Appendix G

Background for Benefits-Sharing and Technology Transfer

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Although this FEIS has been prepared due to the precedent-setting nature of implementing benefits-sharing in the National Park Service (NPS), benefits-sharing has already been implemented by various other organizations in the U.S. and around the world. For purposes of this FEIS, the term "benefits-sharing" refers to the equitable and efficient sharing of benefits between researchers, their institutions, and a land management agency that result from research involving research specimens originating from the lands under that agency's jurisdiction.

Appendix G provides an overview of existing benefits-sharing arrangements. Depending on the facts and circumstances, the research results subject to a benefits-sharing agreement may generate either monetary or non-monetary benefits (or both). Existing benefits-sharing arrangements were examined by the NPS in preparation for proposing to implement benefits-sharing.

G.1 Benefits-Sharing by the U.S. Government

A U.S. Government agency (the National Cancer Institute) initiated the earliest known benefits-sharing agreements in 1988.[1] Two examples of benefits-sharing agreements that were developed in the 1990s by U.S. Government agencies are described in this section: the Yellowstone–Diversa Cooperative Research and Development Agreement (CRADA) and the International Cooperative Biodiversity Groups program.

G.1.1 Benefits-Sharing in the NPS: The Yellowstone–Diversa CRADA

Despite the phenomenal success of the discoveries relating to *Thermus aquaticus* by private-sector researchers, Yellowstone National Park did not share any of the resulting benefits. As a consequence, the large economic gains resulting from the successful research activities involving samples of *T. aquaticus* first acquired from Yellowstone has prompted headlines such as "Industries Exploit First Park."[2]

In the mid-1990s, prior to enactment of the National Parks Omnibus Management Act of 1998, the NPS evaluated the potential use of CRADAs as a "benefits-sharing" mechanism in circumstances involving joint research projects between units of the National Park System and visiting scientific researchers.

In August 1997, Yellowstone announced that it had negotiated a draft CRADA with the Diversa Corporation of San Diego, California, a biotechnology research firm that already had an NPS research permit to conduct research and collect microbial research specimens at the park, and whose scientists had been conducting research at Yellowstone for many years. Although the mechanisms and mandates authorizing and implementing CRADAs had been in place government-wide for more than a decade, the Yellowstone–Diversa CRADA was the first benefits-sharing agreement ever negotiated between a private-sector research firm and a U.S. national park.

The Yellowstone–Diversa benefits-sharing agreement provided that a portion of the economic and scientific benefits from discoveries made during Diversa's ongoing laboratory research involving research specimens collected at Yellowstone would be provided directly to the park for resource conservation purposes.[3] The benefits to be shared included payment of royalties and other monetary benefits, scientific training, and technology transfer to Yellowstone.

The CRADA negotiated by Yellowstone was designed to operate in addition to the terms and conditions of Diversa's existing research permit. The agreement did not expand the scope of authorized research specimen collection activities at the park.[4]

The Yellowstone–Diversa agreement was revised and finalized in May 1998, after review by the NPS Office of the Solicitor and the NPS director and receipt and consideration of comments from the public.

In early 1998, the Yellowstone–Diversa CRADA was challenged in the U.S. District Court for the District of Columbia. The plaintiffs alleged that the CRADA violated the NPS Organic Act (16 USC § 1), Yellowstone National Park Organic Act (16 USC § 21), Federal Technology Transfer Act of 1986 (FTTA) (15 USC §§ 3710a–3710d), NPS regulations (36 CFR §§ 2.1 and 2.5), the Administrative Procedure Act (5 USC §§ 702, 706), and the so-called "public trust doctrine." The plaintiffs also alleged that the NPS failed to comply with the National Environmental Policy Act before negotiating the CRADA with Diversa. This FEIS is being prepared to comply with the court's decision.

The court dismissed the plaintiffs' case with prejudice and upheld the Yellowstone–Diversa CRADA as consistent with the NPS Organic Act, Yellowstone National Park Organic Act, FTTA, NPS regulations, and the public trust doctrine.[5] The court also required the NPS to "suspend implementation of the Yellowstone–Diversa CRADA pending the completion of any and all review mandated by the National Environmental Policy Act"[6] due to the precedent-setting nature of the Yellowstone–Diversa agreement within the NPS.[7]

The court's analysis concluded that units of the National Park System (such as Yellowstone) that satisfy the definition of a federal "laboratory" provided in the FTTA are eligible to negotiate CRADAs with qualified researchers. The FTTA defines "laboratory" as "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."[8] The statute also gives federal agencies broad discretion in making laboratory determinations.[9] The legislative history explains that "[t]his is a broad definition which is intended to include the widest possible range of research institutions operated by the Federal Government."[10]

The plaintiffs appealed the court's decision upholding the Yellowstone–Diversa CRADA under the NPS Organic Act, the Yellowstone National Park Organic Act, the FTTA, and NPS regulations in the U.S. Court of Appeals for the District of Columbia Circuit. After the NPS filed a brief in support of the U.S. District Court's ruling upholding the Yellowstone–Diversa CRADA, the plaintiffs asked the federal appeals court to dismiss their own appeal. The appeal was dismissed on December 22, 2000.

In 2002, the Diversa Corporation introduced an enzyme product for sale to the petroleum industry that was developed from research involving microbes first collected from Yellowstone. Although the discovery that led to development of the product involved research on microbial research specimens Diversa had collected at Yellowstone, the product ("Pyrolase 200™") was synthesized in Diversa's laboratories in San Diego. Diversa reports that Pyrolase 200™ can assist with the extraction of oil from underground reservoirs as well as with textile processing.[11] Diversa's revenues from Pyrolase 200™ are not known.[12] Because the Yellowstone–Diversa benefits-sharing agreement is currently suspended, Yellowstone National Park is realizing no benefits from Diversa's successful development of Pyrolase 200™.

