

# **BIOPROSPECTING: ISSUES AND POLICY CONSIDERATIONS**

**PETER G. PAN**  
Researcher

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Legislative Reference Bureau  
State Capitol  
Honolulu, Hawaii 96813

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## FOREWORD

This report was undertaken in response to House Concurrent Resolution No. 146, H.D. 1, 2005. The Bureau has been requested to "conduct a study on the fair and equitable sharing of benefits arising from research, indigenous knowledge, intellectual property, or application of biological resources that are public natural resources held in trust by the State for the benefit of the people."

This study examines the nature of bioprospecting and certain problematic issues surrounding the use of biological resources. These include certain assumptions that may not necessarily be correct or relevant. The study further discusses the issue of the public land trust and benefit sharing with indigenous knowledge holders. We also examine several models of bioprospecting guidelines for the Legislature's consideration.

Ken H. Takayama  
Acting Director

January 2006

## FACT SHEET

Bioprospecting involves searching for, collecting, and deriving genetic material from samples of biodiversity that can be used in commercialized pharmaceutical, agricultural, industrial, or chemical processing end products. By the early 1990s, objections to uncompensated bioprospecting that does not share benefits with the source country became contentious. Since 1991, the Convention on Biological Diversity (CBD) has embodied the principles of compensated bioprospecting globally.

Compensated bioprospecting involves obtaining prior informed consent from the source country, sharing benefits, and promoting sustainable use of biodiversity. Where indigenous knowledge holders are involved, efforts are made to recognize and protect their rights. Benefits can take various forms, from royalties to negotiated advance and milestone payments, capacity building, facilities and equipment transfer, personnel training, sharing of research, and other forms.

The United States (and six other nations) are not parties to the CBD, which is an international protocol meant to apply to sovereign nations, not to individual cities, provinces, or states. The CBD encourages parties to enact national bioprospecting legislation. The United States has not done so. Neither has any individual state.

Without participation in the CBD and in the absence of national and state laws, bioprospecting is not regulated in Hawaii. The CBD is difficult to enforce and relies on voluntary compliance. However, it provides guidelines for implementing the principles of prior informed consent, benefit sharing, and promotion of sustainable use of biodiversity.

The Legislature is faced with the decision whether to regulate bioprospecting in Hawaii and who, including native Hawaiians, should share in the benefits. At present, it is the opinion of the Attorney General that the State does not automatically hold title to the genetic material derived from biodiversity taken from public lands. The Attorney General further opines that, at present, revenues from the sale of that genetic material do not qualify for transfer into the Ceded Lands Trust Account to be distributed by the Office of Hawaiian Affairs for the benefit of native Hawaiians. Thus, if the Legislature desires to regulate bioprospecting, it needs to ensure that the State retains title to share in benefits. It must also decide whether native Hawaiians should share in benefits, how, and how much.

It does not make sense to implement actual bioprospecting regulation without first setting policy guidelines. It is important that all stakeholders have the opportunity to be heard and help shape policy through the political process. After the Legislature determines overall policy, the actual implementation of a regulatory framework may fall to a bioprospecting working group composed of representatives of stakeholder groups, including state agencies, to work out the details, guided by legislative policy.

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## Chapter 1

### INTRODUCTION

H.C.R. No. 146, H.D. 1: H.C.R. No. 146, H.D. 1, 2005 – the measure to which this report responds – is attached as *Appendix A*. The resolution asks the Bureau to "conduct a study on the fair and equitable sharing of benefits arising from research, indigenous knowledge, intellectual property, or application of biological resources that are public natural resources held in trust by the State for the benefit of the people." The resolution further directs the study to "focus on assisting in the formation of a public policy strategy to commercially develop the State's biological resources in a way that will be environmentally sustainable, culturally sensitive, economically feasible, and mutually beneficial to all the people of the State." Specifically, the resolution requests the study to include identification and development of issues and policies for:

- (1) The conservation and sustainable use of biological diversity;
- (2) The responsible regulation of bioprospecting and biotechnology as it relates to bioprospecting;
- (3) The rights of traditional, indigenous knowledge holders;
- (4) The fair and equitable sharing of benefits arising from the research, indigenous knowledge, intellectual property, or application of biological resources; and
- (5) The meaningful participation in these processes by traditional, indigenous knowledge holders.

The study was also requested to review relevant information from other jurisdictions.

Aside from the Bureau's involvement, the Office of the Governor was requested to compile "an inventory of current bioprospecting research projects and activities in the State that are public." The Department of the Attorney General was asked to assist the Bureau in carrying out the study. Finally, the Bureau was asked to consult with the following:

- (1) Office of Hawaiian Affairs;
- (2) University of Hawaii;
- (3) Department of Business, Economic Development, and Tourism;
- (4) Department of Land and Natural Resources;
- (5) Department of Agriculture;

- (6) Department of Health;
- (7) Native Hawaiians or organizations representing native Hawaiian interests;
- (8) The biotechnology industry;
- (9) Scientists with interests in Hawaiian ecological systems;
- (10) Scientists with interests in genetics; and
- (11) Any other organizations or persons that the Legislative Reference Bureau deems appropriate.

*Organization of the Study:* Chapter 2 begins with a brief description of bioprospecting. The chapter then explores various problematic issues both central and tangential to bioprospecting. These include the concepts of indigenous knowledge, intellectual property, and benefit sharing. Chapter 2 also attempts to rectify and clarify incorrect or irrelevant assumptions that may lead to inappropriate conclusions. Chapter 3 examines several international bioprospecting protocols that offer guiding principles for prior informed consent, fair and equitable sharing of benefits, and conservation and sustainable use of biodiversity stemming from bioprospecting activity. Chapter 4 offers a brief overview of the public land trust issue and benefit sharing with native Hawaiians. Chapter 5 presents the responses of those parties that the Bureau consulted in accordance with the Resolution's directions. Chapter 6 presents the study's conclusions and outlines for the Legislature the issues and policies that need to be resolved.

## Chapter 2

### BIOPROSPECTING ISSUES

#### BIOPROSPECTING

In neutral terms, bioprospecting involves the exploration for any biological resource, otherwise termed "biodiversity," for potential commercial use. It should be noted at the outset that the term "bioprospecting" is ambivalent. For some people, prospecting conjures up images of claim jumping and other lawless activity during the free-for-all gold rush days of the Wild West. A touch of this negative connotation may have carried over to bioprospecting – not for gold but for *biological* resources. On the other hand, public perception links bioprospecting to technology. For the most part, technology has been acknowledged as a positive that has benefited the world.

Whether inadvertent or intentional, the coining of the like-sounding term "biopiracy" may also have somewhat tainted the term "bioprospecting." Biopiracy rejects the legitimacy of bioprospecting in its entirety. Biopiracy in its extreme form holds that all knowledge is public and free. Proponents morally object to the principle of intellectual property rights that privatize knowledge that they believe should be used for the good of all. Those who view bioprospecting as biopiracy view a potential remedy embodied in a certain global agreement<sup>1</sup> as "an initiative of the North to globalize the control, management, and biological diversity of resources which lie primarily in the Third World." This view considers bioprospecting as political, economic, and cultural oppression perpetrated by the money-rich, resource-poor north against the money-poor, resource-rich south. Furthermore, biopiracy considers benefit-sharing agreements with host countries not worth the harm caused by bioprospecting. Thus, bioprospecting is an ambivalent term depending on one's perspective. Yet, for better or worse, the term has entered the lexicon and gained universal currency.

This chapter examines various aspects of and issues relating to bioprospecting. This includes the concepts of conservation of biodiversity and its sustainable use as well as compensation or benefit sharing in its many forms for access to biodiversity. In the process, this chapter also explores some of the reservations the general public may have about bioprospecting. Some of these are rooted in misconceptions and others are based on fact. This chapter explores both types of reservations and the conditions that give rise to them that contribute to bioprospecting's uncertain reputation.

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1. Vandana Shiva, Biopiracy: The Plunder of Nature and Knowledge, Cambridge, MA: South End Press, 1997, referring to the Convention on Biological Diversity.

## FEAR: LACK OF CONSERVATION EFFORT AND UNSUSTAINABLE USE OF BIODIVERSITY

This is a major reservation many have concerning bioprospecting. The term "biodiversity" encompasses all living organisms found in the earth's various environments – on land and in the air or water. The Convention on Biological Diversity defines the term as:

the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.<sup>2</sup>

One bioprospecting firm defines biodiversity as the total variety of life on earth, including genes, species, and ecosystems and the complex interactions among them.<sup>3</sup> For example, biodiversity samples can be collected from "geothermal and hydrothermal vents, acidic soils and boiling mud pots, alkaline springs, marine and freshwater sediments, marine symbionts, manure piles, contaminated industrial sites, arctic tundra, dry Antarctic valleys, super cooled sea ice, microbial mats, bacterial communities associated with insects and nematodes, and fungi and plant endophytes."<sup>4</sup>

Bioprospecting involves searching for, identifying, and collecting appropriate biospecimens. In addition, bioprospecting uses various cutting-edge technologies to process and develop *genetic* material from these specimens that exhibit characteristics desirable in a commercial product. It is the *genetic* material, not the biospecimen itself, that is of interest. Generally then, it would be inefficient, irresponsible, and unnecessary for bioprospectors to collect massive volumes of plants or animals for processing. Consequently, it is a misconception that bioprospecting decimates an organism's population to near extinction and denudes entire rainforests like wholesale strip-mining for gold. Bioprospecting firms or their partners or clients generally need only a few specimens to extract the genetic material they need.

***Bioprospecting vs. Final Commercial Manufacture.*** At this point, there is a need to distinguish bioprospecting *per se* from the development or actual manufacture of a commercial product. With pharmaceuticals as an example, certain large global pharmaceutical firms operate their own bioprospecting units. In other words, they are vertically integrated and can take a product from start to finish all in-house. Specifically, they can develop a commercial drug from idea conception to bioprospecting for likely genetic material, synthesis of active compounds, clinical trials, manufacturing, marketing, and distribution. On the other hand, stand-alone bioprospecting firms typically work mostly on the front end. They normally identify likely samples, organize sample collection, and isolate and process active compounds from samples into a form usable by the pharmaceutical client. In this case, the bioprospecting firm merely delivers processed molecules to its client. The pharmaceutical firm then decides, with no guarantee of success, whether to proceed to develop a new drug with the processed compounds.

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2. Convention on Biological Diversity: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-02> (hereafter "CBD").

3. Diversa Corporation website at: <http://www.diversa.com/techplat/disc/default.asp>.

4. Ibid.

In another example, a bioprospecting firm may have contracted to isolate an enzyme that exhibits a high tolerance to certain chemicals. After receiving the enzyme, its agricultural client may further develop the enzyme to resist specific pesticides and perhaps breed it into feed grains. In turn, farmers gain an incentive to use even more pesticide without fear on their newly bred crops to increase yield, spur growth, and reduce the planting to harvest cycle. Although it is the agriculture firm that bred the new pesticide-resistant grain, the bioprospecting firm facilitated the situation. In any case, bioprospecting has more to do with the discovery of useful fundamental building blocks. On the other hand, biotechnology has to do with multiple technology areas and techniques that transform these building blocks into pharmaceutical, agricultural, industrial, and chemical processing products. (See "*Bioprospecting Does Not Equal Biotechnology*", below.)

***Bioprospecting Generally Requires Minimal Sample Quantities.*** Returning to the issue of the quantity of biodiversity samples required for bioprospecting, the Pacific yew bark provides another subtly nuanced illustration. The bark was used to produce paclitaxel, the generic name of taxol, which was identified in 1962. Taxol, the registered trade name, is an anti-cancer drug. For the purpose of *bioprospecting*, only small amounts were needed. Renewed interest in taxol's anti-cancer properties in the 1980s spurred the renewed collection of the Pacific yew bark. Because many groups wanted to conduct clinical trials, large quantities of the bark were then required. Killing the tree was necessary to produce taxol. The problem was that the Pacific yew was a protected species and is among the slowest growing species. At its peak, the collection of Pacific yew bark reached several hundred thousand pounds of bark per year. It took the bark of an entire tree to make one dose and it took six 100-year-old trees to treat one patient.

The point is, *bioprospecting* to identify and isolate the active compound required only a minimal amount of the Pacific yew bark. The problem was that, until the active compound in taxol could be artificially synthesized for clinical trials and eventual commercialization, huge quantities of the bark had to be used. At that stage, the work of *bioprospecting* had long been finished. It was the drug manufacturers who triggered the extreme harvesting to develop a commercial drug, not bioprospecting. However, bioprospecting is painted with the same broad brush and shares the blame for unsustainable use of the Pacific yew tree.

A second point to note is that economics and the law of supply and demand would have controlled the commercialization of taxol. As long as the active compound could not be economically synthesized, the drug could not be commercialized. In other words, at some point, continued failure to synthesize taxol would have stopped the harvesting of the Pacific yew. There simply would not have been enough yew trees to make a sufficient amount of doses. Fortunately, Bristol Myers Squibb later succeeded in converting the active compound to taxol by chemical manipulation. The drug firm also substituted a compound from the common yew, a more abundant relative of the Pacific yew. Bristol Myers Squibb now uses a cell culture method to produce taxol.<sup>5</sup> Thus, in general, economic considerations prevent *biotechnology* from blindly over-harvesting biodiversity for commercialization. In contrast, *bioprospecting* is done early on and rarely requires large quantities of environmental specimens.

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5. Information from: [http://www.phcog.org/Taxus/Taxus\\_Web.html](http://www.phcog.org/Taxus/Taxus_Web.html).

***Distinction between Pharmaceutical Bioprospecting and Phytomedicine.*** Related to the foregoing is another common misconception concerning bioprospecting – at least with regard to *pharmaceuticals*. There is a general belief that pharmaceutical bioprospecting invariably requires high-volume harvesting of whole organisms for final consumption, thus decimating biodiversity.<sup>6</sup> This is not entirely accurate. However, high-volume harvesting *is* always true of herbal medicine, also called phytomedicine. Although it is possible to bioprospect for potential *herbal* remedies, bioprospecting for regulated *pharmaceuticals* has focused on the higher returns available from commercializing approved and regulated *pharmaceutical* drugs. Herbal medicines, on the other hand, are not marketed as *pharmaceuticals* and are not regulated by the Food and Drug Administration. Further, they are not standardized in dosage or strength, lack quality control, and are mostly sold as dietary supplements.

Bioprospecting that aims to develop a regulated pharmaceutical drug ordinarily does not require wholesale harvesting of plants or animals. Thus, while *pharmaceutical* bioprospecting does not ordinarily endanger biodiversity, current practices in the *phytomedicine* industry always pose a danger. Pharmaceutical firms ordinarily strive to synthesize compounds from a limited amount of natural products. On the other hand, producers of herbal medicines usually do not attempt to do so because of the high costs involved for the relatively low-return industry. In contrast, pharmaceutical bioprospecting involves a high return and requires only low-volume harvesting. The point is that, although one can bioprospect for both pharmaceutical drugs and phytomedicines, the two are not necessarily the same.

In general, the phytomedicine industry harvests various parts of plants, such as stems, roots, or bark, and various animal parts, such as bones, horn, or skin, for consumption with minimal processing. These ingredients are mostly ground into powders or pastes. The plant or animal itself is usually harvested in great numbers. "Herb and phytomedicine companies pay a low price for large volumes of medicinal plant biomass from tropical ecosystems, package it in their own facilities, then sell the products at an inflated price in northern countries .... Despite the CBD, the industry still enjoys a period of uncontrolled, undocumented, and poorly managed free access to medicinal plants and cultural knowledge throughout the world."<sup>7</sup> (The Convention on Biological Diversity (CBD) is discussed in greater detail later in this chapter and in chapter 3.) In other words, the danger to biodiversity lies more in current phytomedicine industry practices than in pharmaceutical bioprospecting. Even so, harvesting phytomedicines does not mean only a slash and harvest approach must be used. Conservation practices can be applied to

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6. There are famous exceptions. Eli Lilly isolated two compounds, vincristine and vinblastine, from *Catharantus roseus*, the rosy periwinkle of Madagascar, which were powerful anti-cancer drugs. The direct extraction of only an ounce of vincristine requires fifteen tons of periwinkle leaves and costs well over six thousand dollars. Small quantities are so effective, however, that only ten pounds of vincristine a year are employed in the United States. Records show that from 1979 through 1988, a total of 6629 tons of *Catharantus roseus* were exported from Madagascar. (Columbia University School of International and Public Affairs, Environmental Policy Studies Workshop, 1999, "Access to Genetic Resources: An Evaluation of the Development and Implementation of Recent Regulation and Access Agreements" Environmental Policy Studies Working Paper #4, June 1999, p. 12 (hereafter "Columbia"). Members of workshop are: Ana Luz Porzecanski, Robin Sears, Taran Grant, Louis Putzel, Liliana Dávalos, Tonya Barnes, Hugh Cross, Gleb Raygorodetsky, Ben Simmons, and Pamela Chasek.
  7. Katy Moran, Steven R. King, and Thomas J. Carlson, "Biodiversity Prospecting: Lessons and Prospects" in *Annual Review of Anthropology*, 2001, 30:505-26, citing Leaman, et al. 1998, Brevoort 1995, and King, et al. 1999 on p. 520 (hereafter "Moran, et al.").

the phytomedicine industry as well. For example, forest farms can be organized to grow and harvest targeted plants for commercial use. Medicinal plants can be cultivated as fallow crops.

To further confuse the issue, a pharmaceutical bioprospecting company may "cross over" into a phytomedicine company. A crossover example is the transformation of Shaman Pharmaceuticals into Shaman Botanicals. The former was a pioneer in formulating principles of benefit sharing, sustainable use and conservation of biodiversity, preservation of indigenous knowledge, and informed prior consent. (These principles are discussed in greater detail later in this chapter.) In fact, the framework of principles established in Shaman Pharmaceuticals' contracts predated and served as a model for the Convention on Biological Diversity.

Originally, Shaman Pharmaceuticals was interested in developing an anti-diarrhea drug to treat AIDS patients. Indigenous knowledge holders directed it to the sap of the *Croton lechleri* tree found in the Amazon. From this, Shaman Pharmaceuticals developed SP-303/Provir and actually received favorable results from their single pivotal Phase III study on December 22, 1998. However, the Federal Food and Drug Administration required further testing, at which point Shaman Pharmaceuticals declined to proceed for cost reasons. It continues today as Shaman Botanicals with the same protocols selling Shaman Botanicals-Normal Stool Formula as a dietary supplement with the active compound in Provir.<sup>8</sup> Shaman Botanicals claims its failure does not mean the end of ethnobotany as an approach to drug development. Rather, it blames the extremely difficult and expensive drug development process in the United States.<sup>9</sup>

***Bioprospecting Generally Focuses on Genetic Material.*** Unlike the phytomedicine industry, bioprospecting firms often work with microbial *genomes*. Microbes are either bacteria or fungi. Microbes are of interest because they are easily accessible and omnipresent in every ecosystem, including oceans, deserts, rain forests, and arctic regions. Through natural selection in diverse environments, microbes have developed traits that are broader and more varied compared to plants and animals. Thus, microbes, compared to other organisms, offer a greater chance of discovering useful commercial traits. Microbes contain DNA, which is a fundamental molecule composed of four nucleotides, or chemical bases. These nucleotides are arranged into units called genes. These genes produce proteins. Bioprospectors are interested in a key class of proteins called enzymes. Enzymes carry out chemical reactions that give each microbe its unique character.

Microbes that survive in extreme environments, such as high or low temperatures, pH, or salinity, exhibit characteristics that may be highly desirable for commercialization. For example, microbes can survive in arctic conditions and thrive in extremely hot hydrothermal vents. Some have survived the radiation at Chernobyl. Enzymes can enrich the soil, clean the environment, produce oxygen, make drugs, etc. For example, a certain enzyme enhances the reactivity of pulp fiber to bleaching, allowing paper mills to reduce the use of harsh chemicals while achieving

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8. Glenn Gaylord, "New diarrhea treatment available for sale as dietary supplement" in AIDS Project Los Angeles, September 9, 1999.

9. Peter May, Shaman Pharmaceutical's Response to the Economist Article "Shaman loses its magic" (Issue February 20-26th, 1999), quoting letter of 3/9/99 from Beto Borges of Shaman Pharmaceuticals Inc. Manager of Sustainable Harvesting, Ethnobotany and Conservation, Shaman Pharmaceuticals, Inc. at: <http://www.amazonia.net/Articles/197.htm>.

desired pulp brightness. Another enzyme helps convert corn to ethanol to significantly improve ethanol production by allowing efficient operation at a cost-effective pH.<sup>10</sup>

Bioprospecting often targets end uses in the pharmaceutical, industrial, agricultural, and chemical processing markets. In any case, it is the *genetic* material in microbial specimens that bioprospectors want to get at for further processing and possible development into commercial products for these markets. To sample target microbes, a handful of soil is often sufficient – there is no need to strip-mine a mountainside or clear a rainforest. A summer 2005 Newsweek article quoted bioprospectors as saying that they take only what they absolutely need. If an active compound is identified, the bioprospector injects genes from the specimen into *E. coli* bacteria and yeast. "These microbes, known for their ability to propagate, act as nature's own drugmaking factory' so that there is no need to harvest the rain forest or the seafloor."<sup>11</sup>

### **FEAR: BIOPROSPECTING IS UNNATURAL**

This is a second reservation some portion of the public holds with regard to bioprospecting. Bioprospecting necessarily involves the use of technology. There are those who oppose any form of technological progress. Discounting a purely Luddite perspective, there are those who believe that the application of technology is unnatural and that it is unwise to tinker with nature. The concept is that the balance of nature must be preserved and that human intervention through the use of technology upsets that natural balance. The rationale behind this view is that technology causes unnatural negative consequences that may not be intended ("Don't fool with Mother Nature"). That technology often brings unintended harmful effects is undeniably true. However, even if the benefits of technology are taken into account, this view judges that the benefits are not worth the harm caused.

Numerous examples abound. Nuclear fission has been a source of scarce energy, especially to nations poor in energy resources. Yet, nuclear bombs and reactor accidents such as the one at Chernobyl in 1986 are part of human history. In 1984, Union Carbide's plant in Bhopal, India leaked methyl isocyanate, killing at least 20,000. More generally, the automobile has become essential for transportation and yet has facilitated huge numbers of traffic deaths. Modern-day manufacturing provides much of the essentials of daily living but is blamed for depleting the ozone layer, creating the greenhouse effect, poisoning deep sea fish – and thus ourselves – with mercury, etc.

Closer to home, in the 1980s, the pesticide heptachlor (a man-made compound) worked wonders killing termites but was found to have contaminated the milk supply in Hawaii. Indeed, the rejection of pesticides, developed with technology, has spawned an entirely new organic produce industry. On the island of Hawaii, geothermal energy production was rejected over fear of the release of sulfur and other air pollutants.

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10. Diversa Corporation website at: <http://www.diversa.com/>. The paper pulp enzyme is Luminasetm and Ultra-Thin alpha amylase is the enzyme for ethanol conversion.

11. Claudia Kalb, "Pharmacy Island" in Newsweek, Special Edition: The Future of Medicine, summer 2005, pp. 54-58.



Bioprospecting often applies technological processes to natural substances to enable the synthesizing of artificial compounds. Thus, some view bioprospecting as further artificial and unnatural tinkering with the balance of nature. The fear is that bioprospecting facilitates the creation of artificial mutations that, when propagated, could cause unintended, uncontrollable, and irreversible harm.

***Bioprospecting Does Not Equal Biotechnology.*** Another facet of this concept is that *bioprospecting* is often erroneously confused with *biotechnology* lock, stock, and barrel. Bioprospecting does frequently use advanced biotechnological processes and techniques. However, it is only a very small subset of the vast field of biotechnology. According to the Convention on Biological Diversity, biotechnology "means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."<sup>12</sup> Thus, bioprospecting also tends to be vulnerable to the slings and aspersions that may be cast at biotechnology as a whole.

For example, biotechnology may one day advance to a stage where human cloning is possible. The controversy over human stem cell research involves the use of biotechnology. However, neither human cloning nor human stem cell research is bioprospecting. In yet another example, it is well known that various agricultural companies have used biotechnology to grow genetically modified crops. The focus of much passionate local interest, especially among the Hawaii's organic farmers, is the growing of genetically modified crops and the conducting of seed trials by agricultural biotechnology firms in the State. There is an economic fear that genetically modified crops will contaminate non-modified crops and thus hurt the export of produce to countries that prohibit the import of genetically modified products. There is also concern about unintended harmful effects that genetically modified crops may have on human health. However, these concerns relate to a specific application of biotechnology and do not directly relate to bioprospecting, the subject of this study requested by the Legislature.

Bioprospecting does use biotechnology techniques to search for desirable characteristics in genetic material, although on occasion ethnobiological bioprospecting may target indigenous knowledge that focuses on non-genetic biological resources. (*See discussion of the distinction between bioprospecting per se and the development or actual manufacture of a commercial product, above and "Three Approaches to Bioprospecting," below.*) For example, bioprospecting may use recombinant gene technology to store target genes in retrievable form in representative environmental gene collections. One bioprospecting firm does this by cloning or splicing DNA fragments into a vector, a piece of DNA that acts as a carrier or a transporter into a host cell. The DNA fragment spliced into the vector DNA is called a recombinant molecule or clone. A representative gene collection is the collection of these clones representing the entire DNA isolated from the organisms in a specimen.<sup>13</sup>

A bioprospecting firm may get "hits" from this type of biotechnology research. For example, it might be able to derive a catalytic enzyme that allows the paper-making process to use less environmentally harmful bleach. On the other hand, it may isolate and derive an agent that makes corn more resistant to insects. In the latter case, the bioprospecting firm may sell the

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12. CBD: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-02>.

13. Diversa Corporation website at: <http://www.diversa.com/techplat/innobiod/divegene.asp>.

agent to an agricultural firm that, in turn, might decide or not to genetically modify a strain of corn to incorporate the insect-resistant characteristic. In this sense, bioprospecting can be related to the issue of genetically modified organisms. However, bioprospecting and genetically modified foods are not synonymous and the former does not always lead to the latter. Genetically modifying foods always has to do with biotechnology; it does not always have to do with bioprospecting. On a higher level, bioprospecting almost always involves biotechnology. However, biotechnology is an all-encompassing field in which bioprospecting is only one very small component that makes use of biotechnology techniques. Thus, the two must not be treated as if they were one and the same.

## **FEAR: LACK OF COMPENSATION OR BENEFIT SHARING**

National governments and holders of indigenous knowledge are the main parties who object to bioprospecting because of concern over a lack of compensation. Over the ages, humans have stumbled upon or intentionally developed numerous therapeutic, cosmetic, nutritional, agricultural, industrial, and other uses from earth's biodiversity. Bioprospecting continues that activity but with the express aim to enable the commercializing of a product.

*Evolution of Demand for Compensation.* The conditions that contribute to the current controversy over bioprospecting have come about only during the modern era. The history of aspirin helps to illustrate some of these conditions, if only as a theoretical exercise.

The Willow Bark and Aspirin. Hippocrates knew in 400 BC that a powder made from the bark and leaves of the willow tree relieved pain and reduced fevers. In 1828, Johann Buchner of Munich isolated salicin from the willow bark. By 1829, Henri Leroux improved the extraction procedure. In 1838, Raffaele Piria split salicin into a sugar and salicylaldehyde and converted the latter to salicylic acid. However, salicylic acid was harsh on the stomach and needed buffering. In 1853, Carl Friedrich Gerhardt did just that with sodium salicylate and acetyl chloride, creating acetylsalicylic acid. This is what modern-day aspirin is made of. However, Gerhardt had no desire to market it and abandoned his discovery. In 1897, Felix Hoffmann, who worked for a German company called Bayer, rediscovered Gerhardt's formula and convinced Bayer to market the new wonder drug. Aspirin was patented on March 6, 1899.<sup>14</sup>

From before the time of Hippocrates to Bayer's patent in 1899, humans had used willow bark for therapeutic purposes. It filled a need. Its use did not appear pervasive in the same way that the use of grains was pervasive in making bread. One can speculate that knowledge of the bark's use was valuable only to those who needed it to heal. In any case, it appears that the profit motive to produce a willow bark remedy was not strong although someone *could* have done so. Apparently, no one made or sold large quantities for profit. Even if someone had done so, it appears that no one else thought enough to object or demand a share of the profits. There is no

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14. Information from About.com, at: <http://inventors.about.com/library/inventors/blaspirin.htm>; and from article by Peter E. Childs "The Centenary of Aspirin: Wonder Drug of the Twentieth Century" at [http://www.ul.ie/~childsp/CinA/Issue59/TOC43\\_Aspirin.htm](http://www.ul.ie/~childsp/CinA/Issue59/TOC43_Aspirin.htm). The About.com reference incorrectly claims that Hoffman rediscovered acetylsalicylic acid in 1899. It was 1897. It also incorrectly reported that Bayer patented aspirin in 1889. It was 1899.

record that the governments of the ancient Greek city-states demanded royalties, prior informed consent, or technology transfer from Hippocrates. In turn, did Hippocrates demand compensation from those who used his indigenous knowledge of the willow bark's therapeutic powers? For that matter, did that indigenous knowledge belong exclusively to Hippocrates? Could anyone adequately trace that knowledge back in time in order to share benefits appropriately?

Why No Prior Demand for Sustainable Use. Digressing briefly, with regard to sustainable use in the example of the willow bark and aspirin above, there was no worldwide demand, as there is now, for conservation of biodiversity. The willow bark example serves to highlight several of the likely reasons for such lack of demand for conservation. First, the willow tree was not endangered because the supply of willow trees likely more than met the demand for its bark. Knowledge of its use was probably restricted. Its natural compound, salicin, was too harsh for widespread use and thus probably did not result in a huge demand for the bark. On the other hand, if salicin could have been used as is, like salt, demand for it might have increased dramatically – humans have multiplied exponentially while the willow has exhibited no similar fecundity. However, without artificial synthesis to relieve the demand for any natural resource, conservation and sustainable use of that resource would be threatened. (*See discussion on herbal and phytomedicine.*)

Second, willow trees were not destroyed in sufficient numbers to endanger their survival. Fortunately for the willow, its healing ingredient had been synthesized by the time commercialization vastly increased the use of aspirin.

Third, there was no structural framework to support a global call for sustainable use or conservation. There were no conservation or other interest groups and no north-south political schism that pits one nation against other nations over rights to biological resources. There was no network of instant worldwide communications, no Internet, and no global media to facilitate dissemination of information and polemics.

Why Compensation Demanded. Returning to the discussion of the lack of compensation, the point is that bioprospecting has become controversial because something of value – made possible by modern technology – is now at stake. On the one hand, willow bark was not commercially valuable. On the other hand, technologically synthesized aspirin is valuable. Modern methods for synthesizing natural compounds have enabled large-scale commercialization. Successful commercialization of a product derived from the bioprospecting of biodiversity potentially yields monetary profit. In today's world, with so much at stake, the lack of compensation for access to biodiversity constitutes a major objection to bioprospecting.

Yet it was not always thus. The formal concept that nations possess sovereign rights over the genetic resources of biodiversity located within their borders took shape only in the early 1990s. Free access to bioprospect the world's biodiversity was the standard operating theory and procedure until that time. A standing tradition established by Sandoz Laboratories reflects this thinking. (Sandoz was the Swiss drug firm before its merger with Ciba-Geigy in 1996 into current-day Novartis.) Sandoz had set up a program in 1957 to search for new antibiotic drugs from fungal metabolites. It became a tradition for Sandoz employees on business trips and

holidays to take plastic bags with them to collect soil samples that were later cataloged and screened.<sup>15</sup> In other words, bioprospecting with no prior informed consent or benefit sharing with host countries was the norm and, in the case of Sandoz, routinely institutionalized.

There are "common" areas such as the Arctic, Antarctic, outer space, and seas outside a country's economic zone. These do not fall under any country's jurisdiction. Some believe that access to biodiversity from these common areas is open to all. However, others feel that those who can afford to bioprospect from these areas are obliged to share the fruits of their research with the global community. In any case, regardless of the location, there was "no law or moral obligation requiring a company that collected biological material from another country to pay for access to that material."<sup>16</sup>

Convention on Biological Diversity. This perspective began to change after 1992. During that year, the Convention on Biological Diversity ("Convention") was signed at the United Nations Conference on Environment and Development in Brazil. Prior to that, no formal international guidelines existed to compensate host countries when bioprospecting by outsiders eventually led to commercial products. Host countries received nothing even as they witnessed outsiders reap profits from native biodiversity.

One example should suffice to illustrate. In 1969, a biologist from Switzerland who worked for Sandoz Laboratories (*see above*) took a holiday in Norway. While there, he used the opportunity to bring home some soil samples taken from the Hardangervidda mountain plateau in south-central Norway. Back in Switzerland, these soil samples were subjected to Sandoz's test procedures. In 1972, a strong immuno-suppressive property was found in the biochemical cyclosporin, produced by the fungus *Tolypocladium inflatum*. In November 1983, the U.S. Food and Drug Administration approved the use of cyclosporin to prevent organ transplant rejection. In 1997 alone, Novartis earned \$1.2 billion from this drug. Norway was never compensated. A commentator analyzing this situation reasoned that "in a situation of regulated access, Norway could have had a reasonable claim to two per cent of the annual royalties accruing from Novartis's sale of its cyclosporin medicines."<sup>17</sup> This would have amounted to \$24,000,000 for 1997.

Types of Benefits or Compensation. Things came to a head in 1992 with the signing of the Convention on Biological Diversity. The Convention attempts to address the need for equitable sharing of benefits from bioprospecting and concerns about loss of global biodiversity. The Convention has three goals:

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15. Harriet Upton, "Origin of drugs in current use: the cyclosporin story" 2001 at: [http://www.world-of-fungi.org/Mostly\\_Medical/Harriet\\_Upton/Harriet\\_Upton.htm](http://www.world-of-fungi.org/Mostly_Medical/Harriet_Upton/Harriet_Upton.htm).
  16. Corliss Karasov, "Who Reaps the Benefits of Biodiversity?" in Environmental Health Perspectives, v. 109, no. 12, December 2001, citing Richard S. Cahoon, VP of Cornell Research Foundation, associate director of patents and technology marketing at Cornell University.
  17. Hanne Svarstad, "Analysing Conservation–Development Discourses: The Story of a Biopiracy Narrative" in Forum for Development Studies, no. 1-2002.

