Benefit-Sharing as a Goal of the International Regime: Lessons Learned from Genetic Resources Research at Yellowstone National Park

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Genetic resources research at Yellowstone National Park has a long and rich experiential history that may offer some insights for the international community to consider as discussions continue about how an international ABS regime could further the benefit-sharing aims of the CBD. While the first known genetic-resource specimen collection permit was issued at Yellowstone more than 100 years ago, in August 1898, data relating to research activity at Yellowstone since the 1960s may help clarify some of the factual and procedural issues relating to benefit-sharing as a goal for an international ABS regime. However, although the lessons learned from Yellowstone's experience may have some relevance to these issues, it would be premature to suggest that the lessons learned from Yellowstone necessarily reflect any *national* experience in a country as large and diverse as the United States. Nonetheless, the Yellowstone experience may be one of the most instructive and well-documented.[1]

Who is doing research on genetic resources at Yellowstone?

The identity of most of the genetic resources researchers currently working at Yellowstone largely reflects the characteristics of the research community who is interested in the type of unusual genetic resources, found in abundance at Yellowstone, that are of greatest current scientific interest: namely, the thermophilic ('heat-loving') microorganisms being discovered in the thousands of hot springs and related environments protected and preserved at Yellowstone. Whereas this group reflects the largest single concentration of genetic resources scientists currently conducting research at Yellowstone, there are also many other scientists conducting research on other important biological resources found at the park (such as rare or endangered plants and animals). Although Yellowstone hosts a diversity of genetic resources research projects, research projects that have resulted in discoveries with some potential commercial value have been concentrated in the area of thermophilic microorganisms.[2]

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[*] The views expressed and information presented in this paper have been prepared by the author, and do not necessarily reflect the views or positions of Yellowstone National Park, the US National Park Service, the US Department of the Interior, or any other agency or department of the US Government. The author may be contacted by email at *preston@wfed.org*.

[1] An updated history of Yellowstone's experience that may be of relevance to ongoing ABS discussions will appear in late 2004 in a new book entitled *Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity* (Carrizosa, S., Brush, S.B., Wright, V.D., & McGuire, P.E., eds. (to be published as IUCN Environmental Policy and Law Paper No. 54 (Ch. 8) (Scott, P., 'The United States of America: The National Park Experience', 2004).

[2] Thermophilic ('heat-loving') microorganisms are just one type of 'extremophilic' organisms that thrive in many different types of extreme environments, which have made them of particular interest to science and industry for many years. *See, e.g.,* Madigan, M.T. & Marrs, B.L., 'Extremophiles,' *Scientific American* (April 1997), at pages

All scientific researchers who want to conduct research projects at Yellowstone must be permitted, and US National Park Service (NPS) regulations authorize the issuance of research and specimen collecting permits only to researchers affiliated with reputable scientific organizations.[3] Permits are granted to qualified researchers from academic and non-academic institutions, for-profit and not-for-profit corporate organizations and firms, and governmental and non-governmental entities from the United States and abroad.

While most researchers have some academic affiliation, many do not. In addition, many academic researchers also have some corporate affiliations or support, while corporate researchers also may have some academic connections. In all cases, it is virtually impossible to categorize any researcher as strictly 'commercial' or 'non-commercial' based solely on institutional affiliation.

Most researchers working on Yellowstone's thermophilic microorganisms could be described as working in 'discovery'-related fields. These include researchers who are interested in the discovery of new types of thermophilic microorganisms, as well as researchers who are interested in the discovery of new information about the genetic characteristics of such microorganisms as well as the potential uses of such genetic information and material.[4]

In addition, most such researchers are conducting research in fields where there is some known utility for the type of thermophilic genetic information and material being discovered at Yellowstone. These include a wide range of fields where there is interest in novel uses of enzymes with some potential industrial application and value. Examples include waste remediation, energy production technologies, paper manufacturing, and food processing.[5]

82-87; Adams, M.W. & Kelly, R.M., 'Enzymes from Microorganisms in Extreme Environments,' *Chemical & Engineering News* (Dec. 18, 1995), at pages 32-42.

[3] *See* 36 CFR 1.6 ('Permits') and 2.5 ('Research specimens').

[4] This type of discovery-related diversity among such researchers is exemplified by the principal researchers involved in discovery of *Thermus aquaticus* and subsequent development of the Polymerase Chain Reaction (PCR): *T. aquaticus* was discovered by Dr. Thomas Brock (an academic researcher from Indiana University) in 1966, while a heat-resistant enzyme ('*Taq* polymerase') was subsequently and independently discovered and isolated from *T. aquaticus* by researchers at the Cetus Corporation (a for-profit research firm) who also recognized the utility of *Taq* polymerase for successful development of PCR.

