



Asia-Pacific  
Economic Cooperation

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**The Australian APEC  
Study Centre**

 **MONASH** University

**Developing an effective international regime  
for access and benefit sharing for  
genetic resources**

**Using market-based instruments**

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## Executive Summary

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Work to support an international regime to facilitate access to genetic resources and share benefits from it is underway. Some are pushing for a highly regulatory approach, arguing that the genetic resources of developing countries constitute a potentially valuable source of income and that companies are likely to develop new products from this genetic material. They believe that strict rules need to be imposed as otherwise developing countries will not get their fair share of this “green gold” from royalty payments.

A lot of the focus is misplaced. There have been no major, new drugs developed from bioprospecting by pharmaceutical companies in the genetic material of developing countries. There is no “green gold” bonanza. Bioprospecting is falling off. There is no evidence that biopiracy is a major problem. There is no “failing” in the system which a legally-binding international regime might seek to correct. Establishing such a regime in these circumstances will have a negative effect. It will discourage bioprospecting and inhibit access. Without access, there will be no benefits to share.

A binding system of regulation would also undermine national sovereignty and reduce the flexibility each country needs to institute policies to protect biodiversity which recognize the unique nature of biodiversity in each country.

There is a better way forward. A market-oriented approach based on the clear delineation of property rights to undertake bioprospecting in developing countries, and developing a market whereby such rights can be freely traded, will facilitate access and more readily enable benefits to be equitably shared. Such an approach would optimize the opportunity to develop effective policies to manage biodiversity and maximize capacity building for developing countries. It would not have the negative consequences of a regulated system.

The requirements for a market-based property rights model are relatively simple and are set out in this report. The report draws on the literature to provide an assessment of the market-based and regulatory models against some key criteria; identifies how a market-based system might be constructed; and outlines a model agreement between a host country and a pharmaceutical company. It sets out elements for a non-binding international regime based on property rights.

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## List of Acronyms

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ABS: Access and benefit sharing

AIMS: Australian Institute of Marine Science

ASEAN: Association of South East Asian Nations

CBD: Convention on Biodiversity

CLP: Certificates of Legal Provenance

EU: European Union

IUCN: International Union for the Conservation of Nature

NGO: Non-Governmental Organisation

R&D: Research and development

US: United States of America

WIPO: World Intellectual Property Organisation

WTO: World Trade Organisation

## Chapter One: Introduction

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Work to support an international regime (probably a protocol to the Convention on Biological Diversity (CBD)) to regulate access to and benefit sharing from genetic resources is proceeding in the meetings of Parties to the CBD and in the World Intellectual Property Organisation (WIPO).

The general proposition is that as developing countries are host to a substantial amount of the world's biodiversity, and companies need access to this genetic material to develop new products, considerable royalty payments are in prospect if developing countries adhere to a regulatory regime that "forces" companies to pay a "fair" amount of money for bioprospecting rights.

Non-Governmental Organisations (NGOs) and a number of developing countries accordingly are pushing for a highly regulatory approach to access and benefit sharing (ABS). They want a legally binding instrument. They either distrust markets or believe that the only way that "equity" can be achieved between the private sector and developing countries is through an international system of regulation to govern the use of genetic resources and investment in bioprospecting by these companies in developing countries.

This approach posits fundamental inequality between rich and powerful companies and developing countries which the former will exploit if given the chance.

The positions by the key groups involved in the negotiations could be characterized as follows:

- Some but not all developed countries opposing a regulatory regime governing access to genetic material in developing countries;
- Many developing countries, especially the African Group and the Like-Minded Mega-Diverse countries, insisting on a regulatory arrangement;
- The European Union (EU) supporting elements of both approaches, with some uncertainty as to whether and under what circumstances it might support or oppose either a regulatory approach or a market-based alternative;
- Green and development NGOs convincing developing countries that they will lose without a regulatory outcome; and
- Growing private sector opposition to the regulatory approach.

Those arguing for a legally binding regime are proceeding as if the case has been made for a regime and that it will work. There is no empirical evidence for the claim that there is a problem. The research behind this report did not reveal substantial cases of biopiracy or any instance of highly profitable returns from a product developed via the acquisition of genetic resources from developing countries. Substantial royalty payments from bioprospecting have not materialized.

It is surprising that members of the CBD could be at the point of deciding to develop a binding international regime without commissioning independent analysis which establishes that the facts warrant it. It is not too late to do so.

This report finds that in today's environment, a regulatory approach would be likely to impose such high costs on companies that the potential wealth embodied in the biodiversity assets of developing countries will not be developed.

It is clear that countries can improve how they provide access to their genetic resources, improve how they can secure and share whatever benefits may flow from that access and improve how they protect their biodiversity. Market-based instruments are the most effective tools for this and carry none of the downsides from mandatory regulation.

**Chapter two** brings the practical conclusion of this report to the fore. It sets out the elements of an approach to an international regime which enables members of the CBD to use market-based instruments to improve access and benefit sharing.

**Chapter three** reviews some key issues, pointing out there are a wider range of considerations in access and benefit sharing than obviating the threat of biopiracy. It reports the conclusion of experts in the field that a new approach to access and benefit sharing is necessary if results which support development and improve management of biodiversity are to be achieved.

**Chapter four** reviews studies on the impacts of various systems for access and benefit sharing used to date, comparing the experience with regulatory systems and market-based instruments. It reveals how counterproductive onerous regulation has been to access and benefit sharing.

**Chapter five** examines how market-based instruments can be used. It considers the factors necessary to construct a system for access and benefit sharing based on property rights, considers elements for an international framework and provides model elements for an agreement between companies and governments.

## Chapter Two: Elements of a market-based approach to an international regime

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Members of the Convention on Biological Diversity (CBD) should establish an international regime that enables individual members to use market-based instruments to provide access and benefit sharing for genetic resources.

The regime should identify the elements that members of the CBD should incorporate into national law if they want to establish market-based systems.

The key elements are:

- A definition of property rights to genetic resources;
- Provision for legal protection in national laws of contracts to supply and acquire property rights to genetic resources;
- A national policy on the allocation of property rights to engage in bioprospecting;
- A national policy on conservation of biodiversity which recognizes the role of market-based instruments and provides for possibilities such as
  - exclusion of specified genetic resources from the market-based system, or
  - use of the system to protect biodiversity (for example by governments purchasing or allocating to itself a share of rights which it holds);
- A statement of principle to guide the balance between the price of rights and price of royalties;
- A statement of principle to guide provision of rights across national territory;
- A national policy on how the interests of indigenous peoples are to be served including, among other measures
  - scope for provision to own and trade property rights to genetic resources, or
  - scope for allocation of a share of property rights to specified genetic resources to indigenous parties; and
- A statement of principle providing guidance on the adoption of common approaches to market-based instruments among members of the CBD in the event they are interested in participating in the future in a system of international trading in property rights to engage in bioprospecting.



It is recognized that individual members of the CBD may wish to adopt national approaches to access and benefit sharing which are different to the system envisaged above.

It is essential therefore that any new international regime provides scope for individual members of the CBD or groups of members to have the flexibility to adopt different approaches to access and benefit sharing.

To enable members full flexibility to develop measures which are consistent with their sovereign right to take the measures necessary to protect their national biodiversity in accordance with the obligations under the CBD, the proposed international regime should also contain the following provisions:

- Recognition of the right of each member of the CBD to adopt national measures as necessary to ensure access and benefit sharing to genetic resources, fully mindful of the unique nature of biodiversity in each member and the essentiality of preserving the freedom of each member to implement measures as necessary;
- A commitment to avoid regulatory systems that will hinder access and benefit sharing;
- A commitment to protect existing property rights and intellectual property rights; and
- A commitment to avoid conflict with provisions in other international agreements, specifically those administered by WIPO and the World Trade Organisation (WTO), which relate to measures to enhance access and benefit sharing.

## Chapter Three: Some key issues

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The Convention on Biological Diversity (CBD) commits parties to ensure there is access to genetic resources and that benefits are equitably shared. The perspective that biopiracy is prevalent has skewed thinking about how to meet those obligations around the question of how to stop biopiracy.

Achieving effective access, deriving benefits from it, sharing them equitably and ensuring that action to protect biodiversity is optimized, raises a wider range of issues than those related specifically to controlling biopiracy. The aim of this section is to review them briefly and to identify questions that should be considered if an international regime for access and benefit sharing is to be effective.

### **Importance of Biotechnology**

Measures governing the use and development of genetic resources should not be considered in isolation. Genetic resources are a key element in the biotechnology revolution. Biotechnology will be vital for tackling problems of development and conservation. It offers enormous scope to improve productivity of agriculture and to develop new medicines and cures.

Loosely defined, biotechnology will be the means by which genetic resources and elements in them will be developed into new products. Ensuring effective access to genetic resources as well as providing the most propitious environment for foreign investment and research and the production of biotechnology products is vital for ensuring countries secure the benefits from the development of biotechnology industries and biotech products. Conversely, measures which discourage investment and the supply of biotech products will be counterproductive to that interest. They will work to the disadvantage of the country which would like to develop its biodiversity assets, companies that would like to engage in bioprospecting, and consumers of biotechnology products.

### **The cost of research**

The market capitalization of biotechnology companies is currently estimated to be around US\$400 billion for the United States (US) and US\$25 billion for Europe. Annual research and development (R&D) by US biotechnology companies is estimated to be US\$4.2 billion.<sup>1</sup> It is understandable that a perception would arise among those wishing to regulate bioprospecting that companies are making super normal profits and hence can afford the cost of adhering to highly regulatory arrangements designed to ensure a “fair” share of these super normal profits for developing countries.

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<sup>1</sup> “State of the Biotechnology Industry: A Global Perspective” by G Steven Burrill, at <http://www.burrilldatacenter.com/pdf/BioTechIsrael.pdf>. Page 7.

Such an assumption is not supported by the facts. Biotechnology is a new global growth industry. It requires extensive capital resources, backed up by a preparedness to invest heavily in R&D. The risks involved in developing new drugs are high and the cost of obtaining approvals for drugs is rising: companies need to be large and have deep pockets. Total shareholder returns to biotechnology companies have fallen by 25 percent since 1998.<sup>2</sup>

The investment required for one successful drug launch (from discovery through to launch) is estimated to have increased from US\$1.1 billion in 1995-2000 to US\$1.7 billion in 2000-2002.<sup>3</sup> It has been estimated that:

On average, companies invest 10 years and US\$800 million, to screen 5,000 compounds, get 5 into clinical trials, and launch a single drug. Only 3 of every 10 successful new drugs generate revenues greater than their R&D costs; those three must finance all the unsuccessful efforts. Research with natural bioresources faces even longer odds: only one sample in 250,000 will eventually yield a commercial drug, though many may provide leads to other drugs.<sup>4</sup>

Estimates suggest that only one third of the 415 new drugs approved between 1998 and 2002 were new molecular entities. Only 14 percent were considered by the US Food and Drug Administration as being a “significant improvement” over existing products.<sup>5</sup>

Given the costs to identify, develop and obtain approvals for and launch new products from bioprospecting in developing countries, certainty and confidence are required. A regime that imposes high costs on bioprospectors and weakens the certainty of property rights for business will drive investors away.

