14 Accessing Genetic Resources by Japanese Private Industry under the Convention on Biological Diversity Regime with Particular Reference to Australia

Invited Researcher: Kamal Puri(*)

The preservation, protection and sustainable use of genetic resources including traditional knowledge (TK), innovations and practices of indigenous peoples are of key significance to all humanity.

However, this valuable asset is at risk in many parts of the world. In order to protect the cultural and intellectual property rights of the holders of such rights, the CBD brought genetic resources formally under national sovereignty and invited member nations to act on the three objectives of conservation, sustainable use and fair and equitable sharing of the benefits arising from the use of genetic resources. Further, it made access to genetic resources subject to the prior informed consent (PIC) of the State.

Instead of perpetuating the rhetoric of PIC, mutually agreed terms, self-determination, active protection of cultural systems, and equitable benefit sharing, this paper confronts these perennial issues head on to examine the procedures, if any, which have been devised for gaining PIC. Further, the differences between the common law concept of free consent and the PIC and the interface between the CBD and the patent law are assessed.

Next, the developments in Australia, especially in Queensland, dealing with access to biological resources are considered to inform the Japanese private industry of practical ways to access biological resources in Queensland. By enacting the Biodiscovery Act 2004, the State of Queensland, which is the richest state in biological resources in Australia, has taken a lead role in enacting the principles and procedures for facilitating access to biological material in a responsible and systematic way.

1 Introduction

The preservation, protection and sustainable use of genetic resources including traditional knowledge, innovations and practices of indigenous peoples are of key significance to all people. The sustainable and responsible use of genetic resources plays a critical role in our health care, food security, culture, religion, identity, environment, sustainable development and trade.

However, this valuable asset is at serious risk in many parts of the world. It is frequently alleged that biological diversity and traditional knowledge are being abused and patented by commercial interest with scant regard to the long-term consequences and with few or none of the benefits being shared with the legitimate stakeholders. It is further alleged that either no agreements are entered into with the traditional owners or such agreements do not fulfil the Convention on Biological Diversity's (CBD) criteria of prior informed consent and sharing of benefits in a fair and equitable manner.

The CBD brought genetic resources formally under national sovereignty. Its three objectives are:

(i) conservation of biological diversity,
(ii) sustainable use of its components, and
(iii) fair and equitable sharing of the benefits arising from the use of genetic resources.

(*)Director, Intellectual Property Commercialisation Unit, Queensland Department of Primary Industries & Fisheries, Professor of Law, Queensland University of Technology, Brisbane, Australia

The Convention calls for member nations to act on these objectives. Further, it makes access to genetic resources subject to the prior informed consent of the State.

Is the prior informed consent of indigenous peoples and local communities a legal requirement for use of genetic resources and/or associated traditional knowledge? Putting the rhetoric of prior informed consent, mutually agreed terms, self-determination, active protection of cultural systems, and equitable benefit sharing on one side, the first part of this paper attempts to examine the procedures, if any, which have been devised for gaining prior informed consent. It also examines the differences between the common law concept of free consent and the CBD concept of prior informed consent. Further, it comments on the interface between the CBD and the patent law.

The second part of the paper covers, in inevitably descriptive manner, the developments in Australia, especially in Queensland, dealing with access to biological resources. By enacting the *Biodiscovery Act 2004*, the State of Queensland, which is the richest state in biological resources in Australia, has taken a lead role in laying down the principles and procedures for facilitating access to biological material in a responsible and systematic way. This part is primarily intended to inform the Japanese private industry of practical ways to conduct operations in Queensland in its quest for unique biological materials for scientific R&D and eventual commercial use for the benefit of Japanese people and the international community.

