38 Bioprospecting as a conservation tool: history and background

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For millennia, people around the world have studied nature as part of humanity's never ending search for new ways to improve crops for food production, to combat disease and other maladies, and to make other discoveries that might enhance the overall quality of life on Earth. For example, more than half of the top brand-name pharmaceuticals in use in the USA in the early 1990s contained at least one major active compound derived or patterned after compounds first discovered in Nature (Grifo and Rosenthal 1997). In parts of the world where traditional healing practices remain prevalent, direct reliance on useful discoveries from nature is even more pronounced.

Recent advances in biotechnology and related sciences have generated increased activity and interest in the search for useful biochemical compounds or other potentially valuable biological discoveries in Nature—a very old practice that is now sometimes described by a new term: "biodiversity prospecting" or "bioprospecting." In contrast to timber harvesting, mining, and other traditionally consumptive uses of natural resources, research-focused bioprospecting generates value from the results of scientific study involving biological samples. This value-added approach has been enhanced also by developments in intellectual property rights laws, new biorational approaches in specimen collection and drug and other product-development research, and evolving trade practices.

Reflecting the convergence of all these developments, significant value is now attaching to research results involving biological resources found in many special habitats—ranging from tropical rainforests to coral reefs to frozen tundra to national parks and other protected *and* unprotected areas (Marrs and Madigan 1997). In some places, there is an added sense of urgency as habitats and the biodiversity alive within them are threatened or lost before potentially valuable discoveries from research activities can occur. For example, while more than half of all drugs in use have an origin in nature-based research, it also is now recognized that many of the biological species upon which such discoveries depend are at current risk of loss through habitat destruction and other causes (Grifo and Rosenthal 1997).

The collection of biological specimens for scientific research purposes is not new in U.S. national parks. The first research permit authorizing the collection of microbial specimens from hot springs at Yellowstone National Park was issued in August 1898. The current NPS regulations that apply to the collection of biological specimens for scientific research purposes have been in force since 1983 (36 Code of Federal Regulations 2.5).

The best-known example of valuable research results from "bioprospecting" in U.S. national parks was the discovery and isolation in the late 1980s of an enzyme named "*Taq* polymerase." This development resulted from research involving a sample of a tiny microbe called *Thermus aquaticus* that was first collected from a hot spring at Yellowstone National Park. "*Taq*" was used as a reference to *Thermus aquaticus*. A "polymerase" is an enzyme that catalyzes the formation and repair of DNA and RNA from an existing strand of DNA (or RNA) serving as a template. The importance of the research involving *T. aquaticus* and *Taq* polymerase was summarized in congressional testimony offered by D. Allan Bromley (then director of

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the White House Office of Science and Technology Policy and science advisor to President George Bush) before the Committee on Science, Space, and Technology, U.S. House of Representatives, February 20, 1991:

> Different kinds of research and development tend to have different kinds of returns. With basic research—the majority of which is done by individual scientists and small groups of scientists at universities—it is very difficult to predict when, where, and to whom the returns will eventually accrue. Yet even work that can seem highly abstract can have surprisingly immediate impacts. To take just one example, in 1968 Thomas Brock, a microbiologist at the University of Wisconsin, discovered a form of bacteria in the thermal vents of Yellowstone that can survive at very high temperature. From these bacteria an enzyme was extracted that is stable at near-boiling temperatures. Nearly two decades later this enzyme proved to be vital in the process known as the polymerase chain reaction, which is used to duplicate specific pieces of DNA. Today, PCR is the basis of a multimillion dollar business with applications ranging from the rapid diagnosis of disease to forensic medicine.

(It should be noted that Brock was affiliated with Indiana University when *T. aquaticus* was first discovered in 1966 (not 1968); see also Grifo and Rosenthal 1997, xiii.)

Historically, the owners or custodians of biological resources that have been used in many valuable research projects have not been compensated or otherwise positioned to share in the benefits derived from researchers' uses of biological samples (16 U.S Code 5935d). This issue first arose in connection with the use of biological samples obtained by multinational research firms from biologically rich countries in the tropics. The same issue has now arisen in the USA in connection with biological samples taken from units of the National Park System pursuant to well-established research specimen collection permits.

