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The Sorcerer II Expedition: Intellectual Property and Biodiscovery

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THE SORCERER II EXPEDITION: INTELLECTUAL PROPERTY AND BIODISCOVERY

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This article considers the significance of a leading marine biodiscovery initiative. In March 2004, Dr J Craig Venter announced the official launch of the Sorcerer II Expedition, a scientific expedition of discovery, which would survey marine and terrestrial microbial populations. The Expedition has the potential to uncover tens of thousands of new microbial species and tens of millions of new genes. Venter has disavowed that the Sorcerer II Expedition has any commercial ambitions. However, various civil society groups have accused the Expedition of engaging in 'biopiracy'. This article considers the intersection of intellectual property law, contract law, environmental law, and international law in this field. It provides a blueprint for a nationally consistent scheme for access to genetic resources, and a model for future international developments.

I INTRODUCTION

In one drop of water are found all the secrets of the oceans.
Kahlil Gilbran[1]

Join genome pioneer Dr J Craig Venter as he scours the world's oceans for new life forms and genetic secrets that could help solve the planet's most urgent energy and climate challenges. From Nova Scotia to the Galapagos islands to Antarctica, Dr Venter embarks on a mission to map the DNA of every microscopic organism in the ocean. Along the way, he discovers new species and new methods of tackling weather anomalies, ocean pollutants and even global warming.
'Cracking the Ocean Code', DVD, Discovery Channel[2]

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1 J Craig Venter Institute, *Sorcerer II Expedition*: *A Global Voyage of Discovery* (2004) <http://www.sorcerer2expedition.org/version1/HTML/main.htm> at 1 August 2009.

2 J Craig Venter, 'Cracking the Ocean Code', DVD, Discovery Channel (2005).

Inspired by the scientific expeditions of Linnaeus' 'apostles', Joseph Banks, and Charles Darwin,[3] as well as modern-day marine adventurers such as Jacques Cousteau, Dr J Craig Venter announced the official launch of the *Sorcerer II* Expedition in March 2004.[4] This scientific expedition circumnavigated the globe, surveying marine and terrestrial microbial populations. According to the J Craig Venter Institute,[5] the not-for-profit scientific and educational organisation which organised the expedition:

> The *Sorcerer II* Expedition was inspired in part by the journeys of the *HMS Beagle* and *HMS Challenger* in the nineteenth century. But unlike those pioneering explorers, the *Sorcerer II* team will classify the species they encounter not by their appearance but by their unique genetic codes, or genomes. Micro-organisms represent most of the biomass on the planet, and they are the unsung heroes of the Earth's environment. Micro-organisms capture energy from the sun, remove carbon dioxide from the air, and cycle nitrogen through the ecosystem. The *Sorcerer II* Expedition will catalogue the genes belonging to communities of micro-organisms, providing information that could be used to address some of the world's environmental problems. The information, which will be freely available through internet databases, will advance the new discipline of environmental genomics and will be used to study the environment, biodiversity, ecology, and evolution.[6]

The Expedition sought to uncover tens of thousands of new microbial species and tens of millions of new genes. The voyage and sample collection was funded by the J Craig Venter Science Foundation, the Discovery Channel Quest Program, the United States Department of Energy, and the Gordon and Betty Moore Foundation.

The *Sorcerer II* travelled from Nova Scotia through the waters of the Galapagos Islands, French Polynesia, the Great Barrier Reef and the Amazon River, to the Caribbean Sea. The research team collected samples for analysis in the US using the shotgun technique of identifying an organism's DNA sequence. The initial pilot project in the Sargasso Sea discovered at least 1800 new species and more than 1.2 million new genes, doubling 'the number of genes previously known from all species in the world', and nearly 800 photoreceptor genes that convert sunlight to

3 James Shreeve, (2004), 'Craig Venter's Epic Voyage to Redefine the Origin of Species' (2004) 12 (8) *Wired Magazine* 107-113, 146-151. See also James Shreeve, *The Genome War: How Craig Venter Tried to Capture the Code of Life and Save the World* (2005); and Iain McCalman, *Darwin's Armada* (2009).

4 J Craig Venter Institute, *Sorcerer II Expedition*: *A Global Voyage of Discovery*, (2004) <http://www.sorcerer2expedition.org/version1/HTML/main.htm> at 1 August 2009. See also J Craig Venter, *A Life Decoded: My Genome, My Life* (2007), 342-347.

5 In 2004, the Center for Advancement of Genomics (TCAG), Institute for Biological Energy Alternatives (IBEA), and J Craig Venter Science Foundation Joint Technology Center (JTC) were consolidated to form J Craig Venter Institute.

6 J Craig Venter Institute, 'IBEA Announces *Sorcerer II* Expedition to Sample World's Oceans and Land to Characterize and Understand Microbial Populations Using Environmental DNA Sequencing', 4 March 2004.

energy.[7] In the course of the full expedition, the research team took a total of 41 different samples from a wide variety of aquatic habitats collected over 8000 km: 'The resulting 7.7 million sequencing reads provide an unprecedented look at the incredible diversity and heterogeneity in naturally occurring microbial populations'.[8]

The US Department of Energy provided funding to the *Sorcerer II* Expedition in the hope that it would provide insights into alternative energy sources. The US Secretary of Energy, Spencer Abraham, commented:

> What excites the Department and our Office of Science about this project is its range of potential benefits. Scientists have used DOE funds to determine the genetic sequences of all the micro-organisms occurring in a natural microbial community, which may lead to the development of new methods for carbon sequestration or alternative energy production. This will offer a direct and early test of one of the central tenets of DOE's Genomics: GTL program - that microbes can be used to develop innovative solutions to address national energy needs.[9]

The participation of this funding agency suggests that the *Sorcerer II* Expedition was more than merely an exercise in basic science. The Institute sought to explore biological energy solutions to environmental issues such as global warming and to find new biological sources of cleaner and more efficient fuels, including hydrogen. There was an underlying motivation to conduct research on micro-organisms, with a view to achieving useful commercial outcomes.

The *Sorcerer II* Expedition is an example of a spectacular 'Big Science' project, which seeks to have a broader public appeal beyond science. The venture was funded by the Discovery Channel, which supports projects spearheaded by scientists and explorers who are at the vanguard of their fields: 'Their research activities will be chronicled via online and televised dispatches from sites around the world, in lecture series, and in landmark television specials that capture the toil, genius, setbacks and exhilaration that are the lifeblood of the search for knowledge'.[10] The press release for the Institute observed:

7 J Craig Venter, et al, 'Environmental Genome Shotgun Sequencing of the Sargasso Sea' (2004) 304 *Science* 66-74.

8 Douglas Rusch et al, (2007) '*Sorcerer II* Global Ocean Sampling Expedition: Northwest Atlantic through Eastern Tropical Pacific' (2007) 5 (3) *The Public Library of Science Biology* 398-431. See also Shibu Yooseph et al., 'The *Sorcerer II* Global Ocean Sampling Expedition: Expanding the Universe of Protein Families' (2007) 5 (3) *The Public Library of Science Biology* 432-466; Shannon Williamson et al, 'The *Sorcerer II* Global Ocean Sampling Expedition: Metagenomic Characterization of Viruses within Aquatic Microbial Samples' (2008) 3 (1) *The Public Library of Science One* e1456.

9 J Craig Venter Institute, 'IBEA Announces Sorcerer II Expedition to Sample World's Oceans and Land to Characterize and Understand Microbial Populations Using Environmental DNA Sequencing', (Press Release, 4 March 2004).

10 Ibid.

> Public education about the Expedition, its goals, and environmental genomics is an important component of the *Sorcerer II* Expedition. An interactive website, www.sorcerer2expedition.org is also being launched today so that teachers, students, kids and parents can follow the progress of the *Sorcerer II* Expedition. In addition to public lectures and outreach in the various countries, the Expedition is also being filmed as part of a Discovery Channel documentary. The Expedition has received support from Discovery through the Channel's Quest Program, a unique program intended to help fund scientific projects and capture on film the research activities of scientists.[11]

The Discovery Channel broadcast a film of the *Sorcerer II* Expedition entitled 'Cracking the Ocean Code' to its network, which reaches 89.1 million households across United States with its mix of information and entertainment.[12]

Since leaving Celera Genomics, Venter has taken a new approach to data access and scientific inventions. He has disavowed that the *Sorcerer II* Expedition has any commercial ambitions: 'Given the paramount scientific importance to the world of making these genomic sequencing data freely available, another guiding principle of the Expedition is that no patents or other intellectual property rights will be sought by IBEA or its collaborating scientists on these genomic sequence data'.[13] With the *Sorcerer II* Expedition, Venter has changed his approach to the dissemination of genetic information. He has promised: 'Because genomic sequencing data from the Expedition should be of great interest to the international research and educational communities, these data will be made publicly and freely available to all'.[14] He insisted that 'data will be deposited in the publicly available GenBank database'.[15] He further observed: 'After their public release, these data will be freely and publicly available worldwide and may be used by anyone for any purpose.'[16] It is worth evaluating whether this model of data sharing is a viable means of disseminating information.

The Institute emphasised that it would comply with relevant international treaties, national laws, and memoranda of understanding:

> Consistent with national laws and applicable international treaties, and under the guidance of the US Department of State, IBEA obtains permits for research and sampling from every country in which samples will be taken. Scientific collaboration, education and training are an important part of the *Sorcerer II* Expedition as the vessel travels around the globe. IBEA/the Expedition has signed memoranda of understanding with many country collaborators including those in Mexico and Chile, and is in discussions with

11 Ibid.
12 J Craig Venter, 'Cracking the Ocean Code', DVD, Discovery Channel (2005).
13 J Craig Venter Institute, *Sorcerer II Expedition*: *A Global Voyage of Discovery*, (2004) <http://www.sorcerer2expedition.org/version1/HTML/main.htm> at 1 August 2009.
14 Ibid.
15 Ibid.
16 Ibid.

several other countries on similar MOUs.[17]

The Institute emphasized that such memoranda reflected the five fundamental principles of the *Sorcerer II* Expedition. First, 'the purpose of the Expedition is to advance scientific knowledge of microbial biodiversity and humankind's basic understanding of oceanic biology, yielding insights into the complex interplay between groups of micro-organisms that may affect environmental processes'.[18] Second, 'genomic sequence data from the study will be publicly available world-wide without charge, and freely used by anyone for any purpose'.[19] Third, 'no intellectual property rights will be sought by IBEA or its collaborating scientists on these genomic sequence data.' Fourth, 'IBEA and its research collaborators will co-author one (or more) scientific journal articles that describe and evaluate these genomic sequence data'.[20] Fifth, 'IBEA will provide training opportunities to scientists and students in the countries where sampling is conducted'.[21]

However, some have viewed the *Sorcerer II* Expedition with suspicion. In March 2004, the Canada-based Action Group on Erosion, Technology, and Concentration (ETC Group) issued a press release titled 'Playing God in the Galápagos'.[22] The non-government organisation worried about the implications of such research: 'Although the [J Craig Venter Institute] has promised not to patent the raw microbes it collects and sequences, patents could be claimed on modified microbes or on new life forms engineered from the collected microbes'.[23] The ETC Group noted that there was good reason to suspect J Craig Venter of ulterior commercial motives. In 1991, J Craig Venter became embroiled in controversies over filing patents on express sequence tags when at the National Institutes of Health.[24] In 1999, Venter and his company, Celera Genomics, filed patents on hundreds of medically-significant genes as part of the privately led shotgun-sequencing of the human genome. [25] In 2002, Venter left Celera in 2002 after the genome failed to make the kind of money the investors had hoped for - he is predictably scathing about the 'morons' who controlled the money there and did not understand his vision.[26]

The Group observed that 'Venter's work poses ethical and environmental concerns about the use of biodiversity to build new life forms from scratch'.[27] The ETC

17 Ibid.
18 Ibid.
19 Ibid.
20 Ibid.
21 Ibid.
22 ETC Group, 'Playing God in the Galapagos: J Craig Venter, Master and Commander of Genomics, on Global Expedition to Collect Microbial Diversity for Engineering Life' (2004) 84 *Communique*, March/April.
23 Ibid.
24 Robert Cook-Deegan, *The Gene Wars: Science, Politics, And The Human Genome* (1994).
25 Kevin Davies, *The Sequence: Inside The Race For The Human Genome* (2001).
26 David Ewing-Duncan, 'The Arrogant Adventurer', *The Guardian* (London) 21 July 2005.
27 ETC Group, 'Playing God in the Galapagos: J Craig Venter, Master and Commander of Genomics, on Global Expedition to Collect Microbial Diversity for Engineering Life' (2004) 84 *Communique*, March/April.