2 Key tenets of the Convention on Biological Diversity

The expression "biodiversity" means the variety of life. It was coined in 1986 and is a short form of, and synonymous with, "biological diversity." The *Convention on Biological Diversity*(*1) is about life on earth.(*2) The Convention entered into force on 29 December 1993.(*3)

Until the CBD came into effect, genetic resources were generally treated as the "common heritage of mankind" and their use for new products was largely undertaken with scant regard to the communities from where the materials were sourced. Major discoveries based on natural resources (often involving the use of indigenous traditional knowledge) resulted in no benefits flowing back to the country or community providing that material.

With the ratification of the CBD in 1993 came the end of the "common heritage of mankind" doctrine. The CBD affirmed member nations' sovereign rights over their natural biological resources, including genetic resources.(*4) In return for facilitating access to biological material, member nations are entitled to a fair and equitable share of the benefits that flow from the commercial exploitation of those resources. This is the third of the three objectives of the Convention, the other two being the conservation of biological resources and the sustainable use of biological resources. It is the third objective that has proved to be the most tricky to implement.(*5)

3 Bonn Guidelines

Although the CBD came into effect late in 1993, its provisions did not become operational until the adoption of the *Bonn Guidelines on Access to Genetic Resources and the fair and equitable sharing of benefits arising out of their utilization*.(*6) The *Bonn Guidelines* are a most important step to assist all parties to prepare access and benefit-sharing strategies, and to understand the steps involved in

(*1) The full text of the Convention is available at http://www.biodiv.org/convention/convention.shtml (hereinafter referred to as the "CBD").
(*2) Message of Dr Ahmed Djoghlaf, Executive Secretary of the CBD dated 3 January 2006 accessible from http://www.biodiv.org/doc/press/2006/pr-2006-01-2010-en.pdf.
(*3) The CBD opened for signature on 5 June 1992 at the UN Conference on Environment and Development (the Rio de Janeiro "Earth Summit").
(*4) See Article 3 of the CBD that relevantly states: "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 …." This principle is reinforced by Article 15.1 which provides: "Recognizing 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." See above Note 2.
(*5) Article 1 of the CBD states the objectives thus: "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources" – see above Note 2.
(*6) Available at http://www.biodiv.org/doc/publications/cbd-bonn-gdls-en.pdf.

gaining access to genetic resources and sharing benefits. However, as the title indicates, they are guidelines of voluntary nature. *Bonn Guidelines* therefore lack legal enforcement, although they do carry considerable weight, at least in the moral sense, because 180 countries unanimously adopted them.

One of the major contributions of the *Bonn Guidelines* is that they establish a clear framework for accessing genetic resources to ensure fair and equitable sharing of benefits. In particular, the Guidelines contain detailed and practical information relating to procedures for obtaining prior informed consent. Furthermore, the Guidelines make explicit reference to the need to obtain the prior informed consent of the holders of indigenous and local communities in accordance with their traditional practices, etc., in situations involving access to traditional knowledge associated with the relevant genetic resources.

4 Japan Bioindustry Association's Survey Report(*7)

In 2004, the Japan Bioindustry Association (JBA) conducted a comprehensive survey of 215 companies engaged in R&D and commercialisation work in the burgeoning field of biotechnology(*8) in order to determine in a precise manner how well they appreciated the influence of the CBD on Japanese businesses.

The survey clearly demonstrated the importance that the Japanese government and the JBA attach to Japan's adherence to the CBD.(*9) However, it also revealed an urgent need to raise awareness and educate private industry about the CBD so that access can be gained to genetic resources in an appropriate and expeditious manner.

One of the striking findings of the survey was that only 22% of Japanese companies had appreciation of the CBD and even a fewer (10%) had knowledge of *Bonn Guidelines*. Of the companies surveyed, about 30% had the experience of using foreign genetic resources. The types of genetic resources that had been used were: plants and materials derived from them (80%), microorganisms (47%), animals (27%), and others (2%).

