

NPS Benefits Sharing: A Revolutionary Concept for Parks

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TO SAY THAT THE REVOLUTIONARY INVENTION OF THE POLYMERASE CHAIN REACTION (PCR), as refined and used today, is a legacy of *Thermus aquaticus* (the extremophile bacterium that Thomas Brock collected from Yellowstone National Park in the 1960s), is no exaggeration. To say that the revolutionary concept of National Park Service (NPS) benefits sharing is also a legacy of *Thermus aquaticus*, likewise, is no exaggeration. PCR has been described as one of the most important new scientific technologies of the twentieth century. That makes it revolutionary. But what is NPS benefits sharing and what makes it revolutionary? Further, how does each relate to a microbe from Yellowstone National Park? The stories are fascinating.

What's the PCR story?

In 1966, Thomas Brock, a microbiologist at Indiana University, was studying microorganisms living in Yellowstone National Park's thermal pools. He named one of the organisms, a bacterium that he discovered in a sample from a thermal pool, *Thermus aquaticus*. This microorganism lives and thrives in water so hot that it would kill an ordinary plant or animal. Dr. Brock learned how to grow *Thermus aquaticus* in the laboratory and deposited a living sample at the American Type Culture Collection (a repository maintaining living cultures of microorganisms) for safekeeping and distribution to other researchers, upon request.

In 1985, Cetus Corporation, a biotechnology company, was working on developing a new way to duplicate genetic material to facilitate genetic studies; individual molecules of DNA are too small to study effectively. The key to working with DNA was to replicate the DNA molecules in order to get enough to study. A scientist at Cetus, Dr. Kary Mullis, had previously invented a way to duplicate DNA, for which he received a Nobel Prize. This new process was called the polymerase chain reaction (PCR). But, PCR required high temperatures, which destroyed the polymerase enzymes in the method being used at the time, requiring laboratory technicians to tediously add fresh enzymes throughout the PCR process.

Then, Dr. Mullis's colleagues at Cetus added an enzyme to PCR that had the unusual ability to keep working at high temperatures. Using a previously published process, they isolated that enzyme, Taq polymerase, from the Yellowstone *Thermus aquaticus*, which they had gotten from the American Type Culture Collection. PCR using Taq polymerase was so effective that a whole

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new scientific field has flourished as scientists finally had a convenient way to study DNA. Dr. Brock's academic work in Yellowstone had a practical application that he never imagined during his studies 25 years previously.

Today, the DNA copying process, made practical because of a series of studies using a Yellowstone microorganism, is widely used. Taq polymerase has led to the uses of DNA that are so familiar today, from matching DNA in criminal investigations, to medical diagnoses or cures, bioremediation of toxic wastes, and research into the basic building blocks of life.¹ The commercial uses of PCR are part of a multi-billion dollar industry.

What's the NPS benefits-sharing story?

For NPS, benefits sharing occurs when NPS receives monetary or other benefits from a discovery or invention with a commercial application resulting from research originating under an NPS scientific research and collecting permit, or other permit or authorization. If benefits sharing had been in place at the time of the refinement of the PCR invention using Taq polymerase, NPS would likely be sharing directly in the benefits from the PCR revolution. Instead, the PCR revolution drew attention to the possibilities for benefits sharing in parks. But, as with most revolutionary concepts, there were multiple forces at work.

In 1997, NPS (Yellowstone National Park) entered into a cooperative research and development agreement (CRADA) with the biotechnology firm Diversa Corporation. In 1998, Congress enacted the National Parks Omnibus Management Act (NPOMA), which authorizes the secretary of the interior to "enter into negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements" (54 USC 100705(d)).

In response to a legal challenge (*Edmonds Institute v. Babbitt*, 93 F. Supp. 2d 63 (D.D.C. 2000)), a federal court upheld the NPS-Diversa CRADA but required NPS to complete a National Environmental Policy Act (NEPA) analysis of the CRADA. Accordingly, NPS prepared a final environmental impact statement (FEIS) and, in March 2010, issued a record of decision (ROD) to implement benefits sharing servicewide.²

In 2013, the NPS director issued the benefits-sharing policy (Director's Order #77-10), and in 2014 the NPS Benefits-Sharing Handbook became available (see www.nps.gov/applications/npspolicy/DOrders.cfm). The overall basis for NPS negotiating benefits sharing is the NPS role in preserving and providing access to research sites and the opportunity to collect, study, and use the resources therein. This NPS contribution often represents decades of work. In some cases, NPS also makes available research data, conclusions, or other assistance that informs and supports the research permittee's, or other authorized researcher's, efforts. In other words, the U.S. government has a compensable interest in the research results (compensable interest is a legal share in physical or intellectual property that is entitled to compensation when others use that share of the property).³

NPS policy provides that the parks will be the beneficiaries, but policy also limits how the parks may use the benefits. Parks may use benefits to improve conservation and protection of park resources and strengthen the scientific capacity of NPS scientists through collaboration with other governmental and non-governmental researchers. Parks must document and annually report use of monetary and non-monetary benefits.

