



ARTICLES

BIOPROSPECTING AGREEMENTS: FORGING A COMPREHENSIVE STRATEGY FOR MANAGING GENETIC RESOURCES ON PUBLIC LANDS

BY

Dennis Michaels*†

I.	INTRODUCTION	4
II.	THE DEVELOPMENT OF BIOPROSPECTING	8
	A. <i>Bioprospecting and Biotechnology</i>	9
	B. <i>International Bioprospecting Agreements</i>	11
	C. <i>Bioprospecting in the United States</i>	14
	1. <i>Recent Developments</i>	14
	2. <i>Current Agreements</i>	17
III.	THE REGULATORY FRAMEWORK OF THE PUBLIC LANDS	19
	A. <i>The Public Lands</i>	19
	1. <i>Wilderness Act Lands</i>	21
	2. <i>The National Parks</i>	21
	3. <i>The National Forests</i>	23
	4. <i>Bureau of Land Management Lands</i>	23
	B. <i>Public Land Management Mandates</i>	25
	1. <i>Federal Land Policy and Management Act</i>	25
	2. <i>National Forest Management Act</i>	26
	3. <i>The National Environmental Policy Act</i>	27
	4. <i>The Endangered Species Act</i>	29
	C. <i>The Public Trust Doctrine</i>	30
	D. <i>International Agreements for Protection of Genetic Resources:</i> <i>The Biodiversity Treaty</i>	32

* Dennis Michaels received a J.D. with Great Distinction from University of the Pacific, McGeorge School of Law, in 1999. Mr. Michaels also holds a bachelor of arts degree in Economics from the University of California at Davis.

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IV.	INTELLECTUAL PROPERTY PROTECTION	35
	A. <i>The Patent Act</i>	36
V.	DEVELOPING A GENETIC RESOURCE MANAGEMENT STRATEGY: CONCEPTUALIZING THE ISSUES	38
	A. <i>Animal, Vegetable, or Mineral?</i>	38
	B. <i>Jus Publicum, Inalienability and the Free-Rider</i>	42
	C. <i>Locke May Hold the Key</i>	48
	D. <i>The Goals of a Genetic Resource Management Strategy</i>	50
VI.	ANALYSIS OF THE CURRENT REGULATORY FRAMEWORK AND CONCERNS	52
	A. <i>Preservation of Indigenous Genetic Resources</i>	52
	B. <i>Equitable Distribution of Benefits and Costs</i>	59
	C. <i>Incentives for Innovation</i>	62
VII.	DEVELOPING A COMPREHENSIVE MANAGEMENT STRATEGY FOR FUTURE AGREEMENTS	65
	A. <i>The Office of Biotechnology Policy</i>	65
	B. <i>The Preservationist Imperative</i>	66
	C. <i>The Biofund</i>	67
	D. <i>Distributional Goals</i>	68
VIII.	CONCLUSION	70

I. INTRODUCTION

From the printing press to the atomic bomb, humankind reveals a penchant to pioneer first and plan later. It is a simple truth that technology develops faster and further than policy. Cars and supercomputers are everyday examples of technologies that have grown beyond the highways and byways built to support them.

Pioneers and planners are, by nature, opposites. Pioneers must rebel and revolt against society to renew it. Planners try to relate the novel to the normal to provide continuity and growth.¹

¹ Senator Al Gore, *Planning A New Biotechnology Policy*, 5 HARV. J. L. & TECH. 19 (1991).

In the last twenty-five years, the rapid growth of biotechnology² has given rise to an entire industry which holds the promise of reshaping the world in which we live.³ Coupled with the rapid expansion of the biotechnology industry and the tremendous cost of development, scientists have developed increasingly diverse methods for identifying and producing beneficial biotechnological products and technologies.⁴ One of the most promising and controversial methods embraced by the scientific community is bioprospecting.⁵ Simply put, bioprospecting is the search for chemical and biological products that already exist in nature.⁶

Recently, the United States government signed the first-ever bioprospecting agreement with a private firm. The agreement provides for the sampling and development of biological products from the unique organisms that live in the geysers at Yellowstone National Park.⁷ This agreement allows a private corporation the non-exclusive right to access the park's geysers, pools and hot springs to retrieve sample organisms from which to develop products over a five-year period.⁸ In exchange, the federal government will initially receive an annual

² The Office of Technology Policy defines "biotechnology" in the following manner:

Perhaps unique among industries, biotechnology is not defined by its products but by the technologies used to make those products. Biotechnology refers to a set of enabling technologies used by a broad array of companies in their research, development, and manufacturing activities . . . biotechnology [is] a set of techniques that use organisms or their cellular, subcellular, or molecular components, to make products or modify plants, animals, and micro-organisms to carry desired traits.'

OFFICE OF TECHNOLOGY POLICY, U.S. DEP'T OF COMMERCE, MEETING THE CHALLENGE: U.S. INDUSTRY FACES THE 21ST CENTURY — THE U.S. BIOTECHNOLOGY INDUSTRY 21 (1997) [hereinafter OTP BIOTECHNOLOGY REPORT].

³ See *id.* (discussing rapid growth of biotechnology industry to more than 2000 firms and projected sales of \$24 billion by 2006).

⁴ See *id.* at 23 (describing various methods employed by biotechnology to develop products including: rational drug design — utilization of chemistry, biology, biophysics and computer modeling to specifically design compounds for a particular application; natural product screening (bioprospecting) — screening materials extracted from plants and animals for bioactive compounds; and combinatorial chemistry — synthesis of large diverse collections of molecules from which active compounds are identified).

⁵ See Part II.A. (discussing development of bioprospecting and its impact on biotechnology).