### **Declining interest in bioprospecting**

Although there is a widespread perception that there is a bonanza on offer in “green gold”, the reality is different: interest in bioprospecting is declining.

A (1999) comprehensive report by Columbia University notes that:

No active compound has been advanced into the commercialization phase: as of yet, no royalty or commercialization-derived monetary benefits have resulted from any of the agreements. The odds of finding a new drug from botanical samples are still very low (from 1 in 80,000 to 1 in 250,000 plant samples).<sup>6</sup>

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<sup>2</sup> Op cit, page 63.

<sup>3</sup> Op cit, page 38.

<sup>4</sup> Paul Driessen, “That pot of green gold at the end of the rainbow”, pages 1 and 2, at [http://www.cdfc.org/the\\_pot\\_of\\_green\\_gold.htm](http://www.cdfc.org/the_pot_of_green_gold.htm).

<sup>5</sup> Op cit, page 14.

<sup>6</sup> “Access to Genetic Resources: An Evaluation of the Development and Implementation of Recent Regulation and Access Agreements”, Colombia University School of International and Public Affairs, Environmental Policy Studies, Working Paper Number 4, page 87, at <http://www.biodiv.org/doc/case-studies/abs/cs-abs-agr-rpt.pdf>.

In explaining the lack of success from bioprospecting, commentators have attributed the reasons as the inherently uncertain and risky business of bioprospecting, as well as unrealistic expectations as to what could be obtained.

The Columbia University report observes that “some pharmaceutical companies, such as Shaman, have recently cut back on their bioprospecting activities because costs proved higher than expected.”<sup>7</sup> This situation is unlikely to change. Rosenthal observes that:

Corporate research and development budgets for natural products research in the US are not likely to grow significantly in the next few years, and demands on those budgets are multiplying as conservation and development goals are linked to the research process.<sup>8</sup>

Foreman has noted:

The US industry trade group, Pharmaceuticals Research and Manufacturers of America, has acknowledged that companies may be reticent to talk about bioprospecting in part because they don't want to be perceived as stealing the flora or the intellectual property of indigenous people. But the lack of publicized results also reflects the fact that companies are putting more effort into high-tech drug discovery using genomics to design drugs from scratch rather than combing nature for medicine.<sup>9</sup>

Bioprospecting is as critical to the genetic resources industry as mineral exploration is to mining. Any arrangement governing access and benefit sharing needs to ensure bioprospecting remains attractive.

## Equity

A leading concern of many countries is to ensure equity both in access to genetic resources and distribution of benefits. There is no agreed understanding of how that equity is to be defined, assessed or achieved. NGOs assert that biopiracy is common<sup>10</sup> and that this is a leading source of inequity. The Latin American and Caribbean countries are concerned to prevent “illegal access” to genetic resources.<sup>11</sup> Ethiopia has said it “is now recognized that access will be denied unless benefits are ‘reciprocal’.”<sup>12</sup>

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<sup>7</sup> Ibid.

<sup>8</sup> Rosenthal, J, “Equitable Burden Sharing of Biodiversity Benefits: Agreements on Genetic Resources”, page 16, paper presented to a conference held in Australia in March 1996, entitled “International Conference on Incentive Measures for the Conservation and the Sustainable Uses of Biological Diversity”, at <http://www.fic.nih.gov/programs/oecdub.html>.

<sup>9</sup> Judy Foreman, “Drug Hunters Can't See Rainforest For The Medicines”, at [http://www.myhealthsense.com/F010327\\_rainforest.html](http://www.myhealthsense.com/F010327_rainforest.html), page 3.

<sup>10</sup> The Third World Network refers to “The phenomenon of 'biopiracy' in which corporations (mainly of the North) have been able to patent biological resources and knowledge of their use (most of which originate in the South) ([www.twinside.org.sg/title/undp4.htm](http://www.twinside.org.sg/title/undp4.htm)).

<sup>11</sup> Statement by Ecuador on behalf of the Group, Third Meeting of the Open Ended Working Group on Access and Benefit Sharing, Convention on Biological Diversity, Bangkok 3 March 2005 (UNEP/CBD/WG-ABS/3/7)

<sup>12</sup> Ibid.

However defined, a key measure of equity is how much benefit is bestowed. There cannot be benefit unless there is access to genetic resources and productive development of the resources. Concern about illegal access to resources only becomes pertinent if that activity is significant enough to distort patterns of access. In setting conditions governing access, a primary consideration should be to ensure the rules themselves do not inhibit access or they will defeat the purpose. There has to be access if benefits are to be generated.

Once a benefit is assured, the next question is how it is shared. Benefit sharing not only refers to ensuring developing countries receive their due, but that indigenous peoples in areas where genetic resources are discovered also receive appropriate benefits.

There are many ways to ensure “equity” and a fair distribution of benefits. Regulation is one but not the only option. The task is to select the approach which is likely to be the most effective.

### **Protecting biodiversity**

The overriding goal of the CBD is to conserve biodiversity. This is not an absolute goal. Sustainable development is the objective and that entails ensuring a balance between economic development from utilization of genetic resources as well as conservation of them.

Many CBD members consider that enforceable regulation is the only means by which biodiversity can be protected. This is not the case. To date the consensus among parties to the CBD is to use non-binding measures as reflected in the Bonn guidelines on access and benefit sharing.

Market-based instruments are a practicable alternative to regulation to protect biodiversity. A comprehensive study commissioned by International Union for the Conservation of Nature (IUCN) in 1988 demonstrates the effectiveness of this approach.<sup>13</sup>

### **Cost of regulation**

Good practice in regulation is to ensure that compliance costs are not greater than the benefit derived from the activity being regulated. A principle to test this is “proportionality” – ensuring that the burden of the regulation is proportional in impact to the adverse effect to be controlled. Compulsory compliance with government-mandated regulation is the most onerous form. Voluntary (or facilitative) compliance with guidelines is the least onerous.

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<sup>13</sup> See McNeely, Jeffrey A. Developing and Using Economic Incentives to Conserve Biological Resources (1988), [www.biodiversityeconomics.org/applications/library\\_documents/lib\\_document.rm?document\\_id=714](http://www.biodiversityeconomics.org/applications/library_documents/lib_document.rm?document_id=714)

What is to be regulated? The most common concerns are over bioprospecting and the use of genetic resources. The premise is that bioprospecting is exploitative – and therefore requires regulation. To determine how much regulation is appropriate, we need to measure the size of the problem.

This is straightforward in the case of an environmental externality that is already in existence, such as air pollution from electricity generation, and which is relatively easily measured. The case of regulation can be assessed and other options considered. If regulation is used, the costs need to be proportionate to the benefits. Getting that right is hard enough using established practices where the effects are reasonably well known.

To regulate an activity that is either not yet in existence or at a relatively early stage of development, and where the institutions are untested and/or inefficient, is a very different proposition. In this case, the incidence of bioprospecting is low and the threat of biopiracy is negligible. The instrument of regulation proposed, a legally binding international instrument, is a very high cost model.<sup>14</sup>

If this approach is taken, the full costs are unlikely to ever be known. Highly regulatory arrangements are likely to be so “effective” they will stop all bioprospecting. The benefits which might have accrued under less onerous systems of regulation or a non-regulated system such as a more market-oriented arrangement, will never eventuate.

Assessments of some of the wider compliance costs associated with regulations are worth recalling. Adler argues that:

Most nations lack sufficient resources to establish, demarcate, defend and manage wildlife preserves on a scale sufficient to stem the loss of biological diversity. ... In poorer countries, the prospect of protecting biological diversity through a series of government-owned and managed protected areas is even bleaker. ... More promising would be efforts to increase the value of habitat and underdeveloped land through various forms of commercial utilization. ... Another possibility in this regard actively promoted by some CBD proponents is bioprospecting.<sup>15</sup>

Medaglia recently reviewed the impact of a number of sets of national laws around the world to regulate access and benefit sharing. Authorities had difficulty interpreting overlapping rules governing access; information supporting applications

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<sup>14</sup> A theoretical approach to the issues bearing on the economics of bioprospecting is set out by Oliver Deke, “Supply side externalities in markets for genetic resources”, Institute for World Economics, Kiel, in a presentation to the Fourth Bioecon Workshop of Biodiversity Conservation”, at <http://www.feem-web.it/bioecon/papers/deke.pdf>. Deke emphasizes that “the higher the relative value of genetic information the more natural areas are allocated to conservation.” This analysis seems to be predicated on firms doing the bioprospecting. Evidence suggests however that universities and research institutes undertake the overwhelming majority of initial bioprospecting. Firms tend to become engaged after initial screening has taken place and when synthesizing “finds” and developing new products occurs.

<sup>15</sup> Jonathan Adler, “Do Conservation Conventions Conserve?”, page 9, in “Sustainable Development: Promoting Progress or Perpetuating Poverty”, edited by Julian Morris, published by Profile Books, London, August 2002.

was not available to regulators; and there was regulatory overlap with other environmental regulations.<sup>16</sup> Medaglia called this “double permission required”. Bioprospectors complained about the:

Need to apply different permits to obtain access to the samples. For instance, additional permits to obtain biological resources are required by other institutions without establishing adequate coordinating mechanisms among the governmental entities to facilitate access to genetic resources for sound uses. From a government perspective, this situation was likely not intentionally created, but it is the unintended result of adopting new legislation that regulates a different component (the genetic) contained in biological resources traditionally regulated by other laws.<sup>17</sup>

The lesson is clear enough. Unless the intention of introducing an additional system of global regulation is to ensure there will be no bioprospecting or access to genetic resources, in these circumstances it is logical that an international regime be voluntary.

### **Intellectual property**

A common theme in proposals to improve access and benefit sharing is to create new controls, regulated in international law, on how rights to genetic resources might be used. They include a permanent right to determine how products derived from genetic resources in one country may be asserted over use of derivatives from that resource wherever that occurs. A second proposal is a global system to regulate verification that certain genetic resources have been legally acquired through a system of certificates.

These systems would alter existing legal rights provided under intellectual property law.