What obligates researchers to share benefits?

The scientific research and collecting permit, loan agreements and other agreements that authorize the use of (and track) collected specimens and progeny and unmodified derivatives of collected specimens, museum specimens, or living collection specimens, contain terms and conditions that obligate the signatories to discuss and, as appropriate, develop agreements to share or decline

benefits with NPS. These terms and conditions provide that the:

- Permittee, borrower, user, or recipient (henceforth “researcher”) agrees not to use the collected specimens, museum specimens, progeny, unmodified derivatives, or research results for commercial purposes without first entering into an agreement to share benefits or an agreement wherein NPS declines to share benefits.
- Researcher agrees not to provide the collected specimens, museum specimens, or their progeny and unmodified derivatives to third parties without prior written NPS authorization.
- Sale or commercial use of natural products, such as collected specimens, is prohibited (36 CFR 2.1).
- NPS may seek specific remedies in the event terms and conditions are not met.⁴

Although NPS issues scientific research and collecting permits for scientific or educational purposes only, scientific research may result in a patentable product or process that has commercial value. For example, a researcher authorized to study frog chemical defenses might discover a toxin that has medicinal value, and develop and patent a way to synthesize the toxin.

The onus of responsibility is on the authorized researcher to notify NPS of a potential commercial application. Then NPS evaluates the potential commercial application and decides whether to negotiate benefits sharing or decline benefits sharing. The park research coordinator is generally aware of the progress of permitted research and the curator is aware of research with collections. Because these individuals maintain contact with the researchers, the researchers are likely to notify these park employees of potential commercial applications. These employees, in turn, notify the park benefits-sharing coordinator, who must have no responsibility for issuing permits or other authorizations in order to avoid conflict of interest.

A “firewall” must exist between granting permits and authorizations, and negotiating and managing benefits sharing. Considerations to issue research permits and other authorizations must be kept separate from decisions regarding benefits sharing. The superintendent must not consider past or potential benefits while making a decision to issue a permit.⁵

When considering potential benefits, NPS may negotiate with the party that proposes commercialization for monetary or non-monetary benefits (or both). The benefits are then documented in a benefits-sharing agreement that both parties sign.

Monetary benefits would be payments that derive from the development and commercialization process, such as up-front payments, annual maintenance payments, performance-based payments, or milestone payments (payments that occur at a defined stage of research and development).⁶

Non-monetary benefits include the sharing of knowledge, research relationships, and providing training, supplies and equipment, or special services. Examples of non-monetary benefits include the following: a company that made an invention based on toxins from ants agrees to participate in the park’s ongoing inventory of insects for six years; a company agrees to train park staff in some molecular biology techniques; and a company agrees to give the park DNA extraction kits and DNA “primers.”⁷

NPS makes a decision on a case-by-case basis whether to seek benefits. NPS would seek to share benefits when the potential benefits would have value to NPS and the general public. NPS would decline to share when potential benefits would not create value for NPS and general public. When, after careful consideration, the park decides to decline benefits sharing, the park must draft a letter of agreement, or other agreement, to be signed by the parties wherein the park declines to share in benefits and states any other terms and conditions that may apply. Parks may decline

benefits sharing based on technical or economic reasons, not on an opinion as to whether the commercial activity should occur.⁸

NPS does not require a benefits-sharing agreement when the park superintendent determines that commercial use of research results is primarily educational and would benefit the general public, for example, through scholarly journals, textbooks, field guides, and museum exhibits.⁹

The act (NPOMA) authorizing NPS to negotiate benefits sharing does not specify the mechanism or process to use in sharing benefits. NPS looks to other existing authorities to enter into agreements and receive and retain monetary and non-monetary benefits. Benefits-sharing agreements are between parks and entities other than individuals; are made public, except for confidential information protected by law; and do not authorize any research activities in parks or any activities that require an NPS permit, loan agreement, or other authorization. Generally, benefits-sharing agreements qualify for NEPA categorical exclusion. All NPS agreements are reviewed by the Department of the Interior, Office of the Solicitor.