Group called Venter the 'greediest biopirate', and awarded him a 'Captain Hook Award for Biopiracy' in 2006.[28] The group alleged that he was 'undertaking, with flagrant disregard for national sovereignty over biodiversity, a US-funded global biopiracy expedition on his yacht, *Sorcerer II*, to collect and sequence microbial diversity from the world's oceans and soils'.[29] The ETC Group speculated: 'The genetic material will play a role in his most ambitious project to date: building an entirely new artificial organism'.[30]

The *Sorcerer II* Expedition is at the vanguard of new developments in environmental genomics and biodiscovery. Legal historian Alain Pottage has suggested that the scientific expedition is emblematic of a new mode of bioprospecting:

> Modes of bioprospecting have been profoundly transformed by the emergence of sequencing technologies, bioinformatics, and synthetic biology. These technologies have their effects on the 'materiality' of collections and the media into which they are collected. Bio-collecting was once ordered by the logic of Linnaean nomenclature or Darwinian genealogies, but in the era of 'bio-information' collections are articulated in a number of media, topologies and 'kinetic' modes.[31]

The *Sorcerer II* Expedition provides a strong impetus for timely debate about the legal protection of research of environmental genomics, the distribution of benefits related to those developments, and the type of legal regimes necessary to prevent and remedy biopiracy. Given the significant potential for exploitation of public resources, there is a need for a comprehensive analysis of the available options for federal and state regulation.

This article will consider the legality of the *Sorcerer II* Expedition in light of larger issues about intellectual property, informed consent, and benefit sharing. Section II considers the framework established by the *Convention on Biological Diversity 1992* (*CBD*), and the development of the *Bonn Guidelines on Access to Genetic Resources and Benefit-Sharing 2002* (*Bonn Guidelines*) in respect of informed consent and benefit-sharing. Section III considers the collaborative agreements reached between the Venter Institute and a number of Nation States – including Bermuda, Ecuador, Mexico, Chile, French Polynesia, New Caledonia, and Vanuatu. It evaluates the allegations made by the ETC Group that the *Sorcerer II* Expedition is engaged in 'marine biopiracy' and assesses whether the intellectual property and data-sharing policies of the *Sorcerer II* Expedition have sufficient rigour and integrity. Section IV discusses the collaborative agreement reached between the Venter Institute and the Australian Government. It explores the emerging

28 The Coalition Against Biopiracy, 'The Captain Hook Awards' (2006) <http://www.captainhookawards.org/winners/2006_pirates> at 1 August 2009.

29 Ibid.

30 Ibid.

31 Alain Pottage, 'Too Much Ownership: Bio-prospecting in the Age of Synthetic Biology' (2006) 1 *Biosocieties* 137-158.

patchwork of federal and state regulation on access to genetic resources within Australia. Such developments were contemporaneous with the *Sorcerer II* expedition. The Conclusion suggests that large-scale bioprospecting ventures, such as the *Sorcerer II* Expedition, demand better local, national, and global regulation of access to genetic resources.

II THE INTERNATIONAL LEGAL FRAMEWORK

> In the balmy atmosphere of the 1992 Earth Summit in Rio de Janeiro, a convention to conserve global biodiversity seemed like an idea whose time had come. The *Convention on Biological Diversity* was agreed at Rio, in principle, as a framework that would help the world's biological resources to be utilized in a controlled and prudent way. Scientists, governments and commercial companies would work together in harmony, the convention's authors hoped.
>
> Rex Dalton, 'Natural Resources: Bioprospects Less Than Golden'[32]

The *Sorcerer II* Expedition took place against the backdrop of a complex web of international environmental, trade and intellectual property treaties dealing with access to genetic resources. The *CBD* provides a framework for access to genetic resources based upon access permits, informed consent, and benefit-sharing.[33] The *Bonn Guidelines* provide further guidelines for the development of nation regimes dealing with access to genetic resources[34] Furthermore, there are also a number of other relevant treaties affecting access to genetic resources, including *United Nations Convention on the Law of the Sea 1982*,[35] the *TRIPS Agreement 1994* (*TRIPS*)[36] and the *United Nations Declaration on the Rights of the Indigenous Peoples 2007*.[37]

A *The Convention on Biological Diversity 1992*

The *CBD* has lofty aspirations and ambitions. Article 1 provides a sense of the sweeping aims of the treaty**:**

> The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the

32 Rex Dalton, 'Natural Resources: Bioprospects Less Than Golden' (2004) 429 *Nature* 598 - 600 (10 June).

33 *Convention on Biological Diversity*, opened for signature 5 June 1992, 1760 UNTS 79 (entered into force 29 December 1993).

34 *Bonn Guidelines on Access to Genetic Resources and Benefit-Sharing* 2002 Conference of the Parties to the *CBD*, *Decision VI/24: Access and Benefit-Sharing as Related to Genetic Resources*, Annex 1 ('*Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization*') <http://www.biodiv.org/decisions/default.asp?m=cop-06&d=24> at 1 August 2009.

35 *United Nations Convention on the Law of the Sea* 1982, opened for signature 10 December 1982, 1833 UNTS 3 (entered into force 16 November 1994) (*UNCLOS*).

36 *TRIPS Agreement* 1994, Opened for signature 15 April 1994, 1869 UNTS 299 (entered into force 1 January 1995).

37 *United Nations Declaration on the Rights of the Indigenous Peoples 2007*, Adopted by General Assembly Resolution 61/295 on 13 September 2007<http://www.un.org/esa/socdev/unpfii/en/drip.html> at 1 August 2009.

> 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.

Biodiversity experts Kerry ten Kate and Sarah Baird note that the *CBD* is premised on a grand bargain: 'The Convention can be seen as an instrument to promote the equitable exchange, on mutually agreed terms, of access to genetic resources, and associated knowledge in return for finance, technology and the opportunity to participate in research'.[38]

The *CBD* is the most highly subscribed environmental treaty in the world, with 189 States and the European Community members as of February 2007. The US Government, though, raised objections about the treaty at the Rio Earth Summit. William K Rielly, then administrator of the Environmental Protection Agency, stated that the US refused to participate in the *CBD* because of objections to its benefit sharing requirements and financial mechanisms, as well as its treatment of intellectual property rights and what it called the conventions 'limited requirements' for domestic conservation.[39] Subsequently, the US Congress has refused to ratify the *CBD*. Professor Robert Blomquist suggests that there are several strong themes behind this recalcitrant response – including institutional tension between the President and the Congress concerning foreign affairs; conservative concern about international environmental law; American corporate interest in maximising biotechnology profits; and complexities in resolving international economic and physical matters through legal policy instruments. [40] Blomquist hoped that the US Government would adopt a more engaging, pro-active, environmental diplomatic posture in the future, and ratify the *CBD*. However, the US has shown no enthusiasm to play such an international leadership role. The *CBD* has thus had limited capacity to influence regulation of the biotechnology industry insofar as it is centred in the US.

Article 3 of the *CBD* emphasizes that genetic resources belong to sovereign States, and are not freely available or 'the common heritage of mankind':

> States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause

38 Kerry ten Kate and Sarah Laird, *The Commercial Use Of Biodiversity: Access To Genetic Resources And Benefit-Sharing* (1999).

39 David E Bell, 'The 1992 Convention on Biological Diversity: The Continuing Significance of US Objections at the Earth Summit' (1993) 26 *George Washington Journal of International Law & Economics* 479-537.

40 Robert Blomquist, 'Ratification Resisted: Understanding America's Response to the Convention on Biological Diversity, 1989-2002' (2002) 32 *Golden Gate University Law Review* 493-585.

> damage to the environment of other States or of areas beyond the limits of national jurisdiction.

Article 15 of the *CBD* provides a comprehensive framework to govern access to genetic resources. Article 15(1) recognises 'the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation'. Article 15(2) provides that 'each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention'. Article 15(3) stresses that 'the genetic resources being provided by a Contracting Party… are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention'.

Article 15(4) declares that access to genetic resources is dependent upon agreements made between access-providers and users of genetic resources: 'Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article'. Article 15(5) explains the key concept of informed consent: 'Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party'. Article 15(6) provides scope for scientific research on genetic resources: 'Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties'. Article 15(7) stresses the importance of benefit-sharing: 'Each Contracting Party shall take legislative, administrative or policy measures… with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources'.

The quid pro quo for access to genetic resources is the sharing of benefits of technology resulting from exploitation, and financial resources more generally. Article 16 of the *CBD* is designed to facilitate technology transfer. Article 17 is intended to facilitate the exchange of scientific information; and Article 18 deals with technical and scientific co-operation. Article 19 focuses upon the distribution of benefits arising from biotechnology; and Article 20 deals with financial support and incentives for biodiversity conservation.

In addition, it is also worth noting that Article 8(j) of the *CBD* places particular emphasis upon the protection of traditional knowledge:

> Subject to its national legislation, [States should] 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.

B *Bonn Guidelines on Access to Genetic Resources and Benefit-Sharing 2002*

The *CBD* has had a mixed history. Kerry ten Kate comments:

> In the wake of the *CBD*, benefit-sharing agreements are increasingly common. Most benefits have flowed to scientific institutions, in the form of training and technology…The story is not one of unalloyed success, however. There is evidence that the anticipated bureaucracy, delay, and expense of compliance with the first wave of access laws have deterred foreign and domestic scientists and thus have unwittingly stifled not only commercial research, but also essential conservation work. Confusion over which government bodies are authorized to grant access has not helped.[41]

Acknowledging such concerns, there have been international efforts to provide a more strategic and flexible approach to access to genetic resources, informed consent, and benefit-sharing.

In April 2002, the 6th Conference of the Parties to the *CBD* adopted the *Bonn Guidelines*.[42] Article 11 emphasises that the Guidelines are intended 'to provide Parties and stakeholders with a transparent framework to facilitate access to genetic resources and ensure fair and equitable sharing of benefits' and 'to provide guidance to Parties in the development of access and benefit-sharing regimes'. Moreover, the Guidelines are designed 'to inform the practices and approaches of stakeholders (users and providers) in access and benefit-sharing arrangements'.' Article 11 emphasises the need to provide financial resources, technology transfer, and capacity building to least developed countries, small island developing States among them, as well as Indigenous communities. Article 11 also stresses that 'taxonomic research, as specified in the Global Taxonomy Initiative, should not be prevented, and providers should facilitate acquisition of material for systematic use and users should make available all information associated with the specimens thus obtained'.

Article 13 stipulates that 'each Party should designate one national focal point for access and benefit-sharing and make such information available through the clearing-house mechanism'. The article describes the functions of this body: 'The national focal point should inform applicants for access to genetic resources on procedures for acquiring prior informed consent and mutually agreed terms, including benefit-sharing, and on competent national authorities, relevant

41 Kerry ten Kate, 'Global Genetic Resources: Science and the Convention on Biological Diversity' (2002) 295 *Science* 2371 - 2372.

42 *Bonn Guidelines*, above n 34.

indigenous and local communities and relevant stakeholders, through the clearing-house mechanism'.

Article 26 stresses that 'consent of the relevant competent national authority lies in the provider country'. In addition, 'the consent of relevant stakeholders, such as Indigenous and local communities, as appropriate to the circumstances and subject to domestic law, should also be obtained'. Article 26 emphasises that a prior informed consent system should embody the virtues of legal certainty and clarity; efficiency; transparency; and harmony with the objectives of the *CBD*.

Appendix 2 of the *Bonn Guidelines* provides inclusive definitions of monetary and non-monetary benefits. Clause 1 notes that monetary benefits may include: access fees; sample fees; up-front payments; milestone payments; payment of royalties; licence fees in case of commercialisation; trust funds; salaries and preferential terms where mutually agreed; research funding; joint ventures; and the joint ownership of relevant intellectual property rights. Clause 2 provides that non-monetary benefits may include the sharing of research and development results; scientific collaboration; product development; education and training; admittance to *ex situ* facilities of genetic resources and to databases; technology transfer; institutional capacity-building; access to scientific information relevant to conservation and sustainable use of biological diversity; contributions to the local economy; food, health and livelihood security benefits; social recognition; and joint ownership of relevant intellectual property rights.