Conditions would be imposed on the use of patents on inventions developed from genetic materials such as approval for uses of products and processes patented from research on genetic materials. It would also require patent applications to disclose the origin of genetic material as well as traditional knowledge in past use of such material.

These measures would severely diminish the value of patents. They even appear to be designed for that purpose.

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<sup>16</sup> This comparative study draws on regional, national and state laws on access and benefit sharing from the Andean Community; Australia; Brazil; Malaysia-Sarawak and Malaysia-Sabah; the Philippines; India; and Bhutan. It also drew on the Model Law of the Organization of African Unity and the ASEAN Framework on Access to Genetic Material. The author is Jorge Cabrera Medaglia, “A Comparative Analysis on the Legislation and Practices on Access to Genetic Resources and Benefit Sharing (ABS): Critical Aspects for Implementation and Interpretation”, at [http://www.iucn.org/themes/law/absdocuments/eng\\_critical\\_aspects.pdf](http://www.iucn.org/themes/law/absdocuments/eng_critical_aspects.pdf). The date of this article is not given but as the latest reference cited is 2003 it may have been written in late 2003 or 2004.

<sup>17</sup> Op cit, page 227.

The right to patent a discovery is essential to support research and development. The cost of developing new drugs and the high failure rate has already been covered. Pharmaceutical companies need to seek patents for drugs fairly early in the process. Otherwise a company could go through all the expense of trials and get nothing for that work. Getting a patent and delivering a medicine to market takes years.

Adding requirements for certification of the origin of the material or traditional knowledge for patent applications and to regulate the use of products based on these patents would further extend the patenting process, and raise the costs and increase uncertainty. It would provide additional grounds for litigation, in a field that suffers enough of it already.

Advocates of restrictions on intellectual property seem to assume that the benefits of new drug discoveries only go to drug companies and consumers in industrialized economies. Everybody benefits from new drugs. They have been responsible for controlling and eliminating debilitating diseases in the developing world.

Satel, quoting research by economists Wolfe and Zycher on weighing down the patent process with new mandates, estimated that 150-200 drugs would have been lost over the next 20 years by excessive bureaucracy.<sup>18</sup>

Biodiversity is a natural asset. To secure the prospective benefits, all countries require technology and investment. A number of developing countries have strategies to develop biotechnology and life science industries. The first impact of introduction of laws which weaken intellectual property rights would be withdrawal of investment.

### **New approach needed**

The Columbia University report is not alone in identifying the problems with a highly regulated approach to access and benefit sharing.

A Policy Brief for a forthcoming book by Sampath, a researcher at the United Nations University's Institute for New Technologies, makes some telling points.<sup>19</sup> In reviewing her book Shanahan quotes her as noting that:

Most bioprospecting partnerships set up since the (CBD) came into force in 1993 have failed to produce the expected drugs. In addition, bureaucracy, legal uncertainties, and weak regulatory frameworks in developing countries have made the companies reluctant to invest in bioprospecting. (She) proposes that to recapture the interest of those investors, developing countries should enact laws balancing the needs of drug companies, local communities and governments, and create relevant institutions to implement the requirements. She says it is

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<sup>18</sup> Sally Satel, "A Cautionary Tale", at <http://www.techcentralstation.com/061405D.html>.

<sup>19</sup> Padmashree Gehl Sampath, "Regulating Bioprospecting: Institutions for Drug Research, Access and Benefit-Sharing", United Nations University Press, 2005 (forthcoming). A review of her book by Mike Shanahan, "Poor countries are 'not mining their green gold'", is at <http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=2051&language=1>, which contains a link to a Policy Brief (Number 1, 2005), entitled Regulating Bioprospecting: Institutions for Drug Research, Access and Benefit-Sharing", by Sampath.



She says it is important that these stakeholders do not view bioprospecting agreements as one-off deals to yield high short-term profits. Rather, she says, the agreements should be part of long-term research and development collaboration.<sup>20</sup>

In assessing the consequences of the lack of property rights or badly defined property rights on bioprospecting contracts, Sampath argues in a Policy Brief drawing on her book that:

Many of these (problems) can be eliminated by well-defined property rights on access and traditional knowledge. Well-defined property rights lead to contracts that achieve three main goals: (a) incorporation of all values that users associate with the resources (potentially, even cultural and spiritual values) into the market price of the resource being traded (;) (b) competitive bargaining conditions so that no one party has an advantage in the negotiating process, and, (c) lack of external effects on third parties or society, such as biodiversity depletion. Such contracts that provide an environment for mutually beneficial exchange with fair distribution of benefits can only be enabled through well-defined property rights that are enforceable in a transparent and accountable regulatory framework.<sup>21</sup>

An assessment by Evans-Illidge and Murphy concluded that:

Bioprospecting is a high cost, high risk process with no guarantee of any financial returns at all. If access controlling agencies try to push the stakes even higher, industry will simply find alternative sources of chemical innovation for the bioproduct discovery process (e.g. combinatorial chemistry, microbial culture). Agencies effectively lose the opportunity to have their biodiversity in their care included in screening programs, and hence eliminate any chance of any benefits downstream.<sup>22</sup>

They describe the importance of private sector support for research on genetic resources in a wealthy country like Australia. Evans-Illidge and Murphy note that “collaborations with industrial partners and other research institutions have been instrumental in the development and success of this project since its inception in 1974. It currently receives funding from AMRAD, an Australian pharmaceutical company” and that the US National Cancer Institute had also provided funding.<sup>23</sup> They note that government funding for compiling an inventory of Australia’s marine resources will remain inadequate, which in turn means that “resource inventories produced through collections for bioprospecting are Australia’s best hope of discovering and documenting its biodiversity within a useful time frame and at reduced cost to Governments.”<sup>24</sup>

Evans-Illidge and Murphy conclude that:

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<sup>20</sup> Op cit, page2.

<sup>21</sup> Op cit, page 4.

<sup>22</sup> Evans-Illidge, EA and Murphy, PT, “A New Approach to Benefit Sharing in Bioprospecting”, page 6, at <http://www.biodiv.org/doc/case-studies/abs/cs-abs-au.pdf>.

<sup>23</sup> Op cit, page 2.

<sup>24</sup> Op cit, pages 4 and 5.

The experience of the (Australian Institute of Marine Science) Marine Bioproducts Project suggests that, if access to marine biota is further reduced, the biodiversity available to natural products screening and development will be increasingly limited and the chance of discovering products which will bring tangible benefits to Australia will be correspondingly lowered. There is therefore a clear need for a fresh approach which facilitates access for responsible bioprospecting and increases the likelihood of commercially useful discoveries, while safeguarding the rights of appropriate authorities to claim a share in potential benefits.<sup>25</sup>

The foregoing makes a strong case for a fresh approach to managing access and benefit sharing.

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<sup>25</sup> Op cit, page 6.

## Chapter Four: Experience to date (regulation versus the market-based approach)

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This chapter reviews the experience to date with regulation and more market-based approaches. The objective is to identify the key lessons from what we know and to identify the issues that would need to be addressed by an alternative, market-based, approach.

### Overview

While there is a range of regulatory arrangements on which we can draw, experience with the use of a market-based system where property rights are established, allocated and can be traded, is very limited. We look in more detail at three systems to identify and assess the key issues:

- At the most market-oriented end of the spectrum is Astra Zeneca's involvement in the Natural Product Discovery Unit at Griffith University in Queensland, Australia, representing a cumulative investment of more than AU\$100 million since 1993;<sup>26</sup>
- The INBio-Merck agreement in Costa Rica, while somewhat less market-oriented than the Astra Zeneca example, is at the market end of the spectrum as regards bioprospecting arrangements in developing countries; and
- The arrangements in the Philippines for bioprospecting, which are firmly placed at the regulatory end of the spectrum.

The Colombia University study assessed the Philippines and Costa Rican models in a review of seven bioprospecting arrangements. They were:

- The INBio-Merck research agreement in Costa Rica;
- The National Cancer Institute - Universidade Paulista Agreement: Bioprospecting in Brazil under a developing regulatory environment;
- An attempt to bioprospect under Decision 391 in Colombia;
- An international cooperative bioprospecting effort and the evaluation of legislation in Cameroon;
- The University of the South Pacific-Strathclyde Institute of Drug Research Bioprospecting Agreement in Fiji;
- Bioprospecting under Presidential Executive Order 247 in the Philippines; and

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<sup>26</sup> See <http://www.astrazeneca.com.au/article/502030.aspx>.

- The Yellowstone-Diversa Agreement in the US.<sup>27</sup>

The Columbia University study examined stakeholder engagement, property rights, prior informed consent, benefit distribution, compliance and dispute settlement and sustainable use and conservation.

Overall, the Columbia University study found that the Costa Rican model was the most effective of those examined and the Philippines arrangements the most ineffective. It found only 2 of 37 applications to access to genetic resources by commercial and academic interests had been approved in the Philippines.<sup>28</sup>

The arrangement among the Andean Pact countries is also important, being an early attempt to set common standards for access and benefit sharing among a group of countries. Bolivia, Colombia, Ecuador, Peru and Venezuela agreed to a common regime on access to genetic material. An attempt was made in 1997 by a private company, BioAndes, for access to drug discovery in all Colombian territory – in return for technology transfer and in-country capacity building.

The Columbia University study reported that “The Colombian Ministry of the Environment purportedly utilized the regulatory framework of Decision 391 to evaluate and reject the BioAndes ... applications – the first of any Andean Pact country.”<sup>29</sup> Following a protracted negotiating process, permission was not granted. The study quoted BioAndes as believing that:

The process itself does not encourage compliance, since the costly application may not be met with fair consideration, but rather one informed by radical advocacy groups, subject to the vagaries of changes in administration, and tainted by an exaggerated appreciation of political correctness. Andes Pharmaceuticals is no longer operating in the Andean Pact countries.<sup>30</sup>

This is a case of an overly regulatory arrangement delivering no material benefits to a region, which, according to Colombia University, “may jointly harbor the largest proportion of the world’s biological diversity, and some still possess a large proportion of their original forest cover” – with Colombia alone “accounting for 10 percent of the terrestrial species of plants and animals in the world in only 0.77 percent of its surface area, while still retaining large tracts of undisturbed lowland forest.”<sup>31</sup>

The contrast with the arrangement in Costa Rica was that despite no significant discoveries having been made during the agreement, Costa Rica received fees to a value of US\$1 million which it was able to use to support conservation activities.

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<sup>27</sup> Op cit, page i.

<sup>28</sup> Op cit, page 55.

<sup>29</sup> Op cit, page 44.

<sup>30</sup> Op cit, page 43.