G.1.2 International Cooperative Biodiversity Groups

In 1992, four federal agencies combined efforts to launch the International Cooperative Biodiversity Groups (ICBG) Program, which provides grants to fund research projects. The IGBC Program aims to promote conservation, discover new drugs, and "ensure that equitable economic benefits from these discoveries accrue to the country of origin."[13]

The agencies sponsoring the program are the National Institutes of Health (NIH), the National Institute of Mental Health (which subsequently became part of the NIH), the National Science Foundation, and the U.S. Agency for International Development (USAID). Acting together, the agencies sought to respond to scientific and public concern about three interdependent issues: (1) conservation of biodiversity among the world's plant and animal resources, (2) sustained economic growth for developing countries, and (3) discovery and development of pharmaceuticals from natural products to improve human health.

In 1997, a panel of six experts reviewed the five ICBG projects that were conducted between 1992 and 1996. The panel's findings and recommendations relating to the "benefits-sharing" aspects of the projects are included in the report.[14] The report identified the types of benefits (both monetary and non-monetary) that could be generated from a project, and some of the related factors relevant for directing benefits to achieving the conservation goals of the ICBG Program.[15]

Monetary benefits included in the terms of these cooperative agreements include, for example:

- Up-front payments based on the potential commercialization of products as well as royalty and milestone payments;
- Contributions by participating industries and local governments;
- Venture capital, risk funds, and trust funds obtained from interested parties; and
- Additional support from USAID, The World Bank, foundations, and other donor organizations.

Non-monetary benefits realized from ICBG projects as of 2002 include:

- More than 250 novel bioactive compounds discovered;
- 25 lead therapeutic compounds for malaria, leishmaniasis, tuberculosis, HIV, various bacterial infections, cancer, and crop protection identified and isolated;

- New species of plants, fungi and insects identified;
- Increased laboratory and field capacity developed in 12 countries;
- 3,000 people trained in multiple scientific disciplines;
- New and enhanced local databases on biodiversity distribution in participating countries;
- New publications in chemistry, biodiversity, and related policy matters; and
- Initiated creation of at least one new biodiversity reserve.

G.2 Benefits-Sharing Around the World

Benefits-sharing related to research results has been implemented or is under development in many countries around the world. The benefits-sharing program in Costa Rica began in 1991, and is described below. The United Nations guidelines for collecting research specimens and establishing benefits-sharing agreements are also described.

G.2.1 Costa Rica: Benefits-Sharing Since 1991

Costa Rica has an extensive system of national parks and conservation areas. When researchers propose study of specimens from those areas that could result in commercial applications, the National Biodiversity Institute (INBio) of Costa Rica develops research agreements that include benefits-sharing terms. INBio is a non-governmental, non-profit, public interest organization that supports efforts to develop scientific information about the country's biological diversity and to promote its sustainable use.[16]

Since 1991, INBio has acted as an intermediary for a variety of national (Costa Rican) and international research organizations wishing to study biological materials collected from Costa Rica's extensive system of national parks and conservation areas, and Costa Rica's Ministry of Natural Resources, Energy and Mines (MINAE), which manages them. In projects that involve biological research activities that could produce results with some valuable commercial application, INBio negotiates and develops collaborative research agreements that include benefits-sharing terms.[17] The terms of every benefits-sharing agreement are different based on differing facts and circumstances, and specific royalty payment totals are treated as confidential business information.[18] In 2001 and 2002, INBio reported that the total revenues generated from these agreements were almost $2 million each year. INBio provides a portion of that revenue to the government agency that manages national parks.

An underlying long-term cooperative agreement between INBio and MINAE provides for two types of research-related payments from INBio to MINAE; ten percent (10%), up-front, of the total annual budget for each respective research project's work in Costa Rica; and fifty percent (50%) of any future royalties or other economic benefits (if any) subsequently earned by INBio if a revenue-generating product results from the collaborative research project.[19]

In 1991, the earliest of these agreements was announced between INBio and Merck &

Company.[20] In that agreement, Merck agreed to an initial two-year research and biological sampling budget of $1,135,000, royalties on any resulting products, and technical assistance and training to help build pharmaceutical research capacity in Costa Rica.[21]

Since 1991, INBio has negotiated many additional agreements with other research firms.[22] While INBio has not published the total revenue earned from all such agreements,[23] a study published in 2001 identified 18 agreements negotiated between September 1991 and February 1998, and noted that INBio had contributed $2,947,911 to research and conservation programs in Costa Rica from the resulting revenues.[24] Information reported by INBio indicates that this sum is approximately 10% of the total revenues received by INBio from such agreements during that period.

G.2.2 The Bonn Guidelines

The United Nations has promulgated the Bonn Guidelines, which make recommendations for permitting access to research specimens and for establishing fair and equitable benefits-sharing agreements.[25] The Bonn Guidelines were developed as a result of a series of meetings organized under the United Nations Convention on Biological Diversity (CBD) between 1999 and 2001 that examined available case studies and best practices for access and benefits-sharing issues. The Bonn Guidelines identify ways that governments and other biological resource managers could implement benefits-sharing programs, and include examples of the wide variety of both monetary and non-monetary benefits that could be part of a benefits-sharing agreement (see Chapter 4, Section 4.4.1).[26] The importance of non-monetary benefits can often be expected to exceed the importance of monetary benefits.[27]

The Bonn Guidelines provide recommendations for establishing fair and equitable benefits-sharing agreements with mutually agreed terms that are intended to achieve:

(a) Legal certainty and clarity;

(b) Minimization of transaction costs;

(c) Inclusion of provisions on user and provider obligations;

(d) Development of model agreements;

(e) Different uses may include, among others, taxonomy, collection, research, and commercialization;

(f) Timeliness and efficiency (mutually agreed terms should be negotiated efficiently and within a reasonable period of time);

(g) Mutually agreed terms should be set out in a written instrument.

Although not a party to the CBD, the U.S. actively participated in and contributed to the process that resulted in the Bonn Guidelines.[28] In addition, at the September 2002 World Summit for Sustainable Development in Johannesburg, South Africa, the U.S. supported adoption of the Johannesburg Plan of Implementation as it relates to the Bonn Guidelines.