The realisation of the lofty aims and aspirations of the *CBD* has been somewhat tortuous. *Nature* journalist Rex Dalton observes that 'the convention has done little to ease tensions that exist between scientists searching for potentially valuable compounds and officials in the developing countries where most bioprospecting takes place'.[43] Sarah Laird and Rachael Wynberg reflect that the *CBD* has engendered increasingly hostile reactions among industry groups:

> Industry and researcher perceptions of the *CBD*, and ABS in particular, have become increasingly negative in the last decade. Some continue to cite the positive role the *CBD* can play in promoting equitable relationships, conservation and best practices in industry, but many more consider the negative impacts to far outweigh the positive. Rather than coming together over the last 13 years to create simple, workable legal and regulatory frameworks for access and benefit-sharing, providers and users of genetic resources are increasingly estranged, and the environment in which bioprospecting takes place is often characterized by misunderstanding, mistrust, and regulatory confusion.[44]

43 Ibid.

44 Sarah Laird, and Rachel Wynberg, *The Commercial Use of Biodiversity: An Update on Current Trends in Demand for Access to Genetic Resources and Benefit-Sharing, and Industry Perspectives on ABS Policy and Implementation* (2006) <http://www.biodiv.org/doc/meetings/abs/abswg-04/information/abswg-04-inf-05-en.doc> at 1 August 2009, 5.

The authors comment that researchers from academia and industry have made a number of recommendations to improve the policy process in respect of access to genetic resources.

C *Other Treaties*

The *CBD* also interacts with a number of other international treaties dealing with access to genetic resources. These include the *United Nations Convention on the Law of the Sea 1982* (*UNCLOS*), *TRIPS*, and the *United Nations Declaration on the Rights of the Indigenous Peoples 2007*.

UNCLOS aims to establish 'a legal order for the seas and oceans which will facilitate international communication, and will promote the peaceful uses of the seas and oceans, the equitable and efficient utilization of their resources, the conservation of their living resources, and the study, protection and preservation of the marine environment'.[45] There has been much policy interest in bioprospecting activities on the high seas.[46] Henry Nicholls comments:

> The *United Nations Law of the Sea Convention 1982* endowed coastal nations with the sovereign right to explore and exploit all resources within their 'exclusive economic zone' - usually a body of water stretching 200 nautical miles out to sea . Most coastal States exercise this right, granting permits to outsiders wanting to conduct research in their waters … Beyond national waters (with a few exceptions) are the 'high seas'. Here, there is little regulation. According to *UNCLOS*, mineral resources on the deep seabed are considered the 'common heritage of mankind'; this means that any benefits deriving from them should be shared with the international community. But when it comes to biological resources, just about anything goes.[47]

Similarly, Julia Jabour-Green and Dianne Nicol have expressed concerns that 'the high seas may be vulnerable to exploitation because of increased levels of interest in freely available biological resources'.[48]

There has been much debate in a variety of forums as to whether the granting of intellectual property rights should be made conditional upon evidence of an access permit, informed consent, and a benefit-sharing agreement. The Working Group on Access to Genetic Resources and Benefit Sharing has decided 'to establish a group of technical experts to explore and elaborate the possible options, without

45 *UNCLOS*, above n 35.

46 Salvatone Arico, and Charlotte Salpin, *Bioprospecting of Genetic Resources in the Deep Seabed: Scientific, Legal, and Policy Aspects*. UNU-IAS Report, (May 2005).

47 Henry Nicholls, 'Sorcerer II: The Search for Microbial Diversity Roils the Waters' (2007) 5 (3) *The Public Library of Science Biology* 380-383 at 381.

48 Julia Jabour-Green and Dianne Nicol, 'Bioprospecting In Areas Outside National Jurisdiction: Antarctica And The Southern Ocean' (2003) 4 (1) *Melbourne Journal Of International Law* 76-111 at 96.

prejudging their desirability, for the form, intent and functioning of an internationally recognised certificate of origin/source/legal provenance and analyse its practicality, feasibility, costs and benefits, with a view to achieving the objectives of Article 15 and 8(j) of the Convention'.[49] The supporters of a development agenda have argued that the *TRIPS* should be amended to require a disclosure of origin and benefit-sharing.[50] However, US industry groups have lobbied against such a proposal, suggesting that it would dampen foreign investment.[51]

Another option would be to enshrine the principle of the disclosure of the geographical origin of genetic resources in the *Patent Co-Operation Treaty 1970* (*PCT*).[52] Switzerland has proposed that the *PCT Regulations* should be amended to permit nations to amend their patent laws to require the lodgement of declarations of the source of genetic resources in patent applications. In Switzerland's view, the proposed amendments to the *PCT Regulations* would 'present one simple and practical solution to the issues arising in the context of access to genetic resources and traditional knowledge and the fair and equitable sharing of the benefits arising out of their utilization'.[53]

Expanding upon Article 8(j) of the *CBD*, Article 31 of the *Declaration on the Rights of Indigenous Peoples* aspires to provide for comprehensive protection of traditional knowledge:

> Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions …[54]

49 Working Group on Access to Genetic Resources and Benefit-Sharing, <http://www.biodiv.org/programmes/socio-eco/benefit/default.aspx> at 1 August 2009.

50 *TRIPS*, above n 36.

51 Susan Sell, 'Intellectual Property and the Doha Development Agenda' (2006) 6 *Global Social Policy* 147-150 at 149.

52 *Patent Co-Operation Treaty 1970* (Agreed at Washington on June 19, 1970, amended on September 28, 1979, modified on February 3, 1984, and October 3, 2001 (as in force from April 1, 2002))

53 World Intellectual Property Organization, *Proposals By Switzerland Regarding The Declaration Of The Source Of Genetic Resources And Traditional Knowledge In Patent Applications, Working Group On Reform Of The Patent Cooperation Treaty, Fourth Session*, Geneva, (19-23 May 2003).

54 *Declaration on the Rights of Indigenous Peoples*, above n 37. For a discussion of the broader issues, see Michael Dodson and Olivia Barr, 'Breaking the Deadlock: Developing An Indigenous Response to Protecting Indigenous Traditional Knowledge' (2007) 11 (2) *Australian Indigenous Law Review* 19-32.

III PLAYING GOD IN THE GALAPAGOS

At the international level, there is widespread concern that the *Sorcerer II* Expedition whilst serving a public good in the form of the database may yet result in a loss of public rights. By the end of 2004, 14 countries, including Chile, Ecuador and French Polynesia, had apparently entered into legal arrangements with the Expedition. The agreements signed by States, research institutions and government bodies raise questions of national sovereignty, ownership, access and research rights. In relation to French Polynesia, France was initially reluctant to grant access because it wanted to protect its national patrimony. However, it acceded to the request after pressure was applied by the US Government. Ecuador is in the midst of a public furore over the allegedly inappropriate authorisation to export samples from the Galapágos National Park.

The ETC Group released a communiqué on the *Sorcerer II* Expedition, raising larger concerns about commercialisation and bioprospecting:

> In the *Sorcerer's* wake, governments are left with troubling questions about public domain diversity and private patenting, unresolved ethical and ecological concerns about the human-made creation of novel life forms, and huge gaps in the global community's capacity to address new technologies.[55]

The ETC Group argued that the *Sorcerer II* Expedition called into question the efficacy of the *CBD*: 'As fascinating as the IBEA initiative is, it challenges national sovereignty and raises more doubts about the already problematic access and benefit-sharing work of the *Convention on Biological Diversity*'. [56] The ETC Group observed: 'In light of the failure of the United Nations *CBD* to provide for protection against the privatization of collective resources and knowledge, societies need to urgently engage in debates about the orientation and implications of new technologies, and strategies to recuperate the social control of science for the common good, as well as strategies to prevent the privatization of collective resources'.[57] The group contended that there needed to be a stronger international forum to regulate the introduction of new technologies: 'The United Nations must create a new mechanism that will make it possible for the international community to monitor the development of new technologies whose introduction could affect (positively and/or negatively) human health, the environment, or society's well-being'.[58]

In a letter to the ETC Group, the Institute's lawyer, Reid Adler, wrote: 'no patents or other intellectual property rights will be sought by IBEA on these genomic DNA

55 ETC Group, 'Playing God in the Galapagos: J Craig Venter, Master and Commander of Genomics, on Global Expedition to Collect Microbial Diversity for Engineering Life' (2004) 8 *Communique*, March/April.

56 Ibid.

57 Ibid.

58 Ibid.

sequence data'.[59] But Adler also asserted: 'After these data are published, researchers in a given country may wish to study microbes that have particular scientific interest or have potential commercial value'.[60] The ETC Group comments: 'In other words - and this is a critical distinction - there is nothing to prevent Venter or any other researcher from claiming monopoly patents on commercially useful results derived from microbes or sequence data'.[61]

The anti-biotechnology group feared that Venter could seek patents in respect of micro-organisms and microbes found during the *Sorcerer II* Expedition:

> A global maritime microbe-hunting expedition launched by J Craig Venter of human genome mapping fame threatens to turn a nation's biomaterials from public domain goods into patentable, private commodities. Although the Institute for Biological Energy Alternatives (IBEA) - one of Venter's three non-profit institutes and the one leading the initiative - has promised not to patent the raw microbes it collects and sequences, patents could be claimed on modified microbes or on new life forms engineered from the collected microbes. [62]

The ETC Group observed that although Venter promises that intellectual property on raw microbes and their gene sequences would not be sought, there was nothing to prevent patent claims on commercially useful results derived from collected diversity.

A *The Pirates of the Caribbean*

The *Sorcerer II* Expedition first conducted a pilot study at the Bermuda Biological Station for Research in St George: 'The Sargasso Sea was chosen as a pilot study for the environmental genome shotgun sequencing strategy because it was thought to have very low nutrients and thus low species diversity'.[63] In February and May 2003, the J Craig Venter Institute researchers undertook a pilot study and collected sea water samples from six marine research sites in the Sargasso Sea off Bermuda. Using the whole genome shotgun sequencing and high-performance computing developed to sequence the human genome, the researchers discovered at least 1800 new species and more than 1.2 million new genes from the Sargasso Sea.[64] J Craig Venter commented:

> The field of environmental genomics has the potential to revolutionize the way our oceans, soil, and whole ecosystems and environments are studied. By taking relatively small samples of water or soil and using the tools and

59 Ibid.
60 Ibid.
61 Ibid.
62 Ibid.
63 J Craig Venter Institute, 'IBEA Researchers Publish Results from Environmental Shotgun Sequencing of Sargasso Sea in *Science*', Press Release, 4 March 2004.
64 J Craig Venter et al., 'Environmental Genome Shotgun Sequencing of the Sargasso Sea' (2004) 304 *Science* 66-74.

> techniques of shotgun sequence analysis, we are able to identify and characterize the vast legions of unseen organisms living in the environment. It is estimated that over 99% of species remain to be discovered. Our work in the Sargasso Sea, an area thought to have low diversity of species, has shown that there is much that we do not yet understand about the ocean and its inhabitants.[65]

The Institute commented: 'One of the most important single discoveries from the Sargasso Sea environmental shotgun sequencing study is the 782 new rhodopsin-like photoreceptor genes'.[66] The Institute stressed that such research could have application in the development of alternative energy sources: 'Better understanding of these photoreceptor genes could be very important to IBEA researchers as they explore the mechanisms of photosynthesis as a means to efficiently and economically produce hydrogen as a fuel source'.[67]
In a piece for *Nature*, Rex Dalton commented that the *Sorcerer II* Expedition to Bermuda and the work of the commercial bioprospecting company, Diversa, had prompted a reconsideration of Bermuda's laws on access to genetic resources:

> [Venter's] voyage into the Sargasso Sea also took the genomics pioneer into uncharted waters. The rules on bioprospecting in this small British protectorate are still a work in progress. And experience with expeditions such as Venter's has prompted Bermuda to temporarily shut down some research projects until it strengthens its regulations. Bermuda is now rewriting its scientific collection rules completely, in preparation for joining the *Convention on Biological Diversity* as a protectorate of the United Kingdom, which has already adopted the convention. And lessons learned from Venter's scientific expedition and from a separate commercial project started in 1999 by Diversa, a San Diego firm seeking drugs from microbes, technology tools and industrial chemicals, will influence the formation of these rules.[68]

Of particular concern was that the *Sorcerer II* Expedition and Diversa collected marine samples under a decades-old collection permit held by the Bermuda Biological Station for Research in St George.[69] The Station is funded by the US National Science Foundation and NASA.