<sup>31</sup> Op cit, pages 34 and 35.

The Columbia University study concludes that:

Extreme regulation raises the overall cost (monetary and otherwise) of using genetic resources – many of which were easily accessible until recently and may prevent genetic resources from being used. This problem affects national, international, commercial and non-commercial ventures alike.<sup>32</sup>

### **How a market based system can define the market for bioprospecting**

There is a conceptual problem in comparing regulatory and market-based models. It is difficult to compare like with like as demand is suppressed under the regulatory model and the market-based model has not yet been widely adopted. There are not as many case studies on which to draw conclusions on the effectiveness of the market-based model. Demand for bioprospecting is not as high as some proponents of the regulatory arrangement claim. De Soto, the famed Peruvian development economist, points out that until property rights are developed and assigned in an efficient manner, the real size of the market cannot be assessed. He observes that:

By our reckoning, over 4 billion people do not have property rights over their assets; therefore they cannot get credit and use collateral, and they cannot create a firm under which they could divide labor. This means that they cannot separate the assets of shareholders from the assets of creditors or from the assets of the workers.<sup>33</sup>

This suggests a paradox: the demand for bioprospecting seems to be falling, which in turn means that the regulatory model has even less to offer than would be the case if demand was strong. But without a properly functioning market-based set of rules, enabling such rights to be traded within and preferably between countries, the potential size of the market is unclear.

Only by establishing a properly functioning, market-based model for bioprospecting can the size of the market be identified. This has yet to happen. There is every reason to expect it to encourage much more bioprospecting than under the regulatory model.

### **Stakeholder engagement**

An effective system of access and benefit sharing needs to satisfy the interests of the key stakeholders. They are government, the public, indigenous groups, the private sector and the research community. We address how market-based arrangements can meet the interests of these stakeholders.

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<sup>32</sup> Op cit, page 84.

<sup>33</sup> Hernando de Soto, “The Mystery of Capital: The Role of Property Rights in Creating Wealth and Alleviating Poverty”, Sir John Crawford Memorial Lecture, page 13.

## ***Government***

Governments in bioprospective host countries will, by definition, be a stakeholder under either a market-based or a regulatory model. To be effective either option must encourage host governments to become and remain engaged. Incentives have to be in place. The costs of becoming and remaining engaged must be kept as low as possible. Administrative capacities in host countries are not infinite. A system that requires a complex set of administrative arrangements will either not sustain the interest of governments or will consume so many resources that other priorities (such as conservation) will suffer.

Experience suggests that what might seem like administratively simple issues in the design of a regulatory system can escalate quickly and in unpredictable ways. It is likely that what might seem like low transactions costs would in practice turn out to be very substantial. It would not be hard for the compliance costs to exceed whatever benefits a regulatory model might deliver.

Based on the research undertaken for this report, it is far from clear what the benefits from a regulatory arrangement might be. There are certainly plenty of costs. A not unreasonable conclusion from this report is that there are no substantive benefits from regulation.<sup>34</sup>

A market-based model would also involve some transactions costs for governments. But unlike the regulatory arrangement, a market-based system can be designed so that these are “one off” rather than recurring costs. It would also require governments to ensure the legal infrastructure to support property rights and complementary policies for conservation were in place. The cost of administration of these would normally be less than under a regulated system.

## ***The public***

The public interest is to ensure that a system is in place that meets the interests of those that would like to undertake bioprospecting, that ensures prospectors pay reasonable prices for that right and that best conserves natural assets; and strikes a fair compromise among those interests. A market-based model is superior in meeting the first two interests: it creates a market and by allowing it to operate, value is created. The regulatory model seeks to satisfy the first two interests by administrative fiat.

There is ongoing debate as to whether conservation can best be achieved by regulation, by allowing markets to work or by some combination of regulation and market forces. By allowing markets to identify prices, market-based instruments are increasingly accepted as having a vital role to play – not only in achieving conservation objectives, but in doing so at minimum cost.<sup>35</sup> There are plenty of examples where market based instruments have been used for conservation. An extensive study commissioned by IUCN provides a good summary.<sup>36</sup>

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<sup>35</sup> See for example Adler, op cit.

<sup>36</sup> See ICUN, op cit.

## ***Indigenous groups***

Under a regulatory model indigenous interests in and income from bioprospecting are determined solely by national governments. In market-oriented countries indigenous peoples' benefits from bioprospecting are dependent on relevant legislation/regulations specifying what they might expect to gain and under what terms.<sup>37</sup>

Whether such legislation/regulations result in payments or other benefits to indigenous people from bioprospecting is therefore entirely dependent on governments. The same would apply to indigenous people in countries which operate under other governance arrangements.

The conclusion is the same: benefits to indigenous people from bioprospecting are entirely dependent on government decisions under the regulatory approach. Benefits might be provided in return or they may not. They might be commensurate with the value of genetic resources to which indigenous groups have, or believe they have, a traditional claim. Or they might not. Those benefits might be commensurate with the income earned from bioprospecting or they might not. Indigenous people only have recourse to the government if commitments under bioprospecting legislation/regulations are not met. The point is that a market-based system can address these issues. The regulatory model cannot.

Rosenthal identifies some practical complexities. He cautions that:

However, a seemingly simple idea like returning benefits to communities can be extraordinarily complicated in practice. Are the communities defined geographically, ethnically, politically? Should the principal beneficiaries be those individuals or groups who actively participate, those who may be related, or everyone in a country?<sup>38</sup>

Proponents of the regulatory model might argue that multilateral instruments can be useful in "requiring" benefits specified in legislation/regulations to be paid – and hence that governments that do not abide by commitments to indigenous people can be "shamed" into action. The evidence in support of such a proposition is not encouraging.

Property rights are discussed in more detail below. For the purposes of this section, the key point is that property rights could be created by national governments. It then becomes an issue of how they might be allocated to the benefit of indigenous people which might have a legitimate claim over bioprospecting in their traditional area. There are two options:

- All of those rights could be allocated to indigenous groups, which could decide whether to sell all or some of those rights; or

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<sup>37</sup> The issues associated with income flows to indigenous people from bioprospecting are complex. It is not simply a case of indigenous people receiving benefits from national governments in return for ceding their revenue rights from bioprospecting, but this is a useful way to look at this issue.

<sup>38</sup> Op cit, page 8.

- A government could sell these property rights and decide to allocate all or a portion of the income from selling such right to indigenous people.

Under the first option it would be up to indigenous people whether to hold or sell all or some of the property rights allocated to them.

The market-based model can deliver benefits to indigenous people as property rights allocated to them – which could be sold, held, used as collateral or a guarantee for the development of other business options. Whatever the benefits of the regulatory model in protecting the interests of indigenous people, creating assets which can be leveraged for business development is not one of them.

The market-based model is clearly superior on transparency grounds. If indigenous people were not to benefit from property rights allocated to others for bioprospecting rights on land to which they had some claim, the value of these rights is at least transparent under a market-based model. Under the regulatory model there is no such transparency. Indigenous people have no option but to raise with governments any complaints that they have not received the benefits specified in legislation. But if they cannot identify the benefits that should have flowed to them, how can they possibly succeed? Theoretically they also have recourse to multilateral commitments. There are no grounds for confidence that this can deliver redress.

Wynberg argues that under the benefit sharing agreement he examined:

Although there is a nominal benefit-sharing agreement, the alternative benefits took a backseat to the negotiation of royalty shares. An additional interpretation is that the San considered non-monetary benefits foisted on them by others to be patronizing, and preferred to obtain the maximum amount of financial benefit so that they could decide upon and implement their own development priorities.<sup>39</sup>

Wynberg concludes that:

There is clearly an urgent need to introduce new forms of protection for traditional knowledge that not only gives communities rights over their knowledge but also enable the wider preservation and promotion of these knowledge systems. The Hoodia case demonstrates not only the value of having an integrated system to protect and promote traditional knowledge, but also the importance of co-called “defensive protection” to prevent the misappropriation of traditional knowledge.<sup>40</sup>

The market-based model can maximize the delivery of benefits to indigenous people – and make it transparent when promised benefits are not forthcoming.

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<sup>39</sup>Rachel Wynberg, “Rhetoric, Realism and Benefit Sharing: Use of Traditional Knowledge of Hoodia Species in the Development of an Appetite Suppressant”, *Journal of World Intellectual Property*, November 2004, Vol 7, No 6, page 7 at <http://www.biowatch.org.za/pubs/wjip.html>.

<sup>40</sup>Op cit, page 11.



### ***The private sector***

The private sector is interested in getting access to bioprospecting rights on a predictable and transparent basis. It needs an incentive to engage in bioprospecting. It has the option of engaging in bioprospecting and/or using existing resources of genetic material to undertake laboratory-based R&D. The literature suggests that this is not a straightforward decision. The costs and benefits from bioprospecting need to be compared with using existing genetic material in laboratories to develop new products. The trade off is complex but the implications for ABS are clear: the higher the costs imposed on companies via regulations, the lower the incentive to engage in bioprospecting. By encouraging bioprospecting, the market-based model is clearly superior to the regulatory approach.

### ***The research community***

The research community has an interest in maintaining genetic resource banks with which to undertake research - which is of course in the interests of all other stakeholders. Its interests will be best served by an arrangement which maintains the most open system possible of access to genetic material.

The Astra Zeneca and INBio-Merck arrangements demonstrate that a system based on property rights can meet the interests of the research community. By stimulating bioprospecting and investing in conservation and research in return for bioprospecting rights, the market-based model is demonstrably superior to the regulatory model for the research community. Regulatory arrangements may appear more attractive. But by discouraging bioprospecting, and hence minimizing investment in conservation and research, regulatory arrangements may limit the development of open and effective genetic resource banks.

In its submission to the Public Inquiry into Access to Biological Resources in Commonwealth (ie, Australian Government) Areas, the Australian Institute of Marine Science was quoted in the report as arguing that:

Key points from the Institute's proposal for a model for access and benefit sharing regulations are as follows:

- a. Sustainable access – all access must be undertaken on a sustainable basis.
- b. Ability to transfer samples to third parties – to provide certainty to investors in biodiversity research, it is essential that the terms and conditions of third-party transfers are set at the time of permission for primary access to resources.
- c. Benefit sharing – a framework for sharing benefits should be established at the outset. This framework should cover issues such as legal certainty over the use of samples; opportunities for Australian capacity building and Australian development of intellectual property in discoveries and their commercialization; other benefits, eg documentation of biodiversity to

support its effective management and conservation; and a genetic definition of monetary benefits, eg as a percentage of defined income.<sup>41</sup>

## Property rights

A government could create property rights to bioprospecting by legislation or regulation specifying that the holder of such rights could engage in bioprospecting under specific conditions. These property rights can be as simple or as detailed as the host government wants to make them.