Additional information about ongoing development and implementation of benefits-sharing concepts and management approaches can be found through the CBD Secretariat's website, <http://biodiv.org>.[29]

G.3 Commercial Use of Research Results Discovered by Federal or Academic Scientists

In general, federal and academic institutions do not themselves commercialize research results. Usually, intermediate research results (the intellectual property of the researcher and his institution) are offered for sale, lease, license, or other transfer for value to another institution for further research and development and eventual commercialization. The term "technology transfer" is used when such intellectual property is sold, leased, licensed, or otherwise transferred for value.

G.3.1 Federal Technology Transfer

The experience of other federal agencies related to the commercial use of research results is reported in the Department of Commerce (DOC)'s annual Technology Transfer Reports.[30] Because the NPS has identified CRADAs as the agreement type for implementing benefits-sharing under Alternative B (see Chapter 2, Section 2.4.2.1), CRADA use by other agencies is reviewed first, followed by information about research results with commercial applications (termed "inventions") and income from technology transfer.

It is the policy of the U.S. Government to improve the economic, environmental, and social well-being of the United States by encouraging cooperative research and development projects involving federal and non-federal entities. Congress has stated, "Cooperation among academia, Federal laboratories, labor, and industry, in such forms as technology transfer, personnel exchange, joint research projects, and others, should be renewed, expanded, and strengthened."[31]

Federal laboratories have used CRADAs since 1987. Department of the Interior bureaus have increased their use of CRADAs from 10 or fewer per year in the early 1990s to 50 active CRADAs in FY2001 (*see* Figure G.3.1-1).[32]

Researchers at federal laboratories reported research results with commercial applications (termed "inventions" in DOC reports) at an average of approximately 3,900 annually from FY1999–FY2003. Federal laboratories disclosed almost twice as many inventions as patent applications (*see* Figure G.3.1-3).

Federal agencies derive income from the licensing of inventions (whether patented or not) to other research institutions for further research, development and commercialization. Income from licensing, including royalties and other payments, was $97 million across all federal laboratories in FY2003, averaging approximately $16,000 annually per license from FY1999 to FY2003.[35]

In the NPS, benefits-sharing likely would be related to biological research (*see* Section 1.2.4). Virtually all current licensing of biological materials for research is managed by the Department of Health and Human Services (HHS).[36] HHS's income from licensing was approximately $55 million in FY2003, accounting for 56% of all federal laboratory licensing

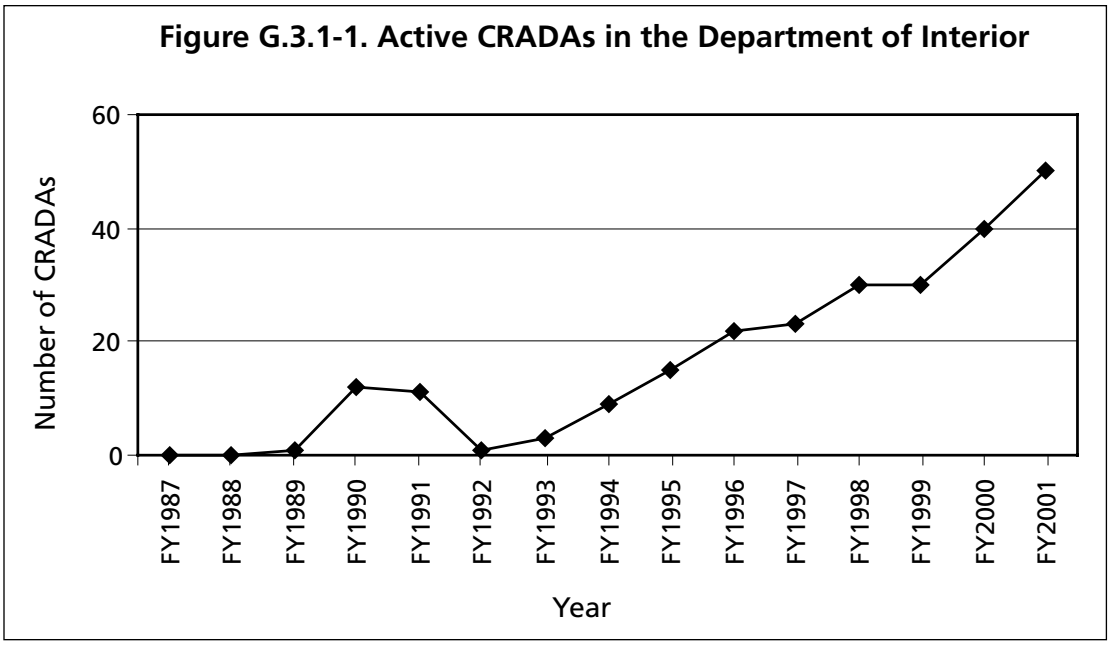

Figure G.3.1-1. The number of active CRADAs managed by the Department of the Interior is increasing.