The Bermuda Government expressed concerns that it was only minimally aware of what was taking place in its waters. As *The Royal Gazette* noted, 'The Bermuda Government, like many around the world, is now waking up to the possibility that genetic material can be taken and used for commercial gain without passing on a

65 J Craig Venter Institute, 'IBEA Researchers Publish Results from Environmental Shotgun Sequencing of Sargasso Sea in *Science*', Press Release, 4 March 2004.
66 Ibid.
67 Ibid.
68 Dalton, above n 32.
69 The Bermuda Biological Station for Research has since been renamed the Bermuda Institute of Ocean Sciences, <http://www.bbsr.edu/> at 1 August 2009.

penny to the Island'.[70] The Director of Conservation Services, Jack Ward, was concerned that the San Diego biotechnology company, Diversa, was marketing a biotechnology tool called DiscoveryPoint Fluorescent Proteins based on a protein collected from a coral in Bermuda, and for which the firm is seeking a patent.[71] The research station would receive a 1% royalty, but the government and people of Bermuda will get nothing.

The Institute was collecting specimens in the Sargasso Sea, which falls under Bermuda's jurisdiction under *UNCLOS*. However, Ward acknowledged that it was almost impossible to police the waters: 'Bermuda has no further control over it all'.[72] He observed that the Bermuda Government found it impossible to regulate the *Sorcerer II* Expedition: '[Venter] basically came in and was opportunistic. He took the samples and ran his processes'.[73] Ward was also wary that the *Sorcerer II* Expedition had received a large amount of funding from the US Department of Energy.

The Bermuda Government was concerned that the State received no financial benefits from such bioprospecting ventures. Ward observed: 'There is a value issue here. Something that held value has been put in the public domain and made valueless for the people of Bermuda'.[74] Ward observed that in future the Government would negotiate benefit-sharing agreements with research teams directly to ensure Bermuda gets a legitimate share of any financial gains earned from its genetic resources: 'We want to be involved through the entire process'.[75] He noted that the Bermuda Government could ask for anything from 1.5% to 15% - 'which is what the Australians are trying to ask for' - of potential profits gleaned from its biological wealth. [76]
However, Ward did not find fault with either Diversa or Venter for the work they did: 'We should have been more proactive'.[77] He observed: 'Right now, because the permit is in place, there would be nothing to say anything they would do would be illegal'.[78] He said: 'I would think that Dr Knap would be sensitive and say "let's talk" though'.[79]

Venter took umbrage that the scientific magazine, *Nature*, reported these charges. He quipped that the reporter who wrote this article 'must have come to *Nature* from the *National Enquirer*'.[80] Similarly, Tony Knap of the Bermuda Biological Station for Research was incensed by the coverage of *The Royal Gazette*:

70 Tania Theriault, 'Preventing Biological Piracy in Bermuda's Waters', *The Royal Gazette* (Bermuda) 9 July 2004
71 Diversa, <http://www.diversa.com/> at 1 August 2009.
72 Theriault, above n 70.
73 Ibid.
74 Dalton, above n 32.
75 Theriault, above n 70.
76 Ibid.
77 Ibid.
78 Ibid.
79 Ibid.
80 David Ewing-Duncan, 'The Arrogant Adventurer', *The Guardian* (London) 21 July 2005.

> We are working with Bermuda Government representatives to determine the best practice. Many other countries are dealing with similar issues. The United States, for example, does not claim any value or collect revenue from its marine genetic resources. We continue to talk to the Bermuda Government officials about equitable benefit sharing, making sure that everyone benefits.[81]

Knap emphasised that the Bermuda Biological Station for Research had only received a milestone payment of $1645 for a product derived from a discovery in Bermuda.[82] The Station had set up a fund to benefit Bermuda's students in order to pay for DNA sequencing chemicals. However, it is questionable whether the US Government represents best practice, as it is not a signatory to the *CBD*.

In response to the *Nature* article, Bermuda's Ministry of the Environment, the Bermuda Biological Station for Research, and Diversa wrote a letter to *Nature*, denying that any moratorium had been placed on bioprospecting activities in Bermuda:

> Bermuda's Ministry of the Environment has not shut down any research projects relating to biodiversity access, even on a temporary basis. New laws and regulations are under development to enhance bioprospecting, not to prevent or hinder such research activities. Contrary to your News story, the Ministry of the Environment is not displeased with Diversa's research activities in Bermuda. The ministry greatly values the ongoing collaborations with the Bermuda Biological Station for Research (BBSR), and appreciates the station's responsibility in ensuring a proactive and consultative approach to issues of environmental access. [83]

The group concluded: 'Diversa, BBSR and the ministry look forward to exploring ways of expanding the bioprospecting benefits realized to date by the people and the government of Bermuda'.[84] Bermuda's Ministry of the Environment stressed that the Biostation's permit would remain in place. However, the permit would be tightened up to ensure that any research with potential commercial spin-offs from Bermuda's genetic material makes some provisions for the Island: 'They will have a collection permit but it will specifically exclude things of a specific nature dealing with genetic resources'.[85] The Bermuda Government would still allow any legitimate collection for scientific purposes.

81 Sarah Titterton, (2004), 'Bio Station's Tony Knap lashes out at 'Inaccurate' Ocean Story', *The Royal Gazette* (Bermuda) 13 July 2004.

82 Anthony Knap, , 'Setting the Record Straight', *The Royal Gazette* (Bermuda) 12 July 2004.

83 Jack Ward, Anthony Knap, and Jay Short, 'Bermuda Welcomes Careful Prospectors' (2004) 430 *Nature* 723 (12 August).

84 Ibid.

85 Theriault, above n 70.

The Bermuda Government plans on becoming a signatory to the *CBD* and will be working with an overseas expert to develop a policy to protect its biological wealth. Ward observed: 'The reason for the convention being signed in the first place was to ensure compensation where appropriate to countries for any product developed from their genetic resources'.[86] He noted, though, that it would be difficult to forge an appropriate regime for access to genetic resources for Bermuda: 'There is no model which we could follow: Every country is struggling with this at the moment because things are changing so fast'.[87]

B *Ecuador and the Andean Pact*

The *Andean Pact* is the first regional agreement of its kind, and binds the countries of Bolivia, Columbia, Ecuador, Peru and Venezuela.[88] Resolution 391 of the *Cartagena Agreement 1996* provides for a common regime on access to genetic resources in the Andean Region. The decision seeks to 'establish the conditions for just and equitable participation in the benefits of the access', to 'lay the foundations for the recognition and valuation of the genetic resources and their by-products and of their associated intangible components', and to 'promote conservation of the biological diversity and the sustainable use of the biological resources that contain genetic resources'. The agreement seeks to 'promote the consolidation and development of scientific, technological and technical capacities at the local, national and subregional levels' and strengthen 'the negotiating capacity of the Member Countries'. The *Cartagena Agreement* lays down extensive directions on national authorities, access to genetic resources, informed consent, and benefit-sharing agreements.

The Institute entered into a memorandum of understanding with the government of Ecuador to collaborate on microbial diversity.[89] The agreement noted that the Institute is undertaking 'a global oceanic expedition to carry out a scientific research project on board the *RV Sorcerer II*, involving microbial sampling for the study of microbiological diversity in the Galapagos using a "whole environment" genomics approach, with the objective of characterizing the microbiological diversity of the coastal waters and the terrestrial communities around the Galapagos Islands to determine the complex interrelationship between groups of micro-organisms that affect regional and global environmental processes'.[90] It also noted that 'the Parque Nacional Galápagos (National Galapagos Park) has authorized the research permit based on the criteria issued by the Estación Científica Charles Darwin (Charles Darwin Scientific Station), a high-level academic and scientific institution that recommended the approval of said research for its great value toward the better understanding of the role played by micro-organisms in the

86 Ibid.
87 Ibid.
88 Ten Kate and Laird, above n 38.
89 J Craig Venter Institute and the Ministry of the Environment of Ecuador (2004), 'Memorandum of Understanding for a Collaboration on Microbial Diversity', (15 March 2004) <http://www.sorcerer2expedition.org/permits/Ecuador_MOU_English.pdf> at 1 August 2009.
90 Ibid.

marine environmental processes, and based on the report issued by the University of Guayaquil's technical and scientific Advisor'.[91] It concluded that 'the parties agree that the output of this collaboration shall be of great scientific value and great benefit to both the public and scientific communities, in Ecuador and worldwide, by ensuring that the genomic data arising from this collaboration be made available to the scientific community pursuant to the provisions established in Resolution 391 of the Cartagena Agreement'.[92]

The terms of the agreement, though, are somewhat lacking in detail and precision. Clause 4 states: 'Given that the collaboration which is the object of this MOU is for the great benefit to the public and to the scientific communities in Ecuador and throughout the world through the publication of basic scientific research, the parties agree that the nucleic acid libraries generated from the sampling activities shall be used exclusively for purposes of generating public information on sequencing'.[93] Clause 4 continues: 'neither party shall pursue nor exercise intellectual property rights over the genomic data and results developed through the Project Plans since this information is part of the genetic patrimony of the State of Ecuador'.[94] Clause 4 concludes: 'The parties agree that the samples collected through the Project Plans are solely for basic scientific purposes, and under no circumstances shall the Parties be able to make any commercial use of the samples or of the information obtained from them'.[95] Clause 5 deals with publication and data-sharing: 'Once the data have been analysed, all the information shall be deposited in public databases and published in scientific forums, where it shall be acknowledged that the information obtained is part of the genetic patrimony of the State of Ecuador'.[96] The weakness of this agreement is that there is nothing preventing the *Sorcerer II* Expedition from commercialising derivative products. The memorandum of understanding has attracted some critical attention, accordingly.[97]

Lucia Gallardo of Acción Ecológica, an environmental advocacy organization based in Quito, contended: 'Venter's expedition challenges national sovereignty over biodiversity'.[98] She added: 'Although Venter's researchers can point to a memorandum of understanding (MOU) signed by government authorities in Ecuador, we believe it is inadequate and violates our laws on access to biodiversity'.[99] Elizabeth Bravo of Acción Ecológica, contended: 'Venter's institute

91 Ibid.
92 Ibid.
93 Ibid.
94 Ibid.
95 Ibid.
96 Ibid.
97 Carl-Gustaf Thornstrom, *The Green Blindness: Microbial Sampling in the Galapagos – The Case of Craig Venter vs the Darwin Institute and the Lessons for the Trip to China by S/V. Gotheberg*, Unpublished manuscript (2005).
98 ETC Group, 'Rocking the Boat: J Craig Venter's Microbial Collecting Expedition Under Fire in Latin America' (22 July 2004), <http://www.etcgroup.org/en/materials/publications.html?id=91> at 1 August 2009.
99 Ibid.

has flagrantly violated our Constitution and several national laws, including the Andean Pact Decision 391 on access to genetic resources'.[100] She added:

> When negotiations on access to genetic resources take place behind closed doors, in the absence of public debate or information, and in the context of opening the doors for monopoly patents - we call it biopiracy. The issue is not simply about IBEA's failure to negotiate legal access and benefit sharing, we are profoundly troubled by the potential of Venter's institute to allow for privatization of all microbial organisms of commercial interest found in one of the richest and most unique ecosystems of the planet.

Although Venter promises that intellectual property on raw microbes and their gene sequences will not be sought, there is nothing to prevent monopoly patent claims on commercially useful results derived from collected diversity. The Institute's research is funded by the US government, so it clearly raises the issue of national sovereignty over biodiversity - a fundamental principle of the *CBD*, which the US government has failed to sign.[101]

Acción Ecológica demanded that samples collected by Venter's institute not be used and be repatriated to Ecuador. They also demanded that the government of Ecuador make all documents public before signing any biodiversity agreements related to the Galapagos or other Ecuadorian territory.

C *Latin America*

As part of the *Sorcerer II* Expedition, the Institute sought to collect marine water and other samples in the territorial waters in association with Dr Valeria Souza from the Institute of Ecology from the National University of Mexico (UNAM) under her Licencia de Colector Cientifico.[102] The Institute maintained that this Scientific Collecting License constituted a permit under Article 87 of the *General Law for Ecological Balance and Environment Protection 1988* (Mexico). The Institute recognised that this Article only allows 'collections made with purposes of basic science only, and not with purposes of developing biotechnological products of actual or potential commercial value nor with the intention of obtaining intellectual property rights protection for the sequences obtained, nor developments derived from them'.[103]Alejandro Nadal, coordinator of the Science and Technology Program of the Colegio de México, questioned whether the *Sorcerer II* Expedition's bioprospecting in Mexico had state approval. He observed that UNAM lacked the authority to grant a permit to Venter to collect microbial diversity:

100 ETC Group, above n 22.
101 Ibid.
102 The J Craig Venter Institute and the Institute of Ecology from the National University of Mexico, 'Statement of Understanding', (2004) <http://www.sorcerer2expedition.org/permits/Mexico_MOU.pdf> at 1 August 2009.
103 Ibid.

