and fair sharing of the results of R&D arising from the utilisation of genetic resources. Article 19 deals specifically with benefits distribution.¹⁸ It enjoins states to provide for effective participation in the research on genetic material that originates from that state. Downes justifiably criticises the CBD for failing to ensure that

the countries or communities of origin will be compensated for the material now being held in international gene-banks. These resources have been extracted from locations in the developing world over many years.¹⁹

Pursuant to the CBD objectives stated above, there have been a number of meetings to develop guidelines on benefit sharing under the headings of PIC, mutually agreed terms, information needs, and capacity building, and, in October 2001, the adoption of the *Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising out of their Utilization* (Bonn Guidelines).²⁰ These guidelines have been adopted by 180 countries. They are not legally binding unless a country has incorporated the Bonn Guidelines into its domestic legislation. However, even if they are not incorporated into domestic legislation, the fact that a country signed on, provides persuasive legal authority for the argument that the country intended to abide by the Bonn Guidelines. This would be useful in a legal dispute.

One question is whether the CBD could also work as a blueprint for regulations aimed at human genetic materials. The CBD covers, for instance, usage of traditional knowledge such as the San people’s knowledge of the hoodia plant’s appetite suppressing properties or the Kani people’s knowledge of a fruit plant’s (*Trichopus zeylanicus travancoricus*) re-energising and strength-providing properties. In this article, we want to compare and critically reflect on benefit sharing approaches taken by, and with, indigenous peoples in four different developing countries, namely Tonga, South Africa, Mexico and India. One of these cases relates to attempts at utilising and exploiting human genetic materials commercially for research purposes while the other cases comprise attempts

¹⁴ Human Genome Organisation (HUGO). 2000. Statement on Benefit Sharing. London: HUGO. Available at: http://www.hugo-international.org/Statement_on_Benefit_Sharing.htm [Accessed 8 May 2006]. Presumably this refers to a benefit to be administered by the government concerned.

¹⁵ Convention on Biological Diversity (CBD). 1992. *Convention on Biological Diversity*, 5 June 1992. Montreal: UNEP/CBD. Available at: www.biodiv.org/doc/legal/cbd-en.pdf [Accessed 8 May 2006].

¹⁶ Ibid.

¹⁷ Ibid.

¹⁸ Ibid.

¹⁹ D. Downes. 2002. New Diplomacy for Biodiversity Trade: Biodiversity, Biotechnology & Intellectual Property in the Convention on Biological Diversity. In *International Environmental Law and Policy*. 2nd ed. D. Hunter, J. Salzman & D. Zaelke, eds. New York, NY: Foundation Press: 945.

²⁰ Convention on Biological Diversity (CBD). 2002. *Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising out of their Utilization*. Montreal: UNEP/CBD. Available at: www.biodiv.org/doc/publications/cbd-bonn-gdls-en.pdf [Accessed 9 May 2006].

to engage in bioprospecting based on indigenous communities' traditional knowledge. Some of the cases in question did not come to fruition and failed for various reasons. Understanding these reasons is important to avoid future frustrations of the kind described below.

BIOPROSPECTING: SAN, MAYA AND KANI PEOPLES

While some anthropologists might beg to differ, a widely used definition of indigenouness highlights the following five elements: 'A priority in time, the voluntary perpetuation of cultural distinctiveness, an experience of subjugation, marginalisation and dispossession, and self-identification.'²¹ This definition certainly holds true for the San peoples of the Central Kalahari Desert of southern Africa, the Kani tribes in the Agasthymalai hills of the Western Ghats in the Indian state of Kerala, and the Maya residing in the Chiapas region of southern Mexico.