⁶ More technically, the term bioprospecting encompasses the search for useful new pharmaceuticals and other useful chemical and biological products from the genetic, chemical and biological resources found in the environment. See *infra* Part. II.A. (examining bioprospecting and biotechnology generally).

⁷ See *Firm Signs Bioprospecting Pact with Yellowstone*, L.A. TIMES, Aug. 19, 1997, at D2; Dan Gallagher, *San Diego Biotech Firm Given Ok to Harvest Yellowstone Microbes*, SAN DIEGO DAILY TRANSCRIPT, Aug. 19, 1997, at 1A; Todd Wilkinson, *Yellowstone's Geysers Open for Prospecting*, CHRISTIAN SCI. MONITOR, Aug. 28, 1997, at US 1.

⁸ See *Diversa Yellowstone Media Kit* (last modified Aug. 14, 1997) <<http://www.diversa.com/mediakit/kit.html>> (copy on file with *Environs*) [hereinafter *Yellowstone-Diversa Agreement*].

fee.⁹ Subsequent royalties will be paid for any highly successful product developed¹⁰ while non-proprietary scientific knowledge obtained from the study of the many thousands of as-yet-identified species found in the geysers will be returned to the Park Service.¹¹

Since Senator Gore's comments six years ago, the federal government has yet to address the fundamental policy concerns of managing our genetic resources on public lands.¹² This agreement represents the federal government's first foray into the uncharted territory of bioprospecting agreements.¹³ Both bioprospecting on public lands and biotechnological innovation from the resources found there have occurred in the past in the United States.¹⁴ This agreement, however, provides the first opportunity to analyze and assess whether the policy concerns that inform the "bioprospecting question"¹⁵ have been adequately addressed by our current regulatory structure.

Part II of this Article will investigate the background of bioprospecting and its impact on biotechnology generally.¹⁶ It will focus on international bioprospecting activity as well as examine current domestic bioprospecting agreements.¹⁷

Part III surveys existing law applicable to resource management on the public lands.¹⁸ The specific mandates associated with each of the major public

⁹ See *id.*

¹⁰ See *id.*

¹¹ See *id.*

¹² While aware of the recent Yellowstone-Diversa Agreement, Deputy Secretary of the Interior, John Garamendi, speaking informally, stated that he knew of no steps being taken to develop a comprehensive management strategy for genetic resources on public lands. Interview with John Garamendi, Deputy Secretary of the Interior, in Sacramento, Cal. (Jan. 1998) (notes on file with *Environs*).

¹³ See *id.*

¹⁴ See, e.g., John R. Adair, *The Bioprospecting Question: Should the United States Charge Biotechnology Companies for the Commercial Use of Public Wild Genetic Resources?* 24 *ECOLOGY L.Q.* 131, 152 (1997) (discussing history and development of polymerase chain reaction DNA sequencing technology from *Thermus Aquaticus* and anti-cancer drug Taxol from Pacific Yew Tree). While Adair discusses whether the federal government should seek compensation for the use of genetic resources found on public lands, this Article addresses the fundamental goals of and problems incident to the implementation of just such a compensation seeking approach in light of the recent Yellowstone-Diversa Agreement, *supra* note 3.

¹⁵ The "bioprospecting question" is used here to describe the myriad policy decisions that surround the use, development and preservation of indigenous genetic resources. In the larger sense, it encompasses the moral and ethical questions concerning the propriety of "ownership" of genetic information and the equitable distribution of the costs of preserving sources of biodiversity as well as the benefits derivative from the technology as well.

¹⁶ See *infra* Part II.A (examining how biotechnology industry uses bioprospecting).

¹⁷ See *infra* Part II.A-B (exploring current bioprospecting activities in the United States and abroad).

¹⁸ See *infra* Part III (surveying existing regulatory schemes applicable to public lands).

domain holdings and general land management statutes are examined. Environmental statutes will also be examined for their applicability in the bioprospecting context.¹⁹ Additionally, the United Nations Conference on Environment and Development's Convention on Biological Diversity is reviewed.²⁰ Part IV briefly surveys the basic tenets of intellectual property law in the context of products and technologies developed from bioprospecting activities.²¹

Part V will examine the unique characteristics of genetic resources found on the public lands.²² These characteristics will be examined in the context of various property rights schemes with a focus on developing goals for a comprehensive genetic resource management strategy.²³

Part VI analyzes whether the goals derived from Part V are being adequately met by current law surveyed in Parts III and IV.²⁴ This part generally discusses whether preservationist goals can be met under existing mandates, whether current schemes adequately internalize these costs into products developed from bioprospecting and whether the benefits that are derived from these beneficial technologies are equitably distributed.²⁵ Finally, an assessment of whether the current regulatory framework creates or suppresses incentives to innovate in the bioprospecting realm is undertaken.²⁶

Part VII synthesizes the problems identified in Part VI and proposes a comprehensive management strategy solution to meet the fundamental goals identified in Part V.²⁷ It discusses how reform of current access and ownership schemes can be achieved to insure preservation of biodiversity, equitable sharing of developmental costs and derivative benefits, and at the same time insure adequate incentive to innovate.²⁸

¹⁹ See *infra* Part III.A-B,D (examining in detail organization of public lands and management mandates generally applicable).

²⁰ See *infra* Part III.C (reviewing principles embodied in United Nations Conference on Environment and Development's Convention on Biodiversity).

²¹ See *infra* Part IV (reiterating basic contours of U.S. patent protection).

²² See *infra* Part V (discussing practical as well as conceptual problems with developing comprehensive management scheme for genetic resources on public lands). As used throughout this Article, "the public lands" refers to lands held by the United States under one of the management regimes discussed in Part V.

²³ See *infra* Part V.A-D (detailing conceptual considerations and positing goals for development of resource management strategy).