> It is at least surprising that reference is made to UNAM having granted Venter's researchers a permit for collecting since the coordinator responsible for research agreements at UNAM doesn't know anything about it. [104]

Nadal reflected that, in a previous dispute in 2001 over a National University of Mexico-Diversa bioprospecting project to collect micro-organisms, it became clear that UNAM did not have the legal authority to grant that type of permit: 'The authorities [PROFEPA] concluded that the contract was not legal and that a widespread public consultation about bioprospecting was needed in Mexico'.[105]

In the past, Costa Rica has had extensive experience of negotiating agreements in respect of access to genetic resources. Famously, in 1991, Merck signed a benefit-sharing agreement with the Instituto Nacional de Biodiversidad de Costa Rica to evaluate plant, insect, and environmental samples.[106] There is little public information about the dealings between Venta and the Costa Rica government over the *Sorcerer II* Expedition to the Cocos Islands. Silvia Rodriguez, from the Biodiversity Coordinating Network in Costa Rica, questioned whether the appropriate authorities had approved the *Sorcerer II* Expedition in Costa Rica:

> There is no public information available in Costa Rica about this expedition. Even the National Commission for Biodiversity Management (CONAGBIO) is completely unaware of any agreement with IBEA and is ignoring that Venter may have collected in Costa Rica. Our Biodiversity Network, which includes farmers, indigenous peoples and others actors is represented at CONAGBIO and we have not received any information. [107]

Rodrigeuz reflected: 'We thought the biodiversity access laws would control it, but obviously they are not working'.[108] She observed: 'Venter's expedition is especially alarming because of the potential misuses of information and resources extracted from Costa Rica'.[109] There has been much debate about the regulation of bioprospecting in Costa Rica in the past.[110]

Chilean activist, Camila Montecinos, also expressed concerns about the memorandum of understanding between Chile and the Institute: 'There is nothing in

104 ETC Group, above n 98.
105 Ibid.
106 Michele Zebich-Knos, 'Preserving Biodiversity in Costa Rica: The Case of the Merck-INBio Agreement' (1997) 6 (2) *The Journal of Environment & Development*180-186.
107 ETC Group, 'Rocking the Boat: J Craig Venter's Microbial Collecting Expedition Under Fire in Latin America', (22 July 2004). <http://www.etcgroup.org/en/materials/publications.html?id=91>, at 1 August 2009.
108 Ibid.
109 Ibid.
110 Rex Dalton, 'Biodiversity: Cashing in On The Rich Coast' (2006) 441 *Nature* 567-569 (1 June).

the MOU with Chile or the Galapagos to prevent monopoly patent claims on any commercially useful results derived from our collected diversity'.[111]

Silvia Riberio of the ETC Group sought to publicise the complaints of civil society about the *Sorcerer II* Expedition: 'We invite the Discovery Channel's Quest TV program, which is partially funding Venter's expedition, to document the civil society protests in Quito and in Brazil next year'.[112]

D *French Polynesia and the South Pacific*

Most island States in the South Pacific only afford weak protection of intellectual property rights.[113] Furthermore, there have been concerns about the institutional capacity of South Pacific States to implement the *CBD*.

In French Polynesia, Venter sought permission from the French Government to take marine samples during a visit to Vanuatu. However, the French Ministry of Foreign Affairs denied his application to conduct research in French Polynesia, because it wished to protect its 'patrimony' by restricting 'extraction of these resources by foreign vessels'.[114] In response, Venter enlisted the French ambassador to the US to lobby Paris on his behalf, and top French scientists were writing letters of protest to the ministry. The scientist ridiculed the claims of the French Government: 'It's French water, so I guess they're French microbes'.[115] As tensions escalated, the Port captain of the French Polynesian island of Hiva Oa in the Marquesas archipelago impounded the *Sorcerer II*. The US State Department protested to the French Ministry of Foreign Affairs that such an act was a violation of international law. The *Sorcerer II* was allowed to proceed from the port on its journey, but with a warning not to attempt to take any samples.

In the end, agreement was reached between the acrimonious parties. Given this controversy, it is surprising that the final agreement negotiated between the Institute and French Polynesia is somewhat unguarded.[116] The preamble declares:

> French Polynesia is rich in animal and plant species that are as yet little known and whose components may prove to possess advantageous biological activity. This natural bounty may represent a major asset for French

111 ETC Group, above n 98.

112 Ibid.

113 Miranda Forsyth, 'Cargo Cults And Intellectual Property In The South Pacific' (2003) 14 *Australian Intellectual Property Journal* 193-207; and Bronwyn Parry, (2002), 'Cultures Of Knowledge: Investigating Intellectual Property Rights and Relations in the Pacific' (2002) 34 *Antipode* 679-706.

114 James Shreeve, (2004), 'Craig Venter's Epic Voyage to Redefine the Origin of Species' (2004) 12 (8) *Wired Magazine* 107-113, 146-151.

115 Ibid.

116 J Craig Venter Institute and the Department of Culture, Higher Education, and Research, French Polynesia, *Agreement on Implementing the 'Study of Microbial Biodiversity In The South Pacific Region' Research Campaign Led by Mr Craig Venter* (2004) <http://www.sorcerer2expedition.org/permits/French_Polynesion_MOU_English.pdf> at 1 August 2009.

> Polynesia's economic development.[117]

Section 1 provides that 'the goal of the present agreement is to define, in French Polynesia, the terms of sampling and collecting natural species, as well as those for the Institute's study of the samples' composition and microbial diversity'.[118] Section 4 demands that 'the Institute agrees to adhere to all of the agreements, laws, and regulations applicable in French Polynesia, in particular those relating to biodiversity and protection of nature and species of animals and plants'.[119] Section 5 provides that the Institute agrees to 'mention the Polynesian origin of these products' in publications and communications on the research of the *Sorcerer II* Expedition.[120] Section 5 contains an odd clause that 'no protection technique of the results considered to be used under the intellectual property shall be introduced prior to concluding an additional clause to the present agreement that defines each right of the parties'.[121] Such provisions seem to offer very weak protection for French Polynesia in terms of access to data, and control of any resulting intellectual property.

A similarly sketchy agreement was negotiated between the Institute and New Caledonia.[122]

The Institute also entered into a standard 'Code of Ethics Agreement for Foreign Researchers Undertaking Researches within the Flora and Fauna of Vanuata'.[123] Outlining the research proposal, the Institute affirmed:

> We are requesting permission to undertake basic scientific research. The results of this research will be published in major scientific journals. All data will be released into a public database where they will be freely available to all. No patents or intellectual property rights will be sought on these data.[124]

The Institute promised to provide the Government of Vanuatu with a complete list of microbial species: 'The results of this research in your waters will be useful as a baseline of information for local scientists as they design additional research to further understand marine ecology and for monitoring marine ecosystem health and

117 Ibid.
118 Ibid.
119 Ibid.
120 Ibid.
121 Ibid.
122 J Craig Venter Institute and the Government of New Caledonia, *Convention Pour La Mise En Oeuvre De La Campagne De Recherche 'Etude de la Biodiversite Micorbienne dans le Pacifique Sud' Menee Par l' Institute For Biological Energy Alternatives* (2004) <http://www.sorcerer2expedition.org/permits/New_Caledonia_project_agreement.pdf> at 1 August 2009.
123 J Craig Venter Institute and the Government of Vanuatu, *Code of Ethics Agreement for Foreign Researchers Undertaking Researches within the Flora and Fauna of Vanuatu* (16 April 2004), <http://www.sorcerer2expedition.org/permits/Vanuatu_MOU.pdf> at 1 August 2009.
124 Ibid.

change'.[125] The Institute also entered into an agreement with the Republic of the Seychelles when it ventured from the Pacific Ocean to the Indian Ocean,[126] and Tanzania.[127]

Venter has scoffed at such accusations of biopiracy.[128] Disavowing the premise of the *CBD*, he questioned whether any country could lay claim to national sovereignty over maritime genetic resources:

> The biopiracy one is my favorite. We're sailing across the open ocean in international waters and there's this current moving across the Pacific at 1 knot. So there are microbes in that current that move from open ocean into the 200-mile limit of French Polynesia, and suddenly the French call that French genetic heritage. Right? And they want to own it and capitalize on it. It takes months of paperwork to take 200 liters of seawater now from the open ocean. Before we published our paper nobody cared, because nobody assumed anything was there. So I think it's quite comical that we're called pirates for describing the data and making it available for the world.[129]

Venter expresses the opinion that genetic resources should be viewed as common heritage, and available for anyone to research or exploit in the public domain. He seems sceptical of the international norm that genetic resources are subject to state sovereignty.

IV MASTER AND COMMANDER: THE AUSTRALIAN SCHEME FOR ACCESS TO GENETIC RESOURCES

The *Sorcerer II* Expedition made a dramatic entrance into Australia. In a startling photo opportunity, Venter steered his research yacht under the Sydney Harbour Bridge in his quest to collect microbes from the world's waters.[130] The Commonwealth of Australia entered into a Biological Resources Agreement with the Institute in November 2004. The parties to the agreement express their commitment to the *CBD* as a backdrop to providing the expedition with access to Australia's biological resources for a genomic survey that will eventually result in a

125 Ibid.

126 J Craig Venter Institute and the Ministry of the Environment and Natural Resources, the Republic of the Seychelles, 'Agreement for Non-Commercial Material Transfer and Carrying Out Research in the Seychelles', (18 August 2005), <http://www.sorcerer2expedition.org/permits/Seychelles_MTA.pdf> at 1 August 2009.

127 J Craig Venter Institute and 'Material Transfer and Carrying Out Research in Zanzibar', (2005), < http://www.sorcerer2expedition.org/permits/Tanzania_MOU.pdf> at 1 August 2009.

128 A number of US academics have expressed scepticism towards the concept of 'biopiracy'. See, for instance: Jim Chen, 'There's No Such Thing as Biopiracy ... And It's a Good Thing Too' (2006) 37 *McGeorge Law Review* 1-35; and Cynthia Ho, 'Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies' (2006) 39 *University of Michigan Journal of Law Reform* 433-542.

129 Bruce Stutz, 'Voyage of the Sorcerer' (2006) 28 (2) *Onearth* 8.

130 Deborah Smith, 'Sailor Scientist Has Designs on Harbour's Germs', *The Sydney Morning Herald* (Sydney) 4 November 2004.

'freely-shared global environmental genomics database that can be used by scientists around the world for any purpose'.[131] For the purpose of establishing the database, the research is non-commercial in so far as the Institute agreed not to patent the raw microbes it collects and sequences. However, the parties agreed that there may be other opportunities for commercialisation. As respected science journalist Leigh Dayton observes, the Commonwealth's agreement with Venter may 'put Australia at the forefront of worldwide scientific and legal efforts to harness – safely and fairly – the genetic and biological potential of the planet's organisms, from micro-organisms to towering trees'.[132] The Biological Resources Agreement between the Commonwealth of Australia and the Institute foreshadowed the development of the federal access to genetic resources scheme, and the *Biodiscovery Act 2004* (Qld).

A *The Environment Protection and Biodiversity Conservation Act 1999* (Cth)

The Australian Federal Government has been slow to implement its obligations under the *CBD* with respect to access to genetic resources.

In 2000, John Voumard released the results of his public inquiry into access to biological resources in Commonwealth areas.[133]

In 2001, the House of Representatives of the Australian Parliament emphasised the need to develop clear guidelines on access to genetic resources in order to encourage investment in biotechnology and bioprospecting in Australia. The Bailey Federal Parliamentary Report emphasises the economic benefits that could arise from natural drug discovery:

> The wide range of applications to which biotechnology can be put offers a great wealth of benefits which Australia must capture fully before others do so. Were Australia to fail in this respect, it would not only deny itself access to the increasing revenues that can be expected from bioprospecting and bioprocessing, but also to improvements to individual health and welfare and to the environment.[134]

To achieve certainty for all stakeholders, a transparent and accountable regime should be established. There is a need for legislation; disclosure of all criteria

131 Department of the Environment and Heritage, *Biological Resources Agreement Between the Commonwealth of Australia and the J Craig Venter Institute*, (4 November 2004), <http://www.environment.gov.au/biodiversity/publications/access/braa.html> and <http://www.sorcerer2expedition.org/permits/Australia_MOU.pdf>, at 1 August 2009.