[5] *The Wall Street Journal* has reported that thermophilic microorganisms from Yellowstone have been used in the development or improvement of the following specific types of industrial processes: improving texture of baked goods; converting milk to cheese; tenderizing meat; improving clarity, flavor and foam in beer brewing; removing oils and grease from fabrics; breaking down wood components in paper production; replacing chemicals in paper bleaching; improving textiles' ability to absorb dyes; and, replacing chemicals in tanning leather. *See* Burton, T., 'Yellowstone's Geysers Spout Valuable Micro-Organisms,' *Wall Street Journal*, Aug. 11, 1997, at page B1.

What is the nature of benefits that can be expected from public research organizations and universities?

The types of monetary and non-monetary benefits described in the Bonn Guidelines[6] can be generated from genetic resources research conducted by public research organizations and universities (especially those with competent technology transfer offices). However, the *value* of both types of benefits is dependant on the quality of the research conducted and the demand for any technological or product development resulting from such research. Legal requirements or constraints, institutional capacities and arrangements, and policy considerations also can affect the types of potential benefits that can be generated.[7]

Technology transfer and related economic data collected and reported by the Association of University Technology Managers (AUTM) suggest that the valuable research discoveries resulting from university-related research are frequently licensed for further evaluation or development to other organizations and firms.[8] However, because the data reflects discoveries resulting from a wide range of research fields (not simply biological or genetic), it is not possible to extrapolate from published AUTM data the values resulting from biological or genetic research activities only. Nonetheless, there appear to be some observable patterns worth monitoring. These include increasing sums earned from technology licensing activities over time, higher returns for universities with established technology-licensing offices (compared to newly established offices), but relatively few high-value (greater than US$1 million) revenues resulting from any single discovery or invention.

In order for the provider(s) of any genetic resources, used in the successful development of any such discoveries or inventions, to share in such benefits (if any), there must be some legally-binding contractual or other arrangement. For example, terms and conditions providing for the negotiation of a commercial use license *prior to* commercialization of research results are increasingly common in many contractual agreements. However, the AUTM data suggests that any such economic benefits would be based on a negotiated 'percentage of a percentage' (which could increase over time, but which is not likely in any single case to be very high-value). Nonetheless, failure to take *any* action to negotiate equitable and efficient benefit-sharing arrangements with public research organizations and universities effectively guarantees that *no* benefits will be realized.[9]

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6 UN Doc. UNEP/CBD/COP/6/20 (7-19 April 2002) (Decision VI/24 ("Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization")).

7 For example, Yellowstone and other US national parks have not historically imposed 'access' or other specimen-collecting fees on researchers.

8 *See* Association of University Technology Managers, 'AUTM Licensing Survey: FY 2002' (survey summary of technology licensing and related performance for U.S. and Canadian academic and non-profit institutions, and patent management and investment firms) (available online at *www.autm.net*.). Two-hundred twenty-two (222) U.S. and Canadian universities, teaching hospitals, research institutes, and patent management and investment firms participated in the FY 2002 Survey.

9 *How* equitable and efficient benefit-sharing arrangements could be structured with public research organizations and universities - *and their downstream licensees* - requires substantial additional data and study.

What are the most important factors determining corporate investments in biodiversity-related research of a commercial nature?

While Yellowstone does not monitor 'corporate investments' in biodiversity-related research that could have some potential commercial value, it has been observed that researchers desire legal certainty and administrative transparency and efficiency with respect to permitting authorizations and the reasonable treatment of any valuable research results (particularly in connection with intellectual property rights). They also are attracted by concentrations of novel genetic resources that are perceived to provide important opportunities for making new discoveries that could be valuable to science as well as to some potentially useful (and therefore valuable) industrial application. Coupled with their interest in the biological resources themselves, firms also have been observed to be willing to increase the value of their research-related investments when it is clear that the investment is supporting sound biodiversity management practices that in turn protect the resources for the future.

Can biodiversity/genetic resources alone be enough to attract foreign direct investment or are other factors that support private sector innovation (e.g., S&T infrastructure, incentives) also necessary? In other words, is biodiversity a necessary but not sufficient condition to attract private sector investment?