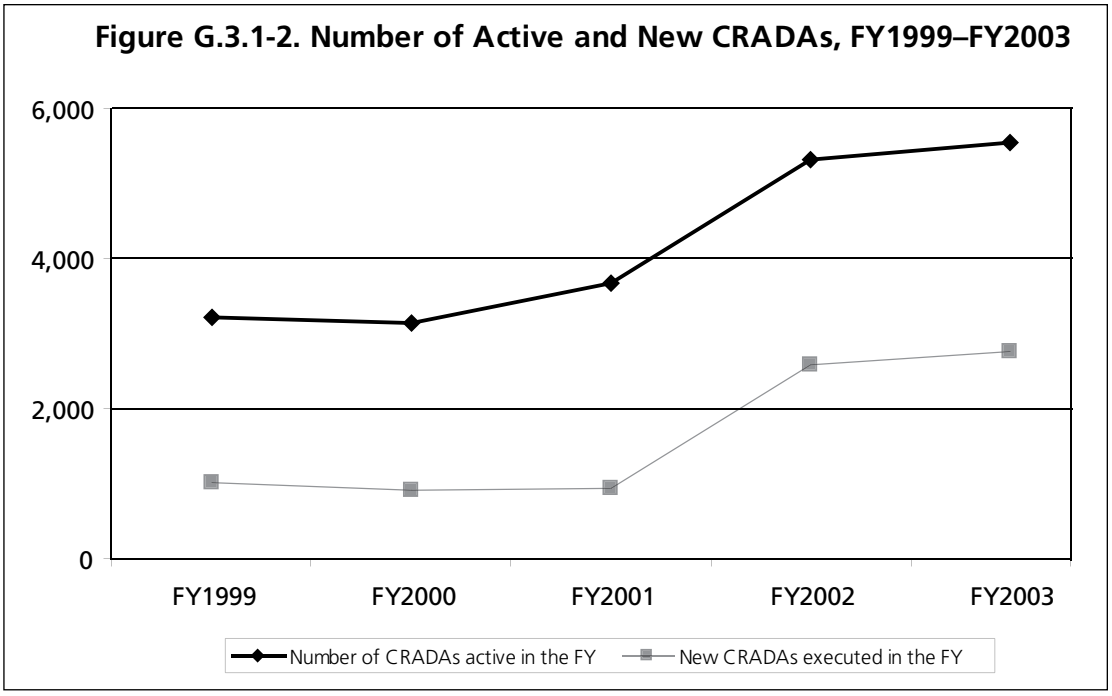

Figure G.3.1-2. Several thousand CRADAs were active annually from 1999 through 2003.

income. In 2004, the DOC concluded that the high proportion of federal laboratory license income generated by HHS licenses is "no doubt reflecting the competitively high economic value and strong commercialization opportunities associated with new technologies in the biosciences realm."[37]

Royalties (when obligated) are earned by federal agencies based on the licensee's income from commercial activities. Royalty income from licensing in FY2003 ranged from individual

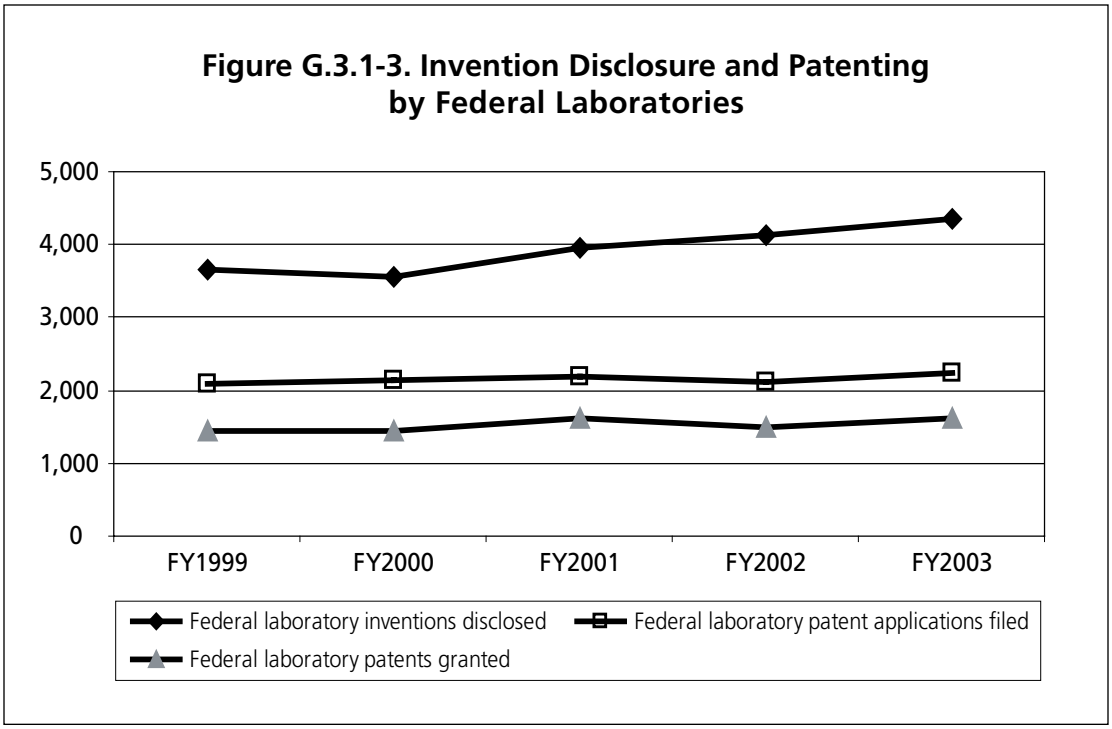

Figure G.3.1-3. During the five-year period FY1999–FY2003, federal researchers reported discovering approximately 3,900 inventions (commercial applications for research results) annually.

license agreements yielding only several dollars to one yielding $1.5 million. Median royalty income per reported royalty-bearing license ranged from a low of approximately $700 to a high of approximately $9,500 annually.[38]

G.3.2 Academic Technology Transfer

The Association of University Technology Managers (AUTM) surveys academic institutions in the U.S. and Canada each year, including most (92%) of the top 100 universities (by total research expenditures) to assemble and report information about their commercial use of research results. Each annual report focuses on how AUTM members manage intellectual property to make the results of academic research available to the public as commercial products, and includes information on technology transfer licensing, research results with commercial applications (termed "inventions" in the AUTM reports), income from technology transfer, and the effort needed to administer a technology transfer program.[39]

During 1999–2002, AUTM survey respondents reported that 19,000–26,000 technology transfer licenses were active annually, and 3,900–4,700 new licenses were executed each year.

What have CRADAs done?