132 Leigh Dayton, 'Sharing Profits of Research', *The Australian*, 4 November 2004.

133 John Voumard, *Commonwealth Public Inquiry Into Access To Biological Resources In Commonwealth Areas*, (Canberra: Environment Australia, 2000), <http://www.ea.gov.au/biodiversity/science/access/inquiry/index.html> at 1 August 2009.

134 House of Representatives Standing Committee on Primary Industries and Regional Services, *Bioprospecting: Discoveries For The Future*, (Canberra: Australian Parliament, September 2001), <http://www.aph.gov.au/house/committee/primind/bioinq/report/contents.htm>, at 1 August 2009.

against which access is granted; an integration of decision making into administrative review systems; and the public availability of information about the grant of access permits and benefit-sharing agreements.

In 2002, a Ministerial Council – an inter-governmental administrative body – agreed to the non-binding *Nationally Consistent Approach for Access to and* 1 *Utilisation of Australia's Native Genetic and Biochemical Resources.*

In 2005, the Commonwealth Department of the Environment released regulations dealing with access to genetic resources under *Environment Protection and Biodiversity Conservation Act* 1999 (Cth) (*EPBC Act*).[135] Under the scheme, a party seeking access to biological resources in commonwealth areas must apply for an access permit to be issued by the minister. The Commonwealth Department of the Environment's role is to assess the application, in consultation with the commonwealth agency or landowner, and make a recommendation to the minister whether the access permit should be granted or refused. While the assessment process is underway the applicant is required to negotiate a benefit-sharing contract covering commercial and other aspects of the agreement with the provider of the biological resources.

Taking its cue from the *EPBC Act*, reg 8A.01 of the *Environment Protection and Biodiversity Conservation Amendment Regulations (No 2) 2005* (Cth) (*EPBC Regulations*) lists the seven objectives of the scheme for the control of access to biological resources in commonwealth areas. First, the Regulations are designed to promote 'the conservation of biological resources in those commonwealth areas, including the ecologically sustainable use of those biological resources'.[136] Second, the scheme is intended to ensure 'the equitable sharing of the benefits arising from the use of biological resources in those Commonwealth areas'.[137] Third, the regime is intended to recognise 'the special knowledge held by indigenous persons about biological resources'. [138] Fourth, the *EPBC Regulations* are designed to establish 'an access regime designed to provide certainty, and minimise administrative cost, for people seeking access to biological resources'.[139] Fifth, the scheme is meant 'to ensure that the social, economic and environmental benefits arising from the use of biological resources in those Commonwealth areas accrue to Australia'. [140] Sixth, the regime is designed to contribute to 'a nationally consistent approach to access to Australia's biological resources'.[141]

The *EPBC Regulations* define 'access to biological resources' as meaning 'the taking of biological resources of native species for research and development on any genetic resources, or biochemical compounds, comprising or contained in the

135 *Environment Protection and Biodiversity Conservation Amendment Regulations (No 2) 2005* (Cth) (*EPBC Regulations*).
136 *EPBC Regulations* reg 8A.01(a).
137 *EPBC Regulations* reg 8A.01(b).
138 *EPBC Regulations* reg 8A.01(c).
139 *EPBC Regulations* reg 8A.01(d).
140 *EPBC Regulations* reg 8A.01(e).
141 *EPBC Regulations* reg 8A.01(f).

biological resources'.[142] As illustrative examples, the Regulations mention 'collecting living material or analysing and sampling stored material, for various purposes including taxonomic research, other research and potential commercial product development'.[143]

EPBC Regulations reg 8A.04(1) identifies the access provider for each class of Commonwealth area and includes any native title holder for any area. The access provider is the party with whom an applicant must enter into a benefit-sharing agreement.[144]

Regulation 8A.06 establishes that a permit is required for lawful access to biological resources in a commonwealth area and provides a penalty for accessing biological resources without a permit. Failure to obtain a permit would result in a penalty of 50 penalty units.

The *EPBC Regulations* create a two-tiered scheme with separate requirements for commercial activities, and purely scientific work. A party who is seeking access to genetic resources in commonwealth areas, and who intends to use the resources in commercial research, is required to do two things. Firstly, they must apply to the Department of the Environment for an access permit and pay the appropriate application fee. The application must include information about the biological resources to which the person seeks access; the location and the amount of biological resources that will be collected; the uses that the applicant intends to make of the biological resources; and the nature and extent of environmental impact. Secondly, a party seeking access to biological resources for use in commercial research is also required to enter into a benefit-sharing agreement with the relevant access provider. Regulation 8A.07 provides that 'an applicant for a permit for access to biological resources for commercial purposes or potential commercial purposes in a Commonwealth area to which this Part applies must enter into a benefit-sharing agreement with each access provider for the resources'.

Regulation 8A.12(1) deals with access to biological resources for non-commercial purposes. The provision provides that 'an applicant for a permit for access to biological resources for non-commercial purposes in a Commonwealth area to which this Part applies must obtain the written permission of each access provider for the resources to: (a) enter the Commonwealth area; and (b) take samples from the biological resources of the area; and (c) remove samples from the area'.[145]

Regulation 8A.15 provides that the Minister may consult with any commonwealth department, any commonwealth agency or any other person in relation to

142 *EPBC Regulations* reg 8A.03.

143 *EPBC Regulations* reg 8A.03.

144 Regulation 8A.02(3)(a) makes it clear that the taking of biological resources by Indigenous people for a purpose not specified in reg 8A.02(1) is not 'access to biological resources'. This addresses concerns that allowing access to biological resources might limit Indigenous people's existing uses of those resources.

145 *EPBC Regulations*.

application for a permit. If the application is for access to biological resources for commercial purposes, the Minister 'must take into account the extent to which the requirements of regulation 8A.08 have been met by the benefit-sharing agreement'; and 'must consider whether all the other requirements of Division 8A.2 have been met.'[146] The minister must take into account other considerations in relation to purely scientific research: 'If the application is for access to biological resources for non-commercial purposes, the Minister must consider whether the requirements of Division 8A.3 have been met'.[147]

In some respects, this division between research and commercial purposes is an artificial one. As Henrietta Fourmile comments: 'A number of submissions noted the need to distinguish between access to biological resources for "pure research" (or "academic research") purposes as distinct from research which has a commercial purpose in mind. In reality, however, the boundaries between the two are often blurred'.[148] The courts could struggle to make such fine distinctions.[149] It could be difficult to disentangle research from commerce in the field of bioprospecting, since public institutions undertake collection of genetic resources on behalf of commercial biotechnology companies and pharmaceutical drugs manufacturers.

The principle of benefit sharing involves the access to genetic resources and related knowledge in return for information, technology, and participation in research. Benefit-sharing can include both monetary and non-monetary benefits. Thus it can extend to an equitable share of the money, which flows from the commercialisation of research based on the access to genetic resources.

The Kew Botanic Gardens Statement provides an indication of some non-commercial forms of benefit-sharing - such as the sharing of the research outcomes and knowledge, technology transfer, education and training.[150]

The remedies available for a breach of the access to genetic resources scheme are capped because of the reliance upon regulations, rather than legislation. Brad Sherman comments that the access to genetic resources scheme does not deal with the situation where biological material is passed to a third party in breach of contract, or where the biological material is obtained through biopiracy and then

146 Ibid.

147 Ibid.

148 Henrietta Fourmile, 'Indigenous Interests in Biological Resources in Commonwealth Areas' in John Voumard, *Commonwealth Public Inquiry Into Access To Biological Resources In Commonwealth Areas*, (2000) 234, <http://www.ea.gov.au/biodiversity/science/access/inquiry/index.html> at 1 August 2009.

149 Witness, for instance, judicial interpretation in the field of patent law. In the case of *Madey* v *Duke University* 307 F.3d 1351 (2002), the US Court of Appeals for the Federal Circuit found that the educational institution Duke University could not rely upon the research exemption because the projects 'further the institution's business objectives, including educating and enlightening students and faculty'.

150 Kew Royal Botanic Gardens, *Principles on Access to Genetic Resources and Benefit-Sharing for Participating Institutions*, Royal Botanic Gardens, Kew, London, 2001. <http://www.rbgkew.org.uk/conservation/principles.html> at 1 August 2009.

sold to a third party. He comments:

> While these commercial practices may provide some protection against the misuse of genetic resources, they are not infallible. In part this is because while some companies may look at the origin of genetic material when they are undertaking their due diligence inquiries, it is not yet universal practice. These potential problems are exacerbated by the fact that it is possible to imagine the situation where a company makes a calculated decision to collect biological samples without an access permit. While the fine of AUD$5500 and the adverse publicity may provide some disincentive against this happening, a company may decide that is outweighed by the legal costs and by the moneys that they would have to pay under a benefit sharing agreement with the access provider.[151]

However, the Department of the Environment and Water is unable to impose greater penalties against individuals or companies who would flout this regime. Notably, the paltry maximum fine of AUD$5500 is unable to be raised any higher without legislative amendment.

The regime represents a bold attempt to satisfy Australia's obligations under the *CBD*. However, the legislation does have a number of important limitations. First, the regime draws a false distinction between research and commerce in the field of natural drug discovery. Second, there is a danger that the requirement for informed consent might be diluted through the use of ministerial discretion. Third, the available remedies in respect of breaches of the permit system are paltry. Fourth, the federal scheme for access to genetic resources has been designed without proper consideration of its interaction with intellectual property regimes. Charles Lawson complains of 'the divorce between the perceived immediate needs of investment in biological resource-based product research and development ahead of other policy imperatives such as the longer term goals and benefits of biological diversity conservation'.[152] Fifth, the federal regime pays inadequate attention to the traditional knowledge of native title holders.[153] Finally, there is a potential for conflict between the federal regulations and state schemes - such as that set up by the Queensland Government under the *Biodiscovery Act 2004* (Qld).

B *Biodiscovery Act 2004* (Qld)

151 Brad Sherman, 'Regulating Access And Use Of Genetic Resources: Intellectual Property Law And Biodiscovery' (2003) 25 (7) *European Intellectual Property Review* 301-308.

152 Charles Lawson, 'Regulating Access to Biological Resources: The Market Failure for Biodiversity Conservation', in Matthew Rimmer (ed), *Patent Law and Biological Inventions* (2006) 24 (1) *Law in Context* 137-163, 153; see also Charles Lawson and Catherine Pickering, 'Successfully Controlling Access Under the *Environment Protection and Biodiversity Conservation Act* 1999 And Its Regulations Requires A Proper Assessment Of The Impact Of The *Patents Act* 1990' (2002) 13 (3) *Australian Intellectual Property Journal* 109-120.

153 Matthew Rimmer, 'Blame It On Rio: Biodiscovery, Native Title, And Traditional Knowledge' (2003) 7 *The Southern Cross University Law Review* 1-49.