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.<sup>18</sup>

The two goals of conservation of biological diversity and its sustainable use depend in large part on a host country negotiating a successful agreement regarding benefit sharing. (See "*Negotiated Bioprospecting Agreements*" below.) Benefits, or compensation, can take various forms. Compensation can be either monetary or non-monetary.

Monetary payments can include bioprospecting fees and fees for each sample obtained. The bioprospecting firm can dedicate a percentage of the research budget to locally preferred use including diseases endemic to the local population. Monetary benefits have also been used to fund conservation programs, universities, and other groups. Monetary benefits can also be applied to develop alternative income-generating schemes. Furthermore, a negotiated agreement may also commit the firm to obtain future supplies of biodiversity from the host country.<sup>19</sup>

Non-monetary benefits include the acknowledgment of contributions in publications or joint authorship and joint research. More substantially, it may provide training and increase scientific capacity by building a technology infrastructure. Portions of monetary benefits can be specifically set aside to fund conservation programs and actions to promote sustainable use of biodiversity. The bioprospecting firm also often provides free access to its technology, equipment, products, and research results. In certain cases involving the use of indigenous knowledge, a negotiated agreement may also provide for co-ownership of intellectual property rights. "Since 1993, over 1,400 developing country collaborators from 12 countries have received formal training in degreed as well as technical training programs from the ICBG."<sup>20</sup>

According to one source, monetary and non-monetary benefits can be described generally as follows:<sup>21</sup>

- Monetary
  - Advance payments: These are used primarily to set up trust funds for the disbursement of small community grants for development projects such as medicinal plant cultivation and marketing, tool purchases, written educational materials, shaman apprenticeship programs, and travel and workshops to build alliances among local community leaders

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18. CBD: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-01>.

19. Moran, et al., pp. 516-517.

20. Moran, et al., p. 517. The ICBG is the International Cooperative Biodiversity Groups, which is funded by the U.S. government in partnership with industry and sponsors projects using principles similar to those of the Convention on Biological Diversity.

21. Francesca Grifo and Joshua Rosenthal, eds., *Biodiversity and Human Health* (Washington, D.C.: Island Press, 1997), chapter 13 "Integrating Drug Discovery, Biodiversity Conservation, and Economic Development: Early Lessons from the International Cooperative Biodiversity Groups", pp. 6-7 (hereafter "Grifo & Rosenthal").

- Royalty earnings: This constitutes a percentage of income from product commercialization stipulated in research and benefit-sharing agreements
- Non-monetary
  - Capacity building through:
    - Training
    - Equipment transfers
    - Development of infrastructure to:
      - Conduct biomedical research
      - Manage natural resources
  - Region-specific disease research that gives priority to local interests in addressing relevant diseases, e.g. malaria cure for African countries
  - Long-term collaboration between various conservation, health, biotechnology, educational organizations and workers of both host and bioprospecting countries

Negotiated Bioprospecting Agreements. Currently, a negotiated agreement is the preferred tool used to provide compensation (which also underwrites sustainable use and conservation capacity building and programs) for access to biodiversity. Specific terms of compensation are left to the parties to agree upon but agreements are beginning to incorporate the principles embodied in the Convention on Biological Diversity. Negotiated agreements that provide balanced rights and benefits for both parties are preferred over the more problematic working out of intellectual property rights. (*See "Intellectual Property Rights" below.*)

Prior Informed Consent. Although not stated as a principle in the Convention on Biological Diversity, the granting of prior informed consent has also become standard in negotiated agreements.

The concept of informed consent was originally conceived with regard to protection of the personal safety of human subjects participating in medical research... Until recent years, informed consent in ethnobiological research was generally interpreted to mean verbal disclosure to the individual regarding the potential uses of his or her knowledge. Today, the possibility that financial benefits may result from this research necessitates complex arrangements with source communities and a very thorough information sharing process. Beyond in-depth discussions with local resource providers, this process can include sharing related contracts and facilitating legal advice during negotiations. It frequently also requires sharing [*disclosing*] project descriptions, lists of collections, and progress reports on research for review by the individuals, participating organizations, and national government authorities.

The principle of disclosure and informed consent, broadly interpreted, can also be a valuable tool for building consensus among stakeholders. Public workshops involving representatives from potential indigenous collaborators, government agencies, environmental NGOs, and researchers can simultaneously provide information, solicit input, and build consensus for the primary objectives of a project...<sup>22</sup>

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22. Grifo & Rosenthal, pp. 11-12.

Thus, prior informed consent now acts as a process through which all parties lay the foundation for the terms of multi-party bioprospecting agreements.

Milestone Payments. In some cases, host countries and their commercial collaborators also make provision for milestone payments. These are payments made upon completion of certain key, definable, and schedulable performance events in a project, as agreed to by the parties. Milestone payments usually precede final commercialization of a product. In theory, they can be made even though a product does not eventually succeed commercially. For example, a bioprospecting firm makes some or all milestone payments to the host country as the firm progresses in its process of identifying and isolating an active anti-cancer compound. Upon finishing its work as contracted and delivering the compound to a pharmaceutical firm, problems may arise. For example, the pharmaceutical firm may encounter insurmountable problems with the compound's toxicity in animal and human clinical trials. Thus, although milestone payments during the bioprospecting process were made, no anti-cancer drug may ever result.

Bioprospecting Does Not Necessarily Achieve Large or Quick Profits. A common misconception is that bioprospecting for genetic materials invariably leads to huge benefits from royalties when a product is commercialized. A review by the Environmental Policy Studies Workshop at the School of International and Public Affairs of Columbia University noted:

However, to date these profits have been elusive, and the win-win opportunities foreseen when uniting environmental and development objectives have been few and far between. The authors of this study have found this true in the cases studied here. They rightly conclude that technology transfer and capacity building is preferable over arrangements anticipating financial windfalls, which may never materialize.<sup>23</sup>

In addition to the misconception that bioprospecting projects always culminate in big payoffs is the further mistaken belief that they necessarily make for *quick* payoffs. Observers have noted the tendency toward this mistaken belief especially in host countries that have weak legal and regulatory frameworks. Referring to the interest of an East African country's government in "taking their share of the pie," one scholar noted: "The rent-seeking behavior is only amplified by over-zealous expectations of 'bio-prospecting' due to a few, unique success stories in the media over the past few years."<sup>24</sup>

On the contrary, it is important to note that "drug development requires expensive and time-consuming studies and clinical trials in order to secure government regulatory approval before any drug may be marketed. In the United States, a product typically takes from 10 to 15 years to materialize."<sup>25</sup> In fact, "since the CBD was introduced ... no pharmaceutical bioprospecting product developed by using traditional [*indigenous*] knowledge has been commercialized; no economic profit has been realized."<sup>26</sup> Although this is true only for products

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23. Columbia, p. v.

24. Justin Stokes, John F. Kennedy School of Government, Harvard University "Life Sciences Research in East Africa: Challenges and Opportunities for Business Incubation", November 2003, p. 14.

25. Moran, et al., p. 508.

26. Moran, et al., p. 508.

developed by means of *indigenous knowledge*, the point is clear that any successful product cannot be developed overnight.

According to a 2005 article in Newsweek, the following represents a typical drug pipeline:

Phase	Years	Process
Discovery/ clinical research	6.5	Find compound; lab and animal tests for human efficacy
Investigation drug application		The FDA evaluates compound's biology and toxicity before human testing
Clinical trials, phase I	1.5	Test drug safety in 20-100 human subjects
Clinical trials, phase II	2.0	Test efficacy/side effects in 100-500 patients who are candidates for the drug
Clinical trials, phase III	3.5	Confirm usefulness; study long-term toxicity in 1,000-5,000 patients
New drug application	1.5	FDA reviews evidence from trials for safety and efficacy for approval

"For every 5,000 compounds that enter preclinical testing, only five make it to human testing. Of these, only one is approved for sale."<sup>27</sup>

Capacity Building Supports Development. Capacity building is considered the most important component of non-monetary compensation by some. There is great flexibility and opportunity for creativity in this area. One observer notes:

Long-term development of the scientific, commercial, and management capacity of source countries may be the single most valuable benefit of bioprospecting research and development work... Capacity-building is a central component of all three goals of the program – drug discovery, conservation, and economic development... Capacity-building means training, equipment transfers, and infrastructure development in collaborating institutions and communities.<sup>28</sup>

Capacity building provides the means to achieve various goals in the host country. It can strengthen a country's science and technology infrastructure by providing training to technicians, graduate, postgraduate and postdoctoral students, and faculty of educational institutions. Individuals are trained in biotechnology as well as in relevant areas such as biodiversity conservation and management. Depending on individual circumstances, provision can also be made for stimulating local economic development.

Equipment transfers to host country collaborators come both through government funding and directly from commercial partners. Laboratory equipment related to the preparation, extraction, storage, and microbiological screening of specimens is commonly transferred to the source country. Other equipment purchases may include herbarium storage cases, computers,

27. Josh Gulick and David Golan, M.D., "The Science of Drugs" in Newsweek, Special Edition: The Future of Medicine, summer 2005, fold-out.

28. Grifo & Rosenthal, p. 9.



software, and field equipment to aid with biodiversity description and management. Infrastructure development efforts include vehicle purchases, renovation of laboratories, herbaria, and medical clinics, and improvements to community-managed enterprises such as ecotourism lodges.<sup>29</sup>

## **FEAR: TRADITIONAL CULTURAL PRACTICES THREATENED OR LIMITED**

This fear of bioprospecting holds sway mainly for holders of indigenous knowledge. Bioprospecting sometimes, but not always, involves indigenous knowledge of the use of local biodiversity. The fear is that bioprospecting firms will patent indigenous knowledge and cultural practices or native biodiversity. The concern is that, because those practices or biodiversity will then be treated as restricted intellectual property, they will no longer be accessible to indigenous people. To understand the significance of indigenous knowledge with respect to bioprospecting, it is necessary at this point to distinguish among three approaches to bioprospecting.

Three Approaches to Bioprospecting. The three approaches have been applied to bioprospecting for drug discovery, although they can also apply to other end uses (industrial, agricultural, and chemical processing). The first is *random* testing in which the greatest diversity of different specimens as possible is sampled. This is the shotgun approach and is expensive as well as inefficient. The second is the *bio-rational* approach, which is more useful and efficient. This approach targets specific organisms based on their biological characteristics. For example, observing bacteria thriving in hydrothermal vents suggests they have high heat and salinity tolerances. The third approach, which is also non-random, is *ethnobiological*. This approach elicits traditional (or indigenous) knowledge to guide sample selection.

The ethnobiological approach is less expensive and more focused. Yet, this approach is "used only by a small segment of bioprospectors."<sup>30</sup> The implication is that the myriad complex problems, including control of intellectual property rights over indigenous knowledge, make this last approach unattractive and problematic.<sup>31</sup> Shaman Pharmaceuticals (now Shaman Botanicals) is the best known of bioprospecting firms to have adopted the ethnobiological approach. The advantage of relying on indigenous knowledge holders is that they:

know the correct species, its location, the proper time of collection (some plants are poisonous in certain seasons), the solvent to use (cold, warm or boiling water; alcohol, addition of salt, etc.), the way to prepare it (time and conditions to be left on the solvent), and finally, posology (route of administration, dosage).<sup>32</sup>

How indigenous remedies are prepared also offers clues as to the chemical compounds involved. However, problems involving intellectual property rights that are integral to this approach abound. This is the wellspring of opposition to ethnobiological bioprospecting. Clearly,

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29. Grifo & Rosenthal, p. 9.

30. Moran, et al., p. 512, citing Farnsworth 1988.

31. Grifo & Rosenthal, pp. 6-7, although the authors use the term "*ethnomedical*" instead because they apply the three approaches exclusively to drug discovery.

32. Moran, et al., p. 512.

indigenous peoples fear the loss of their right to profit sharing. In addition, they also fear the loss of ownership of native biodiversity and the right to carry on their traditional practices.

Intellectual Property Rights. In general, intellectual property rights are rights to make, use, and sell a new product or technology that are granted, usually for a period of 17-20 years, solely to the inventor or the entity that files a claim on the inventor's behalf. They generally take the form of patents, trademarks, or copyrights and have traditionally fallen under the domain of national law.<sup>33</sup> In the case of bioprospecting, intellectual property rights are often preserved by patents, which protect the right of the holder to benefit financially. There are confusing misconceptions about, as well as genuine philosophical objections to, patents, including the morality of patents relating to life forms.<sup>34</sup> In the United States, living or dead plants found in nature cannot, themselves, be legally patented. However, if a plant breeder made a horticultural or genetic change, the change is considered an invention and can be patented.

It is important to note that patents on living organisms in pharmaceutical bioprospecting are uncommon. Typically, patents are granted for scientific advances during the isolation and modification of chemical derivatives and analogs of compounds originally isolated from a plant for an identified use.<sup>35</sup> In this sense, indigenous knowledge holders of native healing remedies need not fear the loss of use of native biodiversity. Another misconception is that patents relating to traditional knowledge somehow infringe on the right to perform indigenous cultural practices. In fact, indigenous rights to use tangible and intangible cultural resources in both traditional and innovative ways are not affected by patents.<sup>36</sup>

Nonetheless, the world of intellectual property rights, especially in the international bioprospecting arena, is both arcane and complex. For example, the Agreement of Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization sets minimum requirements for the protection of intellectual property rights. These include novelty, non-obviousness, and usefulness. Indigenous knowledge, however, fails the novelty requirement. For example, using a certain plant root to treat diarrhea – as part of indigenous knowledge – is not a novel or an original use. Knowledge of that particular treatment was known or used by others.<sup>37</sup> Thus, most countries' patent offices do not provide for the protection of indigenous knowledge. Neither do they require benefit sharing from bioprospecting.<sup>38</sup> National and international legislation on intellectual property rights and bioprospecting are still being discussed and continue to evolve.

Aside from indigenous knowledge, some bioprospecting programs recognize "*know how*." For example, when indigenous knowledge is involved and an invention is patented, if the provider of indigenous knowledge cannot be recognized at the level of an inventor, the

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33. Kristin Dawkins, Michelle Thom, and Carolyn Carr, "Information About Intellectual Property Rights No. 1" Institute for Agriculture and Trade Policy, at: [www.netlink.de/gen/biopiracy.html](http://www.netlink.de/gen/biopiracy.html).

34. Moran, et al., p. 513, citing Greely 1998 and Bruce & Bruce 1998.

35. Moran, et al., p. 513.

36. Moran, et al., p. 513, citing Wagner 1987 and Rosenthal 1999.

37. In cases involving the United States, the novelty requirement is codified in 35 United States Code section 102.

38. Moran, et al., p. 514, citing Axt & Corn 1993.

contribution is treated as valuable "know how." Subsequently, in any related publications and in the patent, the contribution must be credited as "prior art." (Prior art may be very broadly defined as the entire body of knowledge from the beginning of time to the present.)<sup>39</sup> Prior art citations formalize the contribution of such knowledge but do not claim any monopoly rights to use. According to one observer, the absence of a prior art citation may constitute grounds to deny or invalidate a patent.<sup>40</sup>

The concept of prior art further illustrates the convoluted nature of the intellectual property rights regime. To begin with, an invention essentially deals with something new, something unknown. Since it is difficult to define an invention by describing something that is still unknown, the alternative is to state what is *not* an invention.<sup>41</sup> This is done in the patent law by defining what is in the prior art, which in the United States, is codified in 35 United States Code section 102. This part of the patent law lists seven situations under which a person may not claim a patent, including the existence of "prior art" – the body of previous knowledge – that would disqualify something as a patentable invention. The first two situations relate to prior art and are the most common. The first situation consists of the following:<sup>42</sup>

- Others knew or used the "invention" in the United States, or
- It was patented or described in a printed publication in the United States or a foreign country before the date of the invention.

The second situation consists of similar but slightly different circumstances:

- The invention was patented or described in a printed publication in the United States or a foreign country
- The invention was in public use or on sale in the United States more than one year prior to the date of the application for a patent in the United States.

There are five other conditions under which a person is not entitled to a patent, which are footnoted.<sup>43</sup>

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39. Walter J. Blenko, Jr. "Considering What Constitutes Prior Art in the United States" in *JOM*, 43 (6) (1991), p. 45 (hereafter "JOM"). *JOM* is a technical publication of The Minerals, Metals, and Materials Society.

39. 35 U.S.C. §102.

40. Moran, et al., p. 514, citing Rosenthal 1999.

41. *JOM*.

42. 35 U.S.C. §102.

43. 35 U.S.C. §102(c) to (g):

"(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in

(1) an application for patent, published under section 122 (b), by another filed in the United States before the invention by the applicant for patent or

In addition to "know-how" and "prior art," other processes attempt to ensure equitable sharing of benefits from bioprospecting, including the use of *traditional resource rights*. These are bundles of rights that can be used for protection, compensation, and conservation. Moreover, *community registers*, or *peoples' biodiversity registers*, are data banks of local knowledge used in India. The ThirdWorld Network uses *community intellectual rights* primarily as a defensive measure to protect communities from commoditization of their knowledge and resources. In the Peruvian Amazon, *know-how licenses* were used by the native Aguaruna as contractual legal instruments applied to intellectual property.<sup>44</sup>

Because of the difficulties and complexity involved in resorting to the intellectual property rights regime, it is not surprising that only a small minority of bioprospecting firms has opted to deal with indigenous knowledge and use the ethnobiological approach. The most visible example involves the erstwhile Shaman Pharmaceuticals, now Shaman Botanicals. Shaman Pharmaceuticals dealt with the complexities and took the further initiative to develop a set of generous terms in negotiated agreements with indigenous knowledge holders. These terms recognized the knowledge provider's rights to benefit sharing. They also promoted conservation and sustainable use and acknowledged the need for prior informed consent. Furthermore, they provided for capacity building including technology and equipment transfer and training. These contractual terms actually predated the embodiment of similar principles in the Convention on Biological Diversity. Shaman's contracts typically define objectives of the partnership, terms of material transfer, the rights and responsibilities of collaborators, and the types and amounts of benefits.<sup>45</sup>

Relying solely on patent laws and the complexity of the intellectual property rights regime to deal with access to genetic resources is a relatively limiting approach. That system does not adequately address recognition of traditional knowledge and contributes nothing to conservation, sustainable use, prior informed consent, or benefit sharing. On the other hand, all these aspects can be dealt with through the negotiated agreement. It is the mechanism of

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(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351 (a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; [1] or

(f) he did not himself invent the subject matter sought to be patented, or

(g)

(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or

(2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other."

44. Moran, et al., p. 514, citing Posey & Dutfield 1996; Anuradha 1997; Singh Nijar 1996; and Tobin 1997.

45. Moran, et al., p. 515, citing Rosenthal 1999.

choice – contracts can be designed to fit differing relationships between collaborators.<sup>46</sup> (See "Negotiated Bioprospecting Agreements" above.) Not least among its advantages is the ability to include indigenous peoples and allowing them to:

determine for themselves the extent to which they choose to participate. Different culture groups hold different beliefs about entrepreneurship, which can be a double-edged sword when introduced into nonmarket economies. At the same time, however, many communities seek greater access to markets. These differences should never be an excuse to exclude indigenous groups from the sustainable use of biodiversity, for this is their, and only their, decision to make.<sup>47</sup>

## NATIONAL PRIDE AT STAKE

It was only in the 1980s that national governments became aware of the potential inequities that unregulated bioprospecting can cause. Certainly money is involved and, of course, depletion of national biodiversity is an issue. Respect for indigenous culture and traditional practices is also a concern. However, in today's environment of transparency and accountability facilitated by a global media, national pride takes a big hit when a bioprospecting firm takes unfair advantage. The following recent case provides ample illustration.<sup>48</sup>

In 1998, Genencor International, Inc. bioprospected for extremeophiles (tiny organisms that can survive and thrive in extreme environmental conditions) in Kenya. Genencor took samples from a number of alkaline lakes located on the bed of the Great Rift Valley – Bogoria, Magadi, Nakuru, Elementaita and Solai in Kenya, and Natron in Tanzania. However, the only samples that yielded positive results were from the hot geysers of Lake Bogoria and along the shores of Lake Nakuru. The Kenya Wildlife Service alleges that the collection team was composed of scientists from the Department of Microbiology and Immunology at the University of Leicester in the United Kingdom and an employee of Genencor. The Service further alleges that the team did not inform the government of its activities, nor did it obtain permission from governmental authorities. Usually, the Ministry of Education is mandated to issue such permits, although the Service is "empowered to vet proposals made by researchers working in Kenya's protected areas."<sup>49</sup>

The Service recounts that Genencor later purchased the samples from the University of Leicester, made an enzyme discovery, and then sold it to Procter & Gamble. That particular enzyme was then used as a critical ingredient in the manufacture of Tide Alternative Bleach detergent.<sup>50</sup> In fact, Genencor not only had not concealed its unauthorized access to and taking

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46. Moran, et al., p. 515, citing Laird 1993; Rubin & Fish 1994; Shelton 1995; Putterman 1996; and Hunter 1998.

47. Moran, et al., p. 520, citing Pritchard 1998.

48. John Mbaria, "KWS seeks millions from Procter & Gamble" in *The East African* (Nairobi, Kenya), August 24, 2004 at: <http://www.grain.org/bio-ipr/?id=409>.

49. Mbaria.

50. Mbaria, citing Dr Wilber Lwande, project coordinator at the International Centre of Insect Physiology and Ecology, which is assisting the KWS in pursuing compensation from Procter & Gamble, Inc., and Genencor International.

of biodiversity samples from a host country, it touted that fact. Genencor is reported to have stated in its 2000 annual report to shareholders: "To find the enzymes that flourish in alkaline environments, like your Saturday wash water, and enzymes that give your jeans a softer feel and a stonewashed look, we looked for them, that's right, in the soda lakes of Kenya."<sup>51</sup> On its website, Genencor discusses its activity in Kenya:

In 1998, we commercialized an extremophile enzyme. Puradax cellulase enzyme was derived from a new *Bacillus* species found in the Rift Valley soda lake of East Africa during an expedition in 1992. In 1999, Genencor introduced IndiAge Neutra, a cellulase derived from a new species of strictly alkaliphilic *Streptomyces*. The bacterium was isolated from the soda mud flats on the shores of the highly alkaline Lake Nakuru in Kenya. For economic production, the endocellulase gene was cloned and expressed in *Streptomyces lividans*. This innovative, easy-to-use enzyme product, can treat denim to create the popular stonewashed look. We continue to produce new products by accessing the microbial gene pool.<sup>52</sup>

In another portion of its website, Genencor acknowledges the Convention on Biological Diversity but indicates that its guidelines and interpretation are in a state of flux:

The Convention on Biodiversity, one of the results of the 1992 Earth Summit in Rio de Janeiro, established the sovereign rights of nations to share the benefits of valuable discoveries made within their borders. Although the United States has never ratified this treaty, Genencor voluntarily conforms to the treaty's provisions, as we currently understand them. It is important to note that these provisions and guidelines for compliance, as well as the establishment of the necessary infrastructure for compliance are currently in a state of interpretation and development.<sup>53</sup>

There is no mention of having obtained prior informed consent, benefit sharing, or any negotiated agreement for such with Kenya in the case of commercializing the "stonewashed" look enzyme.

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51. Mbaria.

52. Genencor International, Inc. website: <http://www.genencor.com/wt/gcor/biodiversity>.

53. Genencor International, Inc. website: [http://www.genencor.com/wt/gcor/gene\\_biodiversity](http://www.genencor.com/wt/gcor/gene_biodiversity).

## Chapter 3

### MODELS AND GUIDELINES FOR REGULATION

H.C.R. No. 146, H.D. 1, 2005, raises five concerns to be addressed by this study. These were:

- (1) Conservation and sustainable use of biological diversity;
- (2) Responsible regulation of bioprospecting;
- (3) Rights of indigenous knowledge holders;
- (4) Fair and equitable sharing of benefits; and
- (5) Meaningful participation by indigenous knowledge holders.

This chapter examines two international models for the regulation of bioprospecting that contributes to conservation and sustainable use of biodiversity as well as provides for fair and equitable sharing of benefits. This chapter also assesses guidelines issued by a biotechnology industry group for biotechnology companies engaged in bioprospecting.

#### APPROACHES TO BIOPROSPECTING REGULATION

Regardless of the history and different philosophies regarding bioprospecting, the new global reality prevents nations from continuing to permit unregulated bioprospecting. In 1992, the Convention on Biological Diversity (hereafter "CBD") was signed by 150 nations to address the international bioprospecting issue. Also in 1992, a parallel approach embodied in the International Cooperative Biodiversity Groups (hereafter "ICBG") took shape. This chapter examines both regimes.

#### CONVENTION ON BIOLOGICAL DIVERSITY

The CBD was opened for signature on June 5, 1992, at the United Nations Conference on Environment and Development in Rio de Janeiro in Brazil. This international protocol gave expression to the novel idea that the bioprospecting process could yield conservation and development benefits. Carried out properly, the process could provide economic incentives for the conservation of biodiversity as well as for local and regional development.<sup>1</sup> The CBD is an *international* agreement that applies to sovereign nations. It was not meant to address bioprospecting in non-sovereign entities such as individual provinces in France or individual states in the United States.

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1. Grifo and Rosenthal, p. 2, referring mainly to bioprospecting for drug discovery, but is relevant to all types of applications, e.g. agricultural, chemical, and industrial.

It should also be noted that the CBD is widely considered an unenforceable protocol that relies on voluntary compliance among the parties. As a well-known observer notes, although the CBD is a legal document: "It lacks bite. There is no way to enforce it."<sup>2</sup> According to another observer: "Distrust is a problem. Some people think that bioprospecting agreements are inherently unfair and outpriced for indigenous peoples from the outset. They assume that the cards are stacked against them."<sup>3</sup> Regardless of the CBD and its principles, various environmental groups and researchers continue to view bioprospecting as "an initiative of the North to globalize the control, management, and biological diversity of resources which lie primarily in the Third World."<sup>4</sup> Nonetheless, the principles expressed in the CBD are instructive.

**Parties to the CBD.** At present, 188 nations are parties to the CBD, of which 168 are signatories. A party nation is one that has signed, ratified, acceded to, accepted, or approved the CBD. According to the CBD, ratification, accession, acceptance, or approval all signify a country's willingness to be bound by the protocol. However, signing of the protocol does not, in itself, establish consent to be bound, hence the further act of ratification.<sup>5</sup> The United States is the only signatory nation not bound by the CBD – the Senate has yet to ratify after President Clinton signed it on June 4, 1993. Other than the United States, there are only six other sovereign entities that are not parties to the CBD. They are: Andorra, Brunei Darussalem, the Holy See, Iraq, Somalia, and Timor-Leste. Nations that did not sign the CBD during the time it was open for signature can only accede to it. Of the 188 parties, twenty fall into this category.<sup>6</sup> The terms "acceptance" and "approval" are of more recent origin and mean the same as "ratification." The use of these terms stems from the diversity of the world's legal systems.<sup>7</sup>

**Objectives of the CBD.** The objectives of the CBD directly address several of the concerns raised in H.C.R. No. 146. Specifically, Article 1 of the CBD states its objectives as:

[T]he *conservation* of biological diversity, the *sustainable use* of its components and the *fair and equitable sharing of the benefits* arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.<sup>8</sup> (*Emphasis added.*)

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2. Corliss Karasov, "Who Reaps the Benefits of Biodiversity?" in *Environmental Health Perspectives*, v. 109, no. 12, December 2001, p. 4 at: <http://ehp.niehs.nih.gov/docs/2001/109-12/focus.html>, citing a comment by Joshua Rosenthal, Deputy Director and Biodiversity Program Director, Division of International Training and Research, Fogarty International Center (the international component of the National Institutes of Health).
  3. *Ibid.*, citing Richard S. Cahoon, vice president of the Cornell Research Foundation and associate director of patents and technology marketing at Cornell University, pp. 2 & 4.
  4. *Ibid.*, citing Vandana Shiva, *Biopiracy: The Plunder of Nature and Knowledge*, 1997.
  5. Convention on Biological Diversity website at: <http://www.biodiv.org/world/parties.asp> (hereafter "CBD").
  6. CBD. The 20 countries that accede to the CBD are: Albania, Bosnia & Herzegovina, Cambodia, Equatorial Guinea, Eritrea, Georgia, Kiribati, Kyrgyzstan, Lao People's Democratic Republic, Niue, Palau, Saint Lucia, Saint Vincent and the Grenadines, Saudi Arabia, Sierra Leone, Tajikistan, The Former Yugoslav Republic of Macedonia, Tonga, Turkmenistan, and Uzbekistan.
  7. CBD. For example, certain Eastern European counties use "acceptance" or "approval" for purposes of participation in treaties. These terms are also used in cases where organizations rather than nations, e.g. the European Community, become parties to an international treaty.
  8. CBD, at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-01>.



These objectives are based on the principle expressed in Article 2 of the CBD that nations have the sovereign right to exploit their own resources pursuant to their own environmental policies. On the other hand, nations are also responsible for ensuring that activities within their jurisdiction do not damage the environment of other nations or areas beyond the limits of their own national jurisdiction.<sup>9</sup>

The following examines CBD regulatory guidelines that address the concerns raised in H.C.R. No. 146.

***Conservation and Sustainable Use of Biodiversity.*** Article 6 of the CBD requires parties, in general, and in accordance with their particular conditions and capabilities, to:

- a. Develop national strategies, plans or programmes for the *conservation and sustainable use* of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, inter alia, the measures set out in this Convention relevant to the Contracting Party concerned; and
- b. Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies.<sup>10</sup> (*Emphasis added.*)

**Identification and Monitoring of Biodiversity.** Article 7 deals with the more specific processes of *identification and monitoring of biodiversity* for conservation and sustainable use purposes:

- (a) Identify components of biological diversity important for its conservation and sustainable use having regard to the indicative list of categories set down in Annex I;
- (b) Monitor, through sampling and other techniques, the components of biological diversity identified pursuant to subparagraph (a) above, paying particular attention to those requiring urgent conservation measures and those which offer the greatest potential for sustainable use;
- (c) Identify processes and categories of activities which have or are likely to have significant adverse impacts on the conservation and sustainable use of biological diversity, and monitor their effects through sampling and other techniques; and
- (d) Maintain and organize, by any mechanism[,] data, derived from identification and monitoring activities pursuant to subparagraphs (a), (b) and (c) above.<sup>11</sup>

**In-Situ and Ex-Situ Conservation.** Articles 8 and 9 of the CBD require "*in-situ*" and "*ex-situ*" conservation, respectively. "In situ conservation" means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species *in their natural surroundings* and, in the case of domesticated or cultivated species, in the surroundings

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9. Ibid., at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-03>.

10. CBD, at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-06>.

11. CBD, at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-07>.

where they have developed their distinctive properties. "Ex-situ" conservation means the conservation of components of biological *diversity outside their natural habitats*.<sup>12</sup>

The CBD's recipe for *in-situ conservation* consists of thirteen tasks in Article 8. These are as follows:

- (a) Establish a system of protected areas or areas where special measures need to be taken to conserve biological diversity;
- (b) Develop, where necessary, guidelines for the selection, establishment and management of protected areas or areas where special measures need to be taken to conserve biological diversity;
- (c) Regulate or manage biological resources important for the conservation of biological diversity whether within or outside protected areas, with a view to ensuring their conservation and sustainable use;
- (d) Promote the protection of ecosystems, natural habitats and the maintenance of viable populations of species in natural surroundings;
- (e) Promote environmentally sound and sustainable development in areas adjacent to protected areas with a view to furthering protection of these areas;
- (f) Rehabilitate and restore degraded ecosystems and promote the recovery of threatened species, inter alia, through the development and implementation of plans or other management strategies;
- (g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health;
- (h) Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species;
- (i) Endeavour to provide the conditions needed for compatibility between present uses and the conservation of biological diversity and the sustainable use of its components;
- (j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;
- (k) Develop or maintain necessary legislation and/or other regulatory provisions for the protection of threatened species and populations;
- (l) Where a significant adverse effect on biological diversity has been determined pursuant to Article 7, regulate or manage the relevant processes and categories of activities; and
- (m) Cooperate in providing financial and other support for in-situ conservation outlined in subparagraphs (a) to (l) above, particularly to developing countries.<sup>13</sup>

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12. Ibid., at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-02>.

13. CBD, at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-08>.

Article 9 of the CBD offers five guidelines to conserve biological diversity outside their natural habitats, or *ex-situ conservation*. These are:

- (a) Adopt measures for the ex-situ conservation of components of biological diversity, preferably in the country of origin of such components;
- (b) Establish and maintain facilities for ex-situ conservation of and research on plants, animals and micro-organisms, preferably in the country of origin of genetic resources;
- (c) Adopt measures for the recovery and rehabilitation of threatened species and for their reintroduction into their natural habitats under appropriate conditions;
- (d) Regulate and manage collection of biological resources from natural habitats for ex-situ conservation purposes so as not to threaten ecosystems and in-situ populations of species, except where special temporary ex-situ measures are required under subparagraph (c) above; and
- (e) Cooperate in providing financial and other support for ex-situ conservation outlined in subparagraphs (a) to (d) above and in the establishment and maintenance of ex-situ conservation facilities in developing countries.<sup>14</sup>

Sustainable Use. Article 10 of the CBD addresses the *sustainable use* of biodiversity and requires parties to:

- (a) Integrate consideration of the conservation and sustainable use of biological resources into national decision-making;
- (b) Adopt measures relating to the use of biological resources to avoid or minimize adverse impacts on biological diversity;
- (c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;
- (d) Support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced; and
- (e) Encourage cooperation between its governmental authorities and its private sector in developing methods for sustainable use of biological resources.<sup>15</sup>

Incentives, Training Programs, and Public Education. Article 11 directs parties to offer economically and socially sound *incentives for the conservation and sustainable use* of biodiversity. Article 12 requires parties to establish *training programs* and to promote research to support conservation efforts. Article 13 promotes *public education and awareness* of the conservation of biodiversity. Articles 12 and 13 have special relevance to benefits sharing in that these training, research, and public education efforts can be funded through negotiated agreements.