### The nature of property rights

As De Soto and others have made clear, and as the experiences of many countries (especially in Central and Eastern Europe) demonstrate, property rights are one of the key requirements for a market economy. Property rights are however more than ownership. Citing changes which enabled Peru's telephone system to be sold, de Soto observes that "all we did was put in place a circuit of information of enforceable statements" which meant that "all our beliefs that the telephone company belonged to us but was run by government and was now going to be passed over to a company from outside – those beliefs were changed into enforceable statements. And it became clear that understanding the universal language of commerce helped raise the value of (the telephone company) 37 times."<sup>42</sup>

De Soto reaches a key conclusion:

In other words, what this tells us is that the majority of resources will not come from resource transfers. Those are really drops of water compared to what we in the developing world already have. Real wealth grows from the efforts of entrepreneurs who can bring resources together and divide labor efficiently among themselves to raise productivity.<sup>43</sup>

De Soto emphasizes that property rights can be used not only to create income directly, but as collateral for investing in other businesses. The act of creating and conferring property rights allows people to use those assets to develop other businesses.

Astra Zeneca has a continued investment/sponsorship in the Natural Product Discovery unit at Queensland's Griffith University – representing a total commitment of more than AU\$100 million since 1973. The program's goal is to find potential therapies and drugs from the biological compounds that occur in plants from Queensland's rainforest, marine organisms and from the Great Barrier Reef.

Donohoo notes that the National Product Discovery unit "has established an extensive data base and has discovered more than 700 biologically active compounds", and that

<sup>41</sup> Australian Government Inquiry, op cit, Chapter 7, para 7.19, page 4, at <http://www.deh.gov.au/biodiversity/science/access/inquiry/chapter7.html>. Paras 7.34 and 7.35 of this Chapter quotes the Australian Institute of Marine Science as being concerned about bureaucratic duplication for access to biological resources in marine areas.

<sup>42</sup> Hernando de Soto, "The Mystery of Capital: The Role of Property Rights in Creating Wealth and Alleviating Poverty", Sir John Crawford Memorial Lecture, 2004, at [www.cgiar.org/publications/sirjohn](http://www.cgiar.org/publications/sirjohn), pages 8 and 9.

<sup>43</sup> Ibid.

by extending its sample collection activities to Papua New Guinea, India and China the arrangement “places Australian research initiative at the forefront of global bio-discovery.”<sup>44</sup>

For a fee, Astra Zeneca secures the right to explore a nominated area. It agrees as well to pay a royalty to the State Government on any significant discoveries made from bioprospecting. The system is similar to the management of mining rights and payment of royalties in Queensland.

A comprehensive assessment of Queensland’s bioprospecting arrangements has been undertaken by Judith Jones. She notes that “one of the positive outcomes from collecting activities for bioprospecting is the increased information made available on the distribution and abundance of species.”<sup>45</sup> She makes a key point:

These comments consistently suggest that Australian researchers, currently engaged in the discovery of bioactive compounds, are seeking mechanisms to facilitate the financing of not only the discovery of compounds, but also the next stages of development of potentially valuable compounds. However, it can be expected that overseas or local investment in research and development will only be attractive where investors are certain that they will be entitled to receive any subsequent profits. Firm property rights in the resource are an important component to guaranteeing returns to investors. Moreover, intellectual property rights in the product are likely to be a necessary incentive to encourage investment.<sup>46</sup>

Jones concludes that “the results of the interviews portray a generally law-abiding, responsible and environmentally aware culture within Australian research scientists engaged in bioprospecting in Queensland.”<sup>47</sup>

No mention is made of the “owner” of the physical resources in either Costa Rica’s legislation or in the INBio-Merck agreement. The Colombia University report concludes that the agreement implies “that arrangements must be made with private property-owners from whom access to physical resources is sought, but they are clearly not granted ownership rights.”<sup>48</sup> In other words, there is an incentive for Merck to enter into agreements with the owners of the biological resource. As regards patents, marketing and licensing, “each party is authorized to independently prepare, submit, follow-up and maintain all patents, provided they consult the other

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<sup>44</sup> Mark Donohoo, “Australia’s Biodiversity – A Natural Opportunity for Drug Development”, at <http://www.ispe.org/australia/profile/part3/page1.htm>

<sup>45</sup> Judith Jones, “Regulating Access to Biological and Genetic Resources in Australia: A Case Study of Bioprospecting in Queensland”, *Australasian Journal of Natural Resources Law and Policy*, Vol 5, No 1, 1998, page 104. For a more technical treatment, see also Ronald Quinn, Priscilla Leone, Gordon Guymer and John Hooper, “Australian biodiversity via its plants and marine organisms. A high-throughput screening approach to drug discovery”, *Pure and Applied Chemistry*, Vol 74, No 4, 2002. Quinn et al conclude that “... this very successful AstraZeneca-Griffith University partnership is based on respect for relevant international laws and the Convention on Biological Diversity. Benefit sharing arrangements have been in place since 1993. As detailed in the manuscript, significant benefits in conservation of biological diversity have been achieved”, page 525.

<sup>46</sup> Op cit, page 110.

<sup>47</sup> Op cit, page 114.

<sup>48</sup> Op cit, page 20.

party on all plans and developments. The agreement does not address the intellectual property rights of any other stakeholder. However it does conform to the environmental laws of Costa Rica.”<sup>49</sup> The royalty arrangements that might apply should a drug be developed from bioprospecting in Costa Rica are confidential.<sup>50</sup>

In the Philippines the ownership of all genetic material remains with the government.

The arrangements in the Philippines suggest that there are dangers in designing a set of binding, restrictive regulations with high compliance and transactions costs for all parties. As noted above, the Filipino systems discourage bioprospecting.<sup>51</sup>

If the objective is to adopt a flexible and pragmatic set of rules for property rights designed to maximize the incentive for foreign companies to engage in bioprospecting, the Astra Zeneca/Queensland arrangement is the desirable model. If somewhat more regulation is desired, but still within a market-oriented framework, the Costa Rica/Merck arrangement should be followed.

### **Prior informed consent**

Prior informed consent relates to the need to obtain consent for bioprospecting. INBio is required to obtain written prior informed consent from Merck before entering into an agreement with a third party with regard to a product developed by Merck. No reference is made to obtaining prior informed consent from non-parties.<sup>52</sup>

In the Philippines “access to biological and genetic resources will only occur with the prior informed consent of the local indigenous communities according to the customary laws of the community.”<sup>53</sup>

The INBio-Merck agreement does not place caveats on “according to the customary laws of the community”, as is the case in the Philippines. Whether these “customary laws of the community” are clear and transparent is not discussed in the Colombia University report.

Some work has been done on access to biological resources in Australian Government areas – and particularly the terms and conditions under which such access should be granted to protect the long term interests of indigenous people.<sup>54</sup> Recommendations with a bearing on the design of a market-oriented model include: that one agency should be responsible for administering any scheme; that applicants enter into a benefit-sharing contact with the resource provider; and that in deciding to grant or

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<sup>49</sup> Op cit, page 20.

<sup>50</sup> Op cit, page 23.

<sup>51</sup> Op cit, page 55.

<sup>52</sup> Op cit, page 21.

<sup>53</sup> Op cit, page 57.

<sup>54</sup> Op cit. Advice from the Centre for Aboriginal Economic Policy Research at the Australian National University is that no significant payments have been made to an Aboriginal group from bioprospecting, although activities are undertaken for floral species such as *Morinda Citrifolia* in Arnhem Land (in the Northern Territory) and Sandalwood in Western Australia. CAEPR further advises that securing a balance between regulation and equity is required, and that an important issue is widespread “ownership” of species owing to religious sharing or shared indigenous knowledge.

grant or refuse a permit the relevant Minister must take into account the benefit sharing contact between the parties and that it must address prior informed consent, mutually agreed terms and adequate benefit sharing arrangements.<sup>55</sup>

This work in Australia and the INBio-Merck agreement indicates that prior informed consent can be incorporated in the market-based model quite easily.

### **Distribution of benefits**

Under the Queensland/Astra Zeneca arrangements the benefits are transparent. They are provided in the form of a fee for prospecting, and an agreement to pay royalties on discoveries. Griffith University also benefits from working with the company. The Government is responsible for a framework that ensures indigenous people receive benefit, either by requiring the company to make specific provision or by taking responsibility for that itself.

Under the INBio-Merck agreement Merck provides US\$1 million during the first two years for the purchase of laboratory equipment and materials for INBio's processing laboratory. Royalty arrangements are confidential. The Columbia University report found that in any case "no royalties have yet been derived from INBio's samples. No other benefits are reported to have been distributed."<sup>56</sup>

The Philippines agreement requires that in certain cases "the Party shall be required to donate some of the equipment used in conducting the research to a Philippine institution"; and "a Party developing a technology from research of a Philippine endemic species must make the technology available to the Republic of the Philippines without charging royalties."<sup>57</sup> The record would indicate that these arrangements have not been successful.

The superiority of the INBio-Merck agreement over the Philippines agreement is clear: the former is likely to maximize the capacity building benefits flowing to Costa Rica. The arrangements in the Philippines, on the contrary, constitute a disincentive to engage in bioprospecting – and in turn to provide capacity building

Given the probability that royalty payments will never be made as a product will never be produced from bioprospecting, it is not clear that royalty payments should even be negotiated at the outset. The evidence from the Colombia University report suggests that it would be better to focus in the first instance on capacity building – and simply have a reference to a requirement to negotiate royalty payments should a viable product be developed from genetic material found from bioprospecting.

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<sup>55</sup> Op cit, Chapter 2, page 5.

<sup>56</sup> Op cit, page 21.

<sup>57</sup> Op cit, page 58.