²⁴ See *infra* Part VI (analyzing generally whether current regulatory framework addresses goals of resource management strategy).

²⁵ See *infra* Part VI.A-B (evaluating current regulatory mandates in context of preservation and cost sharing).

²⁶ See *infra* Part VI.C (examining incentives to innovate in current mandates).

²⁷ See *infra* Part VII (proposing comprehensive management strategy).

²⁸ See *infra* Part VII (developing management strategy in context of goals established in Part III).

II. THE DEVELOPMENT OF BIOPROSPECTING

More than 3500 years ago, ancient Egyptians and Greeks made infusions of Myrtle leaves and Willow bark to soothe aches and pains.²⁹ This secret of the ancients lay lost until an 18th century English clergyman conducted one of the first recorded clinical trials by giving Willow bark extract to feverish patients in 1763.³⁰ Ninety-six years later, salicylic acid — aspirin — was synthesized in the laboratory.³¹ Though it proved highly effective, salicylic acid would languish thirty years more in a desk drawer until a stable form without undesirable side-effects could be developed.³²

In 1969, a Swiss scientist on vacation in Norway picked up a fungus-laden handful of dirt from north of the Arctic circle.³³ Three years later, cyclosporin, the powerful organ-transplant anti-rejection compound was isolated, though it too would await both the development of organ transplant technology and FDA approval fourteen years later.³⁴

Bioprospecting is not new. Healers throughout humankind's history have turned to nature for solutions to human ills. However, with the rapid growth and expansion of modern biotechnology, many of the legal and ethical issues surrounding bioprospecting are only now being addressed by the scientific and legal communities.

In order to understand the issues presented by bioprospecting activities, a basic understanding of the nature of both bioprospecting and biotechnology is necessary. To that end, this section will examine the role bioprospecting takes in today's rapidly developing biotechnology industry, review the development of international bioprospecting agreements, and finally discuss recent development in the United States.

²⁹ See Peter Sweasey, *Science: Aspirin the Wonderdrug*, THE INDEPENDENT, Oct. 4, 1998, at 76 (recounting history of development of aspirin).

³⁰ See *id.*

³¹ See *id.*

³² See *id.*

³³ See Larry Thompson, *Jean-Francois Borel's Transplanted Dream; The Artist-Turned-Scientist, Father of Cyclosporin, Turns Some of his Creativity Toward Canvas*, WASH. POST, Nov. 15, 1988, at Z12 (recalling history of development of anti-rejection drug cyclosporin).

³⁴ See *id.*

A. Bioprospecting and Biotechnology

The term "bioprospecting" encompasses the search for new pharmaceuticals and other useful chemical and biological products from the genetic, chemical and biological resources found in the environment.³⁵ In the United States alone, plant-derived medicines account for approximately twenty-five percent of all prescription drugs.³⁶ In the developing world, they account for nearly eighty-five percent of all medicines.³⁷ Amazingly these medicines are derived from only ninety species of plants.³⁸ The remaining 250,000 species of higher plants³⁹ and five to thirty million species of animal and microbial sources remain untapped for their medicinal value.⁴⁰

Biotechnology firms use bioprospecting in two fundamental ways. Primarily biotechnology firms use organisms as a chemical "blueprint" for producing a beneficial compound.⁴¹ Typically, the compound may be extracted directly from biological materials, or, once isolated, methods may be developed in a laboratory to synthesize the compound (non-biologically) for commercial production.⁴²

The second way biotechnology firms use biological resources is through the use of genetic material.⁴³ An organism can be selected for a desired genetic trait such as resistance to a particular disease, or the ability to synthesize a par-

³⁵ See Adair, *supra* note 14, at 133 (citing WALTER REID ET AL., WORLD RESOURCES INSTITUTE, *BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT 1* (1993)); See Mark A. Urbanski, Note, *Chemical Prospecting, Biodiversity Conservation, and the Importance of International Protection of Intellectual Property Rights in Biological Materials*, 2 BUFF. J. INT'L L. 131, 137 (1995) (attributing origin of term "chemical prospecting," or the search for useful compounds from animal, plant, and microbial sources, to Dr. Thomas Eisner of Cornell). As used in this Article, "bioprospecting" broadly contemplates not only the search for useful compounds which may be extracted from nature, but also the genetic information contained in those organisms that allows modification, development, and commercial synthesis of these compounds.

³⁶ See Urbanski, *supra* note 35, at 135 (citing Norman R. Farnsworth, *Screening Plants for New Medicines*, in *BIODIVERSITY* 83 (E.O. Wilson ed., 1988)).

³⁷ See *id.*

³⁸ See *id.* at 136.

³⁹ "Higher plants" refers to complex, multicellular plants as opposed to single cell plants such as algae.

⁴⁰ See Urbanski, *supra* note 35.

⁴¹ See Adair, *supra* note 14, at 137 (detailing specifically various ways companies can develop products using genetic resources in non-rivalrous manner); Christopher D. Stone, *What to Do About Biodiversity: Property Rights, Public Goods, and the Earth's Biological Riches*, 68 S. CAL. L. REV. 577, 597-98 (1995) (describing differences between rivalrous extractive use of biological materials — more product requiring more input — and non-rivalrous informational use of genetic information contained in those biological materials — using genetic information to synthesize compound).

⁴² See Adair, *supra* note 14, at 137; Stone, *supra* note 41, at 597-98.