Article 8(j) of the CBD is the foundation of the 2002 Bonn Guidelines of the Convention on Biological Diversity. It mandates that contracting parties shall:

... 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.²²

What is relevant here are the requirements that benefits are shared equitably and that indigenous communities are asked for their approval and involvement in the process. The idea that such

involvement should result in PIC has gained widespread acceptance in recent years. To avoid misunderstandings regarding our next point: we are *very* sympathetic to the objective of uplifting impoverished communities, and of ensuring access to health delivery services, education and housing. However, even if one agreed with the idea that communal knowledge shared somehow among members of tribal or indigenous communities is of a different kind than, say, traditional knowledge among Bavarians in Germany, and one agreed that the commercial exploitation of such knowledge should result in some kind of benefit sharing, one would still have to resolve the question of what exactly it is that constitutes an indigenous community (i.e. what makes someone or a group of individuals indigenous as opposed to non-indigenous, and also, who has reason to claim community membership). If one manages to delineate the community that may share the benefits, there still remains the problem of representation of that community. The traditional leadership may be inherently undemocratic. It may be the cultural practice of that group to exclude women from decision-making as to the types and distribution of any benefits that may accrue. The researchers must elect whether to maintain neutrality or try to inject fairness, or their notion of it, into the consultation process.

Let us start by looking at the bioprospecting cases involving the San, Maya and Kani peoples.

1. The San people²³

The San people are indigenous to an area comprising the Kalahari region of South Africa, Botswana and Namibia. They were originally nomadic hunters well known for their ability to survive in the desert for long periods. It is assumed that this group's ancestors settled in southern Africa some 150,000 years ago. Currently, the San live in isolated settlements, their communities are characterised by high levels of poverty and the associated known

²¹ R. Chennells. 2003. *Ethics and Practice in Ethnobiology, and Prior Informed Consent with Indigenous Peoples, Regarding Genetic Resources*. St Louis, MO. Conference Paper, 6 April 2003. Available at: <http://law.wustl.edu/centeris/Confpapers/ChennelFinalApril2003.htm> [Accessed 8 May 2006].

²² Convention on Biological Diversity (CBD). *Article 8. In-situ Conservation*. Montreal: UNEP/CBD. Available at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-08> [Accessed 8 May 2006].

²³ For further details about this case, see the Global Forum on Bioethics in Research (Forum 5) (GBFR5). 2004. Conference, Paris, 22–23 April. Geneva: GBFR. Available at: http://www.inserm.fr/fr/presse/dossiers_presse/att00000407/19avril2004.pdf [Accessed 15 May 2006]; and Chennells, *op. cit.* note 20. Our summary of the salient features of this case is based in its entirety on these two sources.

consequences for quality of life, life expectancy, and child mortality. The San people have utilised the hoodia plant as an appetite suppressant for hundreds of years. This seems to have been necessary because they sometimes had to survive for several days without any food intake during their hunting expeditions. A government research institute in South Africa, the Council for Scientific and Industrial Research (CSIR) became aware of the plant through a 1937 publication by a Dutch ethnobiologist and also from San people themselves, who worked as trackers for the South African military. In the 1980s scientists at the CSIR managed to isolate its active ingredient and patented it. The compound is called P57. Given the multibillion dollar worldwide weight loss industry, it is somewhat ironic that the discovery of the hoodia plant's appetite suppressing capacity should be used in the 21st century to assist people in losing weight and eating less. In any case, the CSIR licensed its discovery to Phytopharm, a biotech company in the United Kingdom. Clinical trials confirmed the appetite suppressing capacities of P57. The compound was subsequently licensed for US\$2 m to Pfizer a multinational drug company. Pfizer has since withdrawn from the license contract and Phytopharm has sublicensed P57 to another multinational, Unilever, which is developing an appetite-reducing snack bar.

The PIC requirements of the CBD were not actually met in this case (it also predated the CBD, of course). Quite importantly, no PIC took place, or any agreement on benefit sharing. However, after intense lobbying from a San non-governmental organisation (NGO), the players involved (Phytopharm and the CSIR) admitted their 'mistake' and agreed that some form of compensation should be provided to the San people for the exploitation of their traditional knowledge.