## Conservation and sustainable use

The INBio-Merck agreement does not specifically address sustainability – although there are references to how bioprospecting is to be undertaken. The Columbia University report notes:

INBio's primary goal in establishing the agreement with Merck is to support conservation through commercial exploitation of genetic resources. ... Furthermore, and perhaps more importantly, INBio's Merck-supported activities help increase public awareness and appreciation for biological resources.<sup>58</sup>

In the Philippines “the potential impact of the proposed activities on the environment is considered to be minimal.”<sup>59</sup> We are not aware of studies which have compared the environmental impact of the Costa Rican or the Philippine arrangements. What is clear is that the Costa Rican model has generated resources used for conservation. In terms of providing additional resources to devote to environmental protection the INBio-Merck agreement is clearly superior to the Philippines agreement. This is important, as the Columbia University report concluded that “training and capacity building, as emphasized by these agreements, are likely to be much more important than monetary benefits in the short and long term.”<sup>60</sup>

### Costa Rica and biodiversity conservation

Gamez has assessed the achievement of biodiversity and sustainable development objectives from the INBio program in Costa Rica.<sup>61</sup> He emphasizes that the INBio agreement reflects Costa Rican circumstances. He recalls that bioprospecting “done right, has been viewed by INBio in Costa Rica as another form of sustainable utilization and economic valuation of biodiversity, as well as a means to support the conservation and biological diversity.”<sup>62</sup> A key point is that “protected wild lands in Costa Rica have no inhabitants, local farmers or indigenous people. This is the reason why the distribution of monetary benefits in the INBio/MINA agreement does not contemplate directly these particular sectors of society.”<sup>63</sup>

Gamez notes that:

INBio has signed more than 20 agreements with industry, and the total of the research budgets have come to represent an investment of US\$0.5 M per year for bioprospecting activities and US\$0.5 M per year for capacity building, technology transfer, and institutional empowerment. The latter are of transcendental relevance, as they steadily increase INBio's capacity to negotiate fair and equitable agreements.<sup>64</sup>

In noting that INBio considers the non-monetary benefits to have been equal to or greater than the monetary benefits, Gamez concludes that:

the scientific and technological capacity developed by the institution in its 12 years of bioprospecting experience is considered as one of the more important assets, which as discussed before, has contributed directly and significantly to the formation of proper national policy and legislation regulating the access to, and benefit sharing derived from biodiversity resources.<sup>65</sup>

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<sup>58</sup> Op cit, page 23.

<sup>59</sup> Op cit, page 61.

<sup>60</sup> Op cit, page 87.

<sup>61</sup> Rodrigo Gamez, “The Link Between Biodiversity And Sustainable Development: Lessons From INBio's Bioprospecting Program in Costa Rica.” Gamez is with Costa Rica's Instituto Nacional de Biodiversidad.

<sup>62</sup> Ibid, page 5.

<sup>63</sup> Ibid, page 7.

<sup>64</sup> Ibid, page 8.

<sup>65</sup> Ibid, page 11.

The Executive Director of Merck's Natural Products Division, Georg Albers-Schonberg, is quoted as "being skeptical about achieving immediate results from chemical prospecting [under the INBio agreements]. But if not for the agreement, however, regions containing potential drugs would be destroyed, and the prospect of discovering an active ingredient for a drug would decrease even further."<sup>66</sup>

Rosenthal notes that:

Benefits that accrue to individuals or local communities will most effectively translate into conservation incentives when those people believe they have some long-term control over the resources. A community organization or a local government may be able to factor in the long term advantages of preserving their options, but individuals have difficulty seeing the value of reining in their personal consumption patterns on land they do not own or control themselves. This problem is particularly acute at the level of the individual and the marginal hectare under consideration. Unfortunately, "open access" resource regimes characterize much of the regions with the world's greatest biodiversity. Bioprospecting agreements generally involve a commitment to re-supply the same species sample if it proves to be of interest (an implicit promise to conserve the resource). However, it will likely require efforts from governments and organized communities to help turn long term relatively diffuse incentives into decision making tools by guaranteeing some measure of long term control over the resources and clear benefits to sustainable management practices.

Government organizations that manage natural resources typically have responsibility for monitoring biodiversity, and designing conservation and development strategies. These organizations are almost without exception under funded. Whether or not it is required by national law, providing direct benefits to government institutions may be a valuable conservation strategy. Financial returns can be used to build evaluation and monitoring capacity, and even the potential of royalty-based benefits may provide positive incentives for conservation policies and legislation. Even where governments will not be direct beneficiaries of agreements it may be advisable to address their priorities in diseases targeted for bioprospecting research, technologies for transfer, or communities that will receive training.<sup>67</sup>

The evidence demonstrates that the regulatory model is inferior to the market-oriented model in delivering additional resources to developing countries with which to achieve their conservation objectives.<sup>68</sup>

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<sup>66</sup> Elissa Blum, "Making Biodiversity Conservation Profitable. A Case Study of the Merck/INBio Agreement", page 1, at <http://www.ciesin.org/docs/002-270/002-270.html>.

<sup>67</sup> Op cit, pages 9 and 10,

<sup>68</sup> Balakrishna, for example, has concluded (in comparing the Philippines approach with voluntary initiatives) that "Such voluntary example may prove to be more useful as compared to national legislation such as the *Philippine Executive Order No.247* relating to access to genetic resources which almost stopped any form of collaboration with the Philippines." He cites examples where voluntary initiatives in India have provided commercial benefits from the sale of anti-fatigue drugs to local Kani Tribes, whose traditional knowledge has led to the development of that drug. P Balakrishna, "The need for a "TRIPS PLUS", Regime", in *Biotechnology and Development Monitor*, No. 36, at <http://www.biotech-monitor.nl/3604.htm>.

## **Compliance mechanisms and conflict resolution**

There are two broad systems of compliance: punitive or facilitative. Punitive compliance involves penalties (usually immediate and substantive) for breaches and tends to apply until a party has addressed breaches (which may involve fines or losing rights which the party might otherwise have enjoyed). Facilitative compliance encourages a party not in compliance to address the issues quickly. Fines or loss of privileges can apply later, but the initial emphasis is to encourage parties to move back into compliance as quickly and as cheaply as possible.

Columbia University concludes that “The INBio-Merck agreement encourages compliance primarily by requiring frequent and open communication among the parties”, and that “explicit compliance mechanisms involve only the payment of royalties.”<sup>69</sup>

The Philippines agreement requires a quarterly report “indicating the type and quantity of biological or genetic material collected, and a semi-annual progress report must be submitted ... describing the ecological condition of the study area and all research results.”<sup>70</sup>

The Columbia University report does not assess the costs of compliance. Nor have we come across direct estimates of the costs of compliance - on the bioprospector or the host country. Unless there are radically different issues at play between Costa Rica and the Philippines than is evident in the documents cited in this report, it is difficult to avoid the conclusion that the more market-oriented INBio-Merck agreement will impose substantially lower compliance costs on business and governments than the more regulatory approach in the Philippines.

Facilitative compliance entails lower costs – for the party in breach and the administrative entity. The task would be to design a system that encourages a party holding a right to bioprospect to comply with host country requirements. The easiest way to achieve that objective would be to specify that if found not to be in compliance at the end of a specified period a bioprospector would not have the right to take up renewal options.

Compliance is simpler in a market-based model. The agreement to supply and acquire property rights will be bound by commercial law. Disputes are addressed in the legal system. There is no requirement for a system of regulation administered by government to ensure compliance.

## **Certificates of origin**

It is argued that an ABS regime requires a system which certifies that genetic resources have been legally acquired. The case for this as put by Dross and Wolff is representative:

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<sup>69</sup> Op cit, page 22.

<sup>70</sup> Op cit, page 60.



The practical implementation of a system of certificates of legal provenance (CLP) would be feasible and not terribly expensive. Existing systems of certificates are valuable, and these should be integrated into a future system of CLPs.<sup>71</sup>

Dross and Wolff contend a CLP would benefit provider states, user countries and users. Institutions in user countries could limit themselves to ensuring that they were legally issued with the help of a monitoring system. Provider countries would issue a CLP only if all legislation has been complied with. For the users of genetic resources, a certificate of legal provenance would entail costs but also major benefits. These include:

- Legal certainty with regard to their use of the resources;
- CLPs could be used at any time to prove legal use of genetic resources to the international public and thereby protect themselves from accusations of bio-piracy; and
- Simple and consistent procedures in provider countries that users would probably profit from.<sup>72</sup>

These arguments are unconvincing and may also be disingenuous. The only other international system for certifying legality of a product is the Kimberly agreement which binds members not to allow the sale of diamonds unless the provenance is established. This was intended to stop the sale and trade of conflict diamonds.<sup>73</sup> In all other areas where international transactions take place, the working presumption is that national systems of law determine the legality of ownership of any product. The justification for this extraordinary nature of the Kimberly process was that in states in conflict in Africa, law and order has so broken down that illegality was considered widespread.

It is extreme to infer that the phenomenon of biopiracy is comparable. Yet that is the justification for the case an internationally regulated system of certificates of origin for genetic resources.

Imposing a requirement for certificates of provenance would be both unwarranted and involve potentially significant costs. Who would be responsible for issuing such certificates, and on what basis? Presumably a new international arrangement/institution is being suggested. Who would run such a system? How would it operate? Who would pay for it – the issuer, the holder of a right to bioprospect or some combination? If a bioprospector had paid a national government for a bioprospecting right, why should it be required to add a surcharge to fund a body to issue a certificate of provenance – which is not needed? If a national government has issued a bioprospecting right, how could a certificate of provenance add value? Presumably a new institution or existing body would “check” that such a right has

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<sup>71</sup> From “New elements of the international regime on access and benefit-sharing of genetic resources: the role of certificates of origin”, a summary of which is at <http://eldis.org/static/DOC19498.htm>.

<sup>72</sup> Ibid.

<sup>73</sup> The extent of trade in illegally acquired diamonds was never established (some estimated it only US\$25 million per annum). The Agreement required a waiver from WTO rules, so egregious is the idea that an international agreement is required because national systems of law are considered so ineffective.

been issued. If so, it would add nothing of value. If not, on what basis would it challenge the provenance of a right issued by a national government? How might any such differences be resolved? It is not hard to see how this would lead inevitably to the courts.

The argument that such a system would provide legal certainty is suspect. The converse is more likely to eventuate: such a system would amount to an additional disclosure requirement in patent applications that would, inevitably, create legal uncertainty. The prospect is that by creating such uncertainty CLPs would undermine bioprospecting and prevent the use of genetic resources for development.

The argument by Dross and Wolff that CLPs would provide “protection” from allegations of biopiracy does not stand up. Based on the literature surveyed for this report, there is no evidence that biopiracy is occurring on a large scale.<sup>74</sup> The only beneficiaries would be the institution which might be created or commissioned to issue such certificates. The costs of doing so would be paid for by bioprospectors and the compliance costs that such an arrangement would impose on already stretched bureaucracies in developing countries.

It is also unrealistic. The Colombia University report and work by Medaglia demonstrates how difficult it would be for agencies in developing country to certify that all relevant legislation/regulations had been complied with. The result would be to divert resources currently devoted to conservation into administrative support for such a system.

Such a system would certainly conflict with established provisions in the WTO and WIPO.<sup>75</sup> That will not bother NGOs who have consistently campaigned against the provisions of the Agreements of both organizations. But these organizations enjoy the consensus support of their member Governments. Why jeopardize the prospect of arrangements to improve access and benefit sharing by proposing a system for which there is no substantial case and which generates unnecessary conflict with other arms of the official international community?