⁴³ See Adair, *supra* note 14, at 137.

ticular compound.⁴⁴ Genetic engineering technology allows the integration of the gene responsible for this ability into another organism.⁴⁵ The genetically altered organism can then be reproduced with the beneficial trait, producing the desired compound biologically in commercially viable quantities.⁴⁶

Companies typically collect small samples of flora and fauna, and then laboriously screen them for possible beneficial traits or bioactive effects.⁴⁷ Examples of bioengineered products include frost-resistant tobacco plants, pest-resistant strains of corn, cotton and potato plants as well as research organisms with predispositions to certain diseases.⁴⁸ It is estimated that the market for bioengineered products could reach as much as \$100 billion annually by the year 2000.⁴⁹ Annual sales of four pharmaceuticals derived from bioprospecting activity topped \$2 billion in 1990 alone,⁵⁰ and revenues from enzyme technology developed from one domestically available microbe are expected to exceed \$1 billion annually.⁵¹

While the rewards from biologically derived products are extraordinary, the development process can be also be extraordinarily expensive and time consuming before a product is ready for market.⁵² Only one in ten thousand chemicals may show promise, and its development may take dozens of years of research, refinement and testing as well as millions of dollars to produce a market-ready product.⁵³ This is particularly true of the pharmaceutical industry where the development of a naturally occurring drug typically costs \$231 million in development costs and takes more than twelve years to bring to market.⁵⁴

⁴⁴ See *id.*

⁴⁵ See OTP BIOTECHNOLOGY REPORT, *supra* note 2, at 21 (describing various methods of genetic manipulation to produce organisms with desired traits).

⁴⁶ See *id.*

⁴⁷ See *id.*

⁴⁸ See E.P.A. Approves Three Genetically Altered Crops, N.Y. TIMES, Apr. 11, 1995, at A23 (explaining how genetic engineers incorporated natural pesticide production ability of bacterium *Bacillus Thuringiensis* into corn, cotton and potato varieties).

⁴⁹ See Adair, *supra* note 14, at 140 (citing Walter V. Reid, *The Economic Realities of Biodiversity*, ISSUES SCI. & TECH., Winter 1993-94, at 48,49); OTP BIOTECHNOLOGY REPORT, *supra* note 2, at 43 (conservatively estimating market for biotechnology-derived products to top \$32.4 billion by 2006).

⁵⁰ See Adair, *supra* note 14, at 139.

⁵¹ See *id.*

⁵² The Office of Technology Policy reports that the top ten biotechnology firms spent between \$7 million and \$10 million in 1995 alone on research. Research and development totalled more than 36% of all costs on average or more than \$69,000 per employee in 1995. OTP BIOTECHNOLOGY REPORT, *supra* note 2, at 30.

⁵³ See Adair, *supra* note 14, at 141

⁵⁴ See *id.*

B. International Bioprospecting Agreements

Since about half of all species found on the planet are found in tropical rainforests, issues surrounding bioprospecting and the preservation of biodiversity have usually been viewed with an international perspective.⁵⁵ Typically, the discussion has focused on issues surrounding the use of biological materials indigenous to the tropics by multinational corporations for use and sale in the northern hemisphere.⁵⁶ As a result of the growing interest in biodiversity — and the extraordinary rewards that may result from a successful product — many countries in the developing world began fundamentally changing the rules of the bioprospecting game; several countries began limiting access to their biological resources in the early 1980s marking a fundamental paradigm shift in their perspective toward their own biological resources.⁵⁷ Slowly, developing nations began to realize that the biodiversity of their ecosystems could be as valuable a resource as timber or petroleum.⁵⁸

To understand the perils of an unstructured marketplace for bioprospecting, one need only look as far as several recently developed pharmaceuticals. The development of the alkaloids vincristine and vinblastine⁵⁹ from Madagascar's

⁵⁵ See Edward O. Wilson, *The Current State of Biological Diversity*, in *BIODIVERSITY 5* (E.O. Wilson ed., 1988).

⁵⁶ See Stone, *supra* note 41, at 596 n.52 (arguing that controversy over bioprospecting has little to do with unique properties of genetic resources, but rather has more to do with "geopolitical tensions over wealth disparity . . ."). Stone claims this tension between the countries of origin (typically lesser-developed countries in the southern hemisphere with the broadest portfolio of genetic material) and developers of the genetic materials (typically developed countries and newly industrialized countries with superior technology and access to capital) is the result of past inequitable experiences where mere suppliers of raw materials received little if any compensation from the "developers" of the resources. See *id.*

⁵⁷ See, e.g., Edgar J. Asebey & Jill D. Kempenaar, *Biodiversity Prospecting: Fulfilling the Mandate of the Biodiversity Convention*, 28 *VAND. J. TRANSNAT'L L.* 703, 725 (1995) (discussing development of Costa Rica's Merck-INBio agreement); Jon H. Goldstein, *The Prospects for Using Market Incentives to Conserve Biological Diversity*, 21 *ENVTL. L.* 985, 992 (1991) (chronicling development of commercialization strategy for indigenous sea birds that created successful incentives for their conservation); Shayana Kadidal, Note, *Plants, Poverty, and Pharmaceutical Plants*, 103 *YALE L.J.* 223, 224 (1993) (citing experiences such as Madagascar's inequitable treatment by developers of vincristine and vinblastin as impetus for reform that resulted in Convention on Biological Diversity of United Nations Conference on Environment and Development); Frances Williams, 'Bio-piracy' Costs Third World \$5.4 Billion a Year, *FIN. TIMES*, Oct. 28, 1994, at World Trade News 7 (discussing release of report, UNITED NATIONS DEVELOPMENT PROGRAMME, *CONSERVING INDIGENOUS KNOWLEDGE: INTEGRATING TWO SYSTEMS OF INNOVATION*, (1994), which claims that inequitable distribution of benefits from commercializing indigenous plant varieties and local knowledge is exacerbated by patent protection system in industrialized world).

⁵⁸ See Adair, *supra* note 14, at 77 (citing Roger A. Sedjo, *Property Rights, Genetic Resources, and Biotechnological Change*, 35 *J.L. & ECON.* 199, 206 (1992)).