The DOC has found that it is often difficult to analytically demonstrate direct connections between cooperative public–private research activities and the eventual development of any discoveries or inventions into commercially valuable products or processes. This is because there may be many additional actors, actions, and other variables involved in the development process after the initial cooperative public–private research activities are undertaken. In addition, because the actual development and commercialization of an idea or discovery often takes many years, tangible results may not be immediately apparent.[33] Nonetheless, the DOC has identified and reported many case studies of successful downstream results from cooperative public–private research and development projects, including:

- Environmentally friendly mosquito and fly traps that provide an alternative to chemical pesticides and have been reported by the Department of Agriculture to support increasing public interest in less-toxic pest management practices;
- The world's first approved, licensed, and manufactured live fish vaccine that prevents enteric septicemia (a major catfish disease caused by Edwardsiella). The Department of Agriculture reports that this disease costs catfish farmers as much as $60 million a year in losses;
- Testing of new antimalarial drug and transdermal delivery approaches that eliminate the need to use hypodermic needles (Department of Defense);
- New technologies that the Environmental Protection Agency reports improve tests providing both enumeration of total coliforms and E. coli and presence/absence determinations;
- A new system, based on the PCR method, reported by the Environmental Protection Agency to detect and quantify more than 100 species or groups of species of potentially problematic fungi, including black mold; and
- Water treatment and reclamation technologies (Department of the Interior/Bureau of Reclamation).[34]

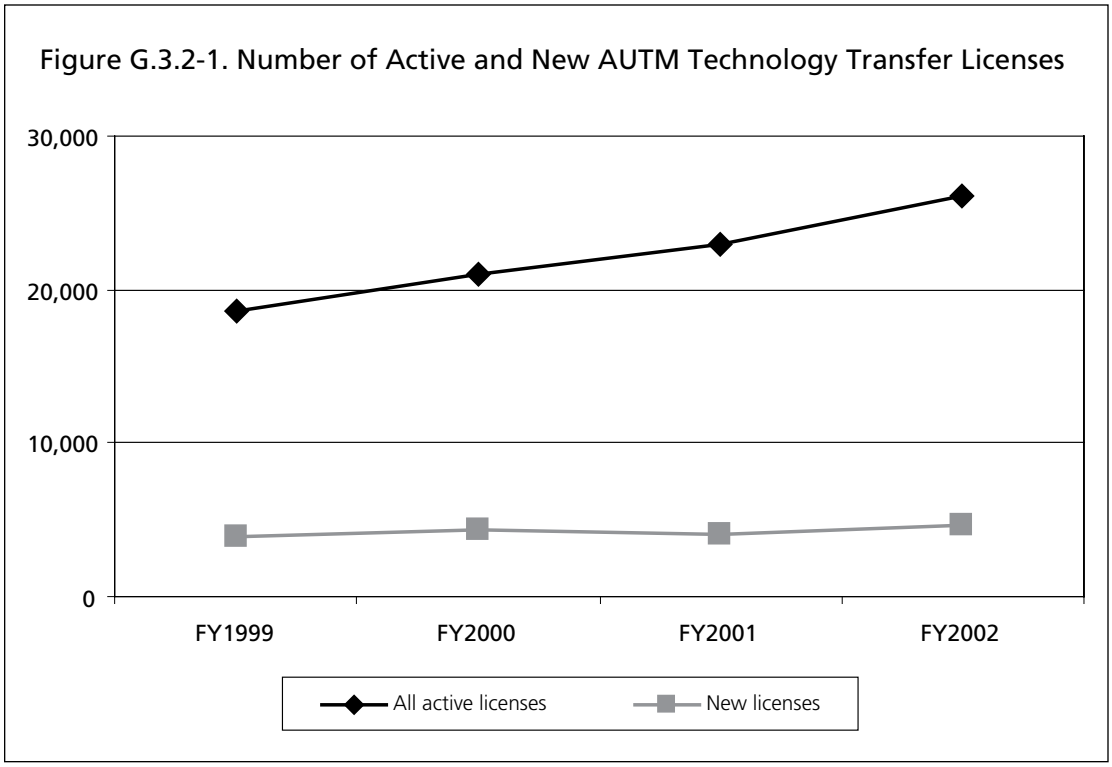

Figure G.3.2-1 On average, more than 22,000 technology transfer licenses were active annually from FY1999–FY2002.

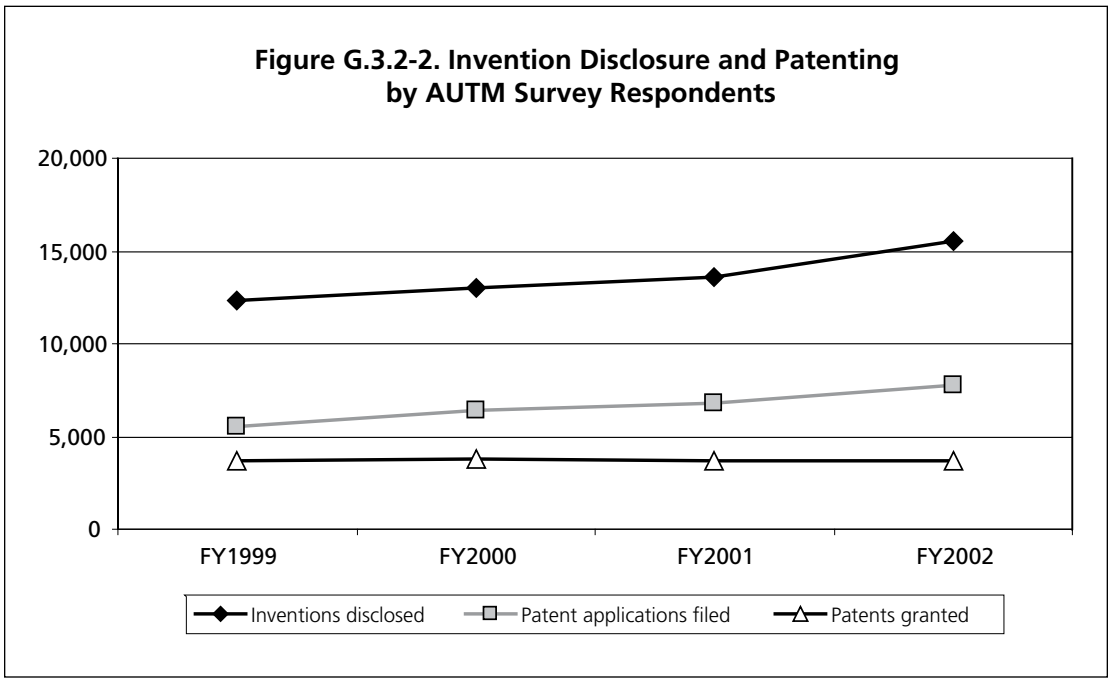

Figure G.3.2-2. During 1999–2002, academic researchers disclosed an average of more than 13,000 inventions (commercial applications for research results) annually.