Speaking of the *Biodiscovery Act 2004* (Qld), which came into force during his visit to the State, Venter said: 'It sounds very reasonable.'[154]The Queensland Government has been at the vanguard of policy development in relation to access to genetic resources, because of the high concentration of biodiscovery research organisations, co-operative research centres and companies within the State.[155] Queensland Premier Peter Beattie first announced the enactment of a *Biodiscovery Act 2004* (Qld) at BIO2003, a US conference on biotechnology. The Premier stressed the commercial benefits of bioprospecting for his State:

> My Government's 'Smart State' fixation is simple. It means we have a planned multi-faceted strategy designed to make Queensland nothing less than the intellectual hub of the Asia-Pacific. Queensland has a competitive edge by enhancing the traditional with the technological. The Smart State initiative has contributed significantly to the repositioning of Queensland as a major player. Queensland's biodiversity gives us a unique position in the world. Australia is one of only 12 'mega' bio-diverse countries in the world, and the only one with a developed economy and world-class scientific infrastructure. In Queensland, we have five of Australia's world heritage-listed sites; 17 of Australia's marine bioregions; and 19 of Australia's terrestrial bioregions. [156]

The Premier emphasised that bioprospecting would not harm the environment: 'Biodiscovery is not a traditional extractive industry like logging - in most cases it's about taking a branch or leaf sample, so it's very environmentally sustainable'.[157] Beattie explained the rationale for the legislation: 'The Queensland Government is developing a framework to allow access to the State's native biological resources for research and commercialisation, because we believe it's a real future growth area for Australia'.[158]

Section 3(1) of the *Biodiscovery Act 2004* (Qld) enumerates the four main purposes of the legislation. First, the instrument seeks 'to facilitate access by biodiscovery entities to minimal quantities of native biological resources on or in State land or Queensland waters … for biodiscovery'.[159] Second, the legislation hopes 'to encourage the development, in the State, of value added biodiscovery'.[160] Third, the Act aspires 'to ensure the State, for the benefit of all persons in the State, obtains a fair and equitable share in the benefits of biodiscovery'.[161] Finally, the legislation aims 'to ensure biodiscovery enhances knowledge of the State's biological diversity, promoting conservation and sustainable use of native biological

154 Leigh Dayton, 'Sharing Profits of Research', *The Australian*, 4 November 2004.
155 Queensland Government, *Queensland Biodiscovery Policy: Discussion Policy*, May 2002.
156 Peter Beattie, 'Beattie's Trade Goals for Queensland', *Business Asia*, February 2003, <http://findarticles.com/p/articles/mi_m0BJT/is_1_11/ai_98593069> at 1 August 2009.
157 Ibid.
158 Ibid.
159 *Biodiscovery Act* 2004 (Qld) s 3(1)(a).
160 *Biodiscovery Act* 2004 (Qld) s 3(1)(b).
161 *Biodiscovery Act* 2004 (Qld) s 3(1)(c).

resources'.[162] The legislation was intended to help fulfil Australia's obligations under the *CBD* to promote the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the use of genetic resources.[163]

The *Biodiscovery Act 2004* (Qld) establishes a single regime authorising collection of native biological resources and makes it mandatory for commercial entities to enter into benefit sharing agreements with the State Government. The Minister for the Department of State Development of Industry may enter into a benefit-sharing agreement with a biodiscovery entity.[164] In return for the State authorising the entity to use native biological material, the entity must in turn agree to provide benefits of biodiscovery to the State. The Schedule of the *Biodiscovery Act 2004* (Qld) defines the 'benefits of biodiscovery' as meaning 'any economic, environmental or social benefits for the State'. Particular emphasis is placed upon investment in state-based biotechnology industries, state-based entities and research and development infrastructure in the State. Reference is also made to other industrial activities, such as technology transfer to State-based entities, the creation of employment in the State, the formation of collaborative agreements with state-based entities, the conduct of biodiscovery research involving field and clinical trials in the State, the undertaking of commercial production, processing or manufacturing of native biological material in the State; and the creation of alternative crops or industries in the State. The Schedule of the *Biodiscovery Act 2004* (Qld) makes clear that the legislation has an industry bias. The objective of promoting investment in state biotechnology is the primary aim of the legislation. By contrast, the conservation of environmental biodiversity, the encouragement of scientific research, and the protection of traditional knowledge[165] are relegated to merely secondary goals.[166]

The *Biodiscovery Act 2004* (Qld) has a much wider range of offences and penalties than its federal counterpart. A person who takes native biological material for biodiscovery without authorisation faces a maximum penalty of 2000 penalty units.[167] Those who take endangered, rare or vulnerable wildlife, or protected animals, within the meaning of the *Nature Conservation Act 1992* (Qld) face penalties of up to 3000 penalty units or two years imprisonment.[168] An applicant who provides false or misleading documents or information to the collective authority can be fined 100 penalty units, as can a person who contravenes a

162 *Biodiscovery Act* 2004 (Qld) s 3(1)(d).
163 *Biodiscovery Act* 2004 (Qld) s 4.
164 *Biodiscovery Act* 2004 (Qld) s 33.
165 There was a great deal of dissatisfaction with the Biodiscovery Policy among Indigenous groups. In particular, there was concern that the legislation did not adequately deal with difficult questions about the interaction between contract law, native title and intellectual property rights. Instead the Queensland Government wanted to deal with such issues under the *Code of Ethical Practice for Biotechnology in Queensland*.
166 Gerald Tooth, 'Bioprospecting In Queensland: Oceans of Opportunity, Forests of Concern', Background Briefing, ABC Radio National, (27 May 2001)
167 *Biodiscovery Act* 2004 (Qld) s 50.
168 Ibid.

condition of the authority, or a condition of a benefit-sharing agreement.[169] The use of native biological material for biodiscovery without a benefit-sharing agreement incurs a maximum penalty of either 5000 penalty units or the full commercial value of any commercialisation of the material, whichever is greater.[170] However, such penalties do not apply to a person who uses the material for scientific classification, the verification of research results, or educational instruction. There are also some minor offences relating to claims by persons about holding a collection authority, and the provision of information for immediate inspection.[171]

The other States and Territories have been slow to follow the lead of Queensland. As of 2007, only the Northern Territory had implemented a legislative regime, with the *Biological Resources Act 2006* (NT).[172] South Australia is currently preparing legislation, and Western Australia has announced its intention to draft legislation. The various federal, state, and territory schemes lack any uniformity or harmonisation. In a submission to the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, the Australian Government candidly testifies: 'Countries with federal structures of government such as Australia face very specific challenges when introducing national access laws'.[173] The lack of a common approach to the regulation of access to genetic resources may well generate problems in Australia.

C *Biological Resources Agreement*

It is worth undertaking an analysis of the Biological Resources Agreement between the Commonwealth of Australia and the Institute to assess the obligations and outcomes for each party.[174] A considered analysis of the Agreement will be undertaken to explore if it is a model for other benefit-sharing and informed consent agreements as against a comparative analysis of agreements signed with other countries, research institutes and government bodies.

The parties entered into the Agreement on 4 November 2004.[175] The Agreement is a fine piece of work: it offers a clear articulation of the aims and objectives of the respective parties; provides careful regulation of the conduct of the *Sorcerer II* Expedition; and offers a blueprint for the subsequent federal regulations promulgated under the *EPBC Act*.

169 *Biodiscovery Act* 2004 (Qld) ss 51, 52, 53, 55, 56, 57 and 58.
170 *Biodiscovery Act* 2004 (Qld) s 54.
171 *Biodiscovery Act* 2004 (Qld) ss 59 and 60.
172 *Biological Resources Act 2006* (NT).
173 Government of Australia, *Expert Workshop on Access to Genetic Resources and Benefit-Sharing*, 14 UNEP/CBD/WG-ABS/3/INF/1/Add, 25 January 2005.
174 Department of the Environment and Heritage, *Biological Resources Agreement Between the Commonwealth of Australia and the J Craig Venter Institute* (4 November 2004), <http://www.environment.gov.au/biodiversity/publications/access/braa.html> and <http://www.sorcerer2expedition.org/permits/Australia_MOU.pdf> at 1 August 2009.
175 Ibid.

The recitals note that 'Australia possesses megabiodiversity within its jurisdiction, and seeks to facilitate access to biological resources for research and development activities'.[176] In particular, it acknowledges that Australia has embraced the *CBD*, and the *Bonn Guidelines*. The recitals observe of the *Sorcerer II* Expedition:

> The Collaborator is undertaking a global sampling expedition to survey micro-organisms that live in the oceans, and in some places soils, to better understand overall species diversity, discover and characterize new bacterial and viral species, evaluate the ecological roles that dominant (but generally unculturable) microbes play in the ecosystem, and establish a freely shared, global environmental genomics database that can be used by scientists around the world for any purpose.[177]

The recitals conclude: 'Wishing to become a contributor to the multi-national genomics database and obtain the benefits of access to genomics data from Australia as well as other nations around the world, Australia has agreed to the Collaborator having access to biological resources from Australia's jurisdiction and this agreement sets out the terms that the parties agree are to apply to the taking and use of the biological resources by the Collaborator'.[178]

The Agreement has some very ingenious provisions dealing with the use of the materials and results. Under clause 4.1, 'the Collaborator must only use the Materials and Results: (a) for the Approved Research; (b) in accordance with the Access Proposal (including working and collaborating with Australian scientists), and must not make Derivatives from the Materials'.[179] Under clause 4.4, 'the Collaborator must not, without the prior written permission of Australia: (a) sell, loan, or otherwise provide the Materials or the Results to any third party; (b) use the Materials or the Results for any purpose other than the Approved Research; or (c) use or store the Materials in any location other than in the laboratory of the Lead Investigator and under his or her direct supervision'.[180] This clause ensures that third parties cannot engage in conduct outside the purview of the agreement. Under clause 4.6, 'the Collaborator warrants that the Approved Research is non-commercial and that the Collaborator, and to the best of the Collaborator's knowledge no associated entity of the Collaborator, or any entity that carries on or proposes to carry on any business with Collaborator, holds any option, licence or other rights to the use or commercialisation of the Materials or the Results, or Intellectual Property arising from the Approved Research'.[181]

Under the cunning clause 4.7, 'the Collaborator must ensure that its use of the Materials complies with all relevant laws, codes of practice and ethical

176 Ibid.
177 Ibid.
178 Ibid.
179 Ibid.
180 Ibid.
181 Ibid.

principles'.[182] Under this broad clause, the *Sorcerer II* Expedition would have to comply with all laws, codes of practice, and ethical principles dealing with access to genetic resources. Thus, the Institute would have to undertake to abide by federal laws, such as the *Environment Protection and Biodiversity Conservation Act 1999* (Cth), the *Great Barrier Reef Marine Park Act 1975* (Cth), and the *Fisheries Management Act 1991* (Cth). Furthermore, the *Sorcerer II* Expedition would also have to abide by state laws, such as the *Biodiscovery Act 2004* (Qld), and accompanying ethical codes of conduct.

The Agreement has extensive provisions relating to the ownership of the materials and intellectual property rights. Under clause 5.1, 'all property rights in and in relation to the Materials and the Results, including Intellectual Property arising (directly or indirectly) from the Collaborator's use of the Materials or the Results vests, or will vest, in Australia'.[183] Furthermore, under clause 5.2, 'all Intellectual Property rights arising from use of the Materials, the Results or any Derivative other than for the Approved Research, or from any other breach of this agreement by the Recipient, will vest in Australia'.[184] Under clause 5.3, 'Australia grants the Collaborator a non-exclusive licence to use the Materials and the Results for the purpose of the Approved Research, and in particular to publish data'.[185] Under clause 5.4, 'Nothing in this agreement, or the use of the Materials by the Collaborator, will give the Collaborator any property rights in and in relation to the Materials or the Results, including Intellectual Property arising (directly or indirectly) from the Collaborator's use of the Materials'.[186] Under clause 5.6, 'If the Collaborator wishes to commercialise or have commercialised any Results or Intellectual Property arising from its use of the Materials, including intellectual property protection, it must first enter into an appropriate agreement with Australia with the understanding that Australia agrees to negotiate non-exclusively in good faith with a view to concluding such an agreement on terms acceptable to the parties'.[187] Under clause 5.7, 'The Collaborator will use reasonable effort to notify Australia as soon as possible of any inquiries for commercial purposes received from a third party regarding rights in, or use, copying, or distribution of Results published or publicly disclosed in accordance with this Agreement'.[188] The clauses serve to ensure that the *Sorcerer II* Expedition cannot seek to exploit the research or any derivative products without the prior approval of Australia.

The Agreement also has comprehensive provisions on publications and reporting. Under clause 6.1, 'the Collaborator must not publish or publicly disclose details of the Materials or the Results without the prior written approval of Australia'.[189] Under clause 6.2, 'The Collaborator will publish or publicly disclose genomic sequence data, including a limited and reasonable description, of the Materials

182 Ibid.
183 Ibid.
184 Ibid.
185 Ibid.
186 Ibid.
187 Ibid.
188 Ibid.
189 Ibid.

consistent with generally accepted database curation standards in accordance with the Publication Requirements specified in the Schedule'.[190] Under clause 6.3, 'the Collaborator may at the time of publication or public disclosure under clause 6.2 publish an article relating to the Approved Research in an appropriate magazine or journal or other publication'.[191] Clause 6.4 provides for attribution of the geographical origin of the source of the material, 'the Collaborator agrees to acknowledge, Australia as the source country and that the Materials were obtained in accordance the laws and requirements of Australia, the role of Australian scientists, in any publication arising out of the Collaborator's use of the Materials and, where any significant advice or recommendations have been provided by an Australian scientist, the Collaborator agrees to acknowledge the authorship of that person'.[192] Further clauses provide that the Institute is to keep the Australian Government informed of the progress of the research of the *Sorcerer II* Expedition. Such provisions allay whatever concerns there might be that the *Sorcerer II* Expedition might seek to maintain proprietary copyright ownership of the environmental genomics database.