⁵⁹ For a discussion of the development of vincristine and vinblastine see Kadidal, *supra* note 57, at 224-26.

Rosy Periwinkle plant⁶⁰ provide a cure for Hodgkin's disease and acute lymphocytic leukemia.⁶¹ They also generate hundreds of millions of dollars in revenue annually for its developer, Eli Lilly.⁶² Madagascar receives nothing.⁶³

Even the research community is not immune to this kind of overreaching. A United States National Cancer Institute mission to Kenya collected over 27,000 kg of *Maytenus buchananni* for extraction of the anti-cancer compound maytansine, eliminating the entire adult population of the species.⁶⁴ Clearly the absence of any moral imperative, market incentive or legal framework creates incentives for overexploitation in the race to reduce these resources to possession.

These experiences and others have gradually forced the international community to address some of the issues raised in subsequent legislation, through private agreements or both. Perhaps the most notable and influential international bioprospecting agreement to date has been Costa Rica's Merck/INBio⁶⁵ agreement.⁶⁶

⁶⁰ Madagascar's Rosy Periwinkle plant is a product of Madagascar's unique evolutionary history. Madagascar, like Australia or the Galapagos is an evolutionary haven with one of the most distinctive ecosystems in the world though it has lost 93% of its forest to reckless development. Wilson, *supra* note 55, at 10.

⁶¹ See Urbanski, *supra* note 35, at 135 (noting that vincristine and vinblastin provide an effective cure for Hodgkin's disease and acute lymphocytic leukemia); Adair, *supra* note 14, at 141 (discussing impact of vincristine and vinblastin).

⁶² See Urbanski, *supra* note 35, at 135, n. 10 (providing that value of vincristine and vinblastin is estimated at over \$200 million per year); Adair, *supra* note 14, at 141, n.76 (citing Kadidal, *supra* note 57, at 224 claiming that Eli Lilly earns at least \$160 million from derivatives of Madagascar's rosy periwinkle, including vincristine and vinblastine).

⁶³ See Urbanski, *supra* note 35, at 135; Adair, *supra* note 14, at 141.

⁶⁴ See Urbanski, *supra* note 35, at 135 (citing generally BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT 3 (Walter V. Reid et al. eds., 1993)).

⁶⁵ Merck, Inc. is a giant U.S. pharmaceutical company. INBio — the Instituto Nacional de Biodiversidad — is a non-profit association created by decree of the Costa Rican government. See Asebey & Kempenaar, *supra* note 57, at n.107 (explaining organizational structure and relationship between INBio and Costa Rican Ministry of Natural Resources, Energy, and Mines).

⁶⁶ When announced the Merck/INBio agreement was "hailed as the wave of the future." Asebey & Kempenaar, *supra* note 57, at 725. Indeed, at the time *San Francisco Chronicle* called the agreement "a prototype of an international system for [bioprospecting] . . . returning to countries of origin a share of profits from . . . substances derived from natural resources." Charles Petit, *New Effort to Save Tropical Rain Forests: Pact on Natural "Chemical Prospecting,"* S.F. CHRON., Sept. 21, 1991, at A15. Other commentators have been less enthusiastic, claiming that the agreement works best as a public relations device rather than a model agreement which acknowledges source country contributions to collection, identification, and preservation of the resource. See Asebey & Kempenaar, *supra* note 57, at 725-30 (claiming that secrecy surrounding exact terms of agreement tend to shift focus to what is known — that INBio will contribute 50% of the royalties it receives to Costa Rican National Parks — rather than what is not known — that royalty rate which Merck will pay INBio may be as low as one to three percent); Michael D. Coughlin, Note,

The basic structure of the agreement gave Merck access to chemical extracts and biological materials collected by INBio in exchange for a one million dollar advance and royalties from products developed from the samples.⁶⁷ Additionally, INBio agreed to dedicate fifty percent of its royalties from the Merck agreement and ten percent of its budget toward conservation of the wildlands used for prospecting.⁶⁸ Merck also agreed to train INBio scientists and parataxonomists.⁶⁹ In this sense, the agreement seemed to address some of the issues raised by international bioprospecting — recognizing the value of traditional biocultural contribution by exchanging money and technical training to create incentives for both preservation and exploration of the biodiversity resource.

If not a model for the international community, the agreement has served, at least, as a first experiment.⁷⁰ One reason for its usefulness is that it has been able to provide protection for intellectual property rights, address development concerns and preserve biodiversity — something international and domestic law had previously been unable to do.⁷¹ While the Merck/INBio agreement took great strides in addressing the concerns of both developers and stewards of biological resources, the question remains whether the basic framework will actually accomplish its stated objectives.⁷²

Using the Merck-INBio Agreement to Clarify the Convention on Biological Diversity, COLUM. J. TRANSNAT'L L. 337, 348 (1993) (arguing that, with respect to technology transfer, Merck/INBio agreement only went as far as Merck would tolerate).

⁶⁷ See Urbanski, *supra* note 35, at 139.

⁶⁸ See *id.*

⁶⁹ See *id.*; see also Charles R. McManis, *The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology*, 76 WASH. U. L.Q. 255, 271 (1998) (describing "parataxonomists" as "lay people of rural extraction who are trained to collect specimens and gather information.").

⁷⁰ Several commentators, while recognizing the primacy of the Merck/INBio agreement, seriously doubt the value of what is known about the confidential agreement. Specifically: "[a]rguably, the [Merck/INBio] agreement's greatest value to developing countries is its tacit recognition that the North[ern hemisphere] accepts developing countries' claims to compensation and realizes that compensation should be given for both the use of genetic material as well as the search for such material." Asebey & Kempenaar, *supra* note 57, at 726.