What is interesting about this particular case is that this indigenous community agreed that its traditional knowledge should not be declared public knowledge, because then they could not reasonably expect any benefits from the commercial development process. They aimed at ensuring that the patent itself was not contested. Instead the San people's representative body, the South Africa based San Council, through its lawyer, demanded that compensation be provided to them. After three

years of negotiations, it was agreed in March 2003 'that CSIR will pay 6% of all milestone payments (estimated to be US\$0.9–1.4 m) it receives from Phytopharm, and 8% of all royalties from products developed from P57.'²⁴ This is clearly a much better deal than the (somewhat arbitrary) 1–3% of net profits that HUGO's Bioethics Committee considers appropriate. The San people set up a trust fund that is required to use the anticipated funds for local development projects. First payments into the trust fund were received in 2005.

2. The Maya people²⁵

The Maya people are an indigenous community living mostly in the impoverished Chiapas region in southern Mexico. They have a long history of using plants for therapeutic purposes. In the mid 1990s, the Maya International Cooperative Biodiversity Program (ICGB) was set up, a joint project of a US university based research team, a Mexican academic institution, a biotech company, and a non-profit institution designed to represent the interests of the indigenous people. The project had three objectives: it was meant to preserve and record local indigenous knowledge (required by the TRIPS agreement in order to ensure that patents on such knowledge cannot be placed by commercial organisations without the agreement of the community in question); to discover new therapies; and to contribute by this means to the local economic development and scientific capacity building.

The Maya ICBG was aimed at, among other things, collecting and cataloguing biological species of the Chiapas highlands, and the evaluation of traditional therapeutic knowledge and remedies. The Maya people do not possess a unified political organisation representing their interests. The Maya people (in excess of 250,000) have a whole range of political, cultural and religious organisations representing their communities. Being confronted with the problem of finding a legitimate representative of the indigenous people the ICBG came up with the plan of setting up a non-profit trust into which

²⁴ Global Forum on Bioethics in Research (Forum 5), *op. cit.* note 23.

²⁵ *Ibid.* Our summary of the salient features of this case is based in its entirety on this source.

potential benefits could be channeled. The governing body of this trust, Promotion of the Intellectual Property Rights of the Highland Maya of Chiapas, Mexico (PROMAYA), was selected by non-indigenous people sympathetic to the Maya people's interests. After lengthy negotiations, it was agreed 'that Maya communities would receive $\frac{1}{4}$ of any royalties and co-ownership of any licenses that emerged from the research.'²⁶ PIC agreement took place in each of the 47 villages (46 of the 47 agreed to participate in the project).

However, the Maya ICGB failed to involve certain local healers in its PIC negotiations, and these healers, jointly with an international NGO, campaigned against the prospective bioprospecting. International media attention and websites highlighted the 'plight' of the 'exploited' indigenous communities. Further international NGOs became involved until, finally, the Mexican research institution withdrew its cooperation in 2001, citing the problems arising from the challenge posed by the healers, arguing that there was 'the need for a self-organised indigenous partner, and for national level regulation to provide some resolution for the impasse.'²⁷

The Maya ICGB collapsed at this stage. It is worth noting that the commercial benefits that would have flown from the agreement were more substantial than anything negotiated internationally up to that point. Furthermore, it is worth noting that local communities were overwhelmingly eager to participate, until international NGOs intervened and used the local situation (namely the failure to involve the healers) to advance their international policy agendas with regard to bioprospecting.

3. The Kani people²⁸

The Kani tribe (population: 16,181 according to 1991 census) is a now settled but traditionally nomadic community, barely making a living in the forests of the Agasthyamalai hills of the Western