The survey report also highlighted the reasons that had contributed to the failings of the CBD. Reasons included absence of reliable framework, lack of central administrative body, long delays, misconceptions among some holders of genetic material and associated traditional knowledge, the intrinsically slow and tortuous process from discovery through to R&D and eventually to commercialisation as well as difficulties in fixing the rate of royalty at an early stage.(*10)

5 Australia's Response to the CBD

The Commonwealth of Australia enacted the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act).(*11) The EPBC Act protects the environment, particularly in matters of national significance. A significant portion of Australia's biodiversity is found on publicly owned lands or waters, and is often represented within its system of protected areas. The EPBC Act streamlines environmental assessment and approvals process, protects biodiversity and integrates management of important natural and cultural places. The Act came into force on 17 July 2000. The Commonwealth of Australia's Department of Environment and Heritage is the lead agency for the CBD implementation.

6 Indigenous Biodiversity Knowledge

There is a common perception that in most cases knowledge of traditional medicine

(*7) Program for the Promotion of Access to Genetic Resources based on the Convention on Biological Diversity in FY 2005 (Unpublished) Japan Bioindustry Association, March 2006.
(*8) Companies involving practical use of biological processes or living microorganisms in industrial production.
(*9) This is also evident from a useful publication produced by the Ministry of Economy, Trade and Industry (METI) and Japan Bioindustry Association (JBA) entitled, Guidelines on Access to Genetic Resources for Users in Japan (February 2006).
(*10) The author acknowledges with gratitude the tremendous help given to him by Dr Seizo Sumida, Managing Director, JBA, in explaining the challenges that are presently being faced by Japanese industry in gaining access to genetic resources.
(*11) Available at http://www.frli.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/E169E81913E19C6ACA25726B001C7FA4/$file/EnvProtBioDivCons99Vol1WD02.doc.

originates in developing countries and is appropriated, adapted, utilised and patented by scientists and industry in developed countries, with little or no compensation to the custodians of this knowledge and without their prior informed consent.

In recent years, the protection of traditional knowledge, the innovations and practices of indigenous and traditional medicine and the equitable sharing of benefits have received increasing attention, and they are being discussed in many international forums, e.g., WIPO and regional organisations such as the South Pacific Communities (SPC).

Australia's Aborigines have close association with biological diversity. No one doubts that benefits from innovative use of traditional knowledge should be shared equitably. In order to achieve this, it is imperative that traditional knowledge is used with the cooperation and express approval of the holders of that knowledge and on mutually agreed terms which are judged as fair and equitable.

The CBD's doctrine of "prior informed consent" is of vital relevance in the context of Aboriginal peoples' vast resources of traditional knowledge because of gross disparity in their capability to negotiate a benefit sharing agreement with R&D and commercial entities. Regrettably, however, examples abound across the globe of commercial exploitation of traditional, indigenous knowledge which are totally devoid of prior informed consent, e.g., commercialisation of Smokebush's anti-HIV properties, Basmati rice, Neem, Kava, to name a few. Few or none of the benefits has been shared with traditional knowledge holders. (*12)

7 Prior Informed Consent

Prior informed consent is a process. The state, private owners, or local and indigenous communities, as appropriate, after having received the requisite information, consent to allow access to their biological resources or to associated intangible components under mutually agreed conditions. (*13)

Researchers and commercial entities desirous of accessing the knowledge of indigenous peoples or a local community must therefore previously seek approval of the knowledge holders or owners and pay for it. In order to authorise access, enough information should be provided to indigenous communities about the purposes, risks and implications of the activities that are intended to be carried out.

Authorisation for research is different from authorization for commercial exploitation. For the former, prior informed consent is required, for the latter, in addition to prior informed consent, a licensing agreement must also be obtained. (*14)

8 Two questions

The concept of "prior informed consent" raises two tricky questions: what constitutes "informed" consent and whose consent the above CBD's provisions envisage? The first question is discussed in the paragraphs below.

As regards the second question, a strict reading of the CBD provisions suggests that it is the "Contracting Party" whose consent is counted on, which means the consent of the member state. However, that is unlikely to be the intent of the provisions because there is no apparent need to provide the extra safeguard of "informed" consent to a contracting member state. The latter is presumably well informed and well resourced to obtain independent legal advice before giving out consent!