Exchange of Information. Article 17 supports benefit sharing through the *exchange of information* about conservation and sustainable use of biodiversity. Parties are to exchange technical, scientific, and socio-economic information as well information relating to training and surveying programs, specialized knowledge, and indigenous and traditional knowledge.

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14. CBD at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-09>.

15. Ibid., at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-10>.

However, the proviso that the information comes "from all publicly available sources" dilutes and limits the effectiveness of this requirement.

Technical and Scientific Cooperation for Conservation and Sustainable Use. Article 18 also supports benefit sharing by urging parties to develop national policies to promote technical and scientific cooperation. This would include cooperation in the training of personnel, exchange of experts, and establishment of joint research program and joint ventures.

***Regulation of Bioprospecting.*** The omnipresent catchphrase "as far as possible and as appropriate" is applied throughout the CBD. This wording reflects the tenor of the international convention and the inherent difficulty of its enforcement. Nevertheless, the CBD does offer various regulatory guidelines.

Environmental Impact Assessments. For example, Articles 14-1(a) and 1(b) require parties to perform *environmental impact assessments* on activities that may harm biodiversity and take them into account in decision-making. Articles 14-1(c) and 1(d) also promote multilateral reciprocity, notification and consultation, and information exchange regarding activities that may harm another party's biodiversity. In addition, Article 14-1(c) also encourages the negotiation of bilateral, regional, and multilateral arrangements to minimize such harm. Article 14-1(e) promotes national arrangements for emergency response to events that present a grave and imminent danger to biodiversity and encourages international cooperation to support these arrangements. Finally, Article 14-2 directs the Conference of the Parties<sup>16</sup> to examine the issue of liability and redress, including restoration and compensation, for damage to biological diversity, except where such liability is a purely internal matter.

Sovereign Rights and National Legislation. Article 15-1 of the CBD is seminal. It recognizes that parties have *sovereign rights* over their natural resources and that "the authority to determine access to genetic resources rests with the national governments and is *subject to national legislation.*" (*Emphasis added*) The remainder of Article 15 further attempts to regulate bioprospecting as follows:

2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

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16. CBD, at: <http://www.biodiv.org/convention/cops.asp>. The Conference of the Parties is the governing body of the CBD. To date, the Conference of the Parties has held seven ordinary meetings, and one extraordinary meeting. It now meets every two years with the next one scheduled for March 20-31, 2006 in Curitiba, Brazil.

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.
6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.
7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.<sup>17</sup>

Parties need only "endeavour" to create conditions to facilitate access to genetic resources and to carry out research with the participation of the other party. They need only "endeavour" to refrain from imposing restrictions counter to the CBD. They are not mandated to do so. Access, if granted, must be on mutually agreed terms. Access must also be subject to prior informed consent.

Access to and Transfer of Technology. Articles 15-7 (see prior discussion) and 16 relate to both regulation of bioprospecting as well as fair and equitable benefit sharing. (*See "Fair and Equitable Benefit Sharing" below.*) Article 16 provides for *access to and transfer of technology* relevant to the conservation and sustainable use of biodiversity among contracting parties (Article 16-1). This transfer is to be facilitated under "fair and most favourable terms, including on concessional and preferential terms where mutually agreed."<sup>18</sup> With regard to patents and other intellectual property rights, such transfer is to be on terms that recognize and are consistent with the adequate and effective protection of intellectual property rights (Article 16-2). Parties are to take legislative, administrative or policy measures to implement such technology transfers (Article 16-3). The transfers are to benefit both the government and the private sector of developing countries (Article 16-4).

Patents and Intellectual Property Rights. Article 16-5 deals with the ongoing conflict between patents and intellectual property rights and the goal of technology transfer under the CBD:

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.<sup>19</sup>

Intellectual property rights limit the distribution of benefits flowing from the use of these rights. The conflict between transfer of technology, as endorsed under the CBD, and maintenance of the

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17. CBD, at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-15>.

18. CBD, at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-16>.

19. CBD, at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-16>.

international intellectual property rights regime remain intractable. Consequently, it seems difficult, if not impossible, to achieve the international cooperation required under Article 16-5.

International Intellectual Property Rights Regime. The Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) under the World Trade Organization (WTO), is the preeminent international agreement governing intellectual property rights. The TRIPS Agreement was agreed to during Uruguay Round, which began in 1986 and ended in Geneva in 1993 and was signed in 1994 in Morocco. The TRIPS Agreement establishes uniform minimum standards for protection and enforcement of intellectual property rights by WTO members. It covers a broad range of intellectual property rights, including copyright, trademarks, geographical indications, trade secrets, and patents.

The TRIPS Agreement is binding on all WTO members, many of whom are also parties to the CBD. Therein lies the problem. The two conventions conflict. Patent offices in the home countries of bioprospecting firms or end-users may grant patents over genetic resources of a source country without consent or benefit sharing. The TRIPS Agreement does not require them to do otherwise. Source countries have incentives to promote CBD objectives, but the TRIPS Agreement can be used to undermine efforts at national benefit sharing legislation. CBD-inspired national legislation requiring benefit sharing and prior informed consent can be challenged in bilateral discussions, and ultimately at the WTO, on the basis that they "unreasonably prejudice" the interests of the intellectual property right holder.<sup>20</sup>

For example, a recent review by the Center for International Environmental Law and the World Wide fund for Nature noted that more study is needed on resolving the CBD-endorsed transfer of technologies protected by intellectual property rights. The review points out that the CBD is voluntary in nature. In other words, the problem remains intractable because the CBD lacks teeth.<sup>21</sup> In contrast to CBD provisions, the WTO has a binding dispute settlement mechanism where one party may impose trade sanctions on another party.

In another example, the TRIPS Agreement grants WTO members several exceptions to offering patent protection to other members. A member may exclude inventions from patentability under four exceptions:

- (1) In order to protect the public order (Article 27.2);
- (2) Plants and animals other than microorganisms are excepted (thus, patents must be granted over micro-organisms as well as nonbiological and essentially biological processes for the production of plants and animals) (Article 27.3(b));
- (3) Members can provide limited exceptions to the exclusive rights conferred by patents, subject to certain qualifications (Article 30); and

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20. Catherine Monagle and Aimee T. Gonzales, "Biodiversity & Intellectual Property Rights: Reviewing Intellectual Property Rights in Light of the Objectives of the Convention on Biological Diversity" (World Wide Fund for Nature/Center for International Environmental Law: Switzerland, March 2001), p. 13, citing Article 30 of the TRIPS Agreement. [WWF was formerly "World Wildlife Fund".]

21. Monagle and Gonzales, pp. 5-6.

- (4) Members may permit use of the patented invention by third parties without the authorization of the patent owner in certain circumstances (Article 31).<sup>22</sup>

The upshot of is that: "So far, the scope and utility of these provisions in ensuring compatibility with CBD objectives remains unclear at the WTO."<sup>23</sup> A separate TRIPS review of Article 27.3(b) also remains inconclusive.<sup>24</sup>

Relationship with Other International Conventions. Article 22-1 asserts that the CBD "shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity."<sup>25</sup> However, the conflict between the CBD and the TRIPS Agreement renders this provision uncertain. Article 22-2 requires parties to "implement this Convention with respect to the marine environment consistently with the rights and obligations of States under the law of the sea."<sup>26</sup>

Settlement of Disputes. In the event of a dispute between parties, Article 27-1 encourages a negotiated resolution. If not successful, Article 27-2 provides for third-party mediation. Article 27-3 provides that if a party has declared that it will accept mandatory dispute settlement, the parties may use one or both of the following methods: arbitration in accordance with Part 1 of Annex II of the CBD,<sup>27</sup> or submission to the International Court of Justice. If parties have made no such declaration, the dispute will be submitted for conciliation in accordance with Part 2 of Annex II of the CBD,<sup>28</sup> unless otherwise agreed to.

***Rights of Indigenous Knowledge Holders.*** Article 8(j) directly addresses two of the concerns raised in H.C.R. No. 146 – "rights of traditional, *indigenous knowledge holders*" and meaningful participation in these processes by traditional, *indigenous knowledge holders*. Parties must, as far as possible and as appropriate:

- (j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;<sup>29</sup>

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22. Monagle and Gonzales, p. 9, paraphrased.

23. Monagle and Gonzales, p. 9.

24. Monagle and Gonzales, p. 10.

25. CBD, at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-22>.

26. CBD, at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-22>.

27. Part I of Annex II sets out the structure and composition of the arbitration panel and its operation.

28. Part II of Annex II sets out the structure and composition of the conciliation commission and its operation.

29. CBD, at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-08>.



Articles 10(c) and (d) also address the issues involving *indigenous knowledge holders* expressed in H.C.R. No. 146 – rights and participation of indigenous knowledge holders. These provisions require parties, as far as possible and as appropriate, to:

- (c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;
- (d) Support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced;<sup>30</sup>

***Fair and Equitable Benefit Sharing.*** Article 15-7 requires a party to take legislative, administrative, or policy measures to fairly and equitably share benefits with the source party from the research and development of commercial or other uses of genetic resources.

Handling of Biotechnology and Distribution of Benefits. Article 19 contains four provisions under the rubric of distribution of benefits as follows:

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.
2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.
3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.
4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.<sup>31</sup>

To summarize, Article 19:

- encourages participation in biotechnology research for the source country
- promotes fair and equitable access by the source country to results and benefits of this research, on mutually agreed terms

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30. CBD, at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-10>.

31. CBD, at: <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-9>.



- encourages establishment of procedures for "advance informed agreement" to safely handle the transfer of modified living organisms derived from biotechnology that may harm conservation or sustainable use of biodiversity
- requires disclosure of information on the safe handling of such organisms and their potential adverse impact

Financial Resources. Article 20 addresses how the objectives of the CBD are to be supported financially by the parties. Article 20-1 states that each party is responsible for financially supporting the CBD's objectives in accordance with its national plans, priorities, and programs. Obviously, the CBD can have no control over a country's national plans or priorities. Article 20-2 requires "developed country Parties" to financially assist "developing country Parties" to implement the CBD on a grant or concessional basis (provided for in Article 21). Article 20-3 notes that financial assistance can also be made through bilateral, regional and other multilateral channels. Article 20-4 recognizes that the success of developing countries in implementing the CBD depends on how effectively developed countries provide financial assistance and transfer technology. This provision further recognizes that economic and social development and eradication of poverty are the first and overriding priorities of the developing country parties. Article 20-5 directs parties to give special attention to the needs of "least developed countries." Article 20-6 gives special consideration to countries in special situations resulting from the dependence on, distribution, and location of biodiversity, such as small island states. Finally, Article 20-7 gives special consideration to developing countries that are the most environmentally vulnerable, such as those with arid and semi-arid zones and coastal and mountainous areas.

Financial Mechanism. In order to implement the financial assistance above, Article 21 sets up a funding mechanism under the Conference of the Parties ("COP"). (*See footnote to COP in "Environmental impact assessments" above.*) The COP is to determine the institutional structure, policy, strategy, program priorities, and eligibility for access to financial assistance. The COP also determines the amounts needed where contributions must be predictable, adequate, and timely. Voluntary contributions are also welcomed. The COP reviews the effectiveness of the financing mechanism two years after its start and on a "regular basis" thereafter.

## **INTERNATIONAL COOPERATIVE BIODIVERSITY GROUPS**

At about the same time that the CBD was being formulated, several entities conceived and implemented the International Cooperative Biodiversity Groups (ICBG) program. According to the ICBG, its conceptual basis was developed during a conference in March 1991 that was sponsored by the National Institutes of Health (NIH), the National Science Foundation (NSF), and the U.S. Agency for International Development (USAID). The conference focused on the potential relationships between drug development, biological diversity, and economic

growth. The ICBG program itself was initiated in 1992 in a collaborative effort of the NIH, the NSF and the USAID to advance their three interrelated goals.<sup>32</sup>

Funding for the ICBG program has been provided by six components of the NIH, the Biological Sciences Directorate of the NSF, and the Foreign Agriculture Service of the U.S. Department of Agriculture. The cooperating NIH components are the Fogarty International Center (FIC), National Cancer Institute, National Institute of Allergy and Infectious Diseases, National Institute of Mental Health, National Institute on Drug Abuse, and the National Heart, Lung, and Blood Institute.<sup>33</sup>

Because of its health affiliation, the ICBG focuses on drug discovery to the exclusion of industrial and chemical processing end uses.<sup>34</sup> Nevertheless, the ICBG presents a valuable model for addressing bioprospecting in general.

**Objectives of the ICBG.** The underlying concept of the ICBG is that drug discovery through natural products research can provide both short- and long-term benefits to source countries through benefit sharing. In addition to advance payments and other immediate benefits, potential royalties from commercialized drugs provide incentives for source countries to conserve their genetic resources. Thus, the three elements, biodiversity conservation, drug discovery, and economic incentives, continually drive each other.

The ICBG's three main objectives reflect the aims of its three government agency sponsors. They are to:

- Improve human health through discovery of new pharmaceutical, agricultural, and veterinary agents to treat diseases of importance in both developed and developing countries
- Conserve biological diversity through the understanding and valuation of diverse biologic organisms and the development of local capacity to manage these resources
- Promote sustainable economic activity in less-developed counties by sharing benefits of drug discovery and conservation research processes and products<sup>35</sup>

ICBG describes its program and objectives as follows:

The ICBG program is a unique effort to integrate improvement of human health through drug discovery, incentives for *conservation of biodiversity*, and new models of *sustainable economic activity* that focus on the *environment*, health, *equity* and *democracy*. This program is based on the belief that the discovery and development of pharmaceutical and other useful agents from natural products can, under appropriate

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32. International Cooperative Biodiversity Groups, at: <http://www.fic.nih.gov/programs/icbg.html#Background%20and%20History>, (hereafter "ICBG").

33. ICBG.

34. ICBG. Other important components include discovery of safe new agents for crop protection and veterinary medicines.

35. Grifo and Rosenthal, p. 3.

circumstances, promote *scientific capacity development* and *economic incentives to conserve the biological resources* from which these products are derived.<sup>36</sup> (*Emphasis added.*)

***Five-Year Cycle Operation.*** The ICBG program operates in five-year cycles and makes awards for various projects through cooperative agreements during each cycle. Five multi-disciplinary, multi-institutional awards were made in 1993 and 1994. The program was renewed in 1998 and six new ICBG cooperative agreement projects were awarded. According to the ICBG:<sup>37</sup>

"The ICBGs are currently working in ten countries in Latin America, Africa and Asia, building research capacity in more than 20 different institutions and training hundreds of individuals. To date, thousands of species of plants, animals, and fungi have been collected to examine biological activity in 19 different therapeutic areas. Numerous publications in chemistry, biodiversity policy, conservation and ethnobiology have emerged from the funded investigators. Broad public attention to the program and its timing relative to international developments associated with the UN Convention on Biological Diversity have allowed the ICBG program to offer useful working models for national and international policy discussions related to *biodiversity conservation incentive measures, technology transfer, intellectual property and benefit-sharing.*" (*Emphasis added.*)

The cooperative agreement projects, which may be funded up to \$600,000, involve a range of activities. These include acquisition and analysis of natural products derived from biodiversity to treat diseases relevant to both developed and developing countries. Such diseases include AIDS, malaria, tuberculosis and other infectious diseases, cancers, heart disease, drug addiction, and central nervous system disorders, including Alzheimer's disease. Project components also include discovery of safe new agents for crop protection and veterinary medicines. Other components:

- implement biodiversity inventories and surveys
- examine and preserve traditional medicine practices
- develop long-term strategies to ensure sustainable harvesting
- promote training and infrastructure support for host-country institutions
- provide long-term funding for biodiversity conservation in the host countries

***ICBG Cooperative Agreement Projects.*** Each ICBG project constitutes a cooperative agreement with the U.S. government. Cooperative agreements differ from grants and contracts in that sponsoring government agencies have substantial programmatic involvement in achieving the goals and objectives of the project.

In the ICBGs this is accomplished through the designation of a Government Scientific Coordinator for each project who has scientific oversight responsibility and is assisted by

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36. ICBG.

37. ICBG.

an advisory committee consisting of staff in relevant technical fields from the participating agencies. There is no intent, real or implied, for government staff to direct group activities or to limit the freedom of scientific investigators. Rather the Government Scientific Advisory Committee for each group serve[s] as a resource and act in an advisory capacity.<sup>38</sup>

***Implementing ICBG Objectives.*** This section examines how each cooperative agreement project may address and implement the ICBG's three main objectives of improving human health, conserving biodiversity, and promoting sustainable economic activity in source countries. In its request for applications document (RFA-TW-04-004) for an ICBG award, the program's objectives are reiterated for applicants:

The unifying theme underlying the ICBG program is the concept that the discovery and development of pharmaceutical and other useful agents from natural products can, under appropriate circumstances, promote economic opportunities and enhanced research capacity in developing countries while conserving the biological resources from which these products are derived.<sup>39</sup>

Implementing the Objective of Improving Human Health. Responding to its health mandate, by definition, each cooperative agreement project must address the issue of human health. The FIC manages the biodiversity program, which seeks to examine the medicinal potential of the earth's plants, animals, and microorganisms. This program guides natural products drug discovery in a way that local communities and other source country organizations can benefit directly from their biodiversity.

Implementing the Objective of Conserving Biodiversity. Conservation of genetic resources can be implemented by creating incentives at various levels to support different aspects of conservation. These include:<sup>40</sup>

- Increasing the conservation knowledge base
- Developing long-term ecological and economic strategies for sustainable harvesting of target organisms
- Using ethnobiological studies and approaches to working with traditional cultures and their knowledge of traditional medicine
- Performing multi-disciplinary integrative surveys of a source country's biodiversity
- Producing and documenting collected material in databases, publications, and inventories

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38. Francesca T. Grifo, "Chemical Prospecting: An Overview of the International Cooperative Biodiversity Groups Program" in J. Feinsilver, ed., Emerging Connections Among Biodiversity, Biotechnology, and Sustainable Development in Health and Agriculture, Washington, D.C., Pan American Health Organization, p. 3. Available at: <http://www.fic.nih.gov/programs/chempro.html> (hereafter "Grifo 1996").

39. ICBG at: <http://grants2.nih.gov/grants/guide/rfa-files/RFA-TW-04-004.html>.

40. Grifo 1996, p. 3.

Implementing the Objective of Promoting Sustainable Economic Activity in Source Countries. Projects implement this second goal of the ICBG through benefit sharing agreements with source countries that incorporate the use of novel contractual or other legal mechanisms. One aspect of stimulating economic activity involves support for targeted research training that is particularly relevant to the source country. Relevant areas may include:<sup>41</sup>

- Systematics (description and naming of species: identification and taxonomy, and description of relationships among and between taxa: phylogenetics)
- Ethnobiology
- Ethnomedicine
- Chemistry
- Cell biology
- Biotechnology
- Production methods and quality control in pharmaceutical development

Research training may be supported through fellowships and linked to degree-granting programs and may include stipends, tuition, travel, and other expenses. Training may include:<sup>42</sup>

- Practical and applied short-term courses or workshops
- Course work, laboratory, or field training in essential research skills
- Fellowships for degree candidates or post-doctoral trainees

***ICBG Principles for Accessing Genetic Resources, Treatment of Intellectual Property, and Sharing of Benefits.*** To receive funding, the ICBG requires each prospective project to comply with the ICBG principles for accessing genetic resources, treatment of intellectual property, and sharing of benefits. The following examines the specific strategies a project must propose to use to implement these principles, according to the ICBG's request for applications.

Access to Genetic Resources. Access to genetic resources must be based on disclosure to and informed consent of source country stakeholders. Projects are required to make arrangements for prior informed consent as a condition of award. The ICBG notes that: "Attaining prior informed consent in today's environment is a long and complex process in many countries. Prior to applying, one should document host country institutional support and where relevant, community support."<sup>43</sup> This is spelled out in the ICBG's request for applications:

Prior to receiving an award, locally appropriate evidence of prior informed consent and formal agreements specifying the rights and responsibilities of each Group member

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41. Grifo 1996, p. 4.

42. Grifo 1996, p. 4.

43. ICBG, frequently asked questions at: <http://www.fic.nih.gov/programs/ICBGFAQS.html>.

institution ... must be signed and dated by the organizational official authorized to enter into such arrangements, and must be on file at the Fogarty International Center.<sup>44</sup>

As part of prior informed consent, projects must respect indigenous concepts of intellectual property:

If, for instance, cooperating indigenous groups, on the basis of religious or other concerns, object to specific uses, widespread dissemination or other treatments of the knowledge they provide, these concerns should be respected in the conduct of ICBG projects.<sup>45</sup>

The process of disclosure and informed consent should be as inclusive and formal as is possible and culturally appropriate. According to the ICBG, the best practice is the development of written agreements with a community following complete and formal mutual agreement on goals and methods. Presentations by scientists to source country stakeholders should provide realistic descriptions of the type, amounts, and probabilities of benefits, as well as any costs or risks that may accrue to cooperating communities or organizations. Arrangements with individuals who cooperate or provide information should be based upon prior community-level agreements whenever possible or appropriate.<sup>46</sup>

Treatment of Intellectual Property Rights. Projects must demonstrate the ability to address the issue of intellectual property rights. A project must evince an awareness of the different types of intellectual property rights available at different stages of product development and for different types of products. A project must also be aware of the intellectual property rights law in the source country and how it affects research and development.

For example, according to an ICBG participant, trade secret protection may be applicable in some countries in lieu of patents during early research and development. Furthermore, certain countries do not permit patents even at the end product stage. Variable national patent laws may disallow protection if the product is a natural compound or plant and not an invention, or if the innovation is too incremental to consider a patentable invention. Still other countries prohibit patents for pharmaceuticals.<sup>47</sup>

The need to address the issue of intellectual property rights is set forth in the request for applications:

It is essential that applicants develop appropriate plans for access to genetic resources and contractual agreements for the treatment of intellectual property and benefits that may arise. Carefully planned and executed approaches to access and benefit-sharing are integral to the goals of this program and must anticipate the rapidly changing regulatory

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44. ICBG application reference RFA-TW-04-004, at: <http://grants2.nih.gov/grants/guide/rfa-files/RFA-TW-04-004.html>.

45. ICBG application reference RFA-TW-04-004, at: <http://grants2.nih.gov/grants/guide/rfa-files/RFA-TW-04-004.html>.

46. ICBG application reference RFA-TW-04-004, at: <http://grants2.nih.gov/grants/guide/rfa-files/RFA-TW-04-004.html>.

47. Grifo 1996, p. 5.

environment in many countries as they respond to the UN Convention on Biological Diversity. The development of these plans and agreements is frequently complex and challenging because multiple institutions and countries are involved, often with very different objectives, perceptions and expectations, and occasionally from very different legal environments.

In the application, each applicant Group must, therefore, provide a detailed description of its approach to prior informed consent, intellectual property and the sharing of benefits from ICBG-sponsored research. Descriptions should encompass both the conduct of collaborative research activities and the nature of contractual agreements among the collaborators. The research plan and contractual agreements among Group members must be designed such that they address the ICBG "Principles for Access, Intellectual Property and Benefit-Sharing" detailed in this RFA.<sup>48</sup>

The ICBG's request for applications document further spells out that non-profit organizations and small businesses

"[r]etain the rights to any patents resulting from U.S. Government contracts, grants, or Cooperative Agreements .... The specific intellectual property arrangements among the institutions may vary and could include joint patent ownership, exclusive licensing arrangements, etc. Valuable intellectual resources that cannot or will not be patented, such as novel assays or traditional medicinal techniques, may require alternative protection methods, such as trade secrets. Applicants are encouraged to develop an arrangement that best suits the particular circumstances of their Group."<sup>49</sup>

In any case, a project must demonstrate an ability to address the complexities and inconsistencies of international patent laws. This requirement can also be viewed as one of the program's strengths in that a project must adopt a tailored and flexible approach to intellectual property rights for each specific undertaking.

Benefit Sharing and Compensation. The requirement for projects to address compensation and benefit sharing – another ICBG principle – is another strength of the ICBG program. Projects must outline their plans for distribution of benefits from final products, including intellectual property rights protection, to include the following:

- Equitable distribution of benefits to all those who contribute to product development, whether they are members of the consortium or not, including research institutions and indigenous people in all countries who provide useful traditional knowledge.
- Flow-back of economic benefits to the area in which the source plant or animal was found, in such a way that they at least indirectly promote conservation of biological diversity (although the type of benefits must be chosen through discussions with indigenous and local people).
- Justification for selection of recipients of benefits (or for exclusion of other potential recipients).

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48. ICBG application reference RFA-TW-04-004, at: <http://grants2.nih.gov/grants/guide/rfa-files/RFA-TW-04-004.html>.

49. ICBG application reference RFA-TW-04-004, at: <http://grants2.nih.gov/grants/guide/rfa-files/RFA-TW-04-004.html>.

- Appropriate structuring of economic benefits, e.g. trust funds managed by community or joint community-project boards rather than cash payments to a single authority or individual may be more effective in support of conservation, and for administration of services like health or education. Note that direct cash compensation may even have injurious effects on non-money economies.
- Design of adequate contracts. Agreements should be among commercial drug developers, source country and US research institutions, and the indigenous people whose knowledge is commercialized.
- Inclusion in contract between drug company and other partners of methods for monitoring R&D to track drug leads derived from samples provided under the contract.
- In instances where one party does not wish to pursue the development of a discovery, clear designation of the rights of all other signatories should be outlined.
- Ideally, compensation begins flowing early in the contract (through an initial payment, payments for samples delivered, or both) in order to provide short-term conservation incentives.<sup>50</sup>

Other Requirements. The ICBG's request for applications further stipulates several other conditions. First is the clear designation of the *rights and responsibilities* of all partners. This is principally done through the design of adequate contractual agreements.

Useful contractual tools for the designation of rights and responsibilities include material transfer agreements, research and development agreements, license options agreements, know-how licenses, benefit-sharing agreements, and structured trust funds.... Unless stipulated otherwise in agreements among source country institutions and their collaborators, biological samples and associated information collected under ICBG-sponsored research is the property of the source country institutions.... The ownership and compensation terms of first generation and subsequent inventions based upon a lead discovered in ICBG work should be clearly stipulated in agreements.<sup>51</sup>

Second, *information flow* must be balanced, taking into account proprietary, collaborative, and public needs. Information should be shared among collaborating organizations to maximize efficiency and ensure equity. However, projects must take into consideration the understandable desire of indigenous or commercial partners for confidentiality of information with potential commercial value.

Third, all parties should respect and *comply with relevant national and international laws, conventions*, and other standards. This, of course, includes the Convention on Biological Diversity and national laws regarding study, use, and commercialization of chemical, biological, and cultural resources. The ICBG encourages the adoption of best practices that exceed the minimum legal standards regarding international research and collaborations.

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50. Grifo 1996, pp. 5-6.

51. ICBG application reference RFA-TW-04-004, at: <http://grants2.nih.gov/grants/guide/rfa-files/RFA-TW-04-004.html>.



**Brief Summaries of ICBG Projects.** Currently, five active comprehensive ICBG award projects are operating in ten countries. These are described by the ICBG as follows:

BIOASSAY AND ECOLOGY DIRECTED DRUG DISCOVERY IN PANAMA: Dr. William H. Gerwick, in collaboration with Dr. Phyllis D. Coley and colleagues at the Smithsonian Tropical Research Institute, building on a previous five-year ICBG award, are using ecological insight to build a sustainable bioprospecting program in Panama for discovery of both pharmaceutical and agricultural products from plants and marine algae in collaboration with Oregon State University, Panama's National Secretariat for Science, Technology, and Innovation, the Nature Foundation of Panama, the University of Panama, Novartis Oncology, and Dow Agrosciences.

BIODIVERSITY CONSERVATION AND DRUG DISCOVERY IN MADAGASCAR: Dr. David G.I. Kingston of the Virginia Polytechnic Institute and State University in Blacksburg, Virginia, is collaborating in a third five-year ICBG to study tropical plants and marine organisms in Madagascar. The group includes Missouri Botanical Garden, Conservation International, the Madagascar National Centers for Pharmaceutical Research, for Environmental Research and for Oceanographic Research, as well as Eisai Pharmaceutical Research Institute and Dow Agrosciences.

BIODIVERSITY OF VIETNAM AND LAOS: Dr. Djaja (Doel) Soejarto and colleagues from the University of Illinois at Chicago are leading a second five year ICBG to integrate studies on biodiversity and the discovery of pharmacological agents for AIDS, cancer, malaria and tuberculosis from tropical forest plants of Laos and Vietnam. Collaborating institutions include the National Center for Natural Sciences and Technology and Cuc-Phuong National Park in Vietnam, the Research Institute for Medicinal Plants in Laos, Purdue University, and Bristol Myers-Squibb Pharmaceutical Research Institute.

CONSERVATION AND SUSTAINABLE USE OF BIODIVERSITY IN PAPUA NEW GUINEA: Dr. Louis R. Barrows and colleagues from the University of Utah are collaborating with several organizations of Papua New Guinea as sources of pharmaceutical and botanical therapies for local and global health needs. Partners in this project include the University of Papua New Guinea, National Forest Research Institute, and PNG Bionet of Papua New Guinea, the Smithsonian Institution, University of Miami, Nature Conservancy, Brigham Young University, and Wyeth Pharmaceuticals.

BUILDING NEW PHARMACEUTICAL CAPABILITIES IN CENTRAL ASIA: Dr. Ilya Raskin and colleagues from Rutgers University lead a project focused on the plant, fungal and microbial biodiversity of Uzbekistan and Kyrgyzstan. Other partners include the University of Illinois at Champaign-Urbana, Tashkent State Agrarian University and Kyrgyz Agricultural Research Institute, Eisai Research Institute, Diversa, and Phytomedics Inc.<sup>52</sup>

In addition, there are two continuing ICBG comprehensive award projects carried over from the first 5-year cycle:

DRUG DEVELOPMENT AND CONSERVATION OF BIODIVERSITY IN WEST AFRICA: Dr. Brian Schuster and colleagues of the Walter Reed Army Institute of Research in Washington, D.C. are working on a second five-year ICBG program to evaluate tropical plants in

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52. ICBG, at: <http://www.fic.nih.gov/programs/icbg.html#ICBG%20Planning%20Grants>.

Cameroon and Nigeria for potential pharmaceutical agents and phytomedicines. Collaborators are the Smithsonian Institution, the Bioresources Development and Conservation Programme, Pace University of New York, the University of Utah, the University of Minnesota, the University of Jos and the International Centre for Ethnomedicine and Drug Development in Nigeria, and the University of Dschang, Cameroon.

BIOACTIVE AGENTS FROM DRYLAND BIODIVERSITY IN LATIN AMERICA: Dr. Barbara Timmermann of the University of Arizona leads a second five-year ICBG program aimed at discovering biologically active agents for pharmaceutical and agricultural uses from arid and semi-arid land plants in Argentina, Chile, and Mexico. Collaborating in this effort are the Institute for Tuberculosis Research, University of Illinois at Chicago; Instituto Nacional de Tecnologia, Agropecuaria (INTA), Argentina; Pontificia Universidad Catolica de Chile; Universidad Nacional Autonoma de Mexico, and Wyeth Research Laboratories.<sup>53</sup>

## **BIOTECHNOLOGY INDUSTRY ORGANIZATION GUIDELINES FOR BIOPROSPECTING**

The Biotechnology Industry Organization ("BIO") was formed in 1993 with the merger of two small biotechnology trade groups representing 503 companies.<sup>54</sup> It represents both the handful of large multibillion-dollar firms that launched the first wave of biotechnology products and the hundreds of startup and mid-size firms at the research and development stage.

In response to the issues and difficulties associated with bioprospecting, BIO has issued a set of voluntary guidelines to its members engaging in bioprospecting. In a cover memo to its members, BIO stressed the following:

- Bioprospecting is not presently regulated in a consistent or comprehensive manner within countries or at the international level.
- The guidelines are not designed to supplant national requirements imposed by countries that regulate bioprospecting activities.
- The intent of the guidelines is to educate members as to relevant issues that can arise in the conduct of bioprospecting activities.
- The guidelines identify certain "best practices" on what steps should be taken prior and incidental to bioprospecting that are generally consistent with emerging international norms relating to bioprospecting activities.
- The guidelines are voluntary and BIO has no authority to enforce any action against a member for taking any action inconsistent with the guidelines.<sup>55</sup>

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53. ICBG, at: <http://www.fic.nih.gov/programs/icbg.html#ICBG%20Planning%20Grants>.

54. Biotechnology Industry Organization website at: <http://www.bio.org/aboutbio/history.asp> (hereafter BIO). One group was the Industrial Biotechnology Association, which primarily represented larger established companies on Capitol Hill and before federal regulatory agencies; the other, the Association of Biotechnology Companies, which represented emerging companies and universities and focused on technology transfer issues, meetings, and other business development activities.

55. BIO, paraphrased, at: <http://www.bio.org/ip/international/200507memo.asp>.

The guidelines' preamble recognizes the importance of sustainable use of biodiversity and equitable benefit sharing arising from use of genetic resources with the source country. Part IA of the guidelines sets out definitions. (The entire document is attached as Appendix B.) The scope of the guidelines, in Part IB, excludes the application of the guidelines to certain situations. For example, genetic materials that were obtained before the CBD became effective are excluded, as are any genetic material of human origin.