Ghats in the Thiruvananthapuram district of Kerala. Like other indigenous communities the Kani use plants for a variety of therapeutic as well as nutritional purposes. A government body, the Tropical Botanic Garden and Research Institute (TBGRI), discovered that the Kani people were using *Trichopus zeylanicus travancoricus*, a rhizomatous herb with anti-fatigue properties. During a field trip, the leaves of the plant were offered to TBGRI scientists by Kani guides. The scientists noticed 'a sudden flush of energy and strength.'²⁹ The scientists took a sample of the plant to the TBGRI and analysed it. The 'study of the leaves revealed the presence of certain glycolipids and non-steroidal compounds which have anti-stress, anti-hepatotoxic and immunomodulatory/immunorestorative properties.'³⁰ Subsequently, phase 1 to 3 clinical trials were undertaken and the drug derived was prepared for marketing. The technology to produce the drug was subsequently transferred from TBGRI to a pharmaceutical company (for a seven year period) in return for a fee of US\$ 50,000. The TBGRI governing board decided that the Kani people should receive 50% of the license fee the Institute received on sale of the drug plus 2% of future royalties.

While the percentage provided to the Kani people is relatively higher than the benefits provided to the San people, or those thought appropriate for the failed Maya ICBG, it is obvious that the absolute amount is rather small. This point was sharply criticised by opposition politicians in Kerala. Furthermore, it was pointed out that at no stage of the development process were the Kani people involved in the negotiation process. There was no PIC in this case either. (We should acknowledge at this stage that this case occurred prior to the CBD.) This is partly due to the fact that the Kani have no cohesive traditional governing structures. Some Kani who were not involved in the process complained about being left out, and objected to the sale of their knowledge to 'private companies'. After various protracted negotiations a trust fund was established and provided with the money

²⁶ Ibid.

²⁷ Ibid.

²⁸ This case study is derived from R.V. Anuradha. 1998. *Sharing with the Kanis: A Case Study from Kerala, India*. New Delhi: Kalpvriksha Mimeo. Available at: <http://biodiv.org/doc/case-studies/abs/cs-abs-kanis.pdf> [Accessed 10 May 2006].

²⁹ P. Pushpangadan. 'Arogyappacha' (*Trichopus zeylanicus*): The 'Ginseng' of Kani tribes of Agasthyar Hills (Kerala) for Evergreen Health and Vitality. *Ancient Sciences of Life* 1988: 8: 13–16.

³⁰ Anuradha, *op. cit.* note 28, p. 129.

received so far, according to the contract laid out by TBGRI.

The results for the Kani tribe: a trust was set-up to use the generated interest for community development projects; support mechanisms for destitute community members; insurance for pregnant women and accidental death. Over 700 families benefit from this model. The initiative has empowered this tribal community to protect, preserve and maintain their knowledge, innovations, and practices of conservation and sustainable use of biological resources.

A FEW THOUGHTS ON THE BIOPROSPECTING CASES

What is interesting about this last case is, obviously, that no negotiations with, or involvement of, the 'owners' of traditional knowledge occurred. At the same time, relatively speaking, a contract was negotiated that ensured a bigger slice of the financial pie than any of the other cases discussed so far, even though there has been no participation by indigenous peoples. Compare this to the Maya case, where indigenous peoples were used by the policy agendas of international NGOs, and ended up without any benefits at all. Then again, the San case illustrates quite nicely that even benefit sharing agreements that do not translate into huge amounts of money can be useful by way of improving the sense of self-worthiness of the indigenous community in question. At the same time, however, we should be concerned about the influence that even a paternalistic, well-meaning capacity builder might have on the decisions made. For instance, the San people's decision to safeguard the patent protection is ironic, given that the very same system they try to exploit for their own small benefits is also to a large extent responsible for their inability to access (as in afford) decent health care services.³¹ Worthy of further research is the intriguing question of whether we should be more concerned about the outcomes or the process. The cases discussed provide at least some anecdotal evidence that an 'above-board' pro-

cess does not necessarily result in an optimal outcome, as far as the material benefits are concerned.

Conceptually there is some scepticism that patents should be granted on traditional knowledge products of the sort described in this article. It seems as if these are well-intentioned yet misguided attempts at improving the living conditions of indigenous communities within a commercial system that has brought them to the bottom of the social hierarchy in the first place. After all, there is no reliable information telling us who invented this method initially, and it is fair to say that this knowledge is common knowledge among modern day San (and many non-San) in southern Africa. How a patent could be granted based on such public knowledge is unclear.