Researchers at academic institutions reported an average of 13,000 research results with commercial applications ("inventions") annually from FY1999 to FY2001. Patent applications were filed for 46% of these inventions (Figure G.3.2-1).

Academic institutions derive income from the licensing of inventions (whether patented or not) to other research institutions, including for-profit institutions, for further research, development, and commercialization. Income from licensing, including royalties and other payments, was more than $1 billion total for all reporting institutions in FY2002. The average income per active license from FY1999 to FY2002 was $49,000.

Royalties (when obligated) are earned by academic institutions based on the licensee's income from product sales. From FY1999 to FY2002, AUTM reported that 23% of licenses generated royalty income, and that such income accounted for 73% of all license income (*see* Appendix C, Table C.3).

There is a workload cost associated with licensing that AUTM reports in terms of "full time equivalents" (FTE), or the amount of time one full-time employee works in one year. In 2006, reporting institutions required a total of 910.7 FTEs for activities associated with licensing and patenting including licensee solicitation, technology valuation, marketing of technology, license agreement drafting and negotiation, and start-up activity efforts (starting a new company based on an academic discovery).[40] AUTM cautions that administration of licenses does not happen all at once. Rather, "as is appreciated by technology transfer practitioners, negotiating license agreements is a process which takes days and weeks over a period of months and sometimes years."[41]

Notes

Section G.1 Benefits-Sharing by the U.S. Government

[1] In 1988, the U.S. National Cancer Institute (NCI) initiated the earliest-known benefits-sharing policy and agreements relating to the collection of biological specimens for use in drug discovery research. The earliest agreements were styled as "Letters of Intent," which provided very generally for the future sharing of royalties resulting from any commercialization of research results involving research specimens subject to the terms of the agreement. The first such "Letter of Intent" actually used by NCI was reportedly negotiated with Madagascar in 1990. For a history of the development of NCI's early benefits-sharing approach, see K. ten Kate and A. Wells, "The Access and Benefit-Sharing Policies of the United States National Cancer Institute: A Comparative Account of the Discovery and Development of the Drugs Calanolide and Topotecan," in *Submission to the Executive Secretary of the Convention on Biological Diversity by the Royal Botanic Gardens*, *Kew*), 9–14.

[2] *See Gazette* Opinion, "Industries Exploit First Park," *Billings Gazette,* (December 6, 1994).

[3] *See Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63, at 65-66 (DDC 2000) ("Prior to the CRADA, Diversa or other researchers were free to remove any specimen within the purview of their permit and develop it as they wished. If such development led to commercial uses, the Park Service never saw any proceeds from the derivative products. Thus, recognizing that resources yielding potentially valuable properties were being removed from Yellowstone with no remuneration to Yellowstone or the American people, officials at Interior began to consider a resource management scheme, patterned on the successes of Costa Rica and other nations, which would use bioprospecting to provide funds and incentives for the conservation of biological diversity.")

[4] Diversa remained subject to all of the restrictions designed to protect NPS resources contained in its pre-existing Scientific Research and Collecting Permits and other underlying NPS regulations. The agreement prohibited the sale or commercial use of research specimens collected in compliance with 36 CFR 2.1.

[5] The court specifically upheld the Yellowstone–Diversa CRADA as consistent with the conservation mandate of the NPS, and ruled that the NPS had not acted arbitrarily or capriciously in terms of compliance with any of its regulations relating to access to and use of research specimens collected from NPS units. The court specifically noted that Congress had authorized "negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements" in Section 5935 of NPOMA (16 USC § 5935). *See Edmonds Institute, et al. v. Babbitt, et al.,* 93 F. Supp. 2d 63 (DDC 2000).

[6] 93 F. Supp. 2d 63, at 72.

[7] *See Edmonds Institute, et al. v. Babbitt, et al.,* 42 F. Supp. 2d 1 (DDC 1999); 42 F. Supp. 2d 1, at 38; 42 F. Supp. 2d 1, at 37, *citing* 516 DM 2, App. 2, Section 2.5. The court stated that "there can be no debate that the Yellowstone–Diversa CRADA is a precedent-setting agreement within the National Park System and the DOI in general" (42 F. Supp. 2d 1, at 38). The court also noted that DOI's NEPA compliance manual provides that actions that "establish a precedent for future action or represent a decision in principle about future actions with potentially significant environmental effects" require NEPA review (42 F. Supp. 2d 1, at 37, citing 516 DM 2, App. 2, Section 2.5).

[8] 15 USC 3710a(d).

[9] 15 USC 3710a.

[10] S.Rep. No. 283, 99th Cong., 2d Sess. (1986), at 11.

[11] *See* <http://www.diversa.com>. Last accessed April 19, 2006.

[12] Under the terms of the CRADA that Diversa negotiated with Yellowstone in 1997–1998, Diversa would have been required to report this type of revenue information to Yellowstone on an annual basis. In addition, under the terms of the Yellowstone–Diversa CRADA, this reporting obligation would survive termination of the CRADA. However, because the Yellowstone–Diversa CRADA has been suspended since early 1999, this information is not available to the NPS.

[13] Report of a special panel of experts on the International Cooperative Biodiversity Groups, 1997, <http://www.fic.nih.gov/programs/finalreport.html>, last accessed April 19, 2006.