Parts II through VII contain the substance of the guidelines and are titled as follows:<sup>56</sup>

Part II	Conduct of Bioprospecting
Part III	Prior Informed Consent
Part IV	Benefit Sharing and Sharing of Research Results, Intellectual Property Procurement, and Related Provisions
Part V	Measures to Protect Interests and Rights of Indigenous or Local Communities
Part VI	Conservation and Sustainable Use of Biological Diversity
Part VII	Compliance with Terms of a Bioprospecting Agreement and the Guidelines

The following summarizes the substantive guidelines contained in Parts II through VII.

**Part II. Conduct of Bioprospecting.** Part II of the guidelines prescribes steps a biotechnology company should take before and after obtaining prior informed consent from the source country. The company should first identify and contact the Focal Party. This is the entity designated by the source country government with authority to identify the Providing Party of genetic resources. The Focal Party also has authority to provide information on procedures for obtaining prior informed consent and benefit sharing requirements. The Focal Party also identifies the representative of local and indigenous communities in the source country. The Providing Party is, of course, the entity authorized to grant access to genetic resources and can include the national or local government, an indigenous community, or any combination.

Assisted by the Focal Party, the biotechnology company then identifies, obtains prior informed consent from, and negotiates a bioprospecting agreement with the Providing Party. The agreement should cover terms of collection, handling, use, and transfer of samples and benefit sharing. The biotechnology company should try to reasonably ascertain that the agreement will be binding on the source country. After obtaining consent, bioprospecting activities should proceed according to the agreement.

**Part III. Prior Informed Consent.** This section of the guidelines directs a biotechnology company to identify conditions, if any, set by the source country or a delegated Providing Party

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56. BIO, at: <http://www.bio.org/ip/international/200507guide.asp>.

for granting prior informed consent and then to comply with them. If there are no conditions, the company should inform the Providing Party of at least the following:

- Nature of the bioprospecting activity, .e.g., sample screening, extraction of chemical compounds, genomic analysis, etc.
- Anticipated use of ultimate end product, e.g. pharmaceutical, agricultural, etc.
- Identity of the lead researcher and contact information.<sup>57</sup>

***Part IV. Benefit Sharing and Sharing of Research Results, Intellectual Property Procurement, and Related Provisions.*** Part IV of the guidelines details types of benefits to be considered:

- Monetary and non-monetary benefits from commercialization of an end product, including advance and royalty payments and provision of equipment and materials
- Sharing of research information according to standard industry practices regarding timing and conditions of public disclosure to preserve options for procuring patents
- Granting of rights to use research technology consistent with the member's commercial needs and interests
- Training of scientists designated by the Providing Party
- Including Providing Party scientists in research activities
- Performing research in the source country
- Transferring scientific knowledge, expertise, and technology to the Providing Party stemming from the research pertaining to conservation and handling of genetic resources
- Commitment to only seek patents on inventions that arise from the use or study of collected genetic resources and that are claimed in a manner clearly distinguishable from the form in which the collected genetic resources are provided by the Providing Party<sup>58</sup>

***Part V. Measures to Protect Interests and Rights of Indigenous or Local Communities.*** According to Part V of the guidelines, a biotechnology company should respect the customs, traditions, values, and customary practices of indigenous communities and respond to requests for information concerning the handling, storage, or transfer of genetic resources. It should also prevent the disclosure of information given in confidence by an indigenous group. Finally, a biotechnology company should avoid taking actions in the course of use or

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57. BIO, paraphrased, at: <http://www.bio.org/ip/international/200507guide.asp?p=yes>.

58. BIO, paraphrased, at: <http://www.bio.org/ip/international/200507guide.asp?p=yes>.

commercialization of the genetic resources collected that impede the *traditional* use of those resources.<sup>59</sup>

**Part VI. Conservation and Sustainable Use of Biological Diversity.** A biotechnology company should avoid harming the local environment or threatening conservation or sustainable use of biodiversity while collecting samples. It should also take all reasonable steps and give good faith consideration to sharing data derived from research that may be useful in supporting conservation efforts related to a species, environment, or habitat from which the genetic resources were collected.<sup>60</sup>

**Part VII. Compliance with Terms of a Bioprospecting Agreement and the Guidelines.** Part VII of the guidelines exhort a biotechnology company to use collected genetic resources only for the purposes specified in the prior informed consent provision of its bioprospecting agreement. A separate prior informed consent should be obtained for uses other than those previously specified. The company should maintain records of the handling, storage, and physical movement of the collected genetic resources and be willing to share them with the host country within reasonable limits. The company should further ensure that the agreement with the source country and Providing Party continues to apply to a successor in interest in their rights and to any entity that obtains a sample from them. This would not apply, of course, if the source country or Providing Party has independently granted that entity rights to the samples. The company should not transfer samples to third parties unless the transfer is consistent with the terms of the bioprospecting agreement. Neither should the company accept samples from a third party that cannot prove it has obtained the samples in compliance with the established prior informed consent conditions. Finally, the company should provide for effective and fair resolution of disputes regarding compliance with the bioprospecting agreement, either by international arbitration or as otherwise agreed to by the source country or Providing Party.<sup>61</sup>

## COLUMBIA UNIVERSITY REVIEW OF BIOPROSPECTING AGREEMENTS AND CASES

The following section reports on a review and analysis by Columbia University of seven bioprospecting projects that attempt to comply with the principles established under the Convention on Biological Diversity or as embodied in the ICBG model.

**Columbia University Review and Analysis.** The Environmental Policy Studies Workshop at the School of International and Public Affairs of Columbia University authored this review and analysis.<sup>62</sup> The review was carried out for the Biodiversity Action Network, an

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59. BIO, paraphrased, at: <http://www.bio.org/ip/international/200507guide.asp?p=yes>.

60. BIO, paraphrased, at: <http://www.bio.org/ip/international/200507guide.asp?p=yes>.

61. BIO, at: <http://www.bio.org/ip/international/200507guide.asp?p=yes>.

62. Columbia University School of International and Public Affairs, Environmental Policy Studies Workshop, 1999, "Access to Genetic Resources: An Evaluation of the Development and Implementation of Recent Regulation and Access Agreements" Environmental Policy Studies Working Paper #4, June 1999 (hereafter "Columbia"). Members of workshop are: Ana Luz Porzecanski, Robin Sears, Taran Grant, Louis Putzel, Liliana Dávalos, Tonya Barnes, Hugh Cross, Gleb Raygorodetsky, Ben Simmons, and Pamela Chasek. (Available at: <http://www.biodiv.org/doc/case-studies/abs/cs-abs-agr-rpt.pdf>.)

advocacy group for biodiversity conservation, sustainable use, and benefit sharing. The Biodiversity Action Network promotes and monitors the implementation of the Convention on Biological Diversity.

Seven Case Studies. The Columbia University Review evaluates the efficacy of seven agreements with regard to access to genetic resources in implementing the CBD. These are:<sup>63</sup>

- The National Biodiversity Institute (INBio)-Merck & Co., Inc. Research Agreement in Costa Rica
- The National Cancer Institute-Universidade Paulista agreement and proposed legislation in Brazil
- The BioAndes attempt to bioprospect in Colombia under Decision 391 of the Andean Pact
- The African International Cooperative Biodiversity Groups' research and development agreements in Cameroon
- Access agreements and legislation in the Philippines
- The Strathclyde Institute of Drug Research-University of the South Pacific agreement in Fiji
- The Yellowstone National Park-Diversa Corporation agreement in the United States

These seven cases represent a broad array of policy responses in different geographic regions involving a variety of stakeholders, including private actors, non-governmental organizations, research institutions, and state agents.

Basis of Analysis. The Columbia University Review based its analysis on the following issues:<sup>64</sup>

- Identification and representation of stakeholders
- Addressing property rights
- Ensuring prior informed consent
- Distribution of benefits
- Compliance with terms of the agreement and methods of dispute resolution
- Addressing conservation and sustainable use

Obstacles to Implementing the Goals of the CBD. The Columbia University Review cites four primary obstacles to reaching the CBD goals of biodiversity conservation, sustainable economic development, and equitable benefit sharing with regard to access to genetic resources. First, policymakers must factor the special character of genetic resources into access policy.

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63. Columbia, p. i.

64. Columbia, paraphrased, pp. i-ii.

Genetic resources are both tangible (physical) and intangible (information), and are distributed independently of political boundaries. Second, genetic resources have been used, modified, and stored in centers around the world for centuries; thus effective policy must accommodate these *ex situ* collections. Third, before addressing the complexities of the distribution of benefits, policymakers must clearly define ownership and tenure of genetic resources. This is a difficult task, because groups as varied as humankind, states, regions, and local communities have all claimed rights over genetic resources. The matter is further complicated by the conflict between customary and legal property rights. Fourth, the dearth of legal, institutional, and scientific capacity in many countries seriously hampers efforts to facilitate and regulate access to genetic resources. In addition, the Columbia University Review acknowledged that the often-conflicting interests of large numbers of stakeholders must be reconciled if policy is to be successful.<sup>65</sup>

Conclusions and Recommendations of the Columbia University Review. The following paraphrases, where necessary, the conclusions and recommendations made by the Columbia University Review.<sup>66</sup>

Columbia University Review Conclusion 1. *During policy development, existing regional institutions and cooperation frameworks have provided operational support.* Regional cooperation among nations facilitates the development of national legislation, reduces redundancy, and makes the process more cost-effective. Similar regional cooperation among academic and non-governmental organizations helps to coordinate bioprospecting efforts. However, the disadvantages of a regional framework include increased complexity, inconsistent implementation, and difficulty in changing regional legislation in the future.

Columbia University Review Recommendation 1. The Columbia University review recommended that nations lacking the capacity to develop regulatory regimes take advantage of existing regional institutions to help them.

Columbia University Review Conclusion 2. *New regulatory regimes lack evaluation procedures that assess compliance with CBD objectives.* It is premature to evaluate the effects of conservation and sustainable use provisions. Agreements lack specific provisions that require assessment of a project's impact on sustainable use, conservation, and equitable distribution of benefits in the long term.

Columbia University Review Recommendation 2. The review recommended incorporating into regulatory regimes an independent, multidisciplinary evaluation of the success of regulatory policy on bioprospecting in achieving CBD objectives.

Columbia University Review Conclusion 3. *Minimizing the number of parties facilitates reaching an agreement but may exclude the interests of relevant stakeholders.* Most projects took samples from publicly owned lands and thus precluded the need to consult with indigenous groups. However, participation of all stakeholders is essential to effectively implement regulations and achieve the long term goals of the CBD.

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65. Columbia, paraphrased, p. i.

66. Columbia, paraphrased, pp. ii-vi.

Columbia University Review Recommendation 3. During the policy development process, the entities directly involved in policy formulation should attempt to identify and seek the participation of other stakeholders.

Columbia University Review Conclusion 4. *The ability of regulated bioprospecting to expand conservation efforts is limited because most agreements take place on land where conservation is already underway.* To facilitate reaching an agreement and to maximize diversity of resources, bioprospectors prefer lands where property rights are clearly established, a minimum number of parties are involved, and biodiversity is high. Consequently, bioprospecting firms tend to conduct their work on state-owned national parks where additional conservation efforts are less critical.

Columbia University Review Recommendation 4. Bioprospecting initiatives based outside state-owned land and protected areas should be encouraged.

Columbia University Review Conclusion 5. *There is a contradiction between disclosure of terms in access agreements for stakeholder involvement and right to confidentiality of parties in the transaction.* On the one hand, it is common business practice for the terms of an agreement to remain confidential. On the other, the public may argue for the right to know when genetic resources are transferred from publicly owned land.

Columbia University Review Recommendation 5. It is not feasible to address this issue in the short term, but it is important to highlight the difficulties associated with the current situation in order to stimulate the discussion of this topic.<sup>67</sup>

Columbia University Review Conclusion 6. *There may be few incentives arising from access to genetic resources to preserve resources that local communities do not legally own.* Governments have asserted their sovereign rights over genetic resources. However, in many cases, the land remains under local communities' traditional tenure. Usually, only resource owners (state governments) and users negotiate agreements and only the resource owners receive benefits. Accordingly, it is unlikely that local communities will implement sustainable use practices unless policy gives them ownership of the genetic resources they tend and thus the benefits as well.

Columbia University Review Recommendation 6. National policy should address the conflict between traditional land tenure and legal property rights of genetic resources so as to match conservation obligations with the benefit sharing rights implicit in access to genetic resources policy.

Columbia University Review Conclusion 7. *Bioprospecting regulations may raise the costs of negotiating access and create a disincentive to use biodiversity.* Prohibitively restrictive bioprospecting regulation would raise the overall cost (monetary and otherwise) of using genetic resources and thus may prevent genetic resources from being used. This problem affects

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67. Columbia, p. 3. The "recommendation" was not set out separately in the original as a "recommendation", but was included in the "conclusion" section. However, the nature of the language indicates that it is clearly a recommendation.



national, international, commercial, and non-commercial ventures alike. Implementing new regulations on access to genetic resources may further increase costs by nullifying preexisting agreements or requiring renegotiation. Consequently, the often lengthy process of developing regulations creates a "window of uncertainty" during which parties are reluctant to apply for access, and source country authorities are inclined to reject or postpone them.

Columbia University Review Recommendation 7. Policymakers should reconcile the conflicting goals of regulating and facilitating access in order to achieve the goals of conservation and distribution of benefits. It is difficult to determine the extent to which the balance between regulating and facilitating bioprospecting access has been achieved.<sup>68</sup>

Columbia University Review Conclusion 8. *An additional hindrance to access to genetic resources is the use of the same standards in commercial and non-commercial research access requests.* Commercial access involves high monetary stakes. Thus, access regulations have become increasingly restrictive and commercially-oriented. It is unfair to impose this cumbersome and unnecessarily strict application process on basic, non-profit research, which is required to understand natural processes and almost invariably precedes commercially oriented research. Failure to explicitly recognize the fundamental differences between commercial and non-commercial research in bioprospecting policy may cause essential research – including research performed by national universities and state agencies – to stop. However, it is often impossible for source country authorities to distinguish between commercial and non-commercial projects.

Columbia University Review Recommendation 8. There is no objective criterion to distinguish between commercial and non-commercial research. Countries should provide a "two-track" application process. An applicant may choose either track according to its priorities.

Type I agreement: A simple research permit that requires researchers to forgo the right to any future monetary benefits arising from commercialization and intellectual property rights, which belong to the resource owners.

Type II agreement: A more complex contractual agreement involving negotiations of intellectual property rights and both monetary and non-monetary benefits with resource owners, as defined in the specific national and local context.

Non-profit researchers opting for a Type I agreement can avoid the cumbersome process of consulting with large numbers of stakeholders and costly negotiations for detailed benefit sharing. They are only granted ownership to the sample itself and permission to study the material they collect. However, Type I applicants continue to be subject to source country requirements for fair compensation. Resource owners (source country governments or institutions) may also commercialize any discoveries. At the same time, a Type I applicant may enter into a more complex Type II agreement requiring benefit sharing provisions in the future. Type II agreements could be structured as a framework containing a variable number of clauses that come into effect as they become applicable.

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68. Columbia, pp. 3-4. This "recommendation" was also embedded in the section containing the "conclusion."

Columbia University Review Conclusion 9. *The main benefits to be obtained from access agreements will most likely be non-monetary, i.e., capacity building, technology transfer, joint research, and training.* A common expectation is that substantial cash profits can be generated from bioprospecting to enhance conservation. Nonetheless, at the time of this analysis, no royalty or commercialization-derived monetary benefits have resulted from any of the agreements.

Columbia University Review Recommendation 9. All parties should realize that benefits obtained from access, for the most part, will be non-monetary and that monetary benefits may be elusive.

## Chapter 4

### BIODIVERSITY ON PUBLIC LANDS AND BENEFIT SHARING

#### PUBLIC LANDS, BIODIVERSITY, AND BENEFIT SHARING

H.C.R. No. 146, H.D. 1, 2005, asserts the following:

- (1) The State holds *public lands* in trust for native Hawaiians and the general public as co-beneficiaries;
- (2) *Biological resources* located on public lands are assets of the public trust; and
- (3) The State has a duty to ensure that these resources are utilized in a judicious manner that also provides a *sharing of benefits* in as universal a manner as possible.

This chapter examines the accuracy and ramifications of these three assertions with regard to bioprospecting.

***Public Lands.*** The public land trust is composed of former government and crown lands of the Kingdom of Hawaii that were appropriated by the Republic of Hawaii upon the overthrow of the Hawaiian Monarchy, ceded to the United States under the Newlands Resolution of 1898, and subsequently transferred to the State under the Admission Act. In accordance with section 5(f) of the Admission Act, the State must dedicate a portion of the revenues derived from the public land trust to the betterment of the conditions for native Hawaiians. Historically, the terms "public land trust" and "ceded land trust" have been used interchangeably.<sup>1</sup>

However, aside from public lands, certain lands in the State are privately owned. These privately owned lands are not subject to the conditions of use imposed on public lands including channeling generated revenues to the Office of Hawaiian Affairs.

***Biodiversity as Assets of the Public Trust.*** The issue as to whether biological resources located on public lands are assets of the public land trust is not so clear as the Resolution states. In legal opinion No. 03-3 dated April 11, 2003, the Attorney General opined on the very question of whether biological resources (biodiversity) on public lands are assets of the public land trust.<sup>2</sup>

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1. However, Hawaii may have obtained certain small parcels of land in the public land trust after Hawaii became a State. Thus, these parcels may not be considered "ceded lands" and may not be subject to the pro rata revenue requirement owed to the Office of Hawaiian Affairs.
  2. On April 1, 2003, Representative Sol P. Kaho'ohalahala requested an opinion from the Attorney General on several relevant questions, including whether the legal title of biological resources gathered from state public lands, including ceded lands, is vested in the State of Hawaii. In response, the Attorney General issued legal opinion No. 03-3 on April 11, 2003, written by Deputy Attorney General Charleen Aina. In telephone conversation of August 17, 2005 with Ms. Aina, she informed us that the Attorney General had

(Attorney General Op. No. 03-03 is attached as Appendix C.) The Attorney General was asked whether the State holds legal title to biological resources gathered from state public lands, including ceded lands. More specifically, the Attorney General was asked whether the "legal title to biogenetic resources gathered from ceded lands [is] part of the ceded lands public trust."<sup>3</sup>

The Attorney General opined that the State holds legal title to biogenetic resources gathered from public lands only under certain conditions:

"The State holds legal title to biogenetic resources gathered from state public lands, including the ceded lands, if the State reserved its title to the biogenetic resources when it allowed third persons to remove the natural resources or thing from which the biogenetic resources were extracted, or it transferred its title to the land from which the biogenetic resources came. Further, the State would not lose its title to the biogenetic resources if the natural resource or thing from which the biogenetic resource originated was removed from the public lands without authority or the State's permission."<sup>4</sup>

In other words, to retain title to genetic material extracted from, say, a plant, the State must stipulate that it reserved title to that biogenetic material when the State:

- (1) Permitted a bioprospecting firm or a collaborator to take the sample plant from public lands; or
- (2) Transferred title to the public land from which the sample plant originated.

However, the Attorney General cautioned that the State cannot simply assume that it owns those biogenetic resources because "there is no statute or law that presently reserves, or prevents or regulates the sale of, biogenetic resources extracted from resources or things situated on lands the State owns."<sup>5</sup> The Attorney General further clarified that:

"Nonetheless, inasmuch as the genetic material or composition of the natural resources and things connected to public lands, including ceded lands, are an integral part of those resources and things, title to the biogenetic resources will still be held by the State if it has not sold the land. However, legal title to biogenetic resources gathered from State public lands will not still be vested in the State if third persons were allowed to remove from public lands the natural resource or thing from which the biogenetic resources were extracted or the State sold or leased title to a parcel of public land without reserving title or retaining control of the resources or things connected to the transferred land, or their biogenetic contents."<sup>6</sup>

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not done any follow-up research on the issues in legal opinion No. 03-03 but that she was not aware of any relevant changes to the situation, including the procedures carried out at the Department of Land and Natural Resources and the University of Hawaii.

3. Ibid., p. 1.  
4. Ibid., p. 2.  
5. Ibid., p. 5.  
6. Ibid., p. 5.

That is, the genetic material of a plant is an integral part of that plant. If the State continues to own the public land from which the sample plant was taken, it would retain title to the plant's genetic material. However, the State would *not* retain title to the genetic material if it granted permission for the sample plant to be removed from public lands. Also, if the State sold or transferred land, it would not have title if it did not specifically reserve title or retain control of the genetic material or the sample plant at the time of sale or transfer.

***Benefit Sharing.*** The Attorney General also opined on whether revenue generated from the sale or transfer of biogenetic material gathered from public lands must be deposited into the Ceded Lands Trust Account. The Attorney General ruled in the *negative*.

By way of background, sections 10-13.5 and 10-3(1), Hawaii Revised Statutes, direct the Office of Hawaiian Affairs to expend twenty per cent of all funds derived from the public land trust to benefit native Hawaiians and Hawaiians. In OHA v. State, 96 Haw. 388 (2001), the Hawaii Supreme Court struck down a 1990 state law, Act 304, Session Laws of Hawaii, which amended chapter 10, HRS, relating to how the State should pay the Office of Hawaiian Affairs its twenty per cent share. The Hawaii Supreme Court stated that the state law conflicted with federal law and, as such, declared it invalid. It then instructed the Office of Hawaiian Affairs to seek a legislative remedy. To date, no legislative remedy has been enacted to replace Act 304, Session Laws of Hawaii 1990.

Nonetheless, the Attorney General opined that the OHA v. State decision "does not foreclose state agencies from transferring funds they receive for the use of ceded lands, to OHA."<sup>7</sup> However, the Attorney General continued:

"[u]ntil the Legislature again makes the policy determinations on which a replacement funding mechanism can be grounded, there are no standards or precedents for determining whether receipts from the sale of extracts from material originating on ceded lands [*i.e. biogenetic materials*] constitute 'funds derived from the public land trust' under section 10-13.5. Until the Legislature re-establishes a funding mechanism, our only precedent is the receipts the Department of Natural Resources ("DLNR") collected in the interval from 1987, when OHA v. Yamasaki, 69 Haw. 154 (1987), was decided, and 1990, when Act 304, Session Laws of Hawaii 1990 was enacted. These collections did *not* include receipts from products from resources or things connected to ceded lands [*i.e. biogenetic materials*]. Because the University [*of Hawaii*] must process the resources or things from the public land in order to get the genetic material ... the receipts from the sale of the genetic material are different from the receipts DLNR transferred to OHA in the 1987 – 1990 interim, and do *not* qualify for transfer under Executive Order No. 03-03."<sup>8</sup> [*Emphasis added.*]

That is, it is up to the Legislature to set policy to determine what income and proceeds constitute funds derived from the public land trust that are to go to the Office of Hawaiian Affairs. Until that happens, Executive Order No. 03-03 is the only mechanism for transferring receipts from the use of ceded lands to OHA. According to the Attorney General, under this order, receipts from biogenetic resources, because they are different from previous receipts, do

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7. Ibid., p. 9.

8. Ibid., pp. 9-10.

not currently qualify for transfer to the Office of Hawaiian Affairs, absent any policy set by the Legislature.

In other words, with regard to ceded lands, in order for benefits to be shared with native Hawaiians and Hawaiians, the biological resource involved must first qualify as an asset of the public trust (*see preceding section*). Next, even under conditions when this is the case, and the State retains title, revenues from the sale of biogenetic material derived from the biological resource do *not* currently qualify for transfer to OHA. Thus, the assumption made by H.C.R. No. 146 that bioprospecting activity on public lands automatically triggers benefit sharing with native Hawaiians through OHA is inaccurate.

What this means is that the *State*, based on its title to biological resources, may attempt to claim a share of benefits – in whatever form – to fund statewide conservation, sustainable use of biodiversity, and other statewide purposes. However, there is currently no legal framework or mechanism to implement this institutionally. Furthermore, as noted previously, *native Hawaiians* currently do not automatically share benefits from bioprospecting because receipts from the sale of genetic material do not qualify as funds that can be funneled to OHA.

The negotiated bioprospecting agreement may be part of the solution. The optimal situation would have the State first set policy by establishing a legal framework to regulate bioprospecting and to institutionalize benefit sharing. Without such a legal mandate, the results would likely be haphazard, uncertain, and inequitable since the parties to an agreement would need to be relied upon to voluntarily share benefits equitably. An institutionalized legal framework would ensure that this is actually done. The legal framework would be the expression of state policy regulating bioprospecting activity, including mandating prior informed consent, benefit sharing, and biodiversity conservation. The negotiating of agreements to comply with these mandates would take place within this mandated framework. Furthermore, negotiated agreements can be tailored to deal with the unique details and requirements of each individual bioprospecting project.

In addition, the use of negotiated agreements can mitigate the complexities of the intellectual property rights and patent law regime. Moreover, negotiated agreements may facilitate benefit sharing with *native Hawaiians*. As noted above, the Attorney General has ruled that "receipts from the sale of genetic material ... do not qualify for transfer [to OHA] under Executive Order No. 03-03."<sup>9</sup> However, nothing prevents a bioprospecting firm and the State from agreeing to *voluntarily* share benefits with native Hawaiians from the sale of genetic materials from public lands. Of course, relying on voluntary benefit sharing is not optimal, as discussed above. However, for the sake of illustration, the State and the bioprospecting firm can choose an agency of their choice, which may or may not be OHA, to receive and disburse benefits. They can further explicitly stipulate that the amount or percentage of revenues transferred is wholly voluntary and entirely outside and separate from the mandate of Executive Order No. 03-03. Thus, as a transaction completely *outside* the current OHA funding mechanism, the amount of benefits would not affect the twenty per cent OHA funding formula. Granted, any such benefits would probably be in excess of the current twenty per cent OHA

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9. Ibid., p. 10.

funding formula. However, this only heightens the need for the Legislature to formulate a rational and comprehensive policy and funding guidelines for OHA.

Of course, a bioprospecting firm may opt to avoid dealing with the State and the ceded lands issue altogether by obtaining samples from privately owned land, if possible. In this case, the State would have no jurisdiction to extract benefits from the bioprospecting firm. On the other hand, it should be noted that nothing would prevent the *private* landowner and the bioprospecting firm from *voluntarily* negotiating a benefit sharing agreement based on guidelines the State may impose for *public* lands.

**Need for Legislative Policy.** To sum up, the issue at hand can be illustrated in a simple matrix below.

Type of Land	Public	Private
Benefit Recipient	State and/or Native Hawaiians	Private landowner
Benefit Uses	Statewide conservation, environmental and/or Native Hawaiian betterment	Private landowner

Bioprospecting is carried out on either *public* or *private* lands. If on private lands, the private landowner receives the sole benefits. The State plays no role.

However, if bioprospecting is carried out on public lands, the Legislature needs to set policy on several issues. First, it needs to clarify and to require that the State retains title to biogenetic resources in bioprospecting projects. For example, it could reserve to the State the title and rights to any biological resource or genetic materials derived from that biological resource in any lease, agreement, or sale involving bioprospecting on public lands.<sup>10</sup>

Next, the Legislature needs to set policy regarding who receives benefits and how the benefits are to be used. As far as statewide benefits are concerned, the State, when receiving benefits as a party to an agreement, needs to determine how those benefits are to be used. Common uses include conservation, sustainable use of biodiversity, and various economically sustainable activities related to the State's biodiversity, or any combination.

As for native Hawaiians, the Legislature needs to set unequivocal policy regarding whether a portion of bioprospecting benefits derived from public lands should be used for the betterment of native Hawaiians. As noted above, receipts from the sale of genetic material from public lands do not currently qualify as funds that are derived from the public land trust. Thus, native Hawaiians are not now automatically entitled to benefits from bioprospecting on public lands. The Legislature needs to make clear whether native Hawaiians should benefit from such sales. If the Legislature does so decide, and it wants OHA to continue to disburse such funds, the Legislature will further need to implement a new funding mechanism for OHA, as the Attorney General noted. In doing so, the Legislature will probably need to determine that

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10. The State already makes a similar reservation of mineral and water rights in section 171-58, Hawaii Revised Statutes.

receipts from the sale of genetic material from ceded lands constitute "funds derived from the public land trust" in order to facilitate the transfer of such receipts to OHA.

Ideally, these policy decisions should be made *before* any agreements are negotiated for the purposes of uniformity and consistency and to ensure equity. The actual nuts and bolts institutional mechanism to regulate bioprospecting, which may involve various state agencies, should be constructed only after the Legislature sets policy to regulate bioprospecting (prior informed consent, benefit sharing, and conservation).



## Chapter 5

### CONSULTANT RESPONSES

#### OFFICE OF THE GOVERNOR, THE UNIVERSITY OF HAWAII, AND STATE DEPARTMENTS

H.C.R. No. 146, H.D. 1, 2005, requested the Office of the Governor to provide a "compilation of an inventory of current bioprospecting research projects and activities in the State that are public." The Resolution also asked the Bureau to consult with the University of Hawaii and the following four state departments concerning the study:

- Department of Agriculture
- Department of Health
- Department of Business, Economic Development, and Tourism
- Department of Land and Natural Resources

*Office of the Governor – Inventory of Current Bioprospecting Research Projects.* Governor Lingle designated the Department of Business, Economic Development, and Tourism (DBEDT) to act as liaison with the Bureau to compile the inventory.<sup>1</sup> According to the DBEDT, letters were sent to the Departments of Land and Natural Resources, Agriculture, and Health and to the University of Hawaii seeking this information. The Oceanic Institute, a private non-profit research organization that receives public funds was also contacted.

The responses from the three state departments are as follows:

Agency/Organization	Response
Department of Health	No projects, studies, activities or funding related to bioprospecting.
Department of Land and Natural Resources	No current permits on file issued with any reference to bioprospecting.
Department of Agriculture	No internal or funded research related to bioprospecting. On occasion, permits are issued for entry of microorganisms isolated and purified elsewhere from environmental samples collected in Hawaii.

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1. Letter from Governor Linda Lingle to Ken Takayama, Director of the Legislative Reference Bureau, dated August 24, 2005, designating Liz Corbin of the Strategic Industries Division, DBEDT.

*BIOPROSPECTING: ISSUES AND POLICY CONSIDERATIONS*

According to the DBEDT, the University of Hawaii project list was compiled by reviewing all research projects listed by the Office of Research Services and working with the university staff. The list of current bioprospecting projects at the University of Hawaii and the Oceanic Institute is presented below.

<b>Public Bioprospecting Projects in Hawaii</b>					
<b>Title/Description</b>	<b>Principal Investigator</b>	<b>Duration</b>	<b>Commercial Partner</b>	<b>Funding Source</b>	<b>Amount</b>
<b>UNIVERSITY OF HAWAII</b>					
Identify Bioterrorism Drug Candidates from Plants and Marine Algae in UH Biological Collections (not all specimens from Hawaii)	Thomas Hemscheidt	Through 2008	Hawaii Biotech, Inc.	UH Accelerated Research Commercialization (ARC) Program	\$47,000
Discovery of Pharmaceutical Lead Compounds from Marine Organisms	Robert Bidigare	2004-2005	Diversa	National Oceanic & Atmospheric Administration (NOAA)	\$339,828
Exploration of Biodiversity and Pharmaceutical Potentials of Marine Fungi in Hawaii	Guangyi Wang	2004-2005	None	NOAA	\$178,024
Screening Dinoflagellates for Bioactive Compounds	Michael Parsons	2004-2009	None	National Institutes of Health and National Science Foundation (NIH/NSF)	\$371,000
Screening Marine Microflora	Stuart Donachie	2004-2007	None	NIH/NSF pilot project	≤\$50,000
<b>OCEANIC INSTITUTE</b>					
Inhibitors of Mast Cell Degranulation and TRPM Cation Channels from Marine Organisms (looking for small molecule inhibitors in marine organisms)	David Horgen, Hawaii Pacific University	2004-2005	None	NIH	\$145,363

It is interesting to note that the data from the DLNR indicate that it has not issued permits relating to bioprospecting, whereas the inventory of current bioprospecting projects indicates that permits must have been issued.

**University of Hawaii.** The University of Hawaii provided the following opinions on how bioprospecting should be regulated in Hawaii:<sup>2</sup>

- First, any bioprospecting activity must begin with prior informed consent of the landowner (PIC). In the case of the state, the landowner is represented by DLNR who gives permission, via a permit process, to people who wish to sample state lands/waters. In the permit process the state should be able to determine exactly what will be sampled and what the samples will be used for. This is PIC. Furthermore, before a permit is granted, the state needs to determine how benefits, if any, will be handled.
- The ceded lands issue complicates the situation, but until it is settled in the courts ... the state should negotiate any commercialization resulting from samples permitted by the state on a case by case basis through the UH Office of Technology Transfer & Economic Development (OTTED). They have the expertise and personnel to handle the estimated 2-5 license requests that may come in any particular year. This would also prevent DLNR from having to build up licensing expertise when they are already short-handed. Revenue from the licensing on these materials would be divided between DLNR and beneficiaries of the ceded lands. DLNR would be required to use the funds to preserve all of Hawaii's natural resources and specifically the resource where the sample was taken from. The ceded lands portion of any revenue/royalty will be held in a trust until that issue is decided in the courts.
- Unfortunately, at this time the state does not have the ability to retain an interest in the samples it gives permission for people to take. The Hawaii Life Sciences Council (HLSC) is proposing legislation this session to require the DLNR to change its permitting process to include language of a material transfer agreement. The permittee will be required to notify DLNR if a discovery is made using samples from state lands/waters and if that invention is to be commercialized, a license from the state will be required. The HLSC believes that protecting the resource is the first step in addressing the bioprospecting issue and that the discussion of distribution of sharing of benefits can be addressed on its own merits to include not only cash, but access to technologies, capacity building, job creation and educational opportunities.<sup>3</sup>

It must be noted that the reference to the courts having to settle the question of payments to the Office of Hawaiian Affairs in connection with ceded lands is inaccurate. It is up to the Legislature to resolve that question of policy. (See chapter 4 for a detailed discussion on this issue.)

**State Departments.** The Bureau asked all four departments basically the same questions regarding bioprospecting and regulation, adjusting for each department's unique duties and activities.