Many holders of traditional knowledge who hail from impoverished communities do not have the means and access to resources to enable them to register patents on their intellectual property. Patent registration is a lengthy and expensive task. The idea behind patent protection is to grant a monopoly on the exploitation of knowledge in order to reap exclusive benefits for a limited period of time. The protection of intellectual property rights serves to encourage innovation and research, and to reward the holder of the right for the R&D cost of a new commodity with profits. Indigenous communities have traditionally shared their knowledge freely and passed it down through the generations, sometimes through local healers and ceremonial use. The communality and openness of indigenous knowledge now operate to the detriment of the indigenous knowledge holder, when representatives of large corporations swoop in, collect samples, and patent the active ingredients.

Clearly benefit sharing cannot be expected to redress gross social inequities or create the kind of social upliftment of impoverished communities that is the proper domain of government action. But a sense of fairness necessitates that the holders of knowledge are compensated when that knowledge is used to generate financial gain for commercial operators. Patent protection seems inappropriate when there is no real monopoly on the traditional remedy. For instance, it is widely known in the San community, as described above, and subsequently by hosts of others in South Africa and elsewhere, that the

31 M.J. Selgelid & U. Schuklenk. Poverty and Patents. *JAMA* 2002; 287: 842-823.

hoodia plant suppresses hunger and thirst. This is hardly a secret remedy that can be protected by patent. The belated collaboration of the San people with the patent holders, and the benefit sharing path that they chose, is surely a result of the pressure of special circumstances and the forced entry of the San into the world of litigation and patent protection.

What this example demonstrates, is that traditional knowledge of the sort described in this article has little reason to clamour for patent protection. The excitement the benefit sharing agenda has created seems to have much to do with the hope that such a strategy, flawed as it might be, will assist indigenous, impoverished communities to improve their quality of life. All the examples discussed in this context suggest that the benefits reaped by indigenous communities are negligible. Access of indigenous peoples to decent health care, and whether or not someone's primary needs should be provided for, cannot be made contingent on 'benefit sharing' schemes of the sort discussed in this article. This, however, seems to be the driving force behind such arrangements.

DETERMINING THE BENEFITS

The process of isolating a curative drug is a long and expensive process. After finding about one in 10,000 promising yields out of drugs tested, less than a quarter of those reaching clinical trials would be approved for use.³² The process is estimated to cost US\$231 m, and about 12 years from 'screening candidate compounds, isolating active compounds, testing for possible toxicity and undertaking clinical trials.'³³ The undertaking also becomes complicated as a commercial enterprise; value is added by various actors, and licensing and outsourcing activities span the globe. Ultimately, if a drug is marketed and sold, the indigenous community may receive a small percentage of sales, but

millions have been spent on developing the drug. Still, a small percentage may still be a significant amount to an impoverished community. If a company is prepared to assume the risks inherent in R&D and the costs of marketing, the calculation of the benefit accruing to the community of origin seems to be arbitrary especially judging by the examples illustrated in this paper. If a successful drug is then patented, the interesting question arises as to whether members of the community or the traditional knowledge holders should be barred from using their knowledge, other than in the form of the patented drug, until the patent has expired – thus effectively halting the customary passing on of the knowledge. The patent makes the remedy part of formal pharmacological science and no longer part of traditional lore.

There is recognition of the need to protect indigenous knowledge but this is in the context of the broad acceptance of Western systems of intellectual property protection all over the world, which are not necessarily suited to traditional knowledge systems. This is especially so if countries wish to trade their goods on the world market, where they are subject to the rules of the WTO and of the TRIPS regime. This regime does not recognise the special type of property, which is indigenous knowledge, and provides protection for the usual legal entities being trademarks, copyright, and patents. TRIPS stipulates that countries cannot exclude plant varieties from patent protection.³⁴ This means that a plant breeder may cultivate a hybrid or mutant of a known plant, i.e. create a plant variety, and apply for a patent on it. There have been sufficient instances of this so called 'biopiracy' to result in calls for some kind of international regulation of the use of indigenous knowledge, of the access to indigenous knowledge, and of the benefit sharing arrangements between research institutes, corporations and the communities who discovered the medicine. International institutions recognise that the problem of the unauthorised (and uncompensated for) use of indigenous knowledge by developed country organisations is a growing problem. International institutions such as the Food and