There are three major categories of research-related institutions that are known to have biological materials originally acquired from units of the National Park System pursuant to research specimen collection permits: (1) researchers to whom permits have been issued directly; (2) culture collections and other custodial institutions that have obtained specimens from researchers; and, (3) researchers who have obtained specimens from third parties (such as culture collections) or other researchers.

The National Parks Omnibus Management Act of 1998 (16 USC 5901-6011) mandates increased scientific research activities in the national parks and use of the results of scientific study in park management decisions (16 USC 5932). The new law encourages the use of units of the National Park System for scientific study by public- as well as private-sector scientific researchers (16 USC 5935a) and mandates development of long-term inventory and monitoring activities that provide baseline information and document trends relating to the condition of resources protected by the national parks (16 USC 5934). In addition, the new law authorizes "negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements" in connection with research activities conducted in units of the National Park System (16 USC 5935d).

Against this background, there are two sets of core issues that emerge relating to the collection of biological specimens from national parks for scientific research purposes: access and benefits-sharing.

Access

Access to biological resources in U.S. national parks for research purposes is governed by National Park Service (NPS) regulations. The NPS research specimen collection permit regulations have been implemented since 1983 (48 Federal Register 30252, 30 June 1983; 47 Fed. Reg. 11598, 17 March 1982 (notice of proposed

rulemaking); 64 Fed. Reg. 46211, 24 August 1999). Issuance of a permit is based on a determination by the park superintendent that "public health and safety, environmental or scenic values, natural or cultural resources, scientific research, implementation of management responsibilities, proper allocation and use of facilities, or the avoidance of conflict among visitor use activities will not be adversely impacted" by issuance of a permit (36 CFR 1.6a). Based on public comment at the time the regulations were promulgated, NPS concluded that these determinations are "adequate to ensure protection of park resources" (48 Federal Register 30252, 30 June 1983).

The superintendent's express regulatory authority to issue permits for the collection of research specimens—with terms and conditions deemed necessary to protect park resources—provides the mechanism by which units of the National Park System govern access to their biological resources for research purposes.

"Permit" is defined under the regulations to mean "a written authorization to engage in uses or activities that are otherwise prohibited, restricted, or regulated" (36 CFR 1.4). The regulations also provide that a superintendent "shall include in a permit the terms and conditions that the superintendent deems necessary to protect park resources" (36 CFR 1.6e).

The regulations provide that specimen collection permits "may be issued only to an official representative of a reputable scientific or educational institution or a State or Federal agency for the purpose of research, baseline inventories, monitoring, impact analysis, group study, or museum display when the superintendent determines that the collection is necessary to the stated scientific or resource management goals of the institution or agency and that all applicable Federal and State permits have been acquired, and that the intended us of the specimens and their final disposal is in accordance with applicable law and Federal administrative policies" (36 CFR 2.5b). The regulations do not discriminate against for-profit or other corporate research firms provided that they are engaged in reputable scientific research activities, reflecting the reality that some of the very best science is practiced in private corporations while some of the most entrepreneurial research activities are carried out in universities and other academic institutions.

NPS policy documents also have recognized the importance of units of the National Park System to scientific research activities that might benefit human society as well as the natural environment. For example, Department of the Interior management policies provide that "[i]n recognition of the scientific value of parks as natural laboratories, investigators will be encouraged to use the parks for scientific studies when such use is consistent with NPS policies." The document *NPS 53* (on "Special Park Uses"; see Appendix 12, "Non-NPS Research") defines "acceptable" non-NPS studies as "those which are scientifically valid, consistent with specific park enabling legislation, and contribute to better understanding of park resources and environments or to the use of those resources and environments by people."

Permits are issued after a researcher has submitted a permit application that provides the information required by the park. The process helps ensure that the permit applicant discloses the information required to enable the park to determine that the proposed research activities are consistent with NPS.