[14] *Ibid.,* 14–17.

Section G.2 Benefit-Sharing Around the World

[15] *See also Pharmaceutical Biology* 37 (supplement) (1999) (special edition of case studies resulting from multiple ICBG projects).

[16] *See* <http://www.inbio.ac.cr>, last accessed April 19, 2006.

[17] INBio's website identifies 18 separate governmental, academic, and philanthropic institutions and 19 private-sector institutions participating in agreements during the period 1991–2001. Participating research partners include private-sector corporations, academic institutions, philanthropic organizations, and publicly-supported research institutions. *See* <http://www.inbio.ac.cr>.

[18] *See* A. Sittenfeld and A. Lovejoy, "INBio's Biodiversity Prospecting Program: Generating Economic Returns For Biodiversity Conservation," *Final Compendium for a Practical Workshop on Biodiversity Prospecting for Cameroon, Madagascar and Ghana* (Santo Domingo de Heredia, Costa Rica: Instituto Nacional de Biodiversidad (National Biodiversity Institute), 1995).

[19] It should be noted that these percentage figures are *not* royalty rates. Rather, they are the percentages INBio is obligated to pay to MINAE under INBio's underlying cooperative agreement with MINAE from the two different types of monetary benefits INBio has negotiated as part of the benefits-sharing terms of its collaborative biological research agreements. These percentages regard sums INBio is obligated to share with MINAE from revenues generated from collaborative research projects coordinated by INBio that involve Costa Rica's conservation areas.

[20] For more information about the Merck–INBio agreement, *see, e.g.,* W. Reid et al., eds., *Biodiversity Prospecting: Using Genetic Resources for Sustainable Development* (Washington, D.C.: World Resources Institute, 1993). Information about access and benefits-sharing regimes and case studies from around the world is provided by a variety of international organizations, governments, the private sector, and NGOs. The World Intellectual Property Organization's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore has developed a pilot database of contractual practices and clauses relating to intellectual property, access to genetic resources, and benefits-sharing as a practical tool in the provision of information in this area. Also, the United Nations Convention on Biological Diversity (CBD) makes information about access and benefits-sharing regimes and case studies available through its "Clearing-House Mechanism." *See, e.g., Synthesis of Case Studies on Benefit-Sharing,* Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity, U.N. Doc. UNEP/CBD/COP/4/Inf/7 (May 4, 1998), available online at <http://www.biodiv.org/doc/documents.aspx>, last accessed April 19, 2006. Moreover, the U.N.'s Food and Agriculture Organization's (FAO) Commission on Genetic Resources for Food and Agriculture handles and reports on access and benefits-sharing with respect to plant and animal genetic resources for food and agriculture. In April 2002, the Sixth Conference of the Parties to the CBD adopted a set of

voluntary guidelines specifically concerning access and benefits-sharing issues. *See* U.N. Doc. UNEP/CBD/COP/6/20 (April 7–19, 2002) (Decision VI/24, available online at <http://www.biodiv.org/doc/documents.aspx>, last accessed April 19, 2006, ("Bonn guidelines on access to genetic resources and fair and equitable sharing of the benefits arising out of their utilization")). The United States has signed but not ratified the CBD. In 1993, the FAO established the International Code of Conduct for Plant Germplasm Collecting and Transfer. The main concepts underlying the NPS approach and the general principles embodied in the CBD's Bonn Guidelines and the FAO's Code of Conduct appear to be in harmony. Finally, at the World Summit for Sustainable Development in Johannesburg, South Africa, in September 2002, the U.S. supported adoption of the Johannesburg Plan of Implementation. Paragraph 44 of that plan reads, in pertinent part, as follows: "A more efficient and coherent implementation of the three objectives of the Convention [on Biological Diversity] and the achievement by 2010 of a significant reduction in the current rate of loss of biological diversity will require the provision of new and additional financial and technical resources to developing countries, and includes actions at all levels to: . . . (n) Promote the wide implementation of and continued work on the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising out of their Utilization of the Convention, as an input to assist Parties to the Convention when developing and drafting legislative, administrative or policy measures on access and benefit-sharing, and contract and other arrangements under mutually agreed terms for access and benefit-sharing."

[21] *See, e.g.,* Reid et al., *Biodiversity Prospecting*, 1; A. Sittenfeld and A. Lovejoy, "Biodiversity Prospecting," *in Our Planet (*Nairobi: U.N. Environment Programme, 1997), 20–21; E. Anderson, *INBio/Merck Agreement: Pioneers in Sustainable Development* (Cambridge: Harvard Business School, 1992), 9. *See also* Instituto Nacional de Biodiversidad, *Summary of Terms: Collaboration Agreement, INBio-Merck & Co., Inc.* (Santo Domingo de Heredia, Costa Rica: Instituto Nacional de Biodiversidad, 1991).

[22] According to Sittenfeld and Lovejoy ("INBio's Biodiversity Prospecting Program," 11), "INBio enjoys other agreements with a variety of industries reflecting the conviction that one collaboration, or many of the same type of collaboration are unable to effectively fulfill all institutional goals and provide solutions to diverse national problems. Each biodiversity prospecting agreement is different, arising from a separate set of circumstances and responding to varying national, institutional and private enterprise needs."

[23] One notable exception relates to the multi-party research project coordinated by INBio between 1993 and 1998 and funded by the International Cooperative Biodiversity Groups program of the National Institutes of Health. A report about this project was prepared by INBio and published in 1999. *See Pharmaceutical Biology* 37 (supplement) (1999), 55–68. According to the report, this project generated research-related funds totaling $1,650,975 allocated to Costa Rica during the project period (*ibid*., 67). Of this sum, the report states that $500,643 was allocated directly to the Guanacaste Conservation Area, and that an additional 10% of the total research budget was allocated to MINAE in accordance with INBio's pre-existing agreement with MINAE noted in the text.

[24] N. Mateo, W. Nader, and G. Tamayo. "Bioprospecting," in *Encyclopedia of Biodiversity, Volume I* (Philadelphia: Academic Press, 2001), 485–486.