⁷¹ See Thomas Eisner & Elizabeth A. Beiring, *Biotic Exploration Fund — Protecting Biodiversity Through Chemical Prospecting*, 44 (2) BIOSCI. 95, 97 (1994).

⁷² In the first six years of the Merck/INBio agreement, Costa Rica has yet to receive any royalties. Michael Milstein, *The Microbe Hunt; Costa Rica Stakes Future on Rich Value of Nature*, SAN DIEGO UNION-TRIB., Mar. 27, 1996, at E1. While the agreement provides funding for the purchase of scientific instruments and royalty payments, Merck is not required to disclose or license any trade secrets developed from the Costa Rican genetic resources. Coughlin, *supra* note 66, at 356.

C. Bioprospecting in the United States

Until recently, most of the focus on bioprospecting has been in the international realm. In the United States however, the focus on bioprospecting activity within the United States has increased with the discovery and development of several significant pharmaceutical compounds. Considering that the federal government owns nearly one-third of all land within the United States, the announcement of the first formal bioprospecting agreement between the United States government and a private company has shifted the focus to bioprospecting activities within the United States.

1. Recent Developments

While the vast majority of the world's species are found outside the United States,⁷³ domestic bioprospecting activity has increased greatly in the last decade.⁷⁴ Several highly successful products have been developed from genetic resources on public land in the United States, heightening the interest of industry and raising domestic issues regarding bioprospecting.⁷⁵

⁷³ See Urbanski, *supra* note 35, at 133, n.85.

⁷⁴ See Natalie Angier, *Rx for Endangered Species Law: Empty Medicine Bottles*, N.Y. TIMES, Mar. 7, 1995, at C4 (recounting efforts of Endangered Species Coalition to raise political consciousness with respect to value of plant products and other wild sources of pharmaceutical products). By way of illustration, Dr. Thomas Eisner of Cornell University described the case of the Lake Placid Mint — valuable for its ability to produce a strong natural insect repellent and strong anti-fungal agent with potential clinical value to AIDS patients. The Lake Placid Mint now only exists on a 300-acre research preserve in Florida. See *id.* See also Barbara Delatiner, *In Charge of Running Peconic Bioreserve*, N.Y. TIMES, Dec. 11, 1994, at 13L145 (describing goals of 575,000-acre Nature Conservancy Peconic Bioreserve to integrate needs of people, and preserve habitat and biodiversity on Long Island's ecologically sensitive East End); Stephen D. Moore, *Gene Hunter Targets Isolated Iceland*, WALL ST. J., July 10, 1997, at B1 (reporting on increasing reliance of pharmaceutical industry on so-called gene hunters to locate and identify unique genetic resources such as pools of relatively homogeneous human genetic material which greatly aids researchers in isolating genes that cause disease); Todd Wilkinson, *Yellowstone's Geysers Open for Prospecting*, CHRISTIAN SCI. MONITOR, Aug. 28, 1997, at U51 (noting interest of at least three other companies in entering bioprospecting agreements with Yellowstone, and interest that other biotech companies have expressed in bioprospecting in other National Parks such as Carlsbad Caverns); Carol Kaesuk Yoon, *Forget the Tropics, Pharmaceuticals May Lie in Nearby Woods*, N.Y. TIMES, Nov. 5, 1996, at C4 (discussing efforts of Finger Lakes Land Trust to establish 270-acre biological preserve in Finger Lakes region of New York where crucial form of fungus responsible for billion-dollar anti-rejection drug cyclosporin used in organ transplantation was discovered).

⁷⁵ The concerns aroused by recent developments range from the ecological to the political. See, e.g., Timothy Egan, *Trees That Yield A Drug for Cancer are Wasted*, N.Y. TIMES, Jan. 29, 1992, at A1 (expressing concern that clear-cutting on lands managed by U.S. Forest Service and Bureau of Land Management was discard-

The most widely known example of domestic bioprospecting is the development of polymerase chain reaction ("PCR") technology for DNA⁷⁶ copying.⁷⁷ Cetus Corporation developed the process from an enzyme isolated from *Thermus aquaticus*, a microbe found in Yellowstone National Park's Mushroom Spring.⁷⁸ The enzyme — described as a thermophile — was extraordinarily valuable because of its unique ability to withstand repeated heating and cooling — a result of the bacterium's unique thermal adaptation.⁷⁹

ing or damaging beyond use large amounts Pacific Yew trees, then only source of taxol); Gallagher, *supra* note 7, at 1A (reciting concerns expressed by groups that park service is ill-equipped to negotiate these agreements and that public has been shut out of decision process); Warren E. Leary, *Companies Accused of Overcharging for Drugs Developed with U.S. Aid*, N.Y. TIMES, Jan. 26, 1993, at C6 (expressing criticism that potent anti-cancer drug taxol, extracted from Pacific Yew tree on public land and developed through government sponsored research, was being marketed by private corporation under exclusive licensing agreement at over eight times its production cost); Craig D. Rose, *U.S. Pays for Work, Scientists Reap Profits*, SAN DIEGO UNION-TRIB., Apr. 4, 1993, at A-1 (discussing criticism of federal governments negotiation of cooperative research and development agreements which effectively grant private companies access to government funded research for little or no cost and grant private companies effective monopolies in marketing products developed from government research contributing to outrageously high prices for many drugs); Wilkinson, *supra* note 74, at US1 (mentioning that recent Yellowstone-Diversa agreement has aroused support from some conservation groups because agreement shows value of permanent ban on developing geothermal resources in park while others express concern that inadequate safeguards are in place to protect park resources in light of increased commercial interest in bioprospecting).