There is an important distinction between "sale or commercial use" of natural products collected from national parks (which is prohibited under 36 CFR 2.1c(3)(5)) and the discovery of valuable useful applications from "research results" that can generate potential benefits (whether commercialized or not). This distinction is supported by developments in U.S. intellectual property rights laws and has been explicitly recognized at some national parks that host major research activities, such as Yellowstone. This distinction also has been upheld as valid by at least one federal court *(Edmonds Institute, et al. v. Babbitt, et al.).*

NPS research specimen collection permits operate in ways similar to the biological materials transfer licenses issued by the National Institutes of Health (NIH), which

grant the permittee/licensee the right to use biological materials accessed from NIH. These arrangements are "licenses" (not "sales"), and the transfer of ownership is not necessarily involved (precisely because the operative instrument is a "license to use" and not a "sale").

Benefits-sharing

While the research specimen collection permits issued under 36 CFR 2.5 govern "access" to NPS biological resources for research purposes, section 205(d) of the National Parks Omnibus Management Act of 1998 specifically authorizes "negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements" involving units of the National Park System.

Prior to enactment of this law, NPS evaluated possible use of cooperative research and development agreements (CRADAs) as a potential "benefits-sharing" mechanism in circumstances involving joint research projects between units of the National Park System and visiting scientific researchers. A CRADA is defined by the Federal Technology Transfer Act (15 USC 3710a *et seq.*) as "any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts which are consistent with the mission of the laboratory..." (15 USC 3710a(d)).

CRADAs provide a framework specifically authorized by statute under which private companies and other research collaborators can contribute financial resources and expertise to a Federal laboratory facility to augment its own research in exchange for rights in any resulting useful or valuable discovery arising from the research (15 USC 3710a). CRADAs are authorized under the Federal Technology Transfer Act of 1986 and Executive Order 12591 (requiring federal agency heads to delegate authority to federal laboratories to enter into CRADAs with other federal laboratories, state and local governments, universities, and the private sector). The Department of the Interior's CRADA policy was outlined in May 1996 in a training handbook entitled *Technology Transfer: Marketing Our Products and Technologies.*

The statute defines the term "federal laboratory" to mean "a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government" (15 USC 3710a(e)). At least one federal court has concluded that national park units that host significant scientific research activities (such as Yellowstone) satisfy this statutory definition *(Edmonds Institute, et al. v. Babbitt, et al.).*

On 17 August 1997, Yellowstone National Park announced that it had negotiated a CRADA with a biotechnology research firm from San Diego, California, that already had a research specimen collection permit to collect microbial research specimens at the park. This CRADA is believed to be the first bioprospecting benefits-sharing agreement ever negotiated between a private-sector research firm and a unit of the National Park System that provides that a share of the economic and scientific research benefits will be reinvested directly in the park for resource conservation purposes.

The CRADA negotiated by Yellowstone was designed to operate in conjunction with the terms and conditions of the existing permit. The CRADA does not expand the scope of authorized research specimen sampling activities at the park, but now provides for the sharing of benefits (including payment of royalties and other contributions, training, and technology transfer to Yellowstone).

While the research specimen collection permits authorize access to and research on biological specimens acquired from a unit of the National Park System, CRADAs

provide one possible benefits-sharing mechanism for those parks which satisfy the relevant "federal laboratory" statutory definition to use to recapture future revenues and other benefits.

NEPA

In accordance with an order issued by the U.S. District Court for the District of Columbia on 24 March 1999 *(Edmonds Institute, et al. v. Babbitt, et al.),* NPS is undertaking an analysis under the National Environmental Policy Act (NEPA) concerning the environmental impacts of negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements relating to research activities involving biological specimens acquired from units of the National Park System. The analysis will consider the environmental impacts of several potential benefits-sharing mechanisms that may be available to NPS (including but not limited to CRADAs) that would strengthen conservation of park resources through management of research activities involving specimens collected or derived from units of the National Park System.

References

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