In stark contrast to the indigenous and local communities, member states do not hold the position of a party with weaker bargaining position. As regards the indigenous and local communities, there is a great disparity in their capacity to negotiate an agreement to share

(*12) See generally, K. Puri, "The Aboriginal Peoples of Australia" in Intérêt culturel et mondialialisation (L'Harmattan, Paris, 2004) 249 and "Indigenous Knowledge and Intellectual Property Rights – the interface" in P.N. Thomas & J. Servaes (eds.), Intellectual Property Rights and Communications in Asia: Conflicting Traditions (Sage, 2006) 116.
(*13) M. Umaña, "A Sui Generis system for protecting traditional knowledge under the CBD: The official position of the Government of Costa Rica" at 213, 214, see at http://www.unctad.org/en/docs/ditcted10_en.pdf.
(*14) See A.M. Pacon, "The Peruvian Proposal for protection Traditional Knowledge at 177 at http://www.unctad.org/en/docs/ditcted10_en.pdf.

benefits on mutually agreed terms. It is because of this ambivalence that there is frequent reference made to the consent of holders/owners of genetic resources and associated traditional knowledge. The Australian and Queensland legislation discussed in this paper are important examples of removing this ambivalence. It is submitted that there is an urgent need for this issue to be clarified worldwide.

It is probably because of this uncertainty that the concept of "prior informed consent" has not been analyzed effectively in academic writings and international fora. Nor has it achieved its intended, albeit unarticulated, purpose. Unfortunately, the WTO's Trade-related Aspects of Intellectual Property Rights (TRIPS)(*15) Agreement is silent on this subject. It is not surprising, therefore, that developing countries are frequently putting forward proposals to introduce a requirement in patent applications regarding disclosure of the source of origin of genetic resources and traditional knowledge as well as evidence of prior informed consent and benefit sharing.

The above aside, the concept has three constituents that are independent of each other, viz., "prior", "informed" and "consent." Before turning to the analysis of the latter two constituents, we may quickly deal with the modifier "prior."

In the present author's view, the word "prior" entails two things: (i) the informed consent must be obtained before the genetic resources are collected and used; and (ii) the consent must be recorded in writing.

It is submitted that the CBD does not make an explicit reference to the writing requirement through a legislative oversight. Otherwise, it will be most difficult, if not impossible, to prove that the consent was informed without there being a written record. A written record should be about the purpose, risks and implications of the R&D and commercialisation activity that is intended to be carried out by the entity seeking consent

9 Informed Consent vs. Free Consent under Contract Law

The doctrine of informed consent should be distinguished from the general doctrine of contractual *free consent*, which applies to agreements. The consent standard in a contract is only that the person understands, in general terms, the nature of and purpose of the intended transaction and the consent is not affected by any of the vitiating factors, viz., coercion, undue influence, fraud, mistake and misrepresentation.

It is suggested that in the case of *informed* consent, however, a higher standard of consent is intended. Otherwise, the qualifier "informed" would be meaningless. To satisfy the existence of informed consent, causation must be shown—that, had the party been made aware of the risk, they would not have proceeded with the transaction.

10 Disclosure of source of origin in patent applications

At present, the Japan Patent Office (JPO) does not require the country of origin to be disclosed in patent applications. Nor has this idea found much support from JPO, academic writings(*16) or Japanese industry.(*17) However, it is noteworthy that the JPO, in cooperation with private sector is actively engaged in debating this issue not only from the perspective of pure patent law but also to ensure that the CBD provisions are followed both in letter and in spirit.