While the concept of 'private sector investment' is not germane in the Yellowstone context because of its special position as a premiere national park, the combination of important genetic resources of significant scientific interest coupled with well-established legal and administrative structures have contributed to Yellowstone's ability to attract substantial scientific research activities (particularly in recent years). It should be noted that it is the policy of NPS to encourage scientific research activities in US National Parks (including but not limited to private sector researchers),[10] and this policy is implemented in part through updated research permit guidelines designed to improve the administrative transparency and certainty relating to permitting procedures.[11] Although these measures are not intended to attract 'investment' (as that term is used for purposes of this discussion), they are intended to attract qualified researchers to undertake valuable research activities in US national parks. Accordingly, in order to attract and cultivate meaningful and productive 'investment' in biodiversity-related programs, there must be important biological resources that are protected, demand for those resources by qualified research institutions, and the political will to implement and manage pragmatic and effective ABS policies and goals.

What is the probability of research success and time frame for realizing benefits from research on genetic resources used to develop innovative to [sic.] pharmaceutical products?

It is difficult if not impossible to predict with any reasonable degree of certainty the probability of 'research success' (which has been described as a 'random variable'[12]).

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[10] See, e.g., National Parks Omnibus Management Act of 1998, 16 USC § 5935.

[11] See National Park Service, Research Permit and Reporting System (available online at *http://science.nature.nps.gov/research*).

[12] See Artuso, A., 1997. *Drugs of Natural Origin: Economic and Policy Aspects of Discovery, Development, and Marketing,* p 121.

However, the number of patents that are known to have been granted on inventions resulting from research involving the use of genetic material originally collected from Yellowstone suggests that this type of 'research success' has occurred with some regularity since the 1980s, and continues. For example, there have been more than 40 such patents granted since the early 1980s (the most recent in June 2003). All have involved the use of microorganisms or genetic material isolated from such microorganisms. The commercial success of the patents resulting from the isolation of *Taq* polymerase from *T. aquaticus* and its use in the development of PCR has been widely reported. The economic value of the other patents is not known because NPS has not historically required the reporting of such information.

Likewise, it is difficult if not impossible to predict with any reasonable degree of certainty the 'time frame for realizing benefits.' However, the Yellowstone experience suggests that the 'time frame' may be significantly shorter for developments in fields focusing on the discovery of enzymes and other bioactive molecules than in pharmaceuticals (widely reported to be more than ten years). For example, the Diversa Corporation announced in 2002 that it had developed a new enzyme product ('*Pyrolase 200*') from Yellowstone-related research initiated in the 1990s.

If 'success' is meant to be something less than final product development and marketing, the 'time frame' also can be shorter. For example, benefit-sharing agreements that provide for milestone payments or other research, *process*-related 'success' can generate the economic circumstances required to trigger a negotiated payment obligation sooner than final product development and marketing.

What type of biodiversity-based products or markets (e.g. microorganisms, food, low regulatory costs) are likely to yield financial benefits from successful commercial products and processes in the short-term?

There have been many studies that have attempted to document the range of products and markets that can yield monetary benefits from successful biodiversity-related research results.[13] While there is a wide and growing diversity of such products and markets, it would appear that high-value but highly-regulated products and markets (such as pharmaceuticals) do not yield product-related benefits in the short term. The record of discoveries resulting from microorganisms originating from Yellowstone suggests that enzyme and other molecular-related developments can yield benefits earlier. However, *no* benefits are yielded in either the short- or long-term *unless* some benefit-sharing arrangement is in place.

What country-to-country scientific partnerships/models might lead to the successful commercialization of products and resulting benefit-sharing?

All of the research activities that have been undertaken involving the use of genetic resources first collected at Yellowstone, and that yielded research results that could have generated benefits, have involved individual researchers affiliated with some reputable scientific organization (either from the United States or abroad). Yellowstone does not discriminate against non-US research applicants or their affiliated institutions; all applicants are subject to

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[13] See, ten Kate, K., & Laird, S., 2000. *The Commercial Uses of Biodiversity*. *See also* Bull, A., Ward, A., & Goodfellow, M., 2000. *Search and Discovery Strategies for Biotechnology: the Paradigm Shift*, Microbiology and Molecular Biology Reviews (American Society for Microbiology) (Sept. 2000), p 573-606.

the same regulatory requirements, terms and conditions. However, the record suggests that all active Yellowstone-related genetic resource research activities that have lead to the successful commercialization of products have been developed and conducted at some ‘organizational’ or ‘institutional’ level presumably since the successful commercialization of products rarely occurs at ‘country-to-country’ levels.