[25] In April 2002, the Sixth Conference of the Parties to the United Nations Convention on Biological Diversity (CBD) adopted a set of voluntary guidelines specifically concerning access and benefits-sharing issues. *See* U.N. Doc. UNEP/CBD/COP/6/20 (April 7–19, 2002) (Decision VI/24 ("Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization")). Note that although the guidelines are concerned with both access and benefits-sharing, this FEIS is about benefits-sharing only.

[26] Bonn Guidelines, Appendix II ("Monetary and Non-Monetary Benefits"); *Ibid*., para. 49.

[27] According to K. ten Kate and S. A. Laird, "It is relatively common for biotechnology companies to share non-monetary forms of benefit. Companies share information and research results, transfer technology, train their collaborators and contribute to capacity building in the institutions from which they obtain supplies, although this often grows informally during a relationship with a supplier, rather than being prescribed up-front. Companies are prepared to share data and information, provided they can protect confidentiality and the opportunity to patent discoveries" (K. ten Kate and S.A. Laird, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing* (London: Earthscan Publications Ltd., 1999). *See also* Mateo, Nader, and Tamayo ("Bioprospecting," 481): "The experiences of the last few years indicate that monetary benefits (unless royalties would materialize) to host countries, although significant, are limited in comparison to other less tangible benefits such as technology transfer, increased scientific expertise, improvements in legal frameworks, and enhanced negotiating capacities. These less tangible benefits may be poorly understood or underappreciated by some segments of society, who quite rightly are interested in achieving a direct flow of resources and economic benefits to the local communities living near conservation areas."

[28] The recommendations outlined in the Bonn Guidelines are noted because they reflect widespread consensus concerning alternative benefits-sharing management approaches notwithstanding the fact that they are voluntary and require adaptation to local legal and administrative circumstances and

needs. For many years, some observers, particularly in the media, have noted similarities between the issues relating to benefits-sharing that have arisen within the context of the National Park Service and in ongoing developments abroad (*see*, *e.g.*, R. Wolf, "Yellowstone discovery: Should U.S. get the profits?" *San Jose Mercury News* (July 25, 1994): 1F; *see also* C. Macilwain, "When Rhetoric Hits Reality in Debate on Bioprospecting," *Nature* (April 9, 1998):535–540).

[29] *See* <http://www.biodiv.org>. Information about access and benefits-sharing case studies from around the world has been collected by a variety of international organizations, governments, the private sector, and NGOs. The CBD Secretariat also makes information about access and benefits-sharing case studies available through its "Clearing-House Mechanism" (*See, e.g.,* Synthesis of Case Studies on Benefit-Sharing, Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity, U.N. Doc.UNEP/CBD/COP/4/Inf/7 (4 May 1998). See also the benefits-sharing case studies reported by the CBD Secretariat at <http://www.biodiv.org>). The case studies collected and reported by the CBD Secretariat represent a very wide range of context-specific experiences and approaches from many different parts of the world. For example, in many cases, "benefits" also are part of the negotiation for "access." Also, the number and interests of the parties to different agreements in different parts of the world also are very different. For example, in some cases there are several intermediaries between the provider(s) of biological materials and the user(s); in other cases, the relationship is direct.

Section G.3 Commercial Use of Research Results Discovered By Federal or Academic Scientists

[30] *See* U.S. Department of Commerce, "Summary Report on Federal Laboratory Technology Transfer (FY 2003 Activity Metrics and Outcomes)," *2004 Report to the President and the Congress under the Technology Transfer and Commercialization Act* (hereinafter referred to as "*DOC 2004 Technology Transfer Report*").

[31] 15 USC 3701(3). *See also* 15 USC 3702. This policy has been implemented throughout the federal government via a series of legislative initiatives, including, most notably, the Technology Innovation Act of 1980, often referred to as the Stevenson-Wydler Act (15 USC 3701–3714); the University and Small Business Patent Procedures Act of 1980, often referred to as the Bayh-Dole Act (35 USC 200–211); and the FTTA (15 USC 3710a *et seq*).

[32] *DOC 2004 Technology Transfer Report,* 17. This report does not contain information regarding DOI CRADAs for FY2002 or FY 2003. The Department of the Interior's CRADA policy was outlined in May 1996 in the Department's handbook, *Technology Transfer: Marketing Our Products and Technologies (A Training Handbook for the U.S. Department of the Interior.* The guidelines were revised in 1998.

[33] U.S. Department of Commerce, "Summary Report on Federal Laboratory Technology Transfer (Agency Approaches; FY 2001 Activity Metrics and Outcomes)," *2002 Report to the President and the Congress under the Technology Transfer and Commercialization Act* (September 2002), 88. *See also ibid.*, Chapter 2 (specific agency reports).

[34] *Ibid.*, 12, 24, 38, 50.

[35] *DOC 2004 Technology Transfer Report,* 37.

[36] The proposal under evaluation in this FEIS similarly concerns research results related to the study of (mostly) biological materials.

[37] *DOC 2004 Technology Transfer Report,* 11.

[38] *Ibid.*, 60, 122.

[39] Association of University Technology Managers, Inc., *AUTM Licensing Survey, FY 2002: A Survey Summary of Technology Licensing (and Related) Performance for U.S. And Canadian Academic and Nonprofit Institutions, and Patent Management Firms* (2003), available online at <http://www.autm.org/surveys/dsp.surveyDetail.cfm?pid=16>, last accessed April 12, 2006.

[40] *AUTM Licensing Survey, FY2002,* 18, 43.

[41] Association of University Technology Managers, Inc. *AUTM Licensing Survey, FY 2001: A Survey Summary of Technology Licensing (and Related) Performance for U.S. And Canadian Academic and Nonprofit Institutions, and Patent Management Firms* (2002), 16, available online at <http://www.autm.org/surveys/dsp.surveyDetail.cfm?pid=17>, last accessed April 12, 2006.