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2. Letter dated June 3, 2005, from David McClain, President of the University of Hawaii, to Ken Takayama, Director of the LRB, designating Kevin Kelly, Director of Business Development for the Center for Marine Microbial Ecology & Diversity at the University of Hawaii, as the University's point of contact.
  3. Email reply of September 2, 2005, from Kevin Kelly, UH System Managing Director, EPSCoR Hawaii, designated by President David McClain as the contact person representing the University's views.

**Departments of Agriculture (DOA) and Health (DOH).** The Bureau asked the Department of Agriculture and the Department of Health to describe step-by-step what each does with regard to bioprospecting in the State. The questions are paraphrased as follows:

- Whether it is requested to review applications to take environmental samples as part of bioprospecting projects and whether it initiated such review actions. (For the Department of Health, we asked if this review was the same as the "environmental review of land use" it already conducts.)
- Whether it has authority to act on an entity's taking of environmental samples out of the State and, if so, what the statutory authority is.
- If authorized, what form does departmental action take – a permit, license, approval, denial, opinion, or other.
- Whether it has any other authority with regard to bioprospecting and environmental samples.
- Whether it believes that its statutory or rule authority is adequate or inadequate.
- If it does take action, is that action binding or advisory.
- Whether it charges any fees and whom it charges.
- Whether it has any official position on:
  - Title or ownership of samples taken by a bioprospecting entity.
  - Obtaining prior informed consent from the sample owner.
  - Compensation in the form of advanced payments, royalties, milestone payments, technology transfer, infrastructure building, training of local personnel, biodiversity conservation, and other benefit sharing in return for the possible commercialization of products stemming from bioprospecting.

We also asked each department, if any of the assumptions underlying our questions concerning departmental action were incorrect, to explain just how the department is involved with bioprospecting. Finally, we asked for open-ended comments or explanations that each department may consider necessary or appropriate.

The Department of Agriculture replied that:

- The DOA has no regulatory authority over the collection of biological material in Hawaii, flora or fauna, collected for purposes of bioprospecting.
- Entities involved in bioprospecting in Hawaii are not required to obtain approval from the DOA to conduct these activities.
- *[In response to what authority the DOA does have]:*  
The DOA does not have authority to act on the taking of environmental samples out of the State. The DOA (i.e., State Plant Quarantine) has authority to provide the following services under Title 4, Subtitle 6, Chapter 73, Plant and Non-domestic animal Quarantine, Plant Export Rules:
  1. Plant inspection and certification;

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2. Plant and fruit fumigation;
  3. Burrowing nematode testing; and
  4. Nursery certification.
- Services are provided given adequate personnel and facilities to help facilitate the movement of plant products out of the state. Services are provided to help exporters meet the receiving state or country's import quarantine requirements. The chapter is silent on the collection and movement of plants collected in Hawaii for reasons of title, ownership, consent or payment concerns.
  - HDOA does not have any specific authorities regarding bioprospecting.
  - *[In response to whether the department has a position on title, prior informed consent, compensation]:*  
No official position regarding the above.
  - *[Additional comments or explanations]:*  
Legislative decisions regarding title or ownership, prior informed consent, compensation and environmental impact will dictate DOA's role in the regulation, if any, of this activity.<sup>4</sup>

Like the Department of Agriculture, the Department of Health is not involved with regulating bioprospecting and provided a similar reply:

- DOH does not conduct sample reviews of plants, soil, microbes, etc., with respect to bioprospecting projects, nor does DOH look for bioprospecting projects or initiate any action involving such.
- DOH does not conduct bioprospecting reviews.
- *[In connection with the DOH's environmental land review, which is not related to bioprospecting]:*  
The DOH environmental land use review pertains to environmental impacts of proposed projects to water and air quality, noise, radiation, and hazardous material. Land use documents submitted for DOH review are environmental assessments, environmental impact statements, stream alterations, subdivisions, etc.  
After the review, DOH programs provide relevant comments that pertains to their jurisdiction; solid & hazardous waste, clean air, clean water, wastewater, safe drinking water, noise, radiation, and vector control. The permits pertain to water programs and food and sanitation issues. The advisory comments are based on DOH rules and therefore binding.
- *[In response to adequacy of DOH's statutory authority]:*  
It is adequate for DOH's purposes but does not address bioprospecting.
- *[In response to whether the department has a position regarding title, prior informed consent, and compensation]:*  
The DOH is not involved with bioprospecting.
- *[In response to whether the assumptions underlying the Bureau's questions are correct or incorrect]:*  
The assumptions are incorrect. DOH State Lab Division performs testing on environmental and clinical samples only to support other programs in DOH, which generally are regulatory or for diagnostic or epidemiologic purposes. SLD has no direct involvement with bioprospecting.
- *[Additional comments or explanations]:*

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4. Email reply of September 19, 2005, from Dr. Lyle Wong, Administrator, Plant Industry Division, Department of Agriculture.

DOH appreciates this opportunity to answer questions about bioprospecting and wish to reiterate that the department of health is not involved with bioprospecting.<sup>5</sup>

*Department of Land and Natural Resources (DLNR).* The Bureau asked a much more detailed series of questions of the DLNR. The Department's response is presented below:<sup>6</sup>

**House Concurrent Resolution No. 146, H.D. 1, 2005**  
**Bioprospecting – Role of DLNR, Primarily the Division of Forestry and Wildlife (DOFAW) and Division of Aquatic Resources (DAR) Response**

- 1 a** When an entity wants, for the purposes of *bioprospecting*, to take certain biodiversity (organic samples – plant or animal but not mineral) from land or in or under the water in Hawaii over which the DLNR has jurisdiction, is that entity required to obtain prior written permission from DLNR? While current rules at DOFAW [*Division of Forestry and Wildlife*] do not specifically mention bioprospecting, written permits are required for collection of any plant, animal, or geological material from lands under the jurisdiction of DOFAW, including but not limited to Natural Area Reserves, Forest Reserves, Game Management Areas, Plant and Wildlife Sanctuaries. Current rules at DAR [*Division of Aquatic Resources*] are inadequate relative to nondescript, multi-species or large-scale collection of marine life for bioprospecting. Only the relatively few (out of the 5,000 plus Hawaiian marine and freshwater) species that are currently regulated would require a permit under existing DAR rules. The overwhelming vast majority of marine species in Hawaiian waters are open to exploitation. Given the extremely high level of endemism for Hawaiian marine species (estimated [a]t around 25% across phyla) it is extremely concerning that strong recognition has not been given to [t]he potential for extirpation or extinction for many of these species as there is no replacement pool and many are limited to single islands, coastal areas or small embayments.
- b** Does DLNR have control over all biodiversity (living organisms) on lands and waters under its jurisdiction to the extent of allowing bioprospecting samples to be taken? DLNR currently has authority to manage all lands under its jurisdiction, for DOFAW, State Parks, Land, and DAR specifically has current authority to manage all aquatic organisms occurring in Hawaiian waters under HRS 187A-2. Furthermore, "all marine waters of the State are hereby constituted a marine life conservation area to be administered by the department of land and natural resources: [HRS 190-1]. In the case of streams and marine portion of `Ahihi-Kina`u Natural Area Reserve, the Division of Aquatic Resources (DAR) may also have joint authority.
- c** Currently, does an entity ever need to obtain the DLNR's permission even though samples are *not* taken from lands/waters under DLNR jurisdiction? Yes, for DOFAW, if research or activities are of a nature that could be potentially harmful to native ecosystems, or would include introductions of any non-native plants or animals. For DAR, yes an entity would need to obtain permission from DLNR/DAR if an activity in State waters (that did not include collection) were to:
- 1) Harm, damage or kill any live rock or coral [HAR 13-95-70 & HAR 13-95-71. 2)

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5. Email reply of September 15, 2005, from Herman Tuiolosega, Environmental Planning Office, Department of Health.

6. Letter and materials dated December 20, 2005 received on December 27, 2005 from Peter T. Young, Director of Land and Natural Resources.

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[C]onduct certain non-extractive activities within Marine Life Conservation Districts (MLCD), Fishery Management Areas (FMA) or other aquatic reserves; such activities may include anchoring boating or mooring [HRS 190-4.5]. 3) Have the potential to release harmful aquatic life into state waters [HRS 187A-6.5] or introduce any aquatic life [HRS 197-3]. 4) Damage or alter State submerged lands [HRS 171-58.5]; this would be administered by the Office of Coastal and Conservation Lands (OCCL). 5) Possession and/or use of certain gear [HAR 13-75]. 6) Harm, damage or kill any fully-protected aquatic organism: certain shellfish [HAR 13-83-1] and HRS 13-124 which provides for species t[h]at are listed as threatened or endangered to have full protection; currently this applies to sea turtles and marine mammals). 7) The Department has authority under HRS 190-3 to establish additional rules to prohibit activities that disturb, degrade or alter the marine environment.

- d Does the DLNR allow biodiversity samples to be taken out of the State? If so, need they be returned?** For DOFAW, with the exception of Threatened and Endangered Plants and Animals, there is currently no prohibition of export. For DAR, with the exception of those few regulated species, there is no prohibition regarding samples being taken out of state. Two years ago some researchers from Massachusetts contacted the Department seeking permission to collect *Stylocheilus* (a type of marine mollusk) for research. As this species (genera and family) is not regulated, DAR basically gave them carte blanche to collect as many as they wanted. An investigation by the U.S. Fish and Wildlife Service (USFWS) on the mainland later documented that they had collected over 10,000 of these animals from O‘ahu and shipped them to Boston. The USFWS impounded the shipment before it could be trans-shipped to France to a pharmaceutical company for "research" purposes. This clearly illustrates the problem here in Hawaii with loss of our marine resources for outside gain and without any compensation or impact on the coastal environment. Given the extremely high level of endemism for Hawaiian marine species (estimated at 25% across phyla), serious questions of "biopiracy" exist regarding the State allowing unique natural resources to be exported for commercial gain outside of State control.
- e As far as you know, is the bioprospecting entity required to obtain prior written permission from governmental agencies other than the DLNR, e.g. DOH, DOA, DBEDT, or others?** Other agencies have their own rules and regulations governing collection or other activities on lands under their jurisdiction.
- 2 a If written permission is required from the DLNR, is it a license or a permit, or is it in some other form?** For DOFAW, a Special Use Permit for Natural Area Reserves [HAR 209-5], License for Threatened and Endangered Plants [HAR 107-4], Scientific Permit for Protected Wildlife (Vertebrate, and Invertebrate) and a separate permit for animals that are Threatened and Endangered [HAR 124[-]34, 6] constitute written permission, signed by the Board or its authorized agent. For DAR, written permission would be in the form of a Special Activity Permit (SAP) [HRS 187A-6], however questions arise regarding specifically the activity of "bioprospecting" as constituting a true form of research since any compounds produced would be patented and therefore commercial in nature. A key question ALL Divisions should be asking it whether this "research" activity is also commercial in nature? In almost all cases, at least marine bioprospecting is conducted with the prospect of commercial application of the products produced.
- b Can you email/fax a copy of a blank license/permit, or an actual one, redacted if necessary?** Copies of the current Permit Guidelines and Application general form for DOFAW are attached. State Parks follows the format of the DOFAW process for

any scientific permits they may issue.

- 3 a Does this permission specifically identify bioprospecting as the purpose for the issuance? That is, does the DLNR overtly acknowledge the applicant's intent to bioprospect?** No, permission currently does not specifically identify bioprospecting as an activity for any particular Division.
- b Or is the license/permit for general, multiple, or unspecified purposes that may possibly be interpreted as including bioprospecting?** Not currently.
- 4 a Is the entity required to disclose its bioprospecting intent?** No, current guidelines do not require applicants to identify bioprospecting as an activity for any Division.
- b What other information does the DLNR require from the entity? Can you list these here?** Applicants are encouraged to include a study plan and maps detailing where they want to conduct their research/collecting on State land.
- c Can you email/fax a copy of a sample application form for a license/permit?** A copy of the current permit guidelines and application form are attached.
- 5 a Does the DLNR license/permit restrict the taking of samples in any way? For example, does it limit: Both DOFAW and DAR permits have the ability within "Special Conditions" to set specific limits based upon staff recommendations. Often such limitations involve numbers, area of collection, size of samples, collection methodology, etc.**
- b Sample taking of organic materials specifically enumerated on the permit?** Not to exceed specific amounts stated in special conditions of the permit.
- c The number or quantity (weight/volume/other) of samples?** Stated amount in the application or a lesser amount as determined by staff.
- d The types of samples?** Enumerates plant or animal parts or whole plant or animal, soil or other geological sample by volume or size.
- c What other restrictions, if any, does the DLNR/DOFAW license/permit impose?** None currently.
- f If no current restrictions, does the DLNR believe there should be restrictions? If so, what would these be?** DOFAW and DAR in particular, believes [*sic*] that the Department should be allowed to set restrictions as necessary based upon both the "Precautionary Principle" and the best available science.
- 6 How long is a permit good for?** Special Use Permits for Natural Area Reserves are issued for one year maximum, starting from the date of issue. Protected Wildlife Permits (Vertebrate) maybe issued for more than one year, depending on the Study Plan. Permits for Protected Wildlife (Invertebrate) and Threatened and Endangered Species of plants and animals are issued on annual basis. For DAR, a SAP is good for one year through the end of the current fiscal year (i.e. all SAPs expire June 30).
- 7 a Is there an application fee or license/permit issue fee, or both, or neither? If so, how much?** Currently, DOFAW and DAR do not charge a fee for any permit (with exception of commercial hike permits under DOFAW's Na Ala Hele Trails and Access Program); other Divisions do not have fees attached to collecting permits.
- b Does the DLNR impose the receipt of any other monetary fees, royalties, advance payments, milestone payments, or other monetary or in-kind benefits of any sort from the bioprospecting entity, from the sale of any commercial products derived originally and processed from the biogenetic material contained in the biodiversity sample taken, to be used for the general purpose of**



- biodiversity conservation in Hawaii?** Not generally. However, New York Botanical Garden entered into a collaborative agreement with DOFAW and offered to provide infrastructure support for equipment, and other items, for permission to collect samples of plant material on State lands for screening for potential medical benefits. They also stated that should there be a collection that was actually developed into a successful product, that the State would benefit, should it have been collected from State land under the specific permit. Permits were given for specific Forest Reserves and State Parks, but not Natural Area Reserves, nor any Threatened or Endangered Plants.
- c If not, does the DLNR recommend the imposition of the receipt of such fees, royalties, or benefits for such purposes?** Yes; particularly DOFAW and DAR.
- 8 a Does the license/permit assert or stipulate that the State reserves and *retains title* to all biodiversity samples taken?** DOFAW and DAR permits do not currently stipulate that the State reserves title over the natural resources.
- b Or, does DLNR/DOFAW assume that once biodiversity samples are removed by the entity under a license/permit, title to the organism is *transferred* to the entity?** Currently silent.
- c Or, is the license/permit *silent* with regard to ownership of the biodiversity samples taken?** Currently silent.
- d What position does the DLNR take regarding who has *title* to the biodiversity samples taken?** Currently silent. DAR and DOFAW believe that title should be maintained by the Department in order to facilitate both data collection overall and improve both synergistic and cumulative management at an ecosystem level.
- 9 In many cases it is the *biogenetic material*, i.e. enzyme-producing *genes* derived from a biodiversity sample, that is desirable to the bioprospector. The genes can belong either directly to the sample itself, e.g. a plant, or from an endophytic microbe that is collected with the plant. For example, an endophyte fungi that lives inside turf grass repels insects harmful to the grass. It is the fungi's genes that are of interest although the biodiversity sample taken is the grass. No Division has a comment on this; but should consider this as part of the application process, requesting disclosure of ultimate destination and use of materials to be collected and removed from the specific area and ultimately from the State.  
**In the DLNR's opinion, does the State retain title to the:****
- a biodiversity sample *itself* and/or the organism collected with the sample**
- b *biogenetic material* (genes) of the biodiversity sample and/or *biogenetic material* of the organism collected with the sample.** There is no opinion, or statement to this effect in any current permit in any Division.
- 10 a What *statutory authority* authorizes the DLNR to permit entities to bioprospect?** Statutory authority does not currently give specific authority to bioprospect. Chapter 6E-61, HRS, designates the Hawaii biological survey as established and designated as a program of the state Museum of natural and cultural history. The survey shall coordinate with and compliment [*sic*] the work of the Hawaii heritage program, established by chapter 195, which manages data on rare native plants, animals and natural communities throughout the State. Chapter 6E-61 officially designates Bernice Pauahi Bishop Museum to be the State of Hawaii Museum of Natural and Cultural History. All DOFAW and DAR permits stipulate that all voucher specimens collected will ultimately be deposited in Bernice Pauahi Bishop Museum. HRS 187A-6 could be used to permit bioprospecting. DAR [c]urrently has authority to

manage all aquatic organisms occurring in Hawaiian waters under HRS 187A-2. Furthermore, "all marine waters of the State are hereby constituted a marine life conservation area to be administered by the department of land and natural resources" [HRS 190-1].

- b Does §171-13, HRS, relating to disposition of public lands, confer that authority?** It does not specifically mention bioprospecting.
  - c Does DLNR/DOFAW also invoke §171-54, HRS, relating to land license, "to enter land for a certain special purpose such as the removal of timber, soil, sand, gravel, stone, hapuu, and plants, but not including water rights, ground or surface, nor removal of minerals" (as defined in "land license" in §171-1, HRS)?** There is no current specific mention of bioprospecting in any Division.
  - d If these HRS sections do not apply, which sections do?** No statutes currently mention bioprospecting specifically.
  - e What Hawaii Administrative Rules, if any, authorize DLNR's permitting actions regarding bioprospecting?** For DOFAW, no rules specifically mention bioprospecting; no other Divisions (except DAR) currently has *[sic]* such provisions either. The following current DOFAW administrative rules allow for scientific collection of various plants, animals, water and geological specimens, as well as for personal use of non-native bamboo and other species, for personal use. Title 13: 104-18, 20, 21, 22, 23; Title *[13:]* 107-3, 4, 5, 6, 7, 9; Title 13: 125-1, 4, 6; Title 13: 209-1, 2, 3, 4, 5, 6. For DAR, HAR 13-28 - HAR 13-64 provides *[sic]* for permitting relating to Marine Protected Areas (MPAs), Marine Life Conservation Districts (MLCD), Fishery Management Areas (FMA) etc. If bioprospecting is determined to be a commercial activity, HAR 13-74 provides for permitting regarding commercial fishing. HAR 13-75 allows for permitting regarding restricted fishing gear use. HAR 13-83 through HAR 13-100 provide for permitting relating to specific regulated aquatic species.
  - f What is the DLNR's position regarding the adequacy of the department's current statutory and rules authority over permitting of bioprospecting?** Neither DOFAW nor DAR has a current permit for bioprospecting; if they did, they and other Divisions should reserve title to both the biodiversity sample and the biogenic resources derived from native or other resources. Specific mention of bioprospecting and all its implications needs to be added to all applicable Divisions in the Department.
- 11 In the license/permit for the purposes of bioprospecting, does DLNR/DOFAW:**
- a sell or lease title to the land or water from which biodiversity samples are taken?**
  - b reserve title or retain control of the both the *biodiversity sample* and the *biogenetic resources* derived from the sample?** DOFAW and other Divisions do not currently have a permit for bioprospecting.
- 12 Please provide us with any formal or working definitions DLNR/DOFAW may have of the following or any other relevant terms:** There are no current definitions within either the HRS or HAR for DOFAW or other Divisions.
- "biodiversity" or organisms that may be taken
  - "bioprospecting"
  - "microbe" (e.g. bacteria and fungi)
  - "microbial genomes", "genes", "genetic material", or similar terms
  - "bioprospecting samples" (environmental samples containing heterogeneous

**populations of uncultured microbes from diverse ecosystems**

- **any other terms relating to bioprospecting**

- 13 How many bioprospecting licenses/permits has the DLNR issued to entities so far? Can you list the entities and permits?** One, [t]o New York Botanical Garden, through DOFAW and State Parks, but it was not specifically listed as bioprospecting. The permits were considered to be scientific collecting permits for specific material in specific Forest Reserves or State Parks to be collected by New York Botanical Garden staff for processing then to Pfizer Company for analysis of any useful properties. These were issued by Oahu Branch of DOFAW and the Division of State Parks for specific lands under their jurisdiction (absent Natural Area Reserves).
- 14 Please describe the DLNR's procedure when licensing an entity to bioprospect by listing and describing each step?** There is currently no procedure; however the Division of Aquatic Resources (DAR) has made suggestions that are appropriate to their Division and could also apply to other Divisions with wording specific to the resources under their jurisdiction: a) Reform DAR's SAP permit application to contain a section specific to bioprospecting (along with appropriate definitions); b) Create a checklist that is used for all SAP permit reviews that results in red flags for further review; c) Modify permit review [so] that permits are reviewed by a minimum of two staff members with recognized expertise in the specific organisms being requested (i.e. freshwater biologists review permits for freshwater organisms, coral reef biologists review for coral reef organisms, pelagic fisheries biologists review for pelagic organisms, etc.; d) Allow for expanded "Special Conditions" sections of SAP permits; and e) A permit guide for all Divisions be placed on the Department's web site for potential applicants to read first before contacting appropriate Divisions with specific questions and to request application forms. DOFAW has already done this to some extent, but a more detailed set of guidelines for the entire Department needs to be the first line of contact. There should also be an interactive set of maps that prospective applicants maybe able to use to indicate exactly where their study area(s) are, to better determine which Divisions need to review and/or grant permission, and allow for a better evaluation filter.
- 15 Please correct any errors or assumptions in this questionnaire.**
- 16 Does DLNR/DOFAW have any comments or recommendations regarding this subject?** DOFAW and DAR recommend that the Department consider rulemaking process that would specifically address bioprospecting and all its implications, for all Divisions, as well as the Kaho'olawe Island Reserve Commission, and to ensure that the Board [o]f Land and Natural Resources has the overall authority to ultimately grant or deny bioprospecting or any of its implications on all waters and lands under DLNR jurisdiction. The Department should make other entities such as the Department of Hawaiian Home Lands and the Office of Hawaiian Affairs, aware of the need to promulgate rules that are complimentary [*sic*] to those being developed by DLNR, to protect the natural resources (land and waters and all the plants and animals) as well finding the appropriate place to include protection of indigenous Hawaiian people and their Ethnobotanical knowledge (considered to be intellectual property rights in the international community) as well as their genetic property (to protect against samples being taken for a particular purpose, but then sold to another company or country for other purposes not disclosed in the original permit). The Department should conduct workshops and outreach programs for staff and in

collaboration with other entities on the topic of bioprospecting, to better understand the issues of bioprospecting and how they [*sic*] may be regulated for the protection and benefit of the State. The Richardson School of Law, University of Hawaii, has a new Center for Excellence in Native Hawaiian Law, which has already sponsored a symposium on Indigenous Traditional and Customary Rights in Modern Legal Systems (October 13 – 15, 2005), and which stands to be an important entity for the Department to collaborate with.

The DLNR also provided two documents: a permit application ("Application for Research/T&E Collection/Access/Activity Permit") and accompanying guidelines ("Guidelines for Research, Collection, Commercial Activity, and Access Permits") issued by the DLNR's Division of Forestry and Wildlife (attached as Appendix D). The single application can be used for multiple permits for research and activities. The Division of Forestry and Wildlife is responsible for issuing permits for Natural Area Reserves, Forest Reserves, Wilderness Preserves, and Game Management Areas. According to the Division, because each of these areas may have their own administrative rules, this may require obtaining more than one permit. Permits may also be required by other divisions within the DLNR or by federal agencies, as in the case of research involving threatened and endangered species.<sup>7</sup>

The permit application and guidelines do not address any significant aspect of bioprospecting other than, possibly, collecting of samples. It is unclear whether the issue of a DLNR permit constitutes the granting of prior informed consent by the State. Nothing in the permitting system addresses title, ownership, or rights to biodiversity taken or genetic derivatives, benefit sharing, conservation or sustainable use, or protection and recognition of indigenous knowledge holders. The DLNR acknowledges that it is operating in a vacuum with regard to bioprospecting, absent clear rules. The subject is not familiar for staff and there is a need for dedicated expertise to handle bioprospecting.

The DLNR also submitted further comments which, in relevant part, are as follows:<sup>8</sup>

No Division has any language specific to bioprospecting. Indigenous organizations in other countries and increasingly here, are using a new term (biocolonialism) to cover bioprospecting, biogenics (genetically modified organisms) and harvesting of human DNA and other material, as well as ethnobotanical knowledge and other knowledge that may be considered as intellectual property rights; but also directly affecting the health of indigenous people and the ecosystems they depend upon.

It should be pretty obvious that there needs to be a statewide effort to address bioprospecting and exactly how to handle this potentially thorny issue. The DLNR should play a central role in this; but other state agencies such as OHA and DHHL and even DOT (they have a lot of roadside lands which are potential collecting areas). There needs to be a set of rules that can be applied across the board; at least where DLNR is concerned; much like the commercial rules, so there is a standard set of conditions and then specialized conditions for Natural Area Reserves or other special areas.

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7. Department of Land and Natural Resources Division of Forestry and Wildlife "Guidelines for Research, Collection, Commercial Activity, and Access Permits", p. 3.

8. Email dated December 14, 2005, from Betsy Gagne of DLNR to Peter G. Pan.

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There really was nothing to address the issue of non-native plants: we have the world's flora growing here...many species more abundant here than in their native home lands; one of the reasons New York Botanical Garden chose to work here. The question is ... if there is a 'hit' and then ultimately a product is developed that goes the full circle to production...who shares in the credit: Hawaii because it was collected here, the country or countries where it is native.... there does not seem to be any consensus on this issue, for starters.

There will need to be clarity between departments, division and other entities such as the University...do we issue permits to each other? How do we keep track of who is collecting what, where, and for what purposes.

We are in the process of revising NARS Rules (HAR 209) but specifically to look at ability to close certain reserves or portions as well as specifics for special use permits and criteria by which they are issued and administered. Bioprospecting should be a concerted and separate effort. Know our previous Land Deputy had tried to get a handle on all Departmental rules to look for consistencies and inconsistencies. Not sure if there is a way to accomplish this...except to have someone who knows rulemaking and does nothing but look at this.

***Department of Business, Economic Development, and Tourism (DBEDT).*** In the case of the DBEDT, the Bureau asked for a departmental statement explaining its role regarding bioprospecting and biotechnology in general. The text of the response from Mr. Ted Liu, Director of Business, Economic Development, and Tourism, in a letter to the Bureau, is reproduced below:<sup>9</sup>

Thank you for the opportunity to provide a statement on the position of the Department of Business, Economic Development & Tourism (DBEDT) relevant to bioprospecting to be included in your report on HCR 146, H.D. 1, adopted by the 2005 Hawaii State Legislature. This is an issue we have been following since the first bill to create a bioprospecting commission was introduced in 2003.

One of DBEDT's core mission objectives is to diversify the economy, basing a strategy on emerging knowledge and innovation areas in which Hawaii has a natural and sustainable competitive advantage. The development of Hawaii's life sciences cluster of industries, including the discovery of useful products based on our natural resources, is a key element of that strategy, with tremendous potential to benefit the State.

As DBEDT testified on bioprospecting-related bills and resolutions over the past few years, we believe that in order for the industry to prosper, care must be taken to develop appropriate guidelines and procedures for sustainable management of the State's natural resources and equitable distribution of any benefits derived from the resources. A legal regime that is fair to Hawaii's residents and provides clear rules governing the use of the State's natural resources is necessary to provide potential investors with the basis for making good business decisions.

We look forward to seeing the results of your study and moving forward to create an appropriate legal framework.

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9. Letter dated December 5, 2005, from Ted Liu, Director of DBEDT to Peter G. Pan of the LRB.

In general, it is fair to say that the DBEDT supports the development of industries in the State that use "high technology." In 1983, the Legislature created the High Technology Development Corporation, which is placed within the DBEDT for administrative purposes. "High technology" is defined as technology-intensive industries that include "electronics, biotechnology, software, computers, telecommunications, and other computer-related technologies."<sup>10</sup> Biotechnology is a sub-category of "high technology" and is thus supported by the DBEDT. Bioprospecting is a yet a much smaller sub-category of biotechnology.

In 1990, the Legislature also created the Hawaii Strategic Development Corporation,<sup>11</sup> also placed within DBEDT for administrative purposes. The purpose of the Hawaii Strategic Development Corporation is to "encourage economic development and diversification in Hawaii through innovative actions in cooperation with private enterprises ... [by establishing] programs to stimulate private capital investment in Hawaii toward investments that promote the welfare of citizens in this State, economic growth, employment, and economic diversification."<sup>12</sup> An "economic development project" under the Corporation includes an endeavor "related to industrial, commercial, or advanced technology-based agricultural enterprises."<sup>13</sup> Bioprospecting activity and research would fall under the umbrella of the Corporation's portfolio.

## **OTHER CONSULTANT RESPONSES**

Aside from the University of Hawaii and the four state departments, H.C.R. No. 146 requested the Bureau to consult with six other individuals, organizations, and interest groups as follows:

- A representative of the biotechnology industry
- A scientist with interests in Hawaiian ecological systems
- A scientist with interests in genetics
- The Office of Hawaiian Affairs
- Native Hawaiian or organizations representing native Hawaiian interests
- Other organizations

The Bureau asked the University of Hawaii to refer us to scientific and biotechnology industry consultants indicated in the resolution. Similarly, we requested the Office of Hawaiian Affairs for a response and for its recommendations of other native Hawaiians or organizations representing native Hawaiian interests with whom we can consult.

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10. The Legislature created the High Technology Development Corporation in Chapter 206M, Hawaii Revised Statutes; "high technology" is defined in §206M-1, HRS.

11. The Hawaii Strategic Development Corporation is codified in Chapter 211F, HRS.

12. §211F-2(b), HRS.

13. §211F-1, HRS.

Subsequently, the Bureau received a response from the Office of Hawaiian Affairs and the designated scientist with interests in Hawaiian ecological systems.<sup>14</sup> We have not received any response from the designated scientist with interests in genetics or the representative for the biotechnology industry. In addition, we have also consulted with the Waikiki Hawaiian Civic Club and obtained a formal statement from its representative, Ms. Mililani Trask. The following section presents these consultants' views.

***Scientist with Interests in Hawaiian Ecological Systems.*** Dr. Kenneth Y. Kaneshiro, Director, Center for Conservation Research and Training, University of Hawaii presented the views of a scientist with interests in Hawaiian ecological systems, as follows.

- Hawaiian ecological systems within the perspective of bioprospecting ... [refer to] ... "[n]atural communities of native Hawaiian plants and animals, i.e. unique to the Hawaiian Islands, which interact within a stable and sustainable environment."
- In my view, bioprospecting is the extraction of organic material, chemical or biotic, from native species for commercial purposes.
- *[In response to personal experience as to whether bioprospecting activities in the State affected Hawaiian ecological systems]:*  
I have not had any experience with bioprospecting activities in the State.
- *[In response to whether there is a need, who, and how to regulate bioprospecting in Hawaii to prevent harmful effects to Hawaiian ecological systems]:*  
Yes. Hawaii is facing an "extinction crises" *[sic]* with many unique organisms on the brink of extinction. Some plant species are represented by a single living specimen left in the wild and we must protect these species especially if there is potential for bioprospecting purposes.

Private, for profit entities interested in collecting samples for bioprospecting purposes should be regulated.

Parties interested in collecting native species for the purposes of bioprospecting should be required to apply for a permit which include *[sic]* a detailed plan indicating the kinds of samples, how much, how many species, what species, etc. need to be collected. A committee of knowledgeable individuals of the unique plants and animals of Hawaii should be called upon to review such applications and recommendations made that would regulate what and how much material is allowed to be collected depending on the population density of the species in question.

- *[In response to what are the advantages and disadvantages of such regulation]:*  
Advantages are that we can regulate the collection of rare and threatened species; disadvantages are that some organizations may want to apply such regulation to all

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14. (1) Email dated September 9, 2005, to Dr. Monto Kumagai, Molecular Biosciences and Biosystems Engineering, Agricultural Science, University of Hawaii, from Peter G. Pan asking for a response to a questionnaire. Email dated November 7, 2005, to Dr. Kumagai resubmitting the questionnaire. Email dated November 22, 2005, resubmitting the questionnaire a third time. (2) Email dated Sept 8, 2005, from Peter G. Pan to David Watumull, President and CEO of Hawaii Biotech Inc. requesting response to a questionnaire. Email dated November 7, 2005, resubmitting the questionnaire. Email dated November 7, 2005, from Mr. Watumull to Peter G. Pan stating a response will be submitted within a week. Reminder email dated November 22, 2005, to Mr. Watumull. Email dated November 22, 2005, assuring that a response will be submitted shortly. Email dated December 12, 2005, to Mr. Watumull fixing a final deadline of December 16, 2005.

collections of native organisms rather than restricting to bioprospecting ventures, i.e. commercial purposes. In some cases, research scientists may be seeking to collect samples in order to better understand the ecological systems in which the species lives so that better management practices could be developed to protect these rare species. These latter activities should not be restricted although a permitting process to allow these kinds of basic science activities should also be enforced especially when dealing with rare and endangered species. For the most part, permitting for scientific research in native Hawaiian ecosystems, i.e. forest reserves, Natural Area Reserves, etc. are already in place under the regulation of DLNR.

- For the purposes of bioprospecting, I am not aware of any models or guidelines although I'm sure that there are such models at the international arena.
- *[In response to who should be given the authority to do the regulating]:*  
Given an appropriate review committee comprised of experts who know the fauna and flora of these islands, or who can consult with taxonomic experts on the species in question, the regulatory authority can reside within an existing government entity.