Certificates of legal provenance are certainly not required under a market-based property rights model. Once a government decides to grant bioprospecting rights under its own national law, the holder by definition has the rights embodied in it. The holder of that right by definition constitutes proof of provenance. There is therefore no need for certificates of provenance. This conclusion holds whether a regulatory or a market-based arrangement is adopted.

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<sup>74</sup> Successful drugs such as Paxel, Artemesinin and Temiflu have been developed from bioprospecting. The evidence surveyed for this report suggests that while there might be debate about whether payments from royalties have been appropriate or “fair” these do not constitute the biopiracy that those supporting the regulatory model imply. Op cit, page 4. In the Hoodia case Pfizer paid a substantial amount to a South African research institute for the rights to use Hoodia in the development of an appetite suppressant. Wynberg observes that “At the national level, the Council for Scientific and Industrial Research in South Africa, has purportedly benefited substantially from Hoodia.” Op cit, page 7.

<sup>75</sup> The WTO is unlikely to recognize restrictions in international trade between legal and illegal goods. It is considered a matter for national governments. Such a system of regulation is also likely to conflict with the intellectual property provisions of agreements administered by the WTO and WIPO.

By interposing themselves between the parties in an unnecessary way, such certificates would impose disclosure obligations on companies that are not required under existing international patent law. There is a very real risk that in doing so such certificates of provenance would undermine patent law and practice, which would in turn constitute a major disincentive for companies to continue to invest in biotechnology.

## Chapter Five: Constructing a system based on property rights

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The foregoing has illustrated how a regulatory approach will work against the objectives of improving access and benefit sharing. It also demonstrates that a system using market-based instruments is the ideal solution in an environment where the size of the market is uncertain, regulation will be counterproductive and a balance needs to be struck between creating incentives for development and protection of biodiversity.

The objective in this section is to consider the foundations of a market-based system. It is not to resolve all possible issues. Effective solutions will emerge as members of the CBD focus more closely on the issues.

We start from the principle that property rights, securely defined, are best placed to achieve the interests of all stakeholders – and that to achieve the maximum benefits these rights should be capable of being traded, both within and between countries.

### **What would the “right” be and how might it be created?**

The right would be a contractual property right to bioprospect for genetic material in a developing country and to develop genetic materials. Such rights would be created and allocated by host governments. They would therefore need to be anchored in domestic law. Rights should be tradeable like any other property right. The objective should be to create as simple, transparent and effective a regime as possible and to allow property rights to be traded.

Creating a right is a very effective way of distributing benefits. If genetic resources secured by rights become more valuable, the value of the right increases for all holders of the right.

Could creating and allocating property rights to engage in bioprospecting be made compatible with existing arrangements? In Costa Rica property rights could be allocated using the mechanism used for the INBio-Merck agreements. New domestic law would presumably not be required. For other countries, such as the Philippines, new laws may be required.<sup>76</sup>

There is however a much easier way forward. The steps required to establish a market-oriented set of property rights could be as follows:

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<sup>76</sup> There is no sense all members of the CBD would be forced to grant property rights to engage in bioprospecting. If they do not wish to adopt this system, that would be their right. But it would be wrong for members which did not want to apply such a system to promote an international regime that restricted the capacity of members who elected to use market-based instruments.

Effective national laws to create property rights to engage in bioprospecting need to be created. Some new laws may be required. Others may need to be abolished and/or amended;<sup>77</sup>

- Host countries may require some assistance in assessing where their current laws are ineffective and require modification. Bilateral and multilateral aid may be available; and
- A market to trade property rights would emerge once these rights had been created and allocated. It then becomes a matter of ensuring that domestic laws enable those rights to be traded.

### **How is value created and maintained?**

Value emerges by creating and allocating property rights. What is needed to maintain that value? If holders of property rights believe that the value of these rights will decline over time (for example flowing from a temptation by national governments to issue too many permits) demand will fall. Those paying for the property rights need to believe that the value of their rights will not be devalued.

The value of bioprospecting property rights could be maintained by the issuing governments making a commitment that it will not issue additional rights for a specified period. A better option would be to design a system where such guarantees were not needed. For example, if it was decided that national governments should issue property rights on an exclusive basis to a bioprospector, and this was reflected in a bilateral agreement between the company and the host country, a concern about maintaining value would not arise.

The literature suggests that bioprospecting permits should be issued for the whole country. The INBio-Merck agreement, for example, covers the whole of Costa Rica.

### **Who gets the rights and under what conditions?**

If national governments are responsible for creating and allocating bioprospecting rights, who should get them and under what circumstances? Two options present themselves:

- A national government could auction all or some of the rights. It could decide the criteria for doing so. It would be useful if these rules were consistent among issuing countries. This would foster international trading. Issues concerning that are considered later;

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<sup>77</sup> The Columbia University study makes it clear that in addition to national laws in developing countries, there is a plethora of regulations that govern bioprospecting property rights. It is self-evident that there is no point in introducing new laws to convey property rights for a market-based bioprospecting model and to leave regulations in place that inhibit the effectiveness of such laws. Achieving consistency between laws and regulations might be easier said than done – albeit not impossible.

- The rights could be allocated without charge to particular stakeholders who could decide to hold or sell all or some of them.

Buyers would primarily be private sector entities which believe that the potential benefits from bioprospecting are warranted by bioprospectivity conditions and permit costs. There would however be no reason why a state agency (or a government-designated NGO such as in the Costa Rican case) could not bid for and hold such rights.<sup>78</sup>

Governments could allocate rights to indigenous communities who would also be free to trade or sell them.

Allocating rights under a scheme whereby entities that had paid for and held bioprospecting property rights could sell them should they wish to do so would be preferable to locking them into long term and fixed arrangements. For a liquid and efficient market to emerge, including a secondary market, entities should be able to decide when and to whom they might sell their bioprospecting rights. If it was thought desirable, the permission of a national government could be required as a condition of sale – on the basis that a national government should have the right to decide who engages in bioprospecting in its territory.

The most effective way of establishing an initial value for bioprospecting property rights would be to auction them. Doing so would also maximize revenue to the issuing country. If however there were only one bidder (which may be the case in some circumstances) the two parties would need to reach a mutually agreeable set of terms.

### **Over what area should rights be provided?**

Unless a property rights system can stimulate demand for bioprospecting rights above its current low level, there are strong arguments in favor of creating property rights that grant the holder an exclusive right to engage in bioprospecting over all of the genetic material found within the borders of the country granting the right.

Doing so does not imply that a host country granting exclusive access thereby forfeits control. As the Costa Rican example demonstrates, conditions can be imposed on the property right to ensure that bioprospecting takes place in accordance with the rules negotiated with the host government. It is for the host country to decide such matters. There are in-principle reasons for expecting that allocating rights to only a part of a country would constitute a major disincentive for a private sector entity to engage in bioprospecting – and thereby inhibit the emergence of trading of such rights within and between countries.

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<sup>78</sup> Moral hazard issues may arise if a government issuing the permits is also trading in them.

## **Over what period should rights extend?**

Queensland's mineral exploration arrangements suggest that rights should not be granted in perpetuity. They should be for a specified period. If a country becomes very attractive for bioprospecting, for example flowing from discoveries made from its genetic material, it would not be in its interests to grant very long term rights which effectively locked out other companies.

There is a balance to be struck between designing a competitive system and granting a sufficiently long term right to encourage bioprospecting. This should be for host governments to decide. The market would determine the extent to which different time periods in different countries could affect prices for rights traded between countries.

## **How should payments be determined?**

Developing countries cannot and should not rely on substantial royalty payments from new products as a result of bioprospecting. The Merck-Costa Rican case suggests that a fixed research payment, combined with provisions for royalty payments should there be a "find", is a better option. We therefore suggest that, initially at least, the Merck-Costa Rican model be followed. In other words, there should be an agreement that a bioprospector pay an annual fee for bioprospecting property rights, with provision for royalty payments should a viable product be developed.

## **Can such negotiations be "fair"?**

Some might argue that if a developing country has to negotiate such matters directly with a multinational company it will by definition be disadvantaged. Many developing countries have had considerable experience in undertaking such negotiations. If not they can usually obtain it from bilateral and/or multilateral donors.<sup>79</sup>

A model agreement that could be applied between a government and company to provide property rights is set out in Annex One.

An issue of fairness applies to indigenous rights, which should be entitled to some reward when they are the custodians/owners of particular genetic resources. A market-based solution is demonstrably superior to a regulatory arrangement in protecting the rights of indigenous people.

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<sup>79</sup> In negotiating a complex agreement with Australia on offshore gas resources, for example, the newly independent government of East Timor obtained assistance for its negotiating approach.

## How can trading be facilitated?

### Case study – Water trading arrangements

Australia is the driest continent. Its river systems are under stress. Salinity problems reflect water having been under priced. Water prices have covered the cost of supplying it rather than reflecting full environmental costs. These problems have arisen as market forces have not been allowed to operate.

Under the National Water Initiative, the Australian Government and the state governments have committed to introduce water trading – to enable water to be applied in areas of the greatest economic use. This system is too new to enable firm design conclusions to be applied to the system which we envisage. The lessons for a market-based bioprospecting system would seem to be:

- Creating the rights for a new system is very straightforward;
- Institutional issues and responsibilities need to be clarified. Establishing new institutional arrangements can be done quickly and efficiently;
- Information technology can minimize transaction costs;
- Allocating permits can be challenging when those used to getting the product at a low price face the prospect of paying a lot more. They want compensation. This should not be an issue for a new bioprospecting system. Some stakeholders (such as local research agencies) may fear being excluded. This suggests that there may be a case for governments holding some rights to itself or allocating some to research agencies – or to use the proceeds to boost the budgets of such agencies.

### *Why trade at all?*

When rights can be bought and sold, the market constantly monitors the value of them and sets a price. Otherwise, government officials will be forced to determine the price of the rights. History shows they invariably get it wrong.

### *How trading is encouraged*

Trading can be encouraged by designing a system that:

- Minimizes transactions costs;
- Has facilitative rather than punitive compliance arrangements;
- Conveys clearly understood and enforceable property rights;
- Is anchored in the realities of national legal and regulatory systems;
- Puts in place incentives to encourage as many developing countries as possible to become involved; and



- Ensures that there are sufficient incentives for pharmaceutical companies to engage in bioprospecting.