In July 2004, JPO sent a questionnaire to several companies to solicit their comments on the "disclosure of the country of origin of genetic resources in patent applications." The survey results, compiled by the Japan Bioindustry Association (JBA), revealed strong opposition to the idea of requiring applicants for patents to provide information regarding

(*15) Available at http://www.wto.org/english/docs_e/legal_e/27-trips.doc.
(*16) For seminal discussion on this issue, see Dr Hajimu Morioka's paper entitled, "Approach of Corporations to Convention on Biological Diversity" (Unpublished, 2006) and Dr Maiko Tanoue's paper on "Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge" (2005) 8 Intellectual Property Law and Policy Journal 59.
(*17) Program for the Promotion of Access to Genetic Resources based on the Convention on Biological Diversity, Report in FY 2004 (Unpublished report compiled by the Japan Bioindustry Association, March 2005).

the country of origin of genetic resources.

The main objection was that protection of genetic resources and sharing of profits with holders/owners of such resources and associated traditional knowledge are matters that are unrelated to patentability. It was argued that the prior informed consent requirement under the CBD should be a sufficient safeguard and it is not the function of the patent law to guarantee proof of country of origin.

The present author respectfully advocates a broader approach. Assuming, though not admitting, that the patent law and the CBD have different goals,(*18) it is submitted that all member nations parties to the CBD should seriously consider requiring all patent applicants to sign a statutory declaration or a sworn statement at the time of submitting a patent application to the effect that the invention claimed in the application was truly and exclusively their own and that they had not made use of any genetic resources and associated traditional knowledge. It is hoped that this simple requirement will not only safeguard the integrity of the powerful patent monopoly and keep the patent system honest but would also help to achieve the two goals that are endorsed by both Dr Morioka and Dr Tanoue, viz., prevention of biopiracy and fair and equitable sharing of profits.

11 Queensland's *Biodiscovery Act 2004*(*19)

In 2004, the State of Queensland enacted the *Biodiscovery Act* in order to fulfil its responsibilities under the CBD and to give legislative effect to those responsibilities. Biodiscovery is the search for active compounds in plants, animals and micro-organisms that can be developed into commercial products. Biodiscovery involves the collection and screening of small quantities of living or dead native biological material, including plants, algae, animals, fungi and microorganisms, to identify bioactive compounds that may be used for commercial applications such as pharmaceuticals and insecticides.(*20)

The Act develops a streamlined and uniform approach regarding access to the Queensland's biological resources for biodiscovery, in a way that will benefit State's community, economy and environment. The need for new legislation stemmed from the inconsistencies and inadequacies of existing laws governing access to Queensland's significant and unique biodiversity.

The Act establishes an administrative machinery to comprehensively regulate the collection of native biological material on all Queensland land(*21) and waters(*22) used for the purpose of biodiscovery.

The Act makes it mandatory for commercial entities to enter into benefit sharing agreements with the State before embarking on biodiscovery research and commercialisation in relation to those resources. A single State regime is established to grant permission to use native biological resources sourced from Queensland.

The Act establishes a regulatory framework for identifying and using State native biological resources in a sustainable(*23) way for biodiscovery. It also stipulates a contractual framework for benefit sharing agreements to be entered into for the use of native biological resources. The Act further creates a compliance code and collection protocols for using native biological resources and ensures appropriate monitoring and enforcement of compliance with the Act.

The Act requires any person,

(*18) Arguably, paragraph 5 of Article 16 of the CBD dismisses this notion, see above Note 2.
(*19) Available at http://www.findlaw.com.au/Legislation/docs/55412.pdf.
(*20) See http://www.epa.qld.gov.au/ecoaccess/biodiscovery/. Section 5 of the Compliance Code for Taking Native Biological Material under a Collection Authority (the Code) specifies what can be collected. Taxa that cannot be taken are listed as restricted in Section 3.5 of the Code.
(*21) State land is all land in Queensland other than freehold land, free holding leases or land subject to a native title determination granting rights of exclusive possession. It includes national parks, road reserves and state forests.
(*22) Queensland waters are all waters within the limits of the State or coastal waters including water reserves and marine parks.
(*23) " Sustainability" is not defined in the Schedule to the Act, but the concept has been derived from the World Commission on Environment and Development's Report entitled, "Our Common Future" (1987), also known as the "Brundtland Report," where it was stated that "Sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs." See further http://www.oecdobserver.org/news/fullstory.php/aid/780/Sustainable_development:_Our_common_future.html.

organisation or institute seeking to undertake biodiscovery using native biological material sourced from State lands or waters to agree to share any benefits with the State.