*Statement of the Office of Hawaiian Affairs.* The Bureau received a letter dated December 20, 2005, and transmitted by email dated December 27, 2005, from the Office of Hawaiian Affairs and signed by Mr. Clyde Namu'ō, Administrator of OHA. The text of the letter is as follows:

**Re: House Concurrent Resolution 146, House Draft 1, Twenty-Third Legislature, 2005 - Relating to Bioprospecting**

The Twenty-Third Session of the Legislature, State of Hawai'i, 2005 Regular Session, requested that the Legislative Reference Bureau consult with the Office of Hawaiian Affairs (OHA) in drafting its Study on Bioprospecting. Thank you for your efforts to consult with OHA. The following text summarizes OHA's current perspective on this multi-faceted issue, our previous involvement in proposed legislation addressing some of the issues of bioprospecting, and our hopes for future legislation and policy pertaining to bioprospecting and biotechnology.

**Introduction**

The issues of bioprospecting and biotech development have raised great public concern in Hawai'i. Not only do they impact the State's public trust obligations, but they also touch the rights and interests of the Native Hawaiian community, higher education and research, business development, and public health, welfare and safety. If Hawai'i wishes to move forward in this arena, to assure fairness, Hawai'i must harmonize a budding industry with the State's constitutional mandates to conserve and protect the integrity of all of Hawai'i's natural resources, promote sustainable development, hold public natural resources in trust for the benefit of the people, and protect traditional and customary Native Hawaiian rights.

Hawai'i is one of the richest places in biodiversity in the world. Its biological and genetic resources are the common heritage of the people, particularly Native Hawaiians, whose culture depends on these resources and has developed, and continues to develop, the use of these resources since before Hawai'i's recorded history. It is possible that bioprospecting can occur in a manner that protects the integrity of the ecosystem,



recognizes Native rights and secures a beneficial economic return for the State, but only with appropriate regulation.

**House Concurrent Resolution 146, House Draft 1**

Through House Concurrent Resolution 146, House Draft 1, the Hawai'i State Legislature, 2005 Regular Session, requested the Legislative Reference Bureau to study "the fair and equitable sharing of benefits arising from":

- 1) "research";
- 2) "indigenous knowledge";
- 3) "intellectual property"; "or"
- 4) "application of biological resources that are public natural resources held in trust by the State for the benefit of the people."

The Office of Hawaiian Affairs notes that "benefit" is not defined, and that the word has multiple meanings to multiple right- and stakeholders. Understanding what benefits whom should be a major element on which to focus.

The Legislature also requested that the "study focus on assisting in the formation of a public policy strategy to commercially develop the State's biological resources in a way that will be environmentally sustainable, culturally sensitive, economically feasible, and mutually beneficial to all the people of the State." While the request seems to balance a number of needs and interests, its basis lies in an effort toward commercial development, which presupposes that an "environmentally sustainable, culturally sensitive, economically feasible" approach to mutually "benefit all the people of the State" will allow for commercial development of said resources in this manner.

The Resolution stated that the study shall include an identification of issues and policies, and possible legislative proposals for:

- 1) What could be interpreted as a balance of "conservation and sustainable use of biological diversity;"
- 2) The interesting request for "responsible regulation of bioprospecting and biotechnology as it relates to bioprospecting;"
- 3) The unexplained "rights of traditional, indigenous knowledge holders;"
- 4) "The fair and equitable sharing of benefits arising from the research, indigenous knowledge, intellectual property, or application of biological research," which insinuates that Hawaiians must share any "benefit" that they derive from the use of their traditional knowledge, which should not be a given; and
- 5) The unclear description of "meaningful participation in these processes by traditional, indigenous knowledge holders."

Also, the study shall review policies, rules and regulations, caselaw and models from other jurisdictions, as well as an inventory of existing bioprospecting research projects and activities in the State that are public. This begs the question of how the public/private line is drawn when many research projects begin under the auspices of a university but spawn elsewhere. According to the April 16, 2004, edition of Pacific Business News, referencing bioprospecting in Hawai'i, "An estimated 5,000 such projects are currently under way in Hawaii's rain forests, volcanic fields, and reefs and

oceans." ("Commission would study bioprospecting") How many of these are public research projects?

### **Legal Framework within Hawai'i**

While the Resolution aptly cites the Hawai'i Constitution as mandating that public lands be held in a public trust for Native Hawaiians and the general public, and that all public natural resources also be held in public trust, some relevant citations are missing. For instance, Article XI, section 6 recognizes the State's right "to manage and control marine, seabed and other resources located within the boundaries of the State, including the archipelagic waters of the State." Article XI, section 7, notes the State's "obligation to protect, control and regulate the use of Hawai'i's water resources for the benefit of its people." And, Article XI, section 9, reaffirms that "Each person has the right to a clean and healthful environment, as defined by laws relating to environmental quality, including control of pollution and conservation, protection and enhancement of natural resources." These sections of Article XI help spell out the importance of conservation when defining the parameters of use of natural resources. The name of the Article – Conservation, Control and Development of Resources – gives some suggestion to the relative importance of conservation in natural resource management: it is named first.

Later in the Constitution, Article XII, section 4 defines the public lands trust as being for the benefit of Native Hawaiians and the general public. Hawai'i is the only state that has public lands held in trust for the indigenous peoples and general public, proving the deeply ingrained and recognized connection between Hawaiians and their land. Later, in the same Article, section 7 clarifies that "[t]he State reaffirms and shall protect all rights, customarily and traditionally exercised for subsistence, cultural and religious purposes and possessed by ahupua'a tenants who are descendants of native Hawaiians who inhabited the Hawaiian Islands prior to 1778...."

The fourth WHEREAS clause of HCR 146, HD 1, attempts to incorporate all of the above by stating: "Hawaii's biological diversity and biological resources are assets of the public trust that are culturally, spiritually, medicinally, and otherwise significant to native Hawaiians and the general public." This wording is not strong enough or inclusive enough. It is too vague. Natural resources are not just tools to Native Hawaiians. Natural resources are cultural resources and genealogical links to Native Hawaiians' creation. The depth of the connection of natural and cultural resources is not adequately addressed in the resolution. Hawai'i cannot have one resource without the other.

The seventh WHEREAS clause explains that Native Hawaiians have used natural resources extensively, thus "developing a rich body of traditional knowledge, innovations, and practices." What the Resolution does not address is that this body of traditional knowledge continues to grow, because Hawaiians have a living culture.

Therefore, when the ninth WHEREAS clause states that "as traditional, indigenous knowledge holders, native Hawaiians have rights to protect, preserve, and control the use of their traditional knowledge and associated biological resources," it must be remembered that traditional knowledge includes more than what is already known by the indigenous culture. Furthermore, when the thirteenth WHEREAS clause mentions that "government entities may enter into material transfer agreements with private parties that purport to transfer the title and ownership of the State's natural, biological, and generic resources and the right to benefit from those material resources through

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commercialization," it is important to note that Native Hawaiian rights to the resources trump that of the State's.

The following WHEREAS clause continues to focus on the "utilization" of natural resources, and the rights of "public agencies and entities" to negotiate those uses. Native Hawaiians contest this presumption of the State's predominant right, and the focus on use instead of conservation and preservation, both of which are viewed as "benefits" for Native Hawaiians and the general public. This "benefit" is recognized in the Hawai'i Constitution in Article XI, section 9, which defines our "Environmental Rights," and in Article XII, section 7, which defines "Traditional and Customary Rights."

The protection of traditional and customary Native Hawaiian uses and preservation of natural resources has endured into the western regime of private property through recognition in the Constitution, Hawaii Revised Statutes and caselaw. Access to those resources has been recognized as "kuleana rights" in HRS §§1-1 (stating that Hawaiian usage usurps English common law) and 7-1 (providing native tenants with access to their kuleana property and to other parts of the ahupua'a to make that kuleana property within the ahupua'a productive). A series of Hawai'i Supreme Court decisions have further defined those access and natural and cultural resource rights, to the detriment of western private property law expectations of the rights of exclusion. (*See Public Access Shoreline Hawai'i v. Hawai'i County Planning Commission*, 79 Haw. 425, 903 P.2d 1246 (1995)) In fact, the Hawai'i Supreme Court has held that the State has an obligation to protect Native Hawaiian customary and traditional practices while accommodating reasonable, and only reasonable, private interests. (*See Ka Pa'akai O Ka'aina v. Land Use Commission*, 94 Haw. 31, 7 P.3d 1068 (2000))

The Hawai'i Supreme Court has further directed the need for preserving Hawai'i's natural ecosystems in parallel with preserving Hawaiians' cultural link to those ecosystems. (*See In re Wai'ola o Moloka'i*, 103 Haw. 401, 439, 83 P.3d 664, 702 (2004), explaining the importance of "(1) maintaining native Hawaiians' religious and spiritual relationship to the land and nearshore environment and (2) perpetuating their commitment to 'malama ka aina,' which mandates the protection of their natural ecosystems from desecration and deprivation of their natural freshwater resources.") In that same case, the Court found a State agency to have inadequately conditioned permitted uses of natural resources that are integral to Native Hawaiian customary and traditional uses of those resources, which allowed the Court to revoke the permit. (*See Wai'ola*, 103 Haw. at 443, 83 P.3d at 706)

The Hawaii State Legislature has also shown considerable deference to Hawaiian culture by recently enacting, in 2000, an amendment to HRS §343-2 that now requires cultural assessments be added to environmental assessments completed after April 6, 2000. In adopting Act 50 (2000), the Legislature noted that:

[P]ast failure to require native Hawaiian cultural impact assessments has resulted in the loss and destruction of many important cultural resources and has interfered with the exercise of native Hawaiian culture...[and] due consideration of the effects of human activities on native Hawaiian culture and the exercise thereof is necessary to ensure the continued existence, development, and exercise of native Hawaiian culture.

(Act 50, 2000 Haw. Sess. Laws 93, §1 (codified as amended at HRS §343-2 (2004))

Thus, the question currently posed by the Legislature in HCR 146, HD 1, is whether bioprospecting, which may or may not lead to further biotechnology and Genetically Modified Organisms, is a reasonable private or public interest in the face of innate Native Hawaiian rights and, if so, what permitting structure would allow for adequate conditions to protect Hawai'i's natural and cultural resources.

These public trust resources, according to the Public Trust Doctrine, are held by the State for the benefit of the people and must be maintained for public, not private, purposes. As such, the presupposition of HCR 146, HD 1 – that natural resources may be negotiated away by the State – is not properly conditioned by the requisite initial need of preservation and conservation of these resources on public lands for the general public and Native Hawaiians. (Hawai'i State Constitution, Article XII, section 4) In fact, bioprospecting seeks to use the patenting regime to convert these public trust resources to private property exploited for private profit. Such a practice is antithetical to the public trust. One cannot patent a living organism, but one can patent a process, including parts of a genetic code. Once an organism has been genetically decoded, all the information is put into the public domain, thus allowing anyone to access that data, gained from local organisms, to create any number of profit-producing products.

Western intellectual property laws were developed to protect the rights of creators and inventors against plagiarism while rewarding and encouraging new innovations. It was not developed to protect the rights of indigenous peoples to their collective, traditional knowledge and culture. Consequently, the current western intellectual property regime often facilitates the theft, misuse and misappropriation of indigenous knowledge. Native Hawaiians must be proactive.

Despite pressures to develop Hawai'i's biological and genetic resources for commercial uses, the State has an affirmative duty under the public trust to develop a basic framework to regulate bioprospecting in Hawai'i. As previously requested in legislative bills for the past four years, the first step should be a moratorium on bioprospecting in the State and creation of a Commission, comprised of relevant rights- and stakeholders, to prepare a comprehensive plan for the conservation and sustainable use of Hawai'i's biological diversity. By creating the Commission, the legislature would not foreclose the future development of these resources, but would ensure that such development would uphold the state's public trust obligations and the interests of all concerned rights- and stakeholders.

Hawaii needs to encourage industry accountability and help such a Bioprospecting Commission complete its duties. Accountability does not require the disclosure of any confidential business information. Hawai'i does, however, need to compile and maintain an inventory of the principal investigator(s) and project title(s) of all biotechnology research projects – public and private – involving the biological resources of public lands.

Biopiracy occurs when biological and genetic resources are accessed and taken without the free, prior informed consent of the rights holders of the resources – the indigenous peoples – and where applicable the national or state government with jurisdiction over the take area. Thus, in Hawai'i, that would include Native Hawaiians as the rights holders and the State, whose jurisdiction covers public lands.

### **Ceded Lands**

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It must be remembered that ceded lands are public lands, held in trust, and OHA has a fiduciary duty to our beneficiaries – all Hawaiians, to assure that these lands are used and treated properly. While not all public lands are ceded, most of them are, and while OHA's concerns for and about natural and cultural resources do not stop at the boundaries of ceded lands, OHA does have heightened concerns about ceded lands, as explained below.

Ceded lands, and the State's responsibilities for and to them, are defined in the Hawaii Admission Act (Act of March 18, 1959, Pub. L. 86-3, 73 Stat. 4), and further explained in the State Constitution and statutes. The State has a Constitutional responsibility to "conserve and protect Hawaii's natural beauty and all natural resources, including land, water, air, minerals and energy sources... All public natural resources are held in trust by the State for the benefit of the people." (Hawai'i State Constitution, Art. XI, Section 1). The State also has a Constitutional responsibility to "protect all rights, customarily and traditionally exercised for subsistence, cultural and religious purposes" possessed by Hawaiians. (Hawai'i State Constitution, Art. XII, Section 7).

Section 5(b) lands of the Hawaii Admission Act (Act of March 18, 1959, Pub. L. 86-3, 73 Stat. 4) are ceded lands, and, per §5(f) of the Admission Act, the public trust lands of §5(b), and the income derived therefrom, "shall be managed and disposed of for one or more" of the five listed purposes. The Act lists the five purposes as:

for the support of the public schools and other public educational institutions, for the betterment of the conditions of native Hawaiians, ... for the development of farm and home ownership on as widespread a basis as possible, for the making of public improvements, and for the provision of lands for public use.

The Admission Act explains that §5(b) lands "shall be managed and disposed of for one or more of the foregoing purposes in such manner as the constitution and laws of said State may provide, and their use for any other object shall constitute a breach of trust ...." The Hawai'i State Constitution, Art. XII, Sec. 4, explains: "The lands granted to the State of Hawaii by Section 5(b) of the Admission Act and pursuant to Article XVI, Section 7, of the State Constitution, excluding therefrom lands defined as 'available' lands by Section 203 of the Hawaiian Homes Commission Act, 1920, as amended, shall be held by the State as a public trust for native Hawaiians and the general public." Thus, these Public Trust lands may be used for educational purposes and for the betterment of Hawaiians. OHA therefore requests that should bioprospecting in Hawai'i move forward, part of any such project should include a guarantee of training and education for Hawaiians.

OHA's concern about any proceeds from bioprospecting on ceded lands originates from Attorney General Opinion 03-03, which was issued on April 11, 2003. That legal opinion suggests that the State must reserve title to biological and biogenetic resources on public lands, including ceded lands, when it allows lessees to remove those resources or transfers title to the land from where the biological and biogenetic resources are extracted. The Attorney General further opined that:

The scope of the University of Hawaii's authority to sell or transfer biogenetic resources from ceded lands depends upon how it acquired the ceded land from which the resource originated. As a result of OHA v.

State, 96 Haw. 388 (2001), the Legislature must again determine which income from public land trust lands are to go to the Office of Hawaiian Affairs (OHA). Until the Legislature re-establishes a funding mechanism for OHA, Executive Order No. 03-03 is the only mechanism for transferring receipts from the use of ceded lands to OHA. Receipts from biogenetic resources do not qualify for transfer under the order.

Thus, OHA requests that any policy that the Legislature adopts about bioprospecting include a straightforward mechanism for the State to reserve title to biological and biogenetic resources, and a mechanism for transferring income from public trust lands to OHA.

### **Hawai'i's Bioprospecting Legislative History**

The Waikiki Civic Club drafted the original bioprospecting bills, beginning four sessions ago, and they intended, and continue to intend, a prohibition on the "conveyance of rights, title, and interest" of biological resources found on public lands (instead of the language "sale and transfer," which UH, the Department of Agriculture, and members of the agricultural community had opposed), and the creation of a Bioprospecting Commission. The prohibition is essential to asserting and protecting Native Hawaiian rights as traditional, indigenous knowledge holders and Native Hawaiian rights to the revenue potentially generated from any patenting and licensing of any useful processes found in the State's biological resources.

The Paoakalani Declaration (2003), which outlines Native Hawaiians' collective responsibility to determine a pono future for Hawai'i, Hawaiian culture, and Native Hawaiians, notes that commercialization and bioprospecting activities have profoundly and adversely impacted Native Hawaiian spiritual practices, cultural expressions, sacred sites and associated objects, and traditional knowledge and practice. Native Hawaiians continue these practices and should be able to protect their traditional knowledge and the innovations derived therefrom, instead of having them simply compiled in a structure of implied State usage. The declaration further articulates the rights and initiatives of Native Hawaiians by supporting a moratorium on patenting, licensing, sale or transfer of any of our plants, animals and other biological resources derived from the natural resources of our lands, submerged lands, waters, and oceans until indigenous communities have developed appropriate protection and conservation mechanisms. It also clarifies that no one group may speak for Hawaiians; that Hawaiians must speak for themselves, which they can do best beginning within the parameters of a moratorium.

The moratorium, as described in prior proposed legislation, would not take away jobs or halt research already underway, but would create the potential for future industry responsibility and accountability. A moratorium or prohibition should apply to all public lands, as defined in HRS Chapter 171, including submerged lands, ocean resources, and land to which the University of Hawai'i holds title, to ensure that the valuable resources are not permanently conveyed out of the State's control. UH cannot be exempted, nor can the Housing and Community Development Corporation of Hawaii, Hawaii Community Development Authority, Department of Agriculture, Aloha Tower Development Corporation, Agribusiness Development Corporation, or the High Technology Development Corporation. (HRS §171-2 excepts the titles to public lands held by the agencies listed above.)

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A legislatively enacted moratorium would protect Native Hawaiians' right to have a say in the use of their resources as much as possible. The University of Hawaii may want to negotiate some kind of benefit sharing arrangement with Hawaiians, which is a concern. "Benefit sharing" often requires an acceptance that biogenetic resources will be genetically engineered, patented, and the resulting product commercialized. OHA hopes that legislation will instead create a Commission that will provide Native Hawaiians a venue to take the most protectionist stance that they can as legislation is developed. OHA does not want the focus to be on facilitating research on and commercialization of Hawai'i's genetic resources.

As HCR 146, HD 1 stated, one of the goals of the Study on Bioprospecting was to include "meaningful participation in these processes by traditional, indigenous knowledge holders." Meaningful participation should include the ability to say yes or no in any given instance. Native Hawaiians, as the indigenous, native peoples of Hawai'i, have never given up their inherent right of self-determination, and with that comes the right to regulate the collection and use of Native Hawaiians' natural, cultural and intellectual resources.

Native Hawaiians' collective intellectual property rights are based upon the traditional, cultural knowledge developed over thousands of years and passed down from generation to generation. Much of the Native Hawaiian peoples' knowledge and plant, animal and human genetic resources were gleaned from Native Hawaiians without free, prior and informed consent. This must stop. Native Hawaiians' collective traditional knowledge and intellectual property rights require free prior informed consent before they can be legitimately shared. Native Hawaiians must always have the right to refuse to participate or to authorize the use of their intellectual property rights, and must be allowed to arrange their own benefit sharing agreements if they desire.

Often, legislators have tried to insert language from the international Convention on Biological Diversity (1994) (Convention) into proposed Hawai'i bioprospecting legislation. To do so would be to potentially eliminate Native Hawaiians' rights as cultural and intellectual property proprietors. The Convention does not recognize or protect indigenous peoples' relation to their lands and territories, traditional and customary management practices, or traditional knowledge systems, yet it encourages the use and sharing of indigenous knowledge. (*See* Convention on Biological Diversity (1994), Preamble)

Therefore, concurrent with the prohibition shall be the creation of a Commission, which would have a membership of rights- and stakeholders, to create a policy on bioprospecting for the State. The Commission shall have the responsibility of addressing the State's trust obligations, science and technology, business development, the rights of the Native Hawaiian peoples, and the health, safety and welfare of Hawai'i's communities and environment.

Over the years, while drafting legislation describing such a commission, business, community, and agency parties worked tirelessly together and apart to draft language mindful of the parties' respective interests and concerns. OHA; the Department of Business, Economic Development, and Tourism; the University of Hawai'i, biotech industry representatives; and members of the Native Hawaiian community have already created the language for a commission that the various rights and stakeholders have accepted. OHA looks forward to continued agency, business, and community

communication on this matter and hopes that the Legislature shall not presuppose to usurp the good faith effort that has already occurred.

OHA also hopes that the good faith negotiations which took place among Native Hawaiians and representatives of the University of Hawai'i will continue to move forward. UH's Board of Regents should create and adopt a policy for UH that acknowledges the collective intellectual property rights of Native Hawaiians and that the Native Hawaiians retain equitable title to the State's biological diversity and biological resources on public lands. During a May 3, 2004 meeting among UH officials and Native Hawaiian groups, UH agreed to honor the language in what was SECTION 3 of a 2004 Legislative Session bill on bioprospecting. The agreed upon language follows, and should be incorporated into any fixture legislation:

SECTION 3: Notwithstanding any provision in title 12, Hawaii Revised Statutes, or any other law to the contrary, upon the effective date of this Act, the exclusive possession or conveyance of the rights, interest and title to the biological resources identified upon or collected from public lands is prohibited, except for existing, permitted farming and research operations whose products are neither indigenous nor endemic to the State, or as set forth below.

Nothing in this section shall be interpreted to inhibit, restrict, or prohibit any research or to prevent the State from entering into joint research or commercial development agreements that:

- (1) Protect the State's title to its biological trust resources; and
- (2) Ensure best practices and bio-safety protocols; and
- (3) Contribute to and support research and educational opportunities for Hawaii's students and faculty; or
- (4) Contribute to and support Hawaii's biotechnology industry,

and the State may actively seek to enter into and support such agreements in order to advance biotechnology education, the biological sciences, and medicine in the State.

(SB643, SD2, HD1, Relating to bioprospecting, State of Hawaii Legislature, 2004, Regular Session).

The following three actions were also agreed upon at the May 3, 2004 meeting, although OHA does not know if any of these actions have actually occurred. We hope so.

1. The UH Chancellor would impose a moratorium on the Hawaiian genome project;
2. The UH Chancellor would convene a UH task force, based upon the language in Section 4(c) of SB 643, SD2, HD1 (2004), which outlined the duties of the Commission, to "Identify and develop issues and policies for the responsible regulation of bioprospecting [at UH]" and to identify research projects at UH related to Native Hawaiians that are planned or underway. The composition of the task force would be determined with Native Hawaiian community consultation; and



3. The Native Hawaiian community groups would propose a policy, directly to the BOR, using the language from Section 3 of SB643, SD2, HD1 (2004).

### **Office of Hawaiian Affairs' Involvement in Recent Proposed Legislation**

The OHA Trustees have considered bioprospecting and the Commission that has been proposed; they consider both to be of great importance. They find that bioprospecting and the development of biotechnology in Hawaii considerably impact the rights and interests of the Native Hawaiian people as traditional knowledge holders and as beneficiaries of the State's public trust.

During the 2004 Legislative Session, OHA even offered to share a portion of the total administrative cost of the Commission. The Trustees have noted concern for Native Hawaiian traditional knowledge and the potential trust land revenue that stands to be generated by reserving the State's title to its biological resources and building a responsible biotech industry in Hawai'i. The OHA Trustees met on March 17, 2004, in the Beneficiary Empowerment and Advocacy Committee, and voted to support the Waikiki Civic Club's bill and to support the proposed Commission at no more than 20 percent of the total cost of the Commission, with the Commission expected to last for two years. OHA encouraged other interested and concerned agencies to consider similar commitments, which were not forthcoming. This funding offer, however, was contingent upon guaranteed preservation of the State's title to biogenetic resources bioprospected from public lands and protection of Native Hawaiian rights and interests of the Native Hawaiian peoples as traditional, indigenous knowledge holders. For the Commission to be effective in its duties and functions, it must be supported by adequate funding. The Commission will have the responsibility of addressing the State's trust obligations, science and technology, business development, the rights of the Native Hawaiian peoples, and the health, safety and welfare of Hawaii's communities and environment. Given the scope and weight of its task, Commission funding must include support staff and clerical personnel as well as logistical and Commission meeting requirements.

The OHA Trustees have committed themselves, via a vote on March 31, 2004, in the Beneficiary Empowerment and Advocacy Committee, to support our Native Hawaiian community partners who had drafted and shepherded the bills since 2002, demonstrating OHA's commitment to asserting and protecting Native Hawaiian rights and customs through quality legislation. In that same vote, the Trustees voted to no longer support amended bioprospecting legislation, which had removed the teeth of the moratorium and of Native Hawaiians' legitimate claims as the traditional, indigenous knowledge holders and their collective intellectual property rights.

### **Conclusion**

OHA seeks regulation that provides that bioprospecting only can occur within a permitting structure that allows for the integrity of Hawaii's ecosystems to be protected and Native Hawaiian rights to be respected. We request that a Bioprospecting Commission analyze whether bioprospecting is a reasonable private or public interest in the face of innate Native Hawaiian and environmental rights, and remind the State of its affirmative duty under the public trust to develop a basic framework to regulate bioprospecting in Hawaii before any more bioprospecting is allowed. OHA further requests that any policy that the Legislature adopts about bioprospecting include a

straightforward mechanism for the State to reserve title to biological and biogenetic resources, and for transferring any subsequent income from public trust lands to OHA.

We hope to continue to be part of the on-going dialogue on bioprospecting and those biotechnological issues that spawn from it. OHA continues to advocate for a moratorium on any new bioprospecting during the lifespan of a Commission, made up of rights- and stakeholders, to set a strong bioprospecting policy for Hawaii that honors Hawai'i's commitment to its natural and cultural resources, and to its indigenous, traditional knowledge holders, Native Hawaiians.

*Statement of Ms. Mililani B. Trask.* The following is a copyrighted statement from Ms. Mililani B. Trask representing the Waikiki Hawaiian Civic Club:

**Bioprospecting, Biopiracy and Hawaii's Public Trust**  
© Mililani B. Trask

Several years ago members of the biotech industry, Federal officials and representatives of some of the world's largest transnational corporations began a dialogue and effort to identify locations within the U.S. suitable for biotech research and expansion. When the dust settled, Hawaii emerged as the primary site with Puerto Rico coming in second.

Our home was targeted because: 1) Hawaii has no regulations or restrictions governing the biotech industry or imposing protective measures on the industry; 2) The weather allows for year round research and open air and ocean testing; 3) There are no industry or best practices standards in Hawaii; 4) Hawaii has no process, procedure or tracking mechanism to monitor the transfer of biological materials, including human genetic material, in or out of the state; 5) Hawaii has no policy requiring that the state keep title to bioresources in the public trust nor does Hawaii have a legal process to ensure that contracts provide research and other benefit sharing arrangements for our students and faculty. Hawaii has no process to ensure that we will get a fair share of any revenues resulting from commercialization of derivatives; 6) Because of Hawaii's location, expected biopollution problems would not impact the U.S. continent; and 7) Hawaii has a wealth of biodiversity.

In the years which have elapsed since the initial dialogue began, Hawaii has emerged as the global capitol of the world for genetically engineered crops. We have experienced extensive biopollution (seed crops on Kauai, papaya on Big Island), increasing litigation, native demonstrations on Molokai and Oahu and a proliferation of legislation, none of which has passed due to the lack of an over-arching policy framework in our state. Our current policy is "support for the biotech industry", which translates into no regulations on biotech activity. There's no requirement it be Hawaii based biotech, that it benefit the public or native people, or protect our agricultural (edibles, ornamentals, organics) or marine (limu, fish) industries. Hawaii's consumers pay tax dollars to ensure that the best papayas sent to Japan are GMO free but our state consumers have no protection or choice because there is no labeling law in our state. This also means that goods exported from Hawaii may be denied entrance into other global markets in countries that outlaw GMOs.

Despite significant media hype and strong political/military support for biotech,

## CONSULTANT RESPONSES

promised benefits have yet to materialize for Hawaii while negative impacts have ballooned. The reasons for this are many and varied.

Hawaii has no real biotech facilities nor does it have the funding (estimated at 400 million dollars for a state of the art research complex) to build such facilities. Hawaii's educational institutions have not developed course or credential programs in technology engineering to ensure that we have a workforce to qualify for promised jobs that will require specialized skills. Hawaii's tax incentive measure, Act 225, resulted in scandalous abuse but was insufficient to persuade transnational corporations to expend millions of dollars duplicating research facilities they have already built elsewhere. Although state law imposes certain obligations on the State Departments of Health and Agriculture, neither has a budget or staff for such purposes and both have deferred to the Dept. of Business Economic Development and Tourism which has interpreted our vague state policy on biotech as a mandate to support a *laissez-faire* hands off approach. In short, Hawaii's lack of sophistication, capacity and law relating to biotech has led to our reputation as being a place where the biotech industry can do what it pleases.

Hawaii is an agricultural state which exports produce and blossoms to a global market. There are now international trade laws that forbid the import of products that have been genetically modified. These laws can and will continue to be problematic because Hawaii does not require that such products be labeled as GMO. The labeling issue has also been supported by consumer groups who have the right to know what they are buying and eating and by health advocates concerned that consumers with allergies and other dietary constraints will be harmed by eating or handling GMO produce and ornamentals. These concerns have been ignored by the State Departments of Agriculture and Health and by the industry and UH.

The inability of the UH and relevant State Agencies and bodies to create and implement a process for benefit sharing, participatory research projects, best practice standards and safety protocols and revenue sharing for our state, the public and native beneficiaries of our public trust is directly related to a general lack of competence in biotech and a lack of political will.

In order to protect Hawaii's valuable biodiversity, the State must have a strong and enforceable policy to protect our bioresources from GMO contamination. Violators of this policy present a major threat to organic industries and to the biotech industry as well. Corporations who became biopolluters should lose their right to do business in our state, but companies in Hawaii who have been rebuked by the Federal Environmental Protection Agency for biopollution, have been allowed to continue in business and, as is the case on Kauai, to continue to engage in biopollution.

Hawaii also needs creative ways to monitor and track biotech research and to obtain benefits from such research. If Hawaii required that our University faculty and students participated in research involving our biodiversity, we would have a way to be informed about the outcomes of such research. In addition, our students would acquire the capacity to learn about the technology and processes utilized in such research. Hawaii does not have a state of the art research complex, but our students can work in labs elsewhere where research on Hawaii biodiversity is being pursued.

Another reason why Hawaii has been targeted is its biodiversity. Corporations, scientists, researchers and the U.S. military have all cast a covetous eye on Hawaii's land based and marine life forms with the intent of obtaining specimens for research, development, and commercialization and for military applications.

Bioprospecting is the removal or use of biological and genetic resources of any organism, mineral or other organic substance for scientific research or commercial development. When bioprospecting is pursued without the knowledge and free prior consent of the owners of the resources and without benefit sharing – it is called biopiracy. In Hawaii biopiracy is occurring with the assistance of the University of Hawaii and the very state agencies that should be protecting the bioresources and genetic resources of the public trust. It is ironic that UH's Office of Technology Transfer and Economic Development (OTTED) is assisting with the transfer of biodiversity to corporations and research groups outside Hawaii rather than protecting Hawaii's pristine biodiversity, securing research opportunities for Hawaii' students and faculty and ensuring that real benefits and revenues from commercialization and research and development inure to our state and native peoples.

A good example involves the Diversa Corporation which for a few thousand dollars obtained an agreement for the entire state marine specimen collection. The agreement states "that Diversa shall own all right, title and interest to any and all Diversa inventions" and that "California law will govern contract interpretations." The day after the Diversa agreement was signed, Diversa placed an add on the global internet notifying the world that it had exclusive rights to Hawaii's unique marine resources and directing all research interests and venture capital investors to their offices in San Diego.

No one in Hawaii was informed about the federal case involving Diversa's effort to obtain biodiversity resources in the U.S. National Parks. The case resulted in the Diversa contract being suspended pending implementation of the Natural Environmental Policy Act. The court also ruled that Diversa did not own the organisms and ordered that a real benefit and revenue sharing had to be negotiated. What is tragic is that in the case of Diversa, no one in Hawaii cared enough to do the research on Diversa, consider the policy implications of trading away public trust assets and forgoing research and educational opportunities for our students and faculty, or conduct due diligence – which is ultimately a fiduciary duty of UH's Board of Regents (who had no knowledge of this Diversa Contract).

Most disconcerting is our states inability to monitor & track research to ensure that contract provisions and benefits are forthcoming. In actuality the University of Hawaii and the State regularly use boilerplate agreements created by the industry to protect their own interests. Most material transfer agreements (MTA's) in Hawaii simply do not preserve title to these precious resources for our state nor do they contain language requiring participatory research or benefit sharing. Given the state of affairs it is no wonder that the University of Hawaii reports little income from such research.

Tracking the performance of legal obligations relating to corporate research must begin with a thorough review of all contracts, agreements and MTA's (material transfer agreements). Legal forms being used must contain language requiring regular and detailed reporting. These written documents should also contain penalties stating that a failure to report will result in cancellation of the contract, and require that the transferred material be returned. In addition, legal documents should state clearly that patents or

## *CONSULTANT RESPONSES*

publications resulting from research or development must be separately negotiated before commercialization and that joint authorship and ownership (patent, trademark) with the State and native peoples must be guaranteed. All contracts and legal documents should contain a provision that makes clear that Hawaii policy and law will govern contract interpretation.

Redrafting legal contracts will not achieve the goal unless there is a trained and diligent staff whose sole job it is to monitor the performance of the contracts and to implement the State protective policy, ensure compliance with standards and implement follow-up action where necessary. Protecting our unique biodiversity and ensuring a real benefit to our peoples will require legal diligence and expertise, a capacity we need to develop.

## Chapter 6

### CONCLUSIONS – ISSUES AND POLICIES

#### ISSUES AND POLICY DECISIONS

The value of this study is in shedding light on and clarifying the many and complex aspects of bioprospecting. The issues need to be identified and brought to the table for consideration before the Legislature takes action. This chapter sets out the relevant issues that point to certain policy decisions that need to be resolved by the Legislature.