⁷⁶ DNA or deoxyribonucleic acid, is the essential component molecule in all living matter and a basic material in the chromosomes of the cell nucleus: it transmits the hereditary pattern. WEBSTER'S NEW TWENTIETH CENTURY DICTIONARY 539 (2d ed. 1979).

⁷⁷ Polymerase chain reaction (PCR) technology uses Taq polymerase, the enzyme named for *Thermus aquaticus*, to replicate fragments of DNA for subsequent study. PCR DNA replication or "amplification" mimics the process cells in nature use to replicate DNA in the following manner: the sample to be replicated is placed in a vial with large quantities of the four nucleotides, or basic building blocks of DNA; large quantities of a "primer" sequence of nucleotides upon which the copies of the DNA will be built, and Taq polymerase. The vial is heated and the DNA to be copied "unzips" itself into two strands. When the vial is cooled so the primers can attach to the separated strands, then the vial is heated slightly so the Taq polymerase can attach the appropriate nucleotides to the separated strands, yielding two copies. The process can be repeated thirty or more times, yielding over one million copies of the initial fragment of DNA in about three hours. See generally, National Center for Human Genome Research, *Polymerase Chain Reaction — Xeroxing DNA* (visited Jan. 10, 1999) <http://www.gene.com/ae/AB/IE/PCR_Xeroxing_DNA.html> (copy on file with the *Enviroins*) (detailing the process by which PCR can be used to replicate DNA for study).

⁷⁸ See Adair, *supra* note 14, at 151 (claiming sample from which enzyme was derived came from national repository for cell samples in Maryland). Kary Mullis later received the Nobel Prize for his discovery. See generally Michael Millstein, *PCR Molecular Technique is Hot Stuff Among Microbe Detectives*, SAN DIEGO UNION-TRIB., June 1, 1994, at E1 (discussing widespread applicability and contribution PCR technology has made to molecular biology and numerous other disciplines).

⁷⁹ See Adair, *supra* note 14, at 151.

The PCR process has revolutionized scientific, medical and criminological techniques, making DNA identification widespread, accessible, fast and affordable to both medical researchers and criminologists.⁸⁰ After Cetus Corporation patented the the process based upon the enzyme, it subsequently sold it to the Swiss pharmaceutical firm Hoffman-Laroche for \$300 million.⁸¹ Revenue from this technology is expected to top one billion dollars by the millenium.⁸² Though developed from resources found on public land, and identified with public research dollars, the United States receives no compensation from its development and commercialization.⁸³

The second major product developed from domestic bioprospecting activity is the anti-cancer drug taxol. Taxol was developed from the bark of the Pacific Yew tree, found largely on public land.⁸⁴ National Cancer Institute researchers discovered and isolated the compound over a period of thirty years.⁸⁵ Taxol has been used to successfully treat some forms of ovarian and breast cancers and continues to be researched.⁸⁶ While taxol has been described as one of the most potent anti-cancer drugs discovered to date, the Bush administration granted Bristol-Meyers-Squibb the exclusive right to harvest the Pacific Yew on public lands, and the exclusive use of the federal research on taxol in order to encourage the commercial development and marketing of taxol.⁸⁷ Now synthesized in

⁸⁰ See, e.g., Mark Abrahams, *Chance Gardener*, BYTE, May 1998, at 160 (examining new \$299 consumer electronic device which analyzes and identifies species of plants found in home gardens using PCR technology and handheld computer); Alex Barnum, *How Winner of Nobel Spawned an Industry*, S.F. CHRON., Oct. 15, 1993 at B1 (recounting profligation of businesses and technologies based upon PCR technology); Millstein, *supra* note 78, at E1 (examining contributions PCR has made to many investigatory fields including criminology and forensic science); *New DNA-Typing system Offers Powerful Technology for Determining Identity in Criminal and Accident Investigations*, BUS. WIRE, Feb. 11, 1998 (announcing development of STR (short tandem repeat) DNA amplification kit based upon PCR technology which allows faster and more accurate DNA typing).

⁸¹ See Barnum, *supra* note 80, at B1.

⁸² See *id.*

⁸³ See Dan Gallagher, *San Diego Biotech Firm Give Ok to Harvest Yellowstone Microbes*, SAN DIEGO DAILY TRANSCRIPT, Aug. 19, 1997, at 1A; Dan Gallagher, *San Diego Biotech Firm Given Ok to Harvest Yellowstone Microbes*, SAN DIEGO DAILY TRANSCRIPT, Aug. 19, 1997, at 1A; Michael Milstein, *Microbe Economics: Park Will Get Fees from Firms Studying Microbes*, BILLINGS GAZETTE, Aug. 16, 1997, at A1; Wilkinson, *supra* note 74, at 1.

⁸⁴ See Douglas Daly, *Tree of Life*, AUDUBON, Mar. 1992, at 76, 78 (examining development of taxol from Yew trees found in national forests in Pacific Northwest); Ralph Nader & James Love, *Looting the Medicine Chest*, PROGRESSIVE, Feb. 1993, at 26 (criticizing Bush administration's handling of taxol's development).

⁸⁵ See Adair, *supra* note 14, at 152.

⁸⁶ See *id.*

⁸⁷ See Nader & Love, *supra* note 84, at 26, 28.

the laboratory, the annual market for taxol is expected to exceed one billion dollars.⁸⁸ Though developed from resources found on the public lands, and with public research dollars, the United States receives no compensation for the use of its research or the effective monopoly grant.⁸⁹

2. Current Agreements

The recent Yellowstone Park-Diversa Corporation bioprospecting agreement is the first formal bioprospecting agreement between the United States government and a private company.⁹⁰ The agreement represents an attempt to address the inequities that have resulted from private development of public biological resources in the past.⁹¹ One of the critical considerations to the negotiations of the agreement was to “close[] the existing loophole that authorizes research activities on biological materials collected in national parks without providing for any benefits-sharing mechanism for the parks to recapture future revenues or other benefits . . . derived from . . . such research.”⁹²

The agreement gives Diversa the non-exclusive right to sample the microbes that live in the parks hot springs and geysers over the next five years.⁹³ Diversa will pay the park an annual fee, subsequent royalties on any commer-

⁸⁸ See Adair, *supra* note 14, at 152 (citing Gene Kaprowski, *Cancer-Fighting Yew Drugs May be Produced in Michigan*, GANNETT NEWS SERVICE, Mar. 29, 1995, available in 1995 WL 2890943).