³² W. Reid et al. 2002. Biodiversity Prospecting: Using Genetic Resources for Sustainable Development. A New Lease on Life. In *International Environmental Law and Policy*. 2nd ed. D. Hunter, J. Salzman & D. Zaelke, eds. New York, NY: Foundation Press: 942–945.

³³ Ibid.

³⁴ World Trade Organization, *op. cit.* note 12, Article 27: Patentable Subject Matter.

Agriculture Organization (FAO), United Nations Conference on Trade and Development (UNCTAD), United Nations Educational, Scientific and Cultural (UNESCO), World Health Organization (WHO), World Trade Organization (WTO), and the World Medical Association (WMA) have all turned their attention to this issue. At this point in time, although there are many difficulties involved in working out benefit sharing arrangements in any given case, bioprospectors would be hard pressed to justify excluding representatives of the country of origin of the remedy or plant material from negotiations on financial benefits.

THE INTERNATIONAL TRADE ARENA

Countries who wish to benefit from the WTO's trading system have no choice but to abide by the WTO's TRIPS, although it protects mainly developed world industries from patent infringement. A number of countries who cannot immediately implement the protections for intellectual property have been given time to bring their local patent regimes into line. In terms of Article 27.3 of TRIPS, members may exclude plants and animals from patentability, but if they do not specifically exclude them they are subject to patenting by foreign companies. By way of illustration, the ayahuasca plant, regarded as sacred by Mexican farmers, and used for centuries in that cuisine, has been patented in the US. The patent-holder then sued Mexican exporters of the bean, claiming patent infringement.³⁵ Global trade in plants with medicinal value was estimated by the WTO at US\$1.3 bn annually in 1996 and growing at 10% to 20% per annum.³⁶ This huge market indicates that proper protection is needed to ensure sustainable supplies of these plants, conservation of biodiversity, and protection of the communities who traditionally harvest the plants.

³⁵ J. VanFleet. Protecting Knowledge. *Human Rights Dialogue* 2003; 2: 9. Available at: <http://www.carnegiecouncil.org/viewMedia.php/prmTemplateID/8/prmID/942> [Accessed 8 May 2006].

³⁶ World Health Organization (WHO) & World Trade Organization (WTO). 2002. *WTO Agreements and Public Health: A Joint Study by the WHO and WTO Secretariat*. Geneva: WHO & WTO. Available at: http://www.wto.org/English/res_e/booksp_e/who_wto_e.pdf [Accessed 8 May 2006].

The Africa Group of the TRIPS Council has drafted recommendations to protect traditional knowledge and genetic resources within the framework of the TRIPS agreement. Implementation of these recommendations would require an agreement to amend TRIPS, which seems unlikely given the opposition of developed countries to the proposals. The Group states that 'databases and access contracts are only supplementary' to the required international mechanisms.³⁷ Clearly what they are trying to do is to make benefit sharing compulsory through the WTO, which has the strongest punitive power of any international organ. The Africa Group holds that patents on life forms, other than microorganisms and on non-biological and microbiological processes for the production of plants or animals, is unethical and should be prohibited by TRIPS. They state that:

... the TRIPS agreement at the moment has gaps, in the sense that it has not provided adequate and equitable means to prevent patents mainly in developed members that have amounted to and resulted in the misappropriation of genetic resources and traditional knowledge mainly from developing members.³⁸

They note that TRIPS provides the minimum, and that they should be free to increase protection under *sui generis* regimes that are suitable locally, after consultation with indigenous peoples. Of course, there is no reason why the countries that make up this group should wait around for amendments to TRIPS. The development of strong domestic legal protection of their biodiversity is allowed under TRIPS. The Africa Group also points out that aggrieved communities cannot afford costly drawn-out litigation against alleged patent holders and that an international protective regime would be most effective.³⁹ The TRIPS Council is currently reviewing Article 27.3(b). The Council is also, enjoined to review the protection of traditional knowledge and

³⁷ Joint Communication from the African Group. 2003. *Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement*. Geneva: WTO. Available at: http://www.wto.org/English/tratop_e/trips_e/art27_3b_e.htm [Accessed 8 May 2006].