There are further provisions dealing with the commercial exploitation of the materials and published data. Clause 9.1 reinforces the sovereignty of Australia over its genetic resources, acknowledging that 'Nothing in this Agreement prevents Australia from exploiting the Materials, the Results or any other modifications or Derivatives, distributing the Materials, or any other modification or derivatives to any third party, including both profit and non-profit organisations'.[193] Clause 9.2 stresses that 'nothing in this Agreement is intended to prevent any person or entity (including Australia and the Collaborator) freely using all data published or made publicly available under clauses 6.2 and 6.3 for any purpose, including for research and development'.[194] Finally, Clause 9.3 stresses that 'any use of such data for commercial purposes will be subject to Australia's rights under clauses 5.1 and 5.2 of this Agreement'.[195]

The Department of the Environment and Heritage hailed the Agreement as a significant achievement in its 2004-2005 annual report.[196] The Agreement is far superior to the preceding memoranda of understanding that were established between the Institute and other jurisdictions. The *Sorcerer II* Expedition has been working with teams of researchers from Australian universities and research institutions. The Institute worked with Professor Tony Haymet at CSIRO Marine Research, Ian Poiner at the Australian Institute of Marine Research, John Mattick at the University of Queensland, Staffan Kjelleberg from the Center of Marine

190 Ibid.
191 Ibid.
192 Ibid.
193 Ibid.
194 Ibid.
195 Ibid.
196 Department of the Environment and Heritage. *Annual Report* 2004-05 (2005), <http://www.deh.gov.au/about/publications/annual-report/04-05/outcome-1-biodiversity.html> at 1 August 2009.

Biofouling and Bio-Innovation at the University of New South Wales and researchers from the University of Melbourne. The *Sorcerer II* scientists also hope to work with local researchers in Western Australia.

A number of research agreements were also entered into between the Institute and Australian research bodies. The Australian Institute of Marine Science (AIMS)[197] held talks with Venter about establishing a research collaboration focused on Queensland's marine estate.[198] Marine Biotechnology Group leader Dr Chris Battershill observed:

> Learning more about the dominant players in the marine community, what they are, and what they do is a very exciting prospect. We're particularly interested in the marine bacteria and micro-organisms of the Great Barrier Reef and figuring out the role newly discovered genes play in making the reef ecosystem function.[199]

Dr Battershill said AIMS was well placed to contribute to Venter's global program, and probe the planktonic realm of the Great Barrier Reef in the long term to determine what drives its health.

The now renamed Department of the Environment, Water, Heritage and the Arts has since established model access and benefit-sharing agreements,[200] and a register of permits.[201] There is an independent review of the federal access to genetic resources scheme underway in 2009.[202]

CONCLUSION

Venter has been proud of the scientific achievements of the *Sorcerer II* Expedition, proclaiming:

> In a trio of papers published in 2007 in the journal [*The Public Library of*

197 The Australian Institute of Marine Science has been a pioneer in developing benefit-sharing agreements dealing with access to genetic resources: <http://www.aims.gov.au/> at 1 August 2009.

198 The Australian Institute of Marine Science, 'Global Ocean Gene Catalogue to Offer Insight into Great Barrier Reef', Australian Associated Press Media Net (Press Release, 10 November 2004).

199 Ibid.

200 Department of the Environment, Water, Heritage, and the Arts, *Model Access and Benefit-Sharing Agreements*, <http://www.environment.gov.au/biodiversity/science/access/model-agreements/index.html> at 1 August 2009.

201 Department of the Environment, Water, Heritage, and the Arts, *Permits – Accessing Biological Resources in Commonwealth Areas*, <http://www.environment.gov.au/biodiversity/science/access/permits/index.html> at 1 August 2009.

202 Allan Hawke, Tim Bonyhady, Mark Burgman, Paul Stein and Rosemary Warnock, *Independent Review of the Environment Protection and Biodiversity Conservation Act 1999: Interim Report*, (Canberra: the Department of the Environment, Water, Heritage and the Arts, 2009) <http://www.environment.gov.au/epbc/review/publications/pubs/interim-report.pdf> at 1 August 2009.

> *Science Biology*], my team, led by Doug Rusch, described four hundred newly discovered microbes and 6 million new genes, doubling the number then known to science. The biggest impact of the expedition has been on established ideas about the tree of life. It used to be thought that the light-detecting protein pigment in our own eyes was relatively rare. But our gene trawl revealed that all surface marine organisms make proteorhodopsins that detect colored light.[203]

Venter suggests that the *Sorcerer II* Expedition provided new insights into climate change, noting: 'Bacterial viruses – phages – may actually be responsible for keeping microbe levels low in some seas'.[204] He notes: 'If we can understand this relationship better, and learn how to inhibit the viruses, or make the bacteria resistant to phage attack, a lot more organisms could be capturing carbon dioxide and damping down climate change'.[205]

However, the *Sorcerer II* Expedition has resented having to deal with questions of access to genetic resources under the *CBD*. Venter remarked at a public lecture at the University of Cape Town, 'If Darwin were alive today, he would not have been able to have done his research'.[206] He was bemused that the *Sorcerer II* Expedition was criticised for engaging in 'biopiracy', in spite of its policy of putting its data in the public domain, and refraining from seeking intellectual property rights in respect of the research:

> The irony is I got falsely accused of not putting the human genome in the public domain, and now we're accused of putting information in the public domain against the wishes of various governments, he says. When people think someone else owns (information), they are all for public release. When they think they own it, they have a very different view. [207]

With a touch of self-pity, Venter lamented: 'My greatest success is that I managed to get hated by both worlds'.[208] He was puzzled by the criticism that he had received: 'I'm getting attacked for putting data in the public domain'.[209]

However, the large-scale bioprospecting project of the *Sorcerer II* Expedition highlighted the need for better global, national, and local regulation of access to genetic resources. There is a need for a global bio-collecting society to help

203 J Craig Venter, *A Life Decoded: My Genome, My Life* (2007), 345-346.
204 Ibid, 347.
205 Ibid, 347.
206 J Craig Venter, 'A History of Genomics: From Human to the Environment', Vice-Chancellor's Open Lecture, University of Cape Town, November 2005<www.venterinstitute.com> at 1 August 2009.
207 Tamar Kahn, 'Maverick Biologist Follows in the Footsteps of Darwin', *Business Day*, South Africa, 14 November 2005, 4.
208 James Shreeve, 'Craig Venter's Epic Voyage to Redefine the Origin of Species', (2004) 12 (8) *Wired Magazine* 107-113, 146-151.
209 Ibid.

regulate access to genetic resources under the *CBD*.[210] At the time of the *Sorcerer II* Expedition, many States had not yet implemented the *CBD*. Bermuda, for instance, had no scheme for access to genetic resources. South Pacific countries had not implemented a regime for benefit-sharing. Ecuador did have a biodiscovery regime; but it is questionable whether its processes were followed. In Australia, the *Biodiscovery Act 2004* (Qld) had barely been implemented; and the Biological Resources Agreement was negotiated prior to the establishment of the federal access to genetic resources scheme. Furthermore, many of the memoranda of understanding entered into the Institute were lacking. Some benefit-sharing agreements seemed to be entered into with research institutions, rather than the proper state authorities. The memoranda of understanding with countries in Latin America and the South Pacific were rather poorly drafted. The Biological Resources Agreement formed between the Commonwealth of Australia and the Institute was, by far, the most rigorous benefit-sharing agreement. The *Sorcerer II* Expedition reinforces the need for a stronger, harmonised national regime for access to genetic resources in Australia.[211]

In 2007 and 2008, the J Craig Venter Institute undertook a second expedition, focusing upon extreme environments: 'From surface waters to deep sea thermal vents, high saline ponds and polar ice, JCVI scientists continued to add to the microbial "earth catalogue" in 2007 and 2008'.[212] This research was conducted in a number sites, including the East and West Coasts of the United States; Alaska and the Glacier Bay National Park; Mexico and the Sea of Cortez; the Pacific; and Antarctic waters.

In March 2009, the J Craig Venter Institute announced the launch of a new, third *Sorcerer II* Expedition – the J Robert Beyster and Life Technologies 2009-2010 Research Voyage.[213] This two-year research project will focus upon sampling the microbial diversity in the Baltic, Mediterranean, and Black Seas. The route of the voyage will include stops in the US, Mexico, Panama, the United Kingdom, and Sweden. Venter has observed of this new endeavour:

> With the success of the initial *Sorcerer II* Expedition in which we have so far discovered approximately 20 million new genes and thousands of new protein families, we are excited to now sample in new environments on this journey to the Baltic, Black and Mediterranean. We are confident this voyage will yield important insights into the microbial universe there and will add to

210 Peter Drahos, 'Indigenous Knowledge, Intellectual Property And Biopiracy: Is A Global Bio-Collecting Society The Answer?' (2000) 22 (6) *European Intellectual Property Review* 245-250.

211 Hawke et al, above n 202.

212 The J Craig Venter Institute, 'Global Ocean Sampling Expedition, 2007-2008', <http://www.jcvi.org/cms/research/projects/gos/past-voyages/ at 1 August 2009>.

213 The J Craig Venter Institute, 'Venter Institute Launches the J Robert Beyster and Life Technologies 2009-2010 Research Voyage of the Sorcerer II Expedition', (Press Release, 19 March 2009).

> the growing catalogue of microbes and genes my team has been compiling through the *Sorcerer II* Expedition.[214]

It will be interesting to see whether the various affected countries in the Baltic, Mediterranean, and Black Seas will be able to better manage the issues related to access to genetic resources, intellectual property and data-sharing than their counterparts in the Americas, the Pacific, and Australasia.

In March 2005, the Institute launched the related Air Genome Project to better understand the diversity of microbes in urban air. Venter observed of the initiative:

> We are beginning to inventory and better understand the vast legion of unseen micro-organisms that live in our oceans and soil through our global sampling expedition and now we our extending this process of discovery to the air environment. Many bacteria and viruses in the air elicit destructive immune responses in some patients and we would like to explore these genes of interest to human health. We will identify airborne bacteria and viruses and sequence their genomes to better understand the diversity of life in the air we breathe.[215]

The Air Genome Project will seek to characterize the genomic spectrum of micro-organisms in the air, including the genes that control them. The Institute hopes that the data arising from the research will provide an insight into ecology and biodiversity, and of important stressors to human health.

Furthermore, the Institute has set up a new spin-off company, Synthetic Genomics, to explore the potential of synthetic biology.[216] In November 2002, Venter and Nobel Laureate Hamilton Smith received a US$3 million grant from the US Energy Department to create a new, 'minimalist' life form in the laboratory - a single-celled, partially human-made organism. The Institute has been hard at work in the field of synthetic biology:

> Fast becoming one of the hottest new fields of biology, synthetic biology has the potential to impact all areas of society. One of the tenets of chemistry states that to prove true understanding of a structure one must be able to synthesize it. The team at the Venter Institute is concentrating on new methodologies to synthesize large segments of DNA to eventually enable the construction of whole artificial chromosomes. This is the next logical step in

214 Ibid.

215 J Craig Venter Institute, 'Venter Institute Studies Microbes Living In Air: Air Genome Project to Sample Air Using Whole Genome Shotgun Sequencing', PR Newswire, (Press Release, 7 March 2005).

216 Synthetic Genomics, <http://www.syntheticgenomics.com/> at 1 August 2009; and Michael Rosenwald, 'J Craig Venter's Next Little Thing: The Man Who Mapped the Human Genome has a New Focus - Using Microbes to Create Alternative Fuels', *The Washington Post*, 27 February 2006.

> genome biology as it is the only way to better understand the minimal component of cellular life and understand the evolution of life. [217]

Such a research agenda has already caused consternation among anti-biotechnology groups. The ETC Group observed that 'Venter's work poses ethical and environmental concerns about the use of biodiversity to build new life forms from scratch'.[218] The organisation alleges that Venter will use the research to create new life forms: 'The extraordinary appeal of solving the world's energy problems by harnessing new, engineered life forms, tends to eclipse the very real concerns about potential negative consequences'.[219] The organisation suggested that 'Intellectual property claims on human-made life also pose concerns about *ordre public*'.[220]

The application of biodiscovery and synthetic biology to the development of clean technologies will raise a host of new legal, ethical, and political challenges for intellectual property law, environmental law, and climate law.

217 J Craig Venter Institute, the Synthetic Biology Group, <http://www.venterinstitute.org/research/> at 1 August 2009. For a discussion of intellectual property issues raised by synthetic biology, see Arti Rai and James Boyle, 'Synthetic Biology: Caught Between Property Rights, the Public Domain and the Commons' (2007) 5 (3) *The Public Library of Science Biology*389-393; and James Boyle, *The Public Domain: Enclosing the Commons of the Mind* (2008) 171-177.

218 ETC Group, above n 22.

219 Ibid.

220 Ibid.