Trading can be discouraged by a system that:

- Imposes high transactions costs on participants;
- Does not provide incentives for maximum participation;
- Over allocates permits and hence undermines confidence in the long term value of permits;
- Does not facilitate the emergence of an efficient and effective secondary market in permits;
- Does not enable easy entry and exit to and from such a market; and
- Has punitive rather than facilitative compliance arrangements, resulting in higher costs for participants.

### **What about conservation?**

There is a common perception that if private rights are accorded to resources that are environmentally sensitive, there is no incentive to conserve. There is a large body of literature which shows how, when carefully applied, private ownership of rights on things that are environmentally sensitive can result in very effective conservation.<sup>80</sup> Valuable environmental and heritage assets more often decay in public ownership than under private ownership.

Governments need to assess their environmental goals for the resources concerned and establish clear policies and goals at the same time as rights are sold. Very sensitive resources may be excluded from private ownership. Covenants can be created which create obligations for owners of environmentally sensitive resources to develop the resource in a way that serves environmental objectives. Governments can decide to hold all or some of the property rights themselves.

### **What can be learned from similar models?**

Royalty payments in return for prospecting rights have been used in the mining industry. Queensland (with Western Australia the main mining state in Australia) operates a scheme similar to what we are proposing.

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<sup>80</sup> See for example the work by Judith Jones on bioprospecting in Queensland. She notes that “It is clear that the current technology permits an analysis for bioactivity on the basis of a very small sample of material. Thus, the collecting practices are relatively less environmentally damaging than reputed to be even just 10 years ago.” Op cit, page 114.

Under Queensland's Mineral Resources Act 1989 and the Petroleum and Gas (Production and Safety) Act 2004, explorers and developers are required to obtain an Exploration Permit (for coal or minerals) or an Authority to Prospect (for Petroleum) from the Queensland Department of Natural Resources and Mines before exploration can begin. Once granted, the explorer is given up to five years to actively investigate the entire area under tenure, with relinquishments required at prescribed intervals. Holders of exploration permits are legally required to submit regular reports on exploration activities carried out on the areas under tenure.

Explorers and developers pay an annual rent on Mining Leases, Mining Claims and Mineral Development Licences in advance. Under the Queensland legislation royalty is usually paid when a mineral is sold, disposed of or used. Royalties on petroleum, coal and most minerals are payable on an ad valorem basis, calculated as a percentage of the value of mineral or petroleum produced as determined by the Minister for Natural Resources and Mines. The Queensland government provides extensive online information on the state's resource base.

The system of bioprospecting in Queensland under which Astra Zeneca operates is based on the above principles.

The section on Environmental Implications from the Agreement between the Australian Institute of Marine Science (AIMS) and the State of Queensland states:

AIMS' bio-prospecting R&D benefits the protection of marine species by increasing knowledge of biota, their taxonomy, and their ecological framework. Actual access to biota will continue to be subject to regulation under resource management legislation, to ensure its environmental sustainability. New techniques have greatly reduced the amounts of material collected. The very small quantities of material required to provide extracts for screening (approximately 2 grams) essentially eliminates concern over environmental impact of primary collecting.<sup>81</sup>

In adapting the Queensland system to bioprospecting, the following issues arise:

- A royalty payment system could be designed to encourage bioprospecting. Where the probability of a "find" is much lower than in exploring for minerals, as is the case here, it is important that compliance costs are minimized if bioprospecting is to be encouraged;
- If bioprospecting rights are not used within a specified period they should lapse. There should however be no restrictions on such rights being sold up to the time when they lapse;
- Rights can be assigned to specific areas for mining as the prospectivity is more certain than with bioprospecting. For the reasons set out above, rights to bioprospecting should cover an entire country; and, most importantly

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<sup>81</sup> Australian Institute of Marine Science, "Biotechnology Benefit Sharing Agreement between AIMS and the State of Queensland", page 2, at [www.aims.gov.au/pages/about/corporate/bsa-aims-qldgov.html](http://www.aims.gov.au/pages/about/corporate/bsa-aims-qldgov.html). For a comprehensive analysis of Queensland's bioprospecting arrangements, see the article by Judith Jones.

- The property rights must be clearly defined.

### **Could rights be traded internationally?**

There is sense in the idea of rights to genetic resources being traded internationally. Companies engaging in bioprospecting are usually global businesses or developing products for global businesses.

To attract bioprospectors, governments will need to know if the price they are demanding for rights is the right one. If it is too high, they will not attract prospectors. If it is low, they will deny themselves the benefits.

If rights were tradeable, then a global price would emerge which would enable governments to assess if they had set prices appropriately.

The Queensland Astra Zeneca and the Merck/Costa Rican cases demonstrate that property rights can be defined, created and allocated. These rights could be traded within and between countries.

To facilitate trading between countries there would be benefits if rights covered the whole country. Efficient markets could price rights applying to a limited part of a country but trading would be made more difficult between countries.

There is no *a priori* reason why trading in bioprospecting rights cannot take place between countries creating and allocating similar property rights.

### ***Moving step by step***

The requirements for trading of such rights between countries are however somewhat more complex than those to enable trading within countries.

As a practical matter, it would be more sensible for individual countries first to establish viable national systems. When established, it might be feasible for groups of countries in similar circumstances, such as the Andean Pact countries or the Association of South East Asian Nations (ASEAN) economies, to work to harmonize their systems and then trial trading of permits among them.

A practical first step would be to ensure there were no restrictions on foreigners purchasing the property rights.

We have proposed that the international regime for access and benefit sharing should aim to set common approaches and standards for systems to support market based instruments. That approach would facilitate the possibility later of systems being established that would support international trading of rights.

### **What sort of compliance regime is necessary?**

The primary means of compliance under a market based system is the commercial legal system. The right to the genetic resource is a property right and is governed by a commercial contract. If the contract is not honored, there is recourse to the legal system. This frees government of the cost of creating its own regulatory system to ensure compliance.

If the rights require compliance with national environmental laws, then compliance is secured by the normal means by which any law is enforced. Once again, no special system of compliance should be necessary.

If there is uncertainty about the capacity of the legal system to enforce contracts, then the value of the property right will accordingly be lower. It may be argued this would reduce the benefits to be derived from selling rights to genetic resources. It is unlikely it would be as great as the deterrent effect of onerous regulation, as has been already demonstrated in some countries.

### **Should trades be registered?**

There is no reason national trading of rights should be registered. Most countries do not require property transactions to be registered. This is a different matter to establishing a register of national genetic resources. That can be established for a variety of reasons entirely unrelated to trading in rights.

If an international market for rights were to be established, some form of register would be needed to track prices. If a serious market developed, a private sector-based exchange could be expected to be established.

If trading is to develop between countries, there needs to be confidence that a seller has the right to sell the property right – and that it can only be sold once.<sup>82</sup> Provisions would need to be negotiated to this effect. National property rights systems need to be designed in such a way that there is no risk of a right being allocated twice. This should not be difficult to resolve.

National legislation covering such rights must however not impose restrictions on selling that property right. Doing so inhibits the emergence of an efficient market and will undermine demand – and hence prices. This might require new legislation/regulation.

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<sup>82</sup> In the Kyoto Protocol negotiations there was concern that a right to emit might be sold more than once. There was accordingly a lot of effort expended in addressing this issue. This concern was primarily directed at the main potential sellers: Russia and the Ukraine. There was a concern that a permit might at a later date be found to have been sold to another party – with implications for being found to be out of compliance with the Kyoto Protocol's (punitive) compliance regime.

**Predictability**

Parties must be confident that the rules governing property rights will not change mid-stream. That could be achieved by anchoring arrangements in domestic law. That said, any country with a reputation for constantly changing its laws and processes affecting foreign investment is hardly likely to be a major candidate for bioprospecting.

## Annex One: A possible model agreement

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To facilitate consideration of this proposal we have developed a possible model agreement. We are not suggesting that this model agreement be the basis on which negotiations might be conducted. Rather, our objective is to identify how a model agreement on which negotiations might be based can be developed.

### **The parties**

The agreement will be between [the country] and [the company].

### **Objective**

The objective is to determine the terms and conditions under which [company] can have bioprospecting rights in [country]. It is the intention of the parties that this bilateral agreement will be consistent with the agreement which has been reached internationally to facilitate the trading of the property rights associated with this agreement.

### **Exclusivity**

The agreement is solely between [country] and [company]. There are no other parties to the agreement. [Country] agrees that for the term of the agreement [company] will have exclusive rights to undertake bioprospecting for the genetic material contained within the border of [country].

### **Nature of the right**

Bioprospecting is defined as the exclusive right to engage in an examination of the biodiversity of [country] for the purposes of identifying new drugs of applications from the genetic material contained within the borders of [country].

### **Payment**

In return for the exclusive right to engage in bioprospecting in [country], [company] agrees to pay [country] US\$ ... per year. It is agreed that this payment is exclusively for bioprospecting and that accordingly this money will be paid on an annual basis to [capacity building institution]. [If it is not possible to reach agreement that this money would be paid directly to an institution in the host country, then this clause would need to be modified to say that the money would be paid to the government.]

Should a drug be developed from the genetic material found exclusively within the borders of [country] as a consequence of the bioprospecting undertaken as part of this agreement, the parties agree that as a condition for the development of this drug that royalty payments will be made by [company] to [country] on a basis to be agreed.

## **Property rights**

It is agreed between [country] and [company] that in return for the payments it will make to [country], [company] is granted exclusive property rights to engage in bioprospecting. If it further agreed that if appropriate [country] will modify its domestic laws regarding such property rights to ensure that the rights that it conveys via this agreement to [company] are fully consistent with the requirements established under the [new international agreement].

[Country] further undertakes to establish the administrative requirements to enable the full international trading of the property rights inherent in [international agreement].

[Country] agrees that it will not seek to impose additional requirements on [company] that are in any way inconsistent with its obligations under [international agreement].

[Country] agrees that [company] will have full rights to engage in bioprospecting within its borders under the terms and conditions set out in this agreement, and consistent with the obligations that [country] has assumed under [international agreement].

[Country] will not impose any restrictions on the rights of [company] to sell its rights to engage in exclusive bioprospecting to another party registered under [the international agreement]. [Country] will ensure that its legislation is consistent with this commitment.

## **Terms of agreement**

[Country] and [company] agree that this agreement will operate for 5 years from the date of signature by both parties, and that it can be renewed for a further 5 years at the agreement of both parties.

Should [company] wish to sell its rights to another party registered under [the international agreement] the parties agree that the [company] buying this right will have an exclusive right to engage in bioprospecting in [country] for the balance of this period. [Company] would then have the exclusive right for the unexpired portion of this agreement, but would then have the right to negotiate with [country] to renew that permit for a further 5 years.

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