³⁸ Ibid.

³⁹ Ibid.

folklore.⁴⁰ Brazil has recommended the following amendments to Article 27.3(b) as conditions of patentability:

- the identification of the source of the genetic material
- the related traditional knowledge used to obtain that material
- evidence of fair and equitable benefit sharing
- evidence of prior informed consent from the state or traditional community for the exploitation of the subject matter of the patent.⁴¹

There is, however, strong opposition from the US and the European Commission to any of the proposed amendments.

MEASURES TO PROTECT INDIGENOUS KNOWLEDGE

NGOs have set up a database in the US 'documenting public domain traditional knowledge for patent offices.'⁴² The American Association for the Advancement of Science has set up a database called Traditional Knowledge Prior Right Database (TEK*PAD). This database has a list of over 30,000 items of traditional knowledge and is accessible over the Internet for patent examiner use.⁴³ TEK*PAD is recognised by the US Patent and Trademark Office as an official database. A database of traditional remedies is an obstacle to patenting by 'biopirates'. Once a remedy is documented in a database, a patent application should fail for lack of 'novelty'.

The World Intellectual Property Organisation (WIPO) has set up an intergovernmental committee on intellectual property and genetic resources, traditional knowledge and folklore to research and discuss the protection of indigenous knowledge and make recommendations to WIPO. The WTO recognises the growing value of traditional medicine and medicinal plants and that there are concerns around

protection of the communities who share this knowledge and who have not documented this.

Communities can also protect their knowledge by taking out a patent, registering a trademark, through trade secrets, plant variety certificates, contractual arrangements, protected/conservation areas, or registration in a public or private registry.⁴⁴ All these options have their advantages and disadvantages. A community would have to weigh these up and make a considered choice on what suits its members best. This requires that states take proactive measures to conscientise communities and assist them in the protection, as well as utilisation, of their traditional knowledge.

BUT WHERE IS THE COMMUNITY AND WHO SPEAKS FOR THEM?

In considering the legitimacy of benefit sharing claims, we have reason to question the modes of representation of some indigenous communities. For instance, in the case of the Kani people, no cohesive community and community leadership exists any longer, hence, even if TBGIR had attempted to negotiate, it would have been unable to address a legitimate community leadership capable of speaking for all Kani people. Not only that, even if a leadership exists in a given community, it might not always be one that is democratically elected. Rather, we might find forms of traditional leaderships that are unacceptable by the *modus operandi* of modern democracies. We might even have to deal with corrupt traditional leaders. The question is whether, if we continue with the benefit sharing strategy at all, we need a basic standard of legitimate representation before we engage in any negotiations at all.

Last but not least, how are we to decide who belongs to the indigenous community. Indigenous communities such as the San people, for instance, have undoubtedly reproduced with other people coming through their territories. How should we determine who belongs in and who belongs outside the pool of beneficiaries of benefit sharing schemes? Community could be defined in terms of

⁴⁰ World Trade Organization (WTO). 2005. TRIPS: Reviews, Article 27.3(b) and Related Issues: Background and the Current Situation. Geneva: WTO. Available at: http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm [Accessed 8 May 2006].

⁴¹ Ibid.

⁴² VanFleet, *op. cit.* note 34, p. 18.

⁴³ Ibid.

⁴⁴ S. Hansen & J. VanFleet. 2003. *Traditional Knowledge and Intellectual Property*. Washington, DC: American Association for the Advancement of Science (AAAS).

culture, language, custom, or even genetically. One would hope that this would not become a new field of activity for the friends of genetic ancestry tracing.