⁸⁹ See *id.*

⁹⁰ See *Diversa: Yellowstone Media Kit* (visited Sept. 27, 1997) <<http://www.diversa.com/mediakit/yellow.html>> (copy on file with *Environs*) (announcing agreement Aug. 17, 1997 as first U.S. bioprospecting agreement).

⁹¹ See World Foundation for the Environment and Development, *Yellowstone National Park/ Diversa Corporation Cooperative Research and Development Agreement: Summary of Principal Terms* (visited Jan. 22, 1998) <http://www.wfed.org/Agr_Sum.htm> (copy on file with *Environs*) [hereinafter *WFED Summary of Principal Terms*] (claiming that cooperative research and development agreement is an attempt at developing equitable and efficient benefits-sharing arrangements with research community). The absence of such benefit sharing provisions in existing research permits has resulted in circumstances where Yellowstone is not positioned to maximize the potential benefits resulting from research on biological resources found in the park. See *id.*

⁹² See *id.* (stating that Yellowstone's purpose behind agreement is to maximize scientific, educational, and economic benefits that can result from research activities at park for greater conservation of park's natural resources). While the cooperative research and development agreement continues to allow biological research, it closes the loophole that does not require any mechanism for benefit sharing from the results of that research. See *id.*

⁹³ See *id.*

cially successful technologies developed from their research, and return to the park service scientific information about the sampled organisms.⁹⁴

The agreement, facilitated by the World Foundation for Environment and Development (“WFED”)⁹⁵ and the National Park Foundation⁹⁶ largely follows the principles embodied in the Merck/INBio agreement as well as the later United Nations Conference on the Environment and Development’s Convention on Biological Diversity.⁹⁷ Like the Merck/INBio agreement, this agreement provides for the payment of up-front fees, but it also requires the payment of royalties based on percentages of revenues generated from agreement-related research.⁹⁸ This agreement, like the Merck/INBio agreement, attempts to link scientific and economic incentives associated with research activities to the conservation imperatives of the park’s biological diversity.⁹⁹

Parties to the agreement hope that the agreement will serve as an “inspiring example for the creative fusion of science and conservation for the 21st century.”¹⁰⁰ However, there are still several aspects of bioprospecting agreements

⁹⁴ See Diversa Corp., *Yellowstone Media Kit: Yellowstone Agreement Release* (visited Sept. 27, 1997) <<http://www.diversa.com/mediakit/yellow.html>> (copy on file with *Environs*).

⁹⁵ See World Foundation for Environment and Development, *Introduction to WFED* (visited Jan. 22, 1998) <<http://www.wfed.org/fedintro.htm>> (copy on file with *Environs*) (noting that WFED is independent non-governmental organization established in 1992 to promote international cooperation and conflict resolution initiatives in field of environment and development).

⁹⁶ See National Park Foundation, *Information About NPF: Charter and Mission* (visited Jan. 22, 1998) <<http://www.nationalparks.org/about-mission.htm>> (copy on file with *Environs*) (stating National Park Foundation, created by U.S. Congress in 1967 is official non-profit partner of National Park Service, whose goal is to conserve, preserve and enhance our National Parks, support education and outreach programs, and generate funds for grantmaking and assistance programs through gifts from private individuals and organizations).

⁹⁷ See Milstein, *supra* note 83, at A1 (claiming officials designed Yellowstone deal after studying agreements under which drug companies fund surveys of organisms in Costa Rican national parks in hopes they may have commercial applications).

⁹⁸ See *WFED Summary of Principal Terms*, *supra* note 62 (providing that cooperative research and development agreement provides package of mechanisms for benefit sharing). The agreement includes minimum annual royalty payments of \$100,000 over five years, annual royalties based on revenues generated from agreement related research results. These contributions may take the form of monetary compensation, scientific information, equipment and professional know-how. *See id.*

⁹⁹ See World Foundation for Environment and Development, *Yellowstone Thermophiles Conservation Project: Biodiversity, Ecology and Evolution in Yellowstone National Park* (visited Jan. 22, 1998) <<http://www.wfed.org/Ystone.html>> (copy on file with *Environs*) (claiming that by linking economic, scientific and conservation incentives through cooperative research and development agreements for park biological resources, sustainable resource conservation is strengthened).

¹⁰⁰ World Foundation on Environment and Development, *Conservation of Hot Spring Biodiversity: 21st Century Priority for Yellowstone National Park* (visited Jan. 22, 1998) <<http://www.wfed.org/PressRel.htm>> (copy on file with *Environs*).

that remain subject to criticism and have yet to be completely addressed by any agreement to date.¹⁰¹

III. THE REGULATORY FRAMEWORK OF THE PUBLIC LANDS

Public land law is anything but a cohesive body of regulatory law. Individual agency mandates, environmental statutes and a multiplicity of statutory schemes designed for particular lands and resources serve widely disparate and conflicting goals.¹⁰² In order to develop a comprehensive strategy to manage genetic resources found on the public lands, however, an investigation of this complex regulatory framework is essential.¹⁰³ First, the classifications of public lands are examined,¹⁰⁴ followed by a review of