Bioprospecting as a technical subject is, in itself, very complex. Yet, bioprospecting is only a very small sub-category in the very large field generally known as biotechnology. Further complicating the situation is the unfair attribution by some of the dangers and faults of biotechnology in general to bioprospecting. A minority view considers the patenting of all biological resources or derivative genetic products to be unfair and that those resources should be free to everyone. Moreover, because bioprospecting activity has the potential to affect the economy through benefit sharing, it has acquired economic and political overtones. The mainstream approach to compensated bioprospecting respects and protects source country indigenous knowledge and therapeutic practices and applies benefits to promote the conservation of biodiversity. Thus, bioprospecting has also taken on environmental, cultural, agricultural, and health aspects.

H.C.R. No. 146 deals with bioprospecting. It does not deal with biotechnology as a whole. In addition to addressing the political, economic, environmental, and cultural aspects of bioprospecting, the Legislature will eventually need to address other issues not directly relevant that have surfaced over the course of the study. This chapter identifies and clarifies the issues and points out policy areas that require legislative decision making.

***Issue: Bioprospecting Regulation.*** The taking of biological samples for commercial application occurs worldwide and is not new. Uncompensated bioprospecting does not recognize the rights of, share benefits with, or obtain prior informed consent from source countries. Uncompensated bioprospecting is no longer the global mainstream and has become an issue beginning in the late twentieth century. Nonetheless, the United States has not ratified the United Nations-sponsored Convention on Biological Diversity (CBD), which attempts to remedy the inequities of uncompensated global bioprospecting. The CBD applies to sovereign nations, is generally acknowledged to be difficult to enforce, and conflicts with other international treaties relating to trade. The CBD acknowledges the need for individual national bioprospecting (access to genetic resources) legislation. However, Congress has not implemented national bioprospecting regulation in this country. Nor has any individual state enacted bioprospecting laws.

As a result, a regulatory vacuum exists in the United States and in Hawaii. In other words, benefit sharing, obtaining of prior informed consent, and promotion of sustainable use of

biodiversity stemming from bioprospecting are purely voluntary in the United States and in Hawaii.

As a rule, business enterprises generally do not voluntarily forego profits. Bioprospecting firms are business enterprises. However, globally, compensated bioprospecting has become the norm and there is increasing pressure to share benefits with source countries. In addition, all business enterprises face risks that threaten profitability. Uncertainty is a major risk. Business enterprises strive to resolve uncertainty and enhance predictability to reduce their exposure to risk. Compensated bioprospecting is here to stay. Thus, bioprospecting firms desire to operate under clear bioprospecting laws that create a level playing field for all competitors and to ensure that a source country does not unpredictably nullify their efforts.

Bioprospecting regulation can also address the sharing and distribution of benefits. These include the promotion of conservation and sustainable use of the State's biodiversity. However, the assumption that benefit sharing will take the form of huge and quick profits is grossly exaggerated. The chances that any individual bioprospecting project will culminate in commercialization of a profitable end product are slim. If commercialization does occur, it may take many years before lucrative royalties can be shared. Instead of royalties, other types of compensation can be used, such as making fixed advanced and milestone payments, building physical infrastructure to facilitate bioprospecting and other research activities, training of students and personnel, and funding of conservation programs. Bioprospecting regulation can also deal with the issue of prior informed consent and, where relevant and needed, protection of the rights of indigenous knowledge holders.

**Issue: Benefit Sharing for Native Hawaiians.** There is a blanket assumption that biogenetic resources derived and gathered from all biodiversity that is not located on privately-owned lands in the State are assets of the public trust. On the contrary, the Attorney General has opined that the State holds legal title to biogenetic resources gathered from public lands only under certain conditions. The State must stipulate that it reserved title to that biogenetic material when the State: (1) permitted a bioprospecting firm or a collaborator to take the sample from public lands; or (2) transferred title to the public land from which the sample originated. The Attorney General cautioned that the State cannot simply assume that it owns those biogenetic resources because "there is no statute or law that presently reserves, or prevents or regulates the sale of, biogenetic resources extracted from resources or things situated on lands the State owns."

There is a further blanket assumption that revenue generated from the sale or transfer of these biogenetic resources are eligible for deposit into the Ceded Lands Trust Account for the benefit of native Hawaiians. The Attorney General has further opined that the nature of the receipts from the sale of biogenetic material is different from current receipts transferred to the Office of Hawaiian Affairs and, thus, such receipts do not currently qualify for transfer under Executive Order No. 03-03.

**Issue: Herbal or Phytomedicine.** Bioprospecting generally does not utilize the whole organism as is but mostly works with its genetic material. Thus, bioprospecting does not necessarily harvest large quantities of biodiversity and generally does not threaten sustainable use of biodiversity. On the other hand, the phytomedicine industry always uses whole organisms

and may harvest large quantities. Thus, concern over sustainable use is legitimate with regard to phytomedicine, especially if native biodiversity is brought to the stage of commercialization. Furthermore, if native biodiversity is commercialized, the protection of indigenous knowledge and cultural practices may be an issue. Although phytomedicine is not the subject of H.C.R. No. 146, if carried out to a significant degree and extent in Hawaii, it may become an issue the State will need to address.

**Issue: Genetically Modified Organisms.** Bioprospecting is a multi-faceted activity and involves the use of biotechnology. However, the same can be said of various other activities such as human stem cell research and growing genetically modified foods. These activities share certain attributes, and the danger is in viewing them as being interchangeable. A bioprospecting firm may scientifically canvass certain biodiversity for desired traits, collect samples, extract genetic material, process that material, and derive active compounds. It is unquestionable that some compounds are targeted for agricultural end product use. (Other end product uses include chemical processing, pharmaceutical, and industrial applications.) In other words, bioprospecting does not always lead to an agricultural end product involving a genetically modified food, but it may. Typically, the bioprospecting firm's role is limited to the front-end of discovery. The discovered compound is then sold to a larger agricultural, pharmaceutical, industrial, or chemical processing partner. The larger partner then decides whether or not to develop and commercialize an end product.

In conducting the study, the Bureau became aware of opposition to the growing of genetically modified crops in the State. Opponents fear that these crops will contaminate other crops and endanger human health. They also believe it will hurt the economy if foreign countries ban the import of Hawaiian-grown produce to avoid consuming produce of uncertain origin. In fact, opposition is not so much to bioprospecting, per se, in Hawaii for active compounds that may be later incorporated into a genetically modified crop. Rather, the opposition is to the current and future growing of genetically modified crops in the State. H.C.R. No. 146 is the latest vehicle for the expression of this point of view. The growing of genetically modified crops in Hawaii is a legitimate issue, although it shares only a tenuous connection with the subject of bioprospecting in this study. Nevertheless, it is an issue that the Legislature will need to address eventually.

## **NEED TO ESTABLISH BIOPROSPECTING POLICY**

The Legislature should ensure that the horse is placed before the cart and not the other way around. To do this, it must first understand the issues and establish clear policy in several areas before proceeding to create a mechanism to regulate bioprospecting in Hawaii. To address the issues presented above, the Legislature needs to determine policy in several areas.

The issue of bioprospecting is complex and affects various stakeholders and different segments of the community. Although it is the Legislature that finally determines policy, all stakeholders retain the right and should take the opportunity to make their views known to the Legislature to help fashion that policy. The time for such lobbying is before policy decisions are made. After the Legislature has set its policy guidelines, the bioprospecting working group (*see*



"*Bioprospecting Working Group*" below) should not serve as a lobbying forum to alter policy but as a vehicle to implement policy into a working regulatory framework.

**Policy: *Bioprospecting Regulation.*** The first policy decision the Legislature needs to make is whether to regulate bioprospecting activity in the State. At present, bioprospecting is not subject to either state or federal regulation. The United States Senate has yet, and is not likely, to ratify the 1991 Convention on Biological Diversity, preventing the United States from participating in that international bioprospecting protocol. The United States, as a sovereign nation, does not submit to the CBD bioprospecting guidelines and no individual state in the nation has enacted bioprospecting laws. The Legislature needs to decide whether it wishes to adopt the principles and guidelines of the CBD, or similar guidelines, when bioprospecting activity occurs in the State.

The following four policy considerations help to give focus to the Legislature's primary policy decision of whether to regulate bioprospecting activity in Hawaii:

- Should prior informed consent be required.
- Should the rights of indigenous knowledge holders be protected.
- Should benefits be shared and by whom.
- Should conservation and sustainable use of biodiversity be promoted.

It should be noted that the Legislature does not necessarily need to answer in the affirmative to all four policy considerations above in order to proceed to implement bioprospecting regulation in Hawaii. Subsequent to making affirmative determinations in whichever of the four areas above, the Legislature can then proceed to the details of implementation.

For example, the Legislature needs to consider who has the right to grant prior informed consent for bioprospecting activity. Because bioprospecting interaction and negotiation normally occur on the national level, various national agencies or departments have been vested with this right. In Hawaii's case, some representative agency of the state government may assume this responsibility. A quasi-public third-party entity may also be authorized to grant consent. If indigenous knowledge may be involved and rights need to be protected, appropriate representation from this group could possibly be incorporated into this third-party entity.

Furthermore, if the Legislature determines that bioprospecting benefits must be shared, it first needs to make several other decisions. It must ensure that the State itself is eligible to share in the benefits by addressing the issue of retention of title to biogenetic resources. The Legislature may consider enacting a statute to reserve to the State the title and rights to any biological resource or biogenetic materials derived from that biological resource in any lease, agreement, or sale involving bioprospecting on public lands.

Second, the Legislature must decide who else may share in the benefits. For example, it must decide whether native Hawaiians are entitled to receive a share of benefits. Should other groups such as private conservation or environmental groups also receive benefits? Should

worthy entities otherwise unconnected in any way to bioprospecting, such as self-help housing or anti-child abuse groups, also receive benefits?

Third, if the Legislature decides that native Hawaiians should share benefits, it must decide whether funds should go to the Office of Hawaiian Affairs or to some other group or groups representing native Hawaiians. If the latter, it must also decide which group or groups are appropriate. If the Legislature decides to channel funds through OHA, it must decide whether revenues from the sale of extracts from materials originating on public lands constitute income or proceeds derived from the public land trust. If the Legislature decides in the affirmative, those funds would become eligible for transfer to OHA under Executive Order No. 03-03. Conceivably, the Legislature may come up with an alternative means of funding OHA from sales of materials derived from the public land trust. The point is, the Legislature must determine policy to address this issue. The Legislature must also decide whether to limit the use of any funds transferred to OHA or another Hawaiian entity for certain purposes such as conservation of native biodiversity or indigenous cultural practices.

Fourth, in addition to benefits for native Hawaiians, the Legislature must determine policy on the purposes for which benefits that will accrue to the State itself are to be expended. It is likely that the State would designate itself as an entity to share in benefits. Concomitant with this determination, the Legislature must determine the statewide purposes for which any benefits are to be applied or expended and whether to limit or restrict the use of those benefits. The same must be done for all other entities, public or private, that the Legislature may decide should share benefits from bioprospecting activity.

For example, should all monetary benefits accruing to the State be allocated to unspecified general statewide uses and thus be deposited into the general fund? Or should all benefits be dedicated only for specific purposes generally recognized in international bioprospecting guidelines such as the CBD? Examples include conservation of biodiversity and sustainable use, technical and scientific training, building of research infrastructure, environmental education, etc. Should a certain portion be allocated to the general fund, a certain portion to dedicated CBD-recognized uses, and yet another portion for completely unrelated uses?

Fifth, should the Legislature adopt the principles contained in the Convention on Biological Diversity, in relevant part as applied to Hawaii as a non-sovereign component of a sovereign nation? There need not be any affirmative action to officially endorse the CBD itself. Instead, the Legislature could pick and choose which CBD principles are relevant to the State. The same applies to the principles used in any other international model such as the International Cooperative Biodiversity Groups.

Sixth, to what extent, if any, should bioprospecting regulation extend to privately owned lands?

## ESTABLISHING A MECHANISM TO REGULATE BIOPROSPECTING

Assuming that the Legislature decides in the affirmative to establish regulation of bioprospecting in Hawaii, creating the actual mechanism to do so will involve further subsequent policy decision making. This is an enormously formidable task if only because, as pointed out in this study, there is a broad lack of understanding (or a general misunderstanding) of the issues surrounding bioprospecting. Among the potential participants in bioprospecting activity and regulation, including the Legislature, the state agencies, collaborators, and indigenous knowledge holders, there is a dearth of experience and expertise. This is only natural given that:

- modern-day bioprospecting and the principles of compensated bioprospecting are relatively new, still evolving, and difficult to enforce;
- the primary protocol for compensated bioprospecting – the Convention on Biological Diversity – is meant to apply internationally to sovereign nations and the United States does not participate in the CBD; and
- individual states in this country have no experience in or incentive to regulate bioprospecting.

***Further Policy Decision Making.*** Assuming it has made an initial legislative policy commitment to implement bioprospecting regulation, the Legislature will need to make subsequent policy determinations on how to actually structure a regulatory framework. A sample of several – certainly not exhaustive – determinations are set out below:

- Which entities are to participate in regulation and how to centralize or streamline the permitting process.
- Should a state department be the lead agency; if so, which one?
- Should there be multiple departments involved?
- Should an inter-departmental entity be created instead?
- Should a new state department be created?
- Should a new division within an existing department be created?
- Should enforcement be given to the Attorney General regardless of which state entity acts as the lead agency?
- Should a quasi-governmental third-party entity be created or a private entity be granted authority to coordinate bioprospecting?
- Whichever agencies are finally chosen, how should the permitting process be centralized and streamlined? What specific steps should make up the permitting process?
- What forms of benefit sharing, monetary and non-monetary, should be mandated or provided for?

- Should certain forms of benefit sharing be mandatory and others optional? If so, which?
- Which state agencies (or private entities) should receive and administer monetary and non-monetary benefits in accordance with the Legislature's policy determinations regarding specific sectors that are to receive benefits for specific purposes? How should monetary benefits be handled?
- Should there be a separate set of bioprospecting requirements for researchers who forgo rights to future monetary benefits arising from commercialization and intellectual property rights?
- How should phytomedicine be handled, especially if it involves indigenous biodiversity and indigenous knowledge, if there is a threat to sustainable use due to over-harvesting?
- What rights of indigenous knowledge holders are involved in legitimate bioprospecting activity and how should they be protected?
- What should be the role of the University of Hawaii with regard to bioprospecting, other than acting as a local collaborator of a bioprospecting entity?
- Should the provision of benefits be built into each bioprospecting permit or should benefits be negotiated on a case by case basis, given a menu of mandatory and optional forms that benefits can take?
- How, specifically, should prior informed consent be obtained and granted. Should this be part of the permit process or separately carried out in negotiations between the entities involved?
- Should there be any licensing or permit fees? If yes, should they be: substantial and be treated as part of an up-front payment in the benefit sharing scheme; or nominal in order to cover administrative expenses only?
- Should there be penalties or fees attached to the violation of any bioprospecting regulation? Should they be civil or criminal penalties?
- What administrative incentives and disincentives can be fashioned to encourage conformance with, and to discourage violation of, bioprospecting regulations?<sup>1</sup>

**Bioprospecting Working Group.** If the Legislature affirmatively decides to establish bioprospecting regulation in Hawaii, it will need the participation of all stakeholders. It should be obvious by this point that the issue of bioprospecting regulation is too complex and involves too many aspects to be implemented unilaterally by any one entity or group, governmental or private. To address this obstacle, the Legislature may wish to create a bioprospecting working

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1 One suggestion by Eric Mathur of Diversa, Inc., is to simply include in any Department of Agriculture exit form a declaration that a person is not carrying any sample of biodiversity out of state for the purposes of bioprospecting, perhaps strengthened by disclosure of a civil or criminal penalty for violation. Given that, often, all it takes is a handful of dirt in a plastic sandwich bag to successfully take a sample, and that such a method is fairly easy to carry out and very difficult to detect, the very fact that an individual needs to affirmatively deny doing so could be a deterrent. If nothing else, at least a written record would be available for any future action.

group to channel the efforts of stakeholders – **guided by legislative policy** – to fashion a workable statewide regulatory framework. It would be the task of this working group to hash out the details of implementation **based on the Legislature's policy guidelines**. The working group should not serve as a venue to re-determine legislative policy but as an instrument to apply all available expertise and experience to implement workable regulation. The Legislature should emphasize that this working group is expected to actually work to produce practical regulation and that it is not meant to be a forum through which to lobby the Legislature at a later date.

Although this working group needs to include all stakeholders, too large a membership may prove unwieldy and counterproductive. The relevant state departments (the Departments of Land and Natural Resources, Agriculture, Business and Economic Development, and Tourism, Attorney General), the University of Hawaii, the Governor's office, the bioprospecting and biotechnology industries, native Hawaiians, and groups representing indigenous knowledge holders all need to be represented. However, it is ultimately the prerogative of the Legislature to determine final membership of the working group.

Appendix A

HOUSE OF REPRESENTATIVES  
TWENTY-THIRD LEGISLATURE, 2005  
STATE OF HAWAII

H.C.R. NO. 146  
H.D. 1

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# HOUSE CONCURRENT RESOLUTION

REQUESTING A STUDY ON BIOPROSPECTING.

1           WHEREAS, article XII, section 4, of the State Constitution  
2 provides that lands granted to the State by section 5(b) of the  
3 Admission Act and pursuant to article XVI, section 7, of the  
4 State Constitution, excluding "available lands" as defined by  
5 Section 203 of the Hawaiian Homes Commission Act, 1920, as  
6 amended, shall be held by the State as a public trust for native  
7 Hawaiians and the general public who are co-beneficiaries of the  
8 public trust; and

9  
10           WHEREAS, article XI, section 1, of the State Constitution  
11 provides that "[a]ll public natural resources are held in trust  
12 by the State for the benefit of the people"; and

13  
14           WHEREAS, section 190-1, Hawaii Revised Statutes, provides  
15 that all marine waters of the State are constituted a marine  
16 life conservation area to be administered by the Department of  
17 Land and Natural Resources; and

18  
19           WHEREAS, Hawaii's biological diversity and biological  
20 resources are assets of the public trust that are culturally,  
21 spiritually, medicinally, and otherwise significant to native  
22 Hawaiians and the general public; and

23  
24           WHEREAS, the biological diversity and biological resources  
25 on public lands are of great potential economic benefit in the  
26 areas of medicine, scientific research, biotechnology, and  
27 commercial development for native Hawaiians and the general  
28 public; and

29  
30           WHEREAS, if properly regulated, the potential economic  
31 benefit of these biological resources can create market-driven  
32 incentives and generate financial resources for the conservation  
33 and sustainable development of Hawaii's biological resources;  
34 and

1  
2 WHEREAS, native Hawaiians have customarily used Hawaii's  
3 biological resources in accordance with their traditional,  
4 cultural, and subsistence practices, thereby developing a rich  
5 body of traditional knowledge, innovations, and practices  
6 associated with Hawaii's biological resources, including in the  
7 areas of agriculture, fisheries, health, and horticulture; and  
8

9 WHEREAS, native Hawaiians are traditional, indigenous  
10 knowledge holders with rights, including those recognized in  
11 article XII, section 7, of the State Constitution and sections  
12 1-1 and 7-1, Hawaii Revised Statutes; and  
13

14 WHEREAS, as traditional, indigenous knowledge holders,  
15 native Hawaiians have rights to protect, preserve, and control  
16 the use of their traditional knowledge and associated biological  
17 resources; and  
18

19 WHEREAS, Hawaii is experiencing a tremendous loss of  
20 biodiversity due to the conversion of natural habitat for  
21 development, environmental degradation, and nonsustainable  
22 consumptive practices; and  
23

24 WHEREAS, the State has a trust obligation to ensure the  
25 preservation and sustainable use and equitable sharing of  
26 benefits of Hawaii's biological resources; and  
27

28 WHEREAS, pursuant to this well-established trust  
29 obligation, the Legislature has the fiduciary duty to protect  
30 and preserve the public trust resources and must prevent all  
31 breaches of the trust obligation; and  
32

33 WHEREAS, government entities may enter into material  
34 transfer agreements with private parties that purport to  
35 transfer the title and ownership of the State's natural,  
36 biological, and genetic resources and the right to benefit from  
37 those material resources through commercialization; and  
38

39 WHEREAS, such actions warrant a review of public agencies'  
40 and entities' procedures when negotiating the use of the State's  
41 natural, biological, and genetic resources to ensure that these  
42 resources are utilized in a judicious manner that also provides  
43 a sharing of benefits in as universal a manner as possible; now,  
44 therefore,

1  
2 BE IT RESOLVED by the House of Representatives of the  
3 Twenty-third Legislature of the State of Hawaii, Regular Session  
4 of 2005, the Senate concurring, that the Legislative Reference  
5 Bureau is requested to conduct a study on the fair and equitable  
6 sharing of benefits arising from research, indigenous knowledge,  
7 intellectual property, or application of biological resources  
8 that are public natural resources held in trust by the State for  
9 the benefit of the people; and

10  
11 BE IT FURTHER RESOLVED that the Legislature requests that  
12 the study focus on assisting in the formation of a public policy  
13 strategy to commercially develop the State's biological  
14 resources in a way that will be environmentally sustainable,  
15 culturally sensitive, economically feasible, and mutually  
16 beneficial to all the people of the State; and

17  
18 BE IT FURTHER RESOLVED that the Legislature requests that  
19 the study include:

- 20  
21 (1) Identification and development of issues and policies  
22 for:
- 23  
24 (A) The conservation and sustainable use of  
25 biological diversity;
  - 26  
27 (B) The responsible regulation of bioprospecting and  
28 biotechnology as it relates to bioprospecting;
  - 29  
30 (C) The rights of traditional, indigenous knowledge  
31 holders;
  - 32  
33 (D) The fair and equitable sharing of benefits  
34 arising from the research, indigenous knowledge,  
35 intellectual property, or application of  
36 biological resources; and
  - 37  
38 (E) The meaningful participation in these processes  
39 by traditional, indigenous knowledge holders;
- 40  
41 (2) Reviews of policies, laws, litigation and outcomes,  
42 and models of other jurisdictions;
- 43



- 1 (3) Preparation of a report addressing the issues in  
2 paragraphs (1) and (2) and appropriate legislative  
3 proposals; and  
4
- 5 (4) Compilation of an inventory of current bioprospecting  
6 research projects and activities in the State that are  
7 public, as provided by the Office of the Governor; and  
8

9 BE IT FURTHER RESOLVED that in conducting the study, the  
10 Legislative Reference Bureau is requested to consult with the  
11 following individuals, organizations, and interest groups:  
12

- 13 (1) Office of Hawaiian Affairs;
- 14 (2) University of Hawaii;
- 15 (3) Department of Business, Economic Development, and  
16 Tourism;
- 17 (4) Department of Land and Natural Resources;
- 18 (5) Department of Agriculture;
- 19 (6) Department of Health;
- 20 (7) Native Hawaiians or organizations representing native  
21 Hawaiian interests;
- 22 (8) The biotechnology industry;
- 23 (9) Scientists with interests in Hawaiian ecological  
24 systems;
- 25 (10) Scientists with interests in genetics; and
- 26 (11) Any other organizations or persons that the  
27 Legislative Reference Bureau deems appropriate; and  
28  
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38

39 BE IT FURTHER RESOLVED that the Attorney General is  
40 requested to assist the Legislative Reference Bureau in carrying  
41 out this study; and  
42

43 BE IT FURTHER RESOLVED that the Office of the Governor is  
44 requested to assist the Legislative Reference Bureau in carrying

1 out this study by providing a compilation of an inventory of  
2 current bioprospecting research projects and activities in the  
3 State that are public; and  
4

5 BE IT FURTHER RESOLVED that the Legislative Reference  
6 Bureau is requested to submit a report of any findings and  
7 recommendations, including any proposed legislation, to the  
8 Legislature no later than 20 days before the convening of the  
9 Regular Session of 2006; and  
10

11 BE IT FURTHER RESOLVED that certified copies of this  
12 Concurrent Resolution be transmitted to the Governor; the  
13 Director of the Legislative Reference Bureau; the Attorney  
14 General; the Board of Trustees of the Office of Hawaiian  
15 Affairs; the Board of Regents of the University of Hawaii; the  
16 Director of Business, Economic Development, and Tourism; the  
17 Chairperson of Land and Natural Resources; the Director of  
18 Agriculture; the Director of Health; and the President of the  
19 University of Hawaii, who, in turn, is requested to transmit  
20 copies to representatives of the biotechnology industry,  
21 scientists interested in Hawaiian ecological systems, and  
22 scientists interested in genetics.

## Appendix B



Biotechnology Industry Organization  
1225 Eye Street NW, Suite 400  
Washington, DC 20005  
202.962.9200  
info@bio.org

# Guidelines for BIO Members Engaging in Bioprospecting

## Preamble

*The Biotechnology Industry Organization,*

- recognizing that the conservation of biological diversity has significant long-term advantages for all and desiring to play a role in achieving those advantages for all;
- recognizing the importance of promoting the sustainable use of biodiversity and of equitably sharing the benefits arising from use of genetic resources with the parties providing access to those resources;
- recognizing the importance of scientific research on genetic resources and the important benefits to society as a whole that arise from such research;
- wishing to promote the adoption of clear and transparent provisions governing use of genetic resources so as to promote the greater use of such resources as well as the flow of more benefits to parties providing such access and society as a whole; and
- desiring to conduct their activities, and those of their agents, in relation to collection of genetic resources, as well as the evaluation and use of those collected genetic resources in a manner that complies with relevant national and international regimes;

*hereby establishes the following Guidelines for bioprospecting.*

## I. Definitions; Scope of the Guidelines

- A. Definitions: As used in these Guidelines, the following terms shall have the meaning provided below.
1. "Benefit Sharing" means the providing of any form of compensation or consideration, monetary or otherwise, by a *BIO Member* to a *Providing Party* in exchange for the *BIO Member* being provided access to and authorization to use *Regulated Genetic Resources*.
  2. "*BIO Member*" means a Member of the Biotechnology Industry Organization.
  3. "*Bioprospecting*" means the collection by a *BIO Member* of physical samples of *Regulated Genetic Resources* existing *in situ* or in maintained in an *ex situ* collection of such resources.
  4. "*Bioprospecting Agreement*" means a written agreement between a *BIO Member* and either a *Contracting Party* or a *Providing Party* that concerns (i) *Prior Informed Consent* and (ii) the terms and conditions governing collection and use of the *Regulated Genetic Resources*, including, *inter alia*, *Benefit Sharing*.

5. *"Collected Genetic Resources"* means physical samples of *Regulated Genetic Resources* that have been acquired by a *BIO Member* through *Bioprospecting*.
6. *"Contracting Party"* means a country that has accepted, ratified or acceded to the Convention on Biological Diversity and thus is a Contracting Party within the meaning of Convention.
7. *"Ex situ collection"* means a collection of physical samples of *genetic resources* that have been previously obtained from an *in situ* location and which are preserved or maintained in a location external to that *in situ* location.
8. *"Focal Point"* means the entity designated or recognized by the government of a country as having the authority to (i) identify the *Providing Party* or Parties within the *Contracting Party* with authority over the *genetic resources* to be collected, (ii) provide information concerning the requirements and procedures for obtaining *Prior Informed Consent* to collect and use *Regulated Genetic Resources* within the territory of that country, (iii) provide information regarding *Benefit Sharing* requirements applicable within the *Contracting Party*, and (iv) identify the representative of local and indigenous communities located within the territory of the country.
9. *"Genetic Resource"* means material of non-human animal, plant or microbial origin containing functional units of heredity.
10. *"In-situ"* means the location in which genetic resources exist within ecosystems and natural habitats within a Country;
11. *"Providing Party"* means any entity within a *Contracting Party* that has been given the legal authority to grant *Prior Informed Consent* or authorization to access and use *Regulated Genetic Resources*, and may include, *inter alia*, an authority of the national government, an authority of a local government, or an indigenous or local community or any combination of these entities.
12. *"Prior Informed Consent"* means an agreement between a *BIO Member* and a *Providing Party* establishing that the *BIO Member* has provided to the *Providing Party* information that meets the requirements of Section III of these Guidelines with respect to a *Regulated Genetic Resource* to which the *BIO Member* has been granted access.
13. *"Regulated Genetic Resource"* means a *Genetic Resource* in respect of which a *Providing Party* in a *Contracting Party*, on or after the date that the Convention on Biological Diversity Party took effect in that *Contracting Party*, imposes requirements concerning *Prior Informed Consent*, collection or use.

B. Scope of the Guidelines:

1. These Guidelines establish principles to govern the conduct of *BIO Members* that are engaged in *Bioprospecting* activities, as defined in section A.3.
2. The Guidelines shall not apply to the acquisition or use of:
  - a. any materials obtained from humans or are of human origin;
  - b. *Genetic Resources* that are not *Regulated Genetic Resources* within the meaning of these Guidelines;

- c. *Genetic Resources* maintained in an *ex situ* collection where such resources were obtained from a *Contracting Party* prior to the date the Convention on Biological Diversity took effect in that *Contracting Party*;
- d. *Genetic Resources* that are made available to the public on an unrestricted basis, either on commercial or non-commercial terms; or
- e. publicly available information, including, in particular, information published in the scientific literature, disclosed in a patent or published patent application, or disseminated in an unrestricted fashion.

## II. Conduct of Bioprospecting

### A. Steps to take before engaging in Bioprospecting.

1. Identify and contact the *Focal Point* of the *Contracting Party* for the *Regulated Genetic Resources*.
  - a. For samples of *Regulated Genetic Resources* to be collected *in situ*, or from an *ex situ* collection located within the territory of or controlled by the *Contracting Party*, contact the *Focal Point* identified by that *Contracting Party*.
  - b. For samples of *Regulated Genetic Resources* to be collected from an *ex situ* collection located outside the territory of or not controlled by the *Contracting Party*, identify the *Focal Point* specified by the custodian of the *ex situ* collection or, if the *Focal Point* is not known to that custodian, take reasonable steps to identify the *Focal Point* for the *Regulated Genetic Resources* to be collected.
2. In cooperation with that *Focal Point*, use all reasonable efforts to identify all entities that comprise the *Providing Party*, and ascertain requirements applicable to *Bioprospecting*.
3. Obtain *Prior Informed Consent* from the *Providing Party* to collect and use *Regulated Genetic Resources* lawfully controlled or held by the *Providing Party*.
4. Reach agreement with the *Providing Party* on the terms and conditions governing collection, handling and use of physical samples of the *Regulated Genetic Resources*, including, *inter alia*, the sharing of benefits arising from the use of such samples, and measures governing the handling or transfer of such samples.
5. Conclude a *Bioprospecting Agreement* with the *Providing Party* that reflects the terms and conditions of *Prior Informed Consent* and concerning the collection, handling and use of the collected physical samples of the *Regulated Genetic Resource(s)* including, *inter alia*, terms and conditions regarding *Benefit Sharing*.
6. Take reasonable steps to confirm that the *Bioprospecting Agreement* will be binding on the Government of the *Contracting Party*, either directly or through the authority conferred by the *Contracting Party* on a *Providing Party*.

- B. After *Prior Informed Consent* has been obtained and a *Bioprospecting Agreement* concluded regarding collection and use of the *Regulated Genetic Resources*, conduct *Bioprospecting*, and use the *Collected Genetic Resources*, in a manner that complies with the terms and conditions specified in the *Bioprospecting Agreement*.

## III. Prior Informed Consent

- A. Make reasonable efforts to determine if any specific requirements for *Prior Informed Consent* apply to the collected *Regulated Genetic Resources*. To do so:
  1. Determine if a *Contracting Party* has established requirements for *Prior Informed Consent*, or, if that authority has been delegated to a *Providing Party*.
  2. Identify the nature of the requirements for *Prior Informed Consent* established by the *Contracting Party* or the *Providing Party*, as the case may be.
  3. Meet the identified requirements to comply with *Prior Informed Consent* obligations of the *Contracting Party* or the *Providing Party* applicable to the collected *Regulated Genetic Resources*, and incorporate evidence of such compliance into the *Bioprospecting Agreement*.
- B. If a *Contracting Party* has not established requirements for *Prior Informed Consent*, make reasonable effort to provide at least the following information to the *Providing Party*:
  1. The general nature of the activities to be conducted with the *Collected Genetic Resources* (e.g., screening of samples for biological properties, growth and study of samples of materials, extraction and isolation of chemical compounds from the samples, genomic analysis of the sample).
  2. The anticipated field of use of any products or services that may be developed through the use of the *Collected Genetic Resources* (e.g., pharmaceutical, agricultural, industrial processing, environmental remediation).
  3. The identity and contact information of the expected lead researcher in the *BIO Member*, or a contact point in the *BIO Member* for such research activities.

#### IV. **Benefit Sharing and Sharing of Research Results, Intellectual Property Procurement and Related Provisions**

- A. *BIO Members* that enter into a *Bioprospecting Agreement* with a *Providing Party* should give good faith consideration to specific terms for the sharing of benefits arising from use of collected *Regulated Genetic Resources*, and should define such commitments in the terms and conditions in the *Bioprospecting Agreement*.
- B. Types of benefits to be considered for inclusion in a *Bioprospecting Agreement*:
  1. Monetary and non-monetary benefits arising from the use or commercialization of the *Collected Genetic Resources*, including provision of equipment and materials, up-front payments and royalty payments;
  2. The sharing of scientific information generated through the conduct of research upon the *Collected Genetic Resources* in conformity with standard industry practices regarding timing and conditions of public disclosure to preserve options for procurement of patents or preservation of rights in undisclosed information;
  3. The granting of rights to use technology resulting directly from the *BIO Member's* use of the *Collected Genetic Resources* where the granting of such rights and the nature of the rights granted, are consistent with the commercial needs and interests of the *BIO Member*;
  4. The provision of training for scientists designated by the *Providing Party*;

5. The inclusion of scientists from the Providing Party in research activities of the *BIO Member* on the *Collected Genetic Resources*;
6. The conduct of research on *Collected Genetic Resources* in the territory of the *Contracting Party* from which such resources have been collected.
7. The transfer to a *Providing Party* of scientific knowledge, expertise, and technology in the control of the *BIO Member* that (a) results from the study of the collected genetic resources and (b) pertains to the conservation, preservation or physical handling of the *Collected Genetic Resources*.
8. Commitments to only seek patents on inventions that arise from the use or study of *Collected Genetic Resources* and that are claimed in a manner clearly distinguishable from the form in which the *Collected Genetic Resources* are provided by the *Providing Party*.