HUMAN GENETIC MATERIAL: TONGA PEOPLE

4. Tonga people⁴⁵

In 2000, Autogen, an Australian biotech company, entered into an agreement with the government of Tonga to collect blood samples of the archipelago's inhabitants for genetic analysis. Tonga comprises of a group of 169 islands in the South Pacific, with a population of about 108,000 inhabitants. Tonga is a monarchy with a very influential Mormon church (about 50% of the country's citizens belong to this church). The company planned to target specific families suffering from diabetes for sampling and genetic analysis. Importantly, individual informed consent from the research participants in question would have been sought. In that regard the activities of Autogen were in line with world best practice. Furthermore, Autogen committed itself to donating financial support to the health ministry for the construction of a new research centre (an important capacity building initiative). It also agreed to part with some of the royalties it might derive from future commercial products developed based on its research. One would have expected everybody to be happy, but nothing could have been further from the truth. Community groups mounted a vigorous campaign against the government's agreement with Autogen, arguing poignantly that they had not been consulted, that the privacy of participating families had not been guaranteed, that there was no guarantee of direct benefits to the Tonga people, etc. Eventually, the project was shelved and no samples were drawn at all.

A few thoughts on the tonga case

At the heart of the activists' objections, it seems, were religious convictions of the sort that patenting

⁴⁵ See Global Forum on Bioethics in Research (Forum 5), *op. cit.* note 23. Our summary of the salient features of this case is based in its entirety on this source.

of life forms would violate the sanctity of life and fundamental religious principles.

This raises an interesting ethical question. The values expressed by the activists were not actually indigenous values but the values of Western missionaries that flooded the Tonga communities many years back. In other words, the question is whether we should accept at face value, as 'indigenous values' deserving of our protection, any values that communities defined as indigenous might express, or are we entitled to ignore bad arguments just as we would if we came across similar arguments if they were expressed in, say, Australia. If we are entitled to ignore bad arguments, however, why should the fact that something might really be a 'pure' indigenous community value make any difference to whether or not we should accept it?

The crucial lesson to be learned from this case is that valuable potential benefits to the community were squandered (the company agreed to pay something significant up-front, so to speak) because of a well-organised campaign by religious groups in the country. Unlike in the bioprospecting cases discussed above, it seems that if a sufficient number of Tonga people had volunteered to guarantee success of the Autogen project, a strong reason, if not for benefit sharing, but certainly for compensation could be made. If they had contributed to a commercial research project, it would seem legitimate to require that they be compensated for the contribution.

CONCLUSIONS

We have shown that benefit sharing as a strategy is conceptually problematic, even if one, as we do, agrees that impoverished indigenous communities should not be exploited and that they should be assisted in improving their living conditions. The accepted concept of intellectual property protection envisages clearly defined originators and owners of knowledge, whereas the concept of community membership is fluid and indigenous knowledge is, by its very nature, open, with the originator(s) lost in the mists of time. The representation in benefit sharing negotiations of a somewhat nebulous entity such as a community further complicates matters

and is open to abuse. If benefit sharing strategies are to be used to improve access to essential health services and other resources, it is our view that governments themselves should negotiate the terms and the distribution of benefits. Benefit sharing arrangements may be fraught with difficulties but considerations of respect and equity demand that prior informed consent and consultation around commercialisation of knowledge take place with the source community and their government.⁴⁶

⁴⁶ Weijer & Emanuel, *op. cit.* note 1.

TRIPS allows for the development of domestic legal systems to exclude plants and animals from patenting as well as for the protection of plant varieties. Amendments to TRIPS as proposed by developing countries, while commendable, could take many years to effect. Governments would do well to use the existing provisions to protect indigenous knowledge in the meantime.

Arguably, sharing of human genetic material, for the reasons mentioned, permits us to make a stronger case in favour of compensation for those who enable such research by means of contributing their genetic material.