The Act does not alter any access rights of landowners or alter existing intellectual property rights that may be generated in the course of biodiscovery. The State will not be a party to, nor will it broker such agreements.

The Act establishes a detailed procedure for granting a licence (referred to as "collection authority") to a commercial entity(*24) to collect and use native biological material for biodiscovery purposes. The prescribed form should be accompanied by the applicant's proposed or approved biodiscovery plan and should contain precise description of the type of material to be used together with the period for which the licence or collection authority is sought. The maximum period for which a licence can be granted is three years. The Biodiscovery Collection Authority is administered by the Environmental Protection Authority (EPA).

12 Benefit sharing agreement(*25)

The Queensland Department of State Development administers and executes the benefit sharing arrangements and approves the biodiscovery plans required by the Act. All benefit sharing agreements must include a Biodiscovery Plan outlining the commercial entity's approach to biodiscovery research and commercialisation, protection of intellectual property and benefits to be delivered. Benefit sharing agreements are legally binding contracts with recourse to the Queensland Courts if disputes were to arise.

Taking of native biological material for biodiscovery from State land or waters without a licence or collection authority is prohibited under the Act and is punishable by severe fine and imprisonment. The conduct of biodiscovery research or commercialisation without a benefits sharing agreement in place is a criminal offence punishable by a penalty of $375,000. Also, in order to ensure that biodiscovery entities comply with the terms of the Biodiscovery Plan, severe financial penalties are imposed for any acts/omissions that are not in accordance with the Biodiscovery Plan.

13 Conclusion and Recommendations

Gaining access to genetic resources is of particular interest to biotechnology and pharmaceutical companies, biological and taxonomic research organisations, venture capital and investment funds, conservation, and environment groups. Japanese private industry, with its advanced technology has a strong interest in accessing genetic resources in harmony with the provisions of the CBD. The JBA's survey pointed to the Japanese private industry's lack of clear appreciation of the workings of the CBD and the associated *Bonn Guidelines* while at the same time maintaining a strong desire to access genetic resources in an appropriate manner as per the letter and spirit of the CBD.

There is undoubtedly an urgent need for a structured education and awareness program covering the CBD, *Bonn Guidelines* and the interface between the CBD and the patent law. Fortunately, JBA is already engaged in this exercise by convening regular seminars and discussions. It is recommended that at least one additional national symposium should be organised jointly by JBA and IIP annually to debate the issues and challenges facing the Japanese industry in accessing genetic resources. Consideration should also be given to reform the patent law by requiring applicants to file a statutory declaration regarding the source of invention.

One of the major difficulties confronting Japanese private industry is the lack of a central agency and practical framework in order to access genetic diversity. The situation is exacerbated when one takes into account the fact that the chance of a new product based on natural genetic resources reaching the market is extremely low: about 1 to 10,000 to 100,000 samples.

(*24) "Entity" includes a person and an unincorporated body, as defined in the Acts Interpretation Act 1954 (Qld).
(*25) See section 33 of the Biodiscovery Act 2004.

Furthermore, the progression from research and development to commercialisation is often very expensive and dilatory.

It is submitted that Queensland's Biodiscovery legislation highlights options for other jurisdictions, including the Commonwealth of Australia, in the regulation of biological resources under their control.(*26) Importantly, the Queensland's new licensing regime provides a viable avenue for Japanese industry to access biological material from a bounteous resource without having to confront burdensome regulatory impediments such as cost, delay, uncertainty, duplication and complexity.

(*26) See A. Rush's comment on the Queensland's Act (14 September 2004) where reference is also made to the present author's views: http://www.aar.com.au/pubs/bt/14sep04/bio02.htm.