#### V. Measures to Protect Interests and Rights of Indigenous or Local Communities

- A. Respect the customs, traditions, values and customary practices of indigenous and local communities within a *Contracting Party* and from which *Collected Genetic Resources* have been obtained.
- B. Respond to requests from indigenous and local communities for information concerning the handling, storage or transfer of *Collected Genetic Resources* consistent with the terms of an applicable *Bioprospecting Agreement*.
- C. Take all reasonable steps to prevent the disclosure of information provided in confidence by a member of an indigenous or local community, and handle such information in accordance with the terms specified by the community that has provided the information. Where feasible, include such terms in the *Bioprospecting Agreement*.
- D. Avoid taking actions in the course of use or commercialization of *Collected Genetic Resources* that impede the traditional use of Regulated Genetic Resources provided by a *Providing Party*.

#### VI. Conservation and Sustainable Use of Biological Diversity

1. Take reasonable steps to prevent harm or alteration to the local environment incidental to acts of collecting samples of genetic resources from an *in situ* location in a *Contracting Party*.
2. Avoid taking actions that pose a threat to the conservation or sustainable use of biological diversity incidental to acts of collecting samples of genetic resources from an *in situ* location in a *Contracting Party*.
3. Take all reasonable steps and give good faith consideration to sharing data with the *Contracting Party* and/or the *Providing Party* which was derived from research on the *Collected Genetic Resources* and which may be useful in the support of conservation efforts related to a species, environment, or habitat from which the *Collected Genetic Resources* were collected.

#### VII. Compliance with Terms of a Bioprospecting Agreement and the Guidelines

1. Use *Collected Genetic Resources* in a manner consistent with the terms and conditions specified in an applicable *Bioprospecting Agreement*.
2. Do not use *Collected Genetic Resources*, for purposes other than those specified in the *Prior Informed Consent* provisions of an applicable *Bioprospecting Agreement*, unless first obtaining a

separate *Prior Informed Consent* in writing for the other use of the *Collected Genetic Resource*.

3. After acquiring *Collected Genetic Resources* pursuant to these Guidelines, maintain records concerning the handling, storage and physical movement of the *Collected Genetic Resources*, and be prepared to share such records with the *Providing Party* upon the request of the *Providing Party*, within reasonable limitations.
4. Ensure that the terms and conditions specified in a *Bioprospecting Agreement* entered into with a *Contracting Party* or a *Providing Party* apply to (i) any successor in interest to their rights under the agreement, and (ii) to any party that obtains a sample of a *Collected Genetic Resource* from it, unless those parties have independently obtained from the *Contracting Party* or the *Providing Party* the right to obtain such samples of the *Collected Genetic Resources*.
5. Do not transfer samples of *Collected Genetic Resources* to third parties unless such transfer is consistent with the terms and conditions of an applicable *Bioprospecting Agreement*.
6. Do not accept samples of *Collected Genetic Resources* from a third party that is not able to provide evidence that it has obtained such samples in compliance with obligations of *Prior Informed Consent* and conditions governing use that are applicable to the sample.
7. Include provisions in the *Bioprospecting Agreement* that provide for effective and fair resolution of disputes regarding compliance with the terms and conditions in the *Bioprospecting Agreement*, either by commitments to international arbitration consistent with the procedures specified in the Annex to these Guidelines or as otherwise agreeable to the *Contracting Party* or *Providing Party*.



## Appendix C

LINDA LINGLE  
GOVERNOR



MARK J. BENNETT  
ATTORNEY GENERAL

STATE OF HAWAII  
DEPARTMENT OF THE ATTORNEY GENERAL  
425 QUEEN STREET  
HONOLULU, HAWAII 96813  
(808) 586-1500

RICHARD T. BISSEN, JR.  
FIRST DEPUTY ATTORNEY GENERAL

April 11, 2003

The Honorable Sol P. Kaho'ohalahala  
Representative, Thirteenth District  
Twenty-Second Legislature  
State Capitol, Room 405  
Honolulu, Hawaii 96813

Dear Representative Kaho'ohalahala:

Re: Legal Title to Biogenetic Resources From Public Lands

By letter dated April 1, 2003, you requested an opinion on the following questions in connection with your consideration of Senate Bill No. 643, and House Concurrent Resolution No. 196, Senate Concurrent Resolution No. 55, and Senate Resolution No. 35:

1. Is the legal title to biogenetic resources gathered from state public lands, including ceded lands vested in the State of Hawaii?
  - a. Is the legal title to biogenetic resources gathered from ceded lands part of the ceded lands public trust?
2. Does the University of Hawaii, through its autonomous status, have the legal authority to sell or transfer any biogenetic resources found on ceded lands or other state lands to third parties?
  - a. If the University does not have legal authority to sell or transfer such resources but has nevertheless purported to sell or transfer such resources to third parties through collaboration agreements, are those agreements null and void? If such an opinion is rendered on the basis that the University did not have the legal authority

to enter into such agreements, are these agreements no longer valid?

- b. What statutes and laws prevent the sale or transfer of biogenetic resources of the ceded lands trust by agencies or divisions of the State of Hawaii?
3. If the Attorney General opines that the University of Hawaii may lawfully enter into a contract with a private corporation for the sale or transfer of biogenetic material of the State of Hawaii, shall revenue generated from such sale or transfer of ceded lands be deposited into the Ceded Lands Trust account?

Brief Answers

For the reasons discussed below, we answer briefly, in order, as follows:

1. The State holds legal title to biogenetic resources<sup>1</sup> gathered from state public lands, including the ceded lands, if the State reserved its title to the biogenetic resources when it allowed third persons to remove the natural resources or things from which the biogenetic resources were extracted, or it transferred its title to the land from which the biogenetic resources came. Further, the State would not lose its title to the biogenetic resources if the natural resource or thing from which the biogenetic resource originated was removed from the public lands without authority or the State's permission.<sup>2</sup>

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<sup>1</sup>This opinion assumes that you are using the term "biogenetic resources" to refer to the genetic material or composition of the natural resources and other things connected to, or gathered from public lands, and that it would not include wild animals or other things found on the land over which the State does not exercise dominion and control. See, Davis v. Green, 2 Haw. 367 (1861); United States v. Gerber, 999 F.2d 1112 (7th Cir. 1993).

<sup>2</sup>If "biogenetic resources" refers instead to the product developed from the genetic material extracted from the resources and things connected to public lands, legal title to that product may not be vested in the State, although the State may have a right of action for damages against the product's developer if the State retained legal title to the resource or thing from which the genetic material was taken to make the product. Relying

2. The scope of the University of Hawaii's ("University") authority to sell or transfer biogenetic resources gathered from ceded lands, depends upon how the University acquired the ceded land from which the biogenetic resource originated. The University has complete authority over the lands that are set aside or conveyed to it by the State. The University would also have limited authority to dispose of biogenetic resources gathered from public lands it leases from the State, or lands that it has permits to use or licenses from which to remove materials.

If the collaboration agreements you ask about are like the May 15, 2002, Biodiversity Collaboration Agreement between the University and the Diversa Corporation, the agreements would not be null and void on their face. The agreements are capable of performance even if the University lacked authority to gather biogenetic material from public lands. Nothing in the agreements specifies that the environmental samples the University collects and transfers to Diversa must come from public lands.

We are not aware of any statutes or laws that prevent the sale or transfer of biogenetic resources extracted from resources or things gathered from ceded lands or any other public lands.

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on patent law that distinguishes between "naturally occurring raw materials," and "organisms that represent the product of 'human ingenuity,'" the California Supreme Court concluded that the owner of the cellular material used to make the biogenetic product did not have a legal interest in the biogenetic product. Moore v. Regents of University of California, 271 Cal. Rptr. 146, 159 (1990), citing Diamond v. Chakrabarty, 447 U.S. 303, 309-10, 100 S. Ct. 2204, 2208, 65 L. Ed. 2d 144 (1980).

We would also note that the Diversa agreement between the University and Diversa Corporation discussed below differentiates between the material the University promised to provide, and the "Product" Diversa could develop from that material. See, Definitions, "The term 'Product(s)', shall mean a gene, gene bank, RNA, DNA, peptide, protein or metabolite which is recovered, obtained or derived from the Material. Product(s) shall also include any other derivatives of the Material, such as whole microorganisms, secondary metabolites and their derivatives (generated either chemically, biochemically, biologically or genetically.)"

3. As a result of the decision in OHA v. State, 96 Haw. 388 (2001), the Legislature must again determine which income and proceeds from the public land trust lands are to go to the Office of Hawaiian Affairs ("OHA"). Until the Legislature re-establishes a funding mechanism for OHA, Executive Order No. 03-03 is the only mechanism in place for transferring receipts from the use of ceded lands to OHA. Under that order, only receipts for the use of improved or unimproved parcels of ceded land are accumulated and transferred to OHA on a quarterly basis. Receipts from the sale or transfer of biogenetic resources do not qualify for transfer under the order.

#### Discussion

##### A. Title to Biogenetic Resources

With ten exceptions, section 171-2, Hawaii Revised Statutes ("HRS"), defines "public lands" as "all lands or interest therein in the State classed as government or crown lands previous to August 15, 1895, or acquired or reserved by the government subsequent to that date by purchase, exchange, escheat, or the exercise of the right of eminent domain, or in any other manner; including submerged lands, and lands beneath tidal waters which are suitable for reclamation, . . . ." "Land" is defined in section 171-1, HRS, as including "all interests therein and natural resources including water, minerals, and all such things connected with land, unless otherwise expressly provided."

"Ceded lands" are all of the lands ceded to the United States by the Republic of Hawaii under the Joint Resolution of Annexation, not otherwise disposed of by the United States prior to the lands' transfer to the State of Hawaii pursuant to section 5(b) of the Admission Act, including the water, minerals, plants, and other things connected with the lands, and "every species of title inchoate or complete." State v. Zimring, 58 Haw. 106, 122-3, 566 P.2d 725, 735-6 (1977).

"Ownership" is a collection of rights to possess, to use and to enjoy property, including the right to sell and transmit it." 63C Am. Jur. 2d Property § 26 (2d ed. 1997). "Ownership of property implies the right of possession and control, . . .

the right to use property is just one of the several rights incident to ownership. Ownership includes the right to protect and defend such possession against the intrusion or trespass of others . . . As one of its incidents, the ownership of property carries with it, at law and equity, the right to its products . . . ." 63C Am. Jur. 2d Property § 28 (2d ed. 1997). Another of the prerogatives of ownership is the right to control the future use of the things one owns, by reserving that right prior to transferring title to those things to third parties. Moore v. Regents of the University of California, 271 Cal. Rptr. at 168 (J. Broussard concurring and dissenting).

Because there is no statute or law that presently reserves, or prevents or regulates the sale of, biogenetic resources extracted from resources or things situated on lands the State owns, we cannot simply assume that the State owns the biogenetic resources gathered from those lands. In an early Hawaii case, the Supreme Court explained that the word "owner" "has no fixed meaning applicable to all circumstances alike. . . . 'Owner may refer to the owner of the fee or one of a lesser estate [i.e., the holder of a leased interest, or a license or a permit] . . . . The word 'owner' is not infrequently used to describe one who has dominion of land, title to which is in another." Paterson v. Rush, 34 Haw. 881, 892-93 (1938) (citations omitted; bracketed explanatory material inserted).

Nonetheless, inasmuch as the genetic material or composition of the natural resources and things connected to public lands, including ceded lands, are an integral part of those resources and things, title to the biogenetic resources will still be held by the State if it has not sold the land. However, legal title to biogenetic resources gathered from State public lands will not still be vested in the State if third persons were allowed to remove from public lands the natural resource or thing from which the biogenetic resources were extracted or the State sold or leased title to a parcel of public land without reserving title or retaining control of the resources or things connected to the transferred land, or their biogenetic contents.

B. Authority to Sell or Transfer Biogenetic Resources

Section 171-13, HRS, allows the Board of Land and Natural Resources ("BLNR") to dispose of public lands by sale, lease,

license, or permit. Section 171-54, HRS, also allows the BLNR to issue land licenses that confer "a privilege . . . to enter land for a certain special purpose such as the removal of timber, soil, sand, gravel, stone, hapuu, and plants, but not including water rights, ground or surface, nor removal of minerals," as "land license" is defined in section 171-1, HRS.

Section 5 of article X of the State Constitution vests in the University legal title to all real property set aside or conveyed to the University by the State. It also directs that the University hold the lands in public trust for the University's purposes, and authorizes the University to administer and dispose of the lands as provided by law. Lands owned by the University are excepted from the definition of "public lands" in section 171-2(5), HRS.

Section 304-2(2), HRS, rather than sections 171-13 and 171-54, HRS, delineates the scope of the University's powers with respect to its lands. Section 304-2(2) provides in pertinent part that the University "under the direction of the board of regents, shall have the [power to] acquire . . . property, real, personal, or mixed, tangible or intangible, or any interest therein; to hold, maintain, use, and operate the same; and to sell, lease, or otherwise dispose of the same at such time, in such manner, and to the extent deemed necessary or appropriate to carry out its purposes."

With the prior approval of the BLNR, state departments to which public lands have been set aside by the Governor under section 171-11, HRS, may also dispose of public lands by sale, lease, license, or permit, and issue land licenses for the privilege of removing natural resources and things from the public lands.<sup>3</sup> However, the authority of departments other than the University to dispose of set aside lands and the natural resources and things connected to them is limited only to dispositions that are consistent with the purposes of the set aside.

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<sup>3</sup>Price v. State of Hawaii, 921 F.2d 950, 957 (9th Cir. 1990), concludes that ceded lands may be set aside for state agencies to use and manage, without violating the public trust imposed upon the lands by the Admission Act.

The State's deeds, leases, and set aside orders include reservations clauses.<sup>4</sup> The leases also typically include a "Character of use" section to limit the uses to which the leased premises may be put. The precision with which leases describe the uses to which leased premises may be put can have the same effect as a reservation clause.<sup>5</sup> Similarly, state land licenses affirmatively describe what the licensee is permitted to remove from the public lands, so that anything not described in the license is not authorized to be removed.<sup>6</sup>

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<sup>4</sup> Typically, these clauses reserve and except the State's minerals and water rights from the sale or lease. Leases and some deeds also reserve prehistoric and historic remains and burial sites. An executive order setting aside parcels of public land on Kauai to the University includes the following provisions:

3. In regards to any commercial activities on the ceded lands, the UH shall negotiate with the Office of Hawaiian Affairs ("OHA"), the matter of entitlement as provided for in chapter 10, Hawaii Revised Statutes, as amended, and the UH shall hold the State of Hawaii harmless from liability on any financial compensation paid to OHA based on any ceded lands claims against the UH arising from this transaction.
4. The UH shall not rent or sublet the whole or any portion of the premises, for uses that are inconsistent with the purpose and intent of the set aside, without the prior consent of the Board of Land and Natural Resources.

<sup>5</sup> For example, the "Character of use" section of General Lease S-5529 between the State and the University provides that "[t]he Lessee shall use or allow the premises leased to be used solely for permanent mid-level facilities, a construction camp, an information station as well as existing facilities." In our view, the University would not have authority to sell or transfer biogenetic resources gathered from this leased parcel, and could not do so without the State's permission to do so.

<sup>6</sup> State and federal regulatory schemes can also qualify the use to which third parties may use public lands, including ceded lands. State deeds, leases, licenses, and permits commonly refer to state or federal laws by name, e.g., the Archeological Resources Protection Act, 16 U.S.C. §§ 470aa, et seq., by their codification, e.g., chapter 6E, HRS, which is the State's Historic Preservation law, or generalized incorporation by a "Compliance with laws" section that requires a lessee, for instance, to "comply with all of the requirements of all municipal, state, and federal authorities and observe all municipal, state and federal laws applicable to the premises, now in force or which may be in force." One of the first sections of the federal act provides: "Any person may apply to the Federal land manager for a permit to excavate or remove any archeological resource located on public-lands or

We can say that the University does not have authority to sell or transfer biogenetic resources it collects from resources or things on ceded lands it does not own. We can also say the University does not have authority to sell or transfer biogenetic resources it extracts from resources and things it lacks authority to remove from ceded lands. However, we cannot conclusively say whether the University has authority to sell or transfer biogenetic resources found on ceded lands it owns or has some amount of control over, until we review all of the deeds and executive orders for every parcel of land the University owns and the terms of the leases, licenses, and permits for all of the parcels of public lands the University is licensed or permitted to use.<sup>7</sup>

C. Collaboration Agreements

The Diversa agreement requires the University to provide Diversa with environmental samples from diverse habitats<sup>8</sup> but does not prescribe from where the samples must or are to be collected. The University appears to be free to gather samples from lands it owns, public lands it is authorized to use for

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Indian lands and to carry out activities associated with such excavation or removal." 16 U.S.C. § 470cc.

<sup>7</sup>Because the state law does not categorically reserve the State's title to biological resources derived from the natural resources and things connected to the lands it owns (and the proposals for the formulation of a task force to wrestle with competing interests and concerns suggest that there are serious questions as to whether there should even be such a law), the documents used to convey the State's interests in the lands it owns to third parties are the only means presently available for protecting any economic benefit the biological resources may have. It is important, therefore, that there be an appreciation of the potential value of the resources and a deliberate evaluation made as to whether an express reservation should be included in each conveyance document.

<sup>8</sup>Paragraph 1 of the Agreement Terms of the Diversa agreement provides in part: "Collaborator [the University] will provide Diversa the Material as set forth in Appendix A hereto. Appendix A elaborates in part as follows: "Collaborator will be responsible for the collection, processing and shipment to Diversa of environmental samples from diverse habitats and/or DNA samples isolated from such environmental samples using the Technology." Appendix A also describes the "environmental samples" the University is required to provide to Diversa under the agreement, as "including soils, sediments, mire, earth, microbial mats and filaments, plants, ecto and endo symbiont microbial communities, endophytes, fungi, animal and/or insect excrement, marine and terrestrial invertebrates, air and water."



this purpose, or private lands. Alternatively, it can secure a land license from the BLNR so that it may provide samples from resources or things gathered on public lands, or extract samples from soil, plants, animals, and other material it already owns, or no one else owns.

Given these circumstances, and because the University at minimum has the power to dispose of biogenetic resources on the land it owns, there is no basis to say that the agreement is invalid for lack of authority. However, if both Diversa and the University intended that all material come from only ceded lands the State owned, the agreement may be voidable but not null and void altogether. The University could still perform under the contract by collecting material from the lands it owns and by securing a land license so that it could collect materials from the ceded lands the State owns. See Restatement Second of Contracts 2d § 152 (1981) (When Mistake of Both Parties Makes a Contract Voidable).

D. Revenue Generated from the Sale of Biogenetic Resources

The decision in OHA v. State does not foreclose state agencies from transferring funds they receive for the use of ceded lands, to OHA. Sections 10-13.5 and 10-3(1), HRS, still provide that "[t]wenty per cent of all funds derived from the public land trust, described in section 10-3, shall be expended by the office, as defined in section 10-2, for the purposes of this chapter," and that for purposes of chapter 10 "the public land trust shall be all proceeds and income from the sale, lease, or other disposition of lands ceded to the United States by the Republic of Hawaii under the joint resolution of annexation," or what Zimring describes as the ceded lands.

Nevertheless, until the Legislature again makes the policy determinations on which a replacement funding mechanism can be grounded, there are no standards or precedents for determining whether receipts from the sale of extracts from material originating on ceded lands constitute "funds derived from the public land trust" under section 10-13.5. Until the Legislature re-establishes a funding mechanism, our only precedent is the receipts the Department of Land and Natural Resources ("DLNR") collected in the interval from 1987, when OHA v. Yamasaki, 69 Haw. 154 (1987), was decided, and 1990, when Act 304, Session Laws of Hawaii 1990 was enacted. These collections did not

The Honorable Sol P. Kaho'ohalahala  
April 11, 2003  
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include receipts from products processed from resources or things connected to ceded lands. Because the University must process the resources or things from the public land in order to get the genetic material the University provides Diversa under the agreement, the receipts from the sale of the genetic material are different from the receipts DLNR transferred to OHA in the 1987 - 1990 interim, and do not qualify for transfer under Executive Order No. 03-03.<sup>9</sup>

Please do not hesitate to call us if there are further questions about these issues.

Very truly yours,



Charleen M. Aina  
Deputy Attorney General

APPROVED:

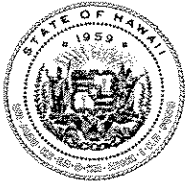


Mark J. Bennett  
Attorney General

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<sup>9</sup>If anything, the receipts from the Diversa agreement are like the receipts from the sale of the plants and animals, and goods Lahainaluna students grew or made on ceded lands after-school, that OHA asserted a twenty percent claim against in OHA v. State.

Appendix D



Department of Land and Natural  
Resources

Division of Forestry and Wildlife

1151 Punchbowl St., Room 325

Honolulu, HI 96813

(808) 587-0063, (808) 587-0064 (Fax)

Application for Research/T&E Collection/Access/Activity Permit



Application Date: \_\_\_\_\_

Name and Title of Principal Investigator or Coordinator:

\_\_\_\_\_

Agency/Organization Supporting Activity:

\_\_\_\_\_

Mailing Address:

\_\_\_\_\_

Telephone Number \_\_\_\_\_ FAX \_\_\_\_\_

E-mail address \_\_\_\_\_ Local Contact \_\_\_\_\_

Type of Permit(s): NARS\_\_ T&E Species\_\_ Research\_\_ Landing\_\_ Access\_\_  
Commercial Activity\_\_\_\_\_

Statement of Proposed Activity (Attach study/activity plans and supplementary material as necessary).

- 1) How will study/activity results benefit the area, resource, or management in the future?
- 2) Study/activity objectives.
- 3) Specific study/activity location(s). Attach map if needed.
- 4) Mode of travel to study/activity site.
- 5) Duration of study/activity:
  - a. Overall
  - b. Dates for this request: Start date \_\_\_\_\_ End date \_\_\_\_\_

6) How is the study/activity to be accomplished? What are the methods to be used? Be specific in listing study/survey techniques and include efforts that will be taken to minimize effects on the resource and/or area.

7) Justification:

Why is the proposed study/activity important?

If work is in a Natural Area Reserve, can it be done elsewhere? If so, justify use of NARS.

How will the information learned be applied?

How will study/activity results be disseminated?

Will any specimens be collected?

If yes, state kind, quantities, storage methods, and ultimate disposition.

8) Have any studies (in the case of research proposals) been made that are similar to the one proposed? If yes, please cite.

9) Who will participate in the study/activity (in the case of groups, list the leaders and/or responsible parties, or the principal permit holder who will carry overall responsibility)?

Principal Coordinator \_\_\_\_\_

(As appears on Drivers License)

Title: \_\_\_\_\_

Background/Qualifications:

\_\_\_\_\_

Assistant: \_\_\_\_\_  
(As appears on Drivers License)

Assistant: \_\_\_\_\_  
(As appears on Drivers License)

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Background/Qualifications:

Background/Qualifications:

Assistant: \_\_\_\_\_  
(As appears on Drivers License)

Assistant: \_\_\_\_\_  
(As appears on Drivers License)

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Background/Qualifications

Background/Qualifications

[Please list all other personnel to be covered by this request on a separate sheet]

**10.)Will your research/activity require camping or night work? If yes, please describe specific locations, duration and dates.**

**11.)Will your research/activity involve the use of aircraft in any way? If yes, please describe specific locations, frequency of use and dates.**

**12.)Will your research/activity involve the use of firearms? If yes, describe locations, frequency of use, safeguard to be employed, etc.**

**13.)Will your research/activity require structures/equipment to be left in the field? If so, when will they be removed?**

**14.)Will permits from other agencies be required for your study/activity? If yes, please list agencies.**

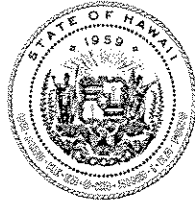
**15.)What is the expected report date for your findings (in the case of research or commercial photographs)?**

**16.)What information will be made available to the Department of Land & Natural Resources?**

**17.)Is this application part of graduate studies? If so, please include the name and affiliation of your major professor/advisor and his/her signature.**

\_\_\_\_\_  
Applicant's Signature

\_\_\_\_\_  
Advisor's Signature



## Department of Land and Natural Resources Division of Forestry and Wildlife

1151 Punchbowl St., Room 325

Honolulu, HI 96813

(808) 587-0166/ (808) 587-0160 (Fax)

### Guidelines for Research, Collection, Commercial Activity, and Access Permits

Before you begin research or any other activity in Hawaii, you will need to obtain appropriate permits. These are **general** guidelines for research, collection (for scientific and educational purposes), and other activities (such as commercial) **1**) on lands under the jurisdiction of the Division of Forestry and Wildlife (DOFAW) and **2**) those involving native species of the state of Hawaii.

These guidelines are intended to help prospective researchers and others seek necessary permit(s) and contact the appropriate offices to obtain an application form and permit approval. The following list provides guidance based on intended activities. More than one permit may be required (i.e. collection & access & activity), however; it is now possible to use the same application form for each permit (a project proposal detailing project specifics must be attached). Appropriate access/activity permits will be cleared by the individual DOFAW Branch/ Island office before a permit is generated.

- Research/activities involving native wildlife (vertebrates): requires a Scientific Collecting permit (Contact: Scott Fretz; [scott.fretz@hawaii.gov](mailto:scott.fretz@hawaii.gov))
- Research/activities involving native plants: requires a Scientific Collecting permit (Contact: Vickie Caraway; [vickie.l.caraway@hawaii.gov](mailto:vickie.l.caraway@hawaii.gov))
- Research/activities within a Natural Area Reserve requires a Special Use Permit through the Natural Area Reserves System Commission, and Research/activities involving native invertebrate wildlife (terrestrial) requires a Scientific Collecting permit (Contact: Betsy Gagne; [betsy.h.gagne@hawaii.gov](mailto:betsy.h.gagne@hawaii.gov))
- Research/ activities requiring access to DOFAW managed land (see map): requires an Access permit (Contact appropriate Branch/Island office – see resource list below)
- Research/activities involving collection or possession of Threatened & Endangered Species or migratory birds: requires a US Fish and Wildlife Service permit (contact the USFWS Hawaii office)
- Permits to collect, or export injurious wildlife (Contact Mindy Wilkinson; [mindy.m.wilkinson@hawaii.gov](mailto:mindy.m.wilkinson@hawaii.gov))
- Research/activities involving fresh water or marine species: contact Division of Aquatic Resources (808) 587-0110

- Research/activities involving historical sites: contact Historic Preservation Division (808) 692-8015
- Research/activities involving State Parks: contact State Parks Division (808) 587-0289
- Research/activities involving unencumbered state lands: contact Land Division (808) 587-0446

**Studies/research with direct management or conservation components are greatly favored on DOFAW managed lands, especially with endangered species.**

Requests for permits should be submitted no later than 30 days before expected start of field work to allow sufficient time for review and processing. Original signatures are required on the final permit, which may take additional time via US mail. Plan accordingly.

Once a written permit (not just verbal “permission”) is granted, read, and signed, the permit holders only need to check in with the appropriate DOFAW Branch office prior to field work (in person if they need to pick up necessary gate keys or other logistics; or by phone so staff can confirm fieldwork). A copy of the permit must be carried with the permit holder in the field. Access may be denied or rescheduled for any reason, including changes in field conditions (hurricanes, fire or other reasons). This is a safety issue and the main reason why contact with the DOFAW Branch/ Island *must* be made prior to beginning fieldwork. Fieldwork in Hawaii can be hazardous and must be approached accordingly.

For studies involving the use of federally listed species such as migratory birds and Threatened and Endangered species, Federal permits must be obtained *prior* to initiation of fieldwork.

Activities include commercial use ranging from guided hikes and tours, to photography and may also require a separate permit.

**The following important information is for those requesting a Special Use Permit for the Natural Area Reserves System (NARS). Those wishing to conduct any activity that requires a permit will need to submit a request at least THREE MONTHS in advance. ALL NARS Special Use Permits must FIRST be approved by the Natural Area Reserves System Commission at one of their meetings, then recommended to the Board of Land and Natural Resources by the NARS Commission for final approval. The Commission meets every other month, so advance notice is necessary. Those not meeting the submittal deadline will have to either reschedule or consider other areas. Applicants will need to attach a detailed study plan, detailed maps, a dive-safety plan for marine and aquatic work, as well as details about vessels (name of vessel, registration number, operator). Application does not guarantee automatic approval. Until such time as the Rules can be amended to delegate authority to an authorized representative other than the Commission as a whole (as rules allow for the Board of Land and Natural Resources), there is no way for the Commission to delegate/assign authority for routine permits until AFTER the rules have been amended. Once the rules are adopted, then staff can seek delegations from both the Commission and Board to process routine permit requests.**

**Required Information for all permit follows; additional information may be requested from staff and a permit is not considered complete until sufficient information is provided to allow for evaluation and processing of permits in a timely manner:**

**Project/Activity Duration** —Applicant must provide information stating the duration of the entire project/activity, as well as the time covered by the request. Duration of any permit will not exceed one year. Permit extensions are dependent on receiving reports for work conducted during the previous year; they may be submitted along with request for renewal/extension. **Failure to do so in advance will result in a denial of any further permitted research/activities in the particular area(s).**

**Project/Activity Location** — Please be very specific, as this indicates our jurisdiction over the area in the permit request. DOFAW is responsible for issuing permits for Natural Area Reserves, Forest Reserves, Wilderness Preserves, and Game Management Areas. Because each of these areas may have their own administrative rules this may result in more than one permit. Permits may also be required by other Divisions within DLNR or by Federal Agencies (as in the case of research involving Threatened and Endangered species). The addresses on page 3 are for DOFAW offices, followed by other Divisions within DLNR that issue permits and can be contacted directly for permits. This list will assist you in contacting the correct offices to obtain the permit(s) necessary before beginning your work.

**Collections** — List by common and scientific names, quantity being proposed, if vouchers will be taken, propagation requests, type of lab work, genetic studies, or other requests. Also indicate if species is native or alien to Hawaii, Threatened or Endangered species, Candidate for listing, or a Species of Concern. The DOFAW administration office in Honolulu is responsible for collection permits for all native species, including federally listed Threatened and Endangered species, Candidate species and Species of Concern on DOFAW managed lands. Bishop Museum, located in Honolulu is the official state repository for all specimens no later than upon project completion, and has first refusal rights for all specimens of native species. Upon accession, duplicate material may be deposited in the host institution of applicant, or other institute with the mutual consent of the Permit Holder, Bishop Museum and Division, as deemed necessary.

**Materials & Methods** — Detail how field work or activity will be accomplished. Be concise but thorough in describing the various study/collecting techniques to be used in the field and the equipment/material to be used (do not expect us to determine/extract this from your reference material). If pesticides are to be used, indicate which ones and attach copies of the labels. For hikes and other such activities, safety precautions, routes, and other information on safe guarding the resources as well as participants should be disclosed.

**Flying and camping** — If you envision camping in non-designated campsites, and/or using helicopters for access, please describe those activities in detail, as these clearances are not normally given. The names of all participants plus specific dates and locations are needed, as separate camping and landing permits are issued. The name of the helicopter vendor is needed, in the case of a landing. Helicopter landing permits are not normally given out for weekends and



Mondays. In especially sensitive locations, camping permits may not be issued and the helicopter may be required to stand-by on site while fieldwork is conducted.

**Validity** — the project must be thoroughly justified. Studies/research with direct management or conservation aspects are greatly encouraged, especially with native and endangered species.

Be sure to:

- Note your affiliation with a valid research, educational institution, or organization and indicate how that institution is supporting this project/activity.
- Provide a study/activity plan showing the value and validity of the research/educational project or activity.
- Show that participating personnel are all essential.
- Provide information on how the results of the research or the activity will benefit the managing agencies or the educational value of the project.
- Provide a local contact (i.e. appropriate museum or university staff/ major professor) or other appropriate contact for reference or safety purposes.

#### **Additional Contact Information:**

##### **Division of Forestry and Wildlife:**

Administration: 1151 Punchbowl St, Room 325, Honolulu, HI 96813; (808) 587-0166; fax (808) 587-0160

Kaua'i Branch Manager: 3060 Eiwa Street, Room 306, Lihue, HI 96766; phone (808) 274-3433; fax (808) 274-3438.

O'ahu Branch Manager: 2135 Makiki Heights Drive, Honolulu, HI 96822; phone (808) 973-9778; fax (808) 973-9781.

Maui Branch Manager (Including Molokai, Lanai, and Kaho`olawe): 54 South High Street, Room 101, Wailuku, HI 96793; phone (808) 984-8100; fax (808) 984-8111.

Hawaii Branch Manager: Mail to: P.O. Box 4849, Hilo, HI 96720; phone (808) 974-4221

##### **State Parks Division:**

State Parks Administrator, 1151 Punchbowl Street, Room 310, Honolulu, HI 96813; phone (808) 587-0289; fax (808) 587-0311.

##### **Historic Preservation Division:**

Historic Preservation Administrator: Kakuhihewa Building, Suite 555, 601 Kamokila Boulevard, Kapolei, HI 96706; phone (808) 692-8015; fax (808) 692-8020.

**Division of Aquatic Resources:**

Aquatic Resources Administrator: 1151 Punchbowl Street, Room 330, Honolulu, HI 96813;  
(808) 587-0110; fax (808) 587-0115.

**Land Division:**

Land Management Administrator: 1151 Punchbowl Street, Room 220, Honolulu, HI  
96813; phone (808) 587-0446; fax (808) 587-0455.