The NPS benefits-sharing agreement types and authorities are as follows:

- **CRADA:** the Federal Technology Transfer Act (FTTA) authorizes parks designated as federal labs to enter into CRADAs, manage federal lab inventions and intellectual property, and retain revenue and other benefits received from federal and non-federal parties. NPS may also provide non-monetary benefits to the other party (15 USC 3710). Note: a federal lab is a “facility owned ... or otherwise used by a Federal agency;” a “substantial purpose of which is the performance of research.”
- **General agreements:** NPS policy, Director’s Order (DO) #20: Agreements, available at www.nps.gov/policy/DOrders/DOrder20.html, authorizes parks to receive non-monetary benefits. Non-federal parties may provide monetary benefits to the U.S. Treasury.
- **Cooperative agreements:** under the provisions of 54 USC 101702, parks may use a cooperative agreement for benefits sharing when NPS receives from or provides to a cooperator a monetary benefit (money or property, services with an assigned monetary value, or anything else of monetary value) and has substantial involvement in the project, which must have a public purpose. Cooperators may include educational institutions and state and local governments that may provide monetary or non-monetary benefits.¹⁰

To make payments, the other party to the agreement uses the pay.gov system to make electronic payments to NPS using the automated clearing house (ACH) system, a credit card, or PayPal. All standard NPS accounting and procurement procedures apply to receipt and expenditure of funds. The FTFTA requires that funds be obligated within two fiscal years from the end of the year when the federal agency received the funds. Funds must be spent to enhance resource protection or to offset costs of administering benefits sharing.¹¹

Parks annually report to NPS headquarters on new and current benefits-sharing agreements and monetary and non-monetary benefits received. In addition, parks that are federal laboratories must report on patents, licenses, and inventions as required by the FTFTA. In accordance with the FTFTA (15 USC 3710c(a)(1)(A)(i)), when an NPS federal laboratory receives royalties or other payments from the licensing and assignment of inventions under CRADAs, the NPS unit pays the first \$2,000 each year, and thereafter at least 15 percent of the royalties or other payments, other than payments of patent costs as delineated by a license or assignment agreement, to the inventor or co-inventors, if the inventor’s or co-inventor’s rights are assigned to the USA.¹²

How does NPS benefits-sharing compare to the global perspective on access and benefits sharing?

NPS benefits-sharing is generally consistent with the Bonn Guidelines on Access to Genetic Re-

sources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, which were adopted in 2002 by the parties to the United Nations Convention on Biological Diversity (CBD). These voluntary guidelines identify general steps that may be established, in appropriate circumstances, for obtaining access to genetic (non-human) resources, seeking prior informed consent of providers, and determining the basis for benefit-sharing. The United States is not a party to the convention or its protocols (for further information see www.cbd.int/abs/bonn/).

In addition, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) is an international agreement under the CBD adopted in 2010. It entered into force on October 12, 2014. The United States is not a signatory to the Nagoya Protocol, but NPS participated in the Nagoya discussions. Many countries' rules are evolving regarding access to, and use of, genetic resources. Countries' domestic regimes implementing the Nagoya Protocol and the CBD may seek to impose restrictions on research, use, or resulting commercialization with respect to genetic resources in those countries (see www.cbd.int/abs/about/ for further information).¹³

What does the future hold for NPS benefits sharing?

Although in 2014 NPS issued over 3,100 scientific research and collecting permits, had over 5,300 active permits, entered into 250 new loan agreements, and had 850 active loan agreements designated for research or object conservation, only one park reported that researchers identified potential commercial applications for their research results. In the two reported cases, the park signed letters of agreement declining benefits sharing.

The revolutionary concept of NPS benefits sharing will, necessarily, be slow to materialize in practice. Researchers rarely have discoveries that lead to potential commercial applications. Most research results contribute to science or education and have no commercial application. Nevertheless, we know from the story of *Thermus aquaticus* that significant commercial applications can happen. NPS now has the authority and the tools to move forward with benefits sharing when the opportunity arises.

Endnotes

1. NPS [National Park Service], "What Kinds of Research Can Lead to Benefits Sharing?" (www.nature.nps.gov/benefitssharing/research.cfm).
2. NPS, *NPS Benefits-Sharing Handbook* (Washington, DC: NPS, 2014), Section 1.2.
3. *Ibid.*, Section 1.1 and glossary.
4. *Ibid.*, Section 4.2.
5. *Ibid.*, Section 13.1.
6. *Ibid.*, Table 7.
7. *Ibid.*, Table 9.
8. *Ibid.*, Section 6.5.
9. *Ibid.*, Section 1.6.
10. *Ibid.*, Section 6.0.
11. *Ibid.*, Sections 8.0 and 9.0.
12. *Ibid.*, Section 7.5.
13. *Ibid.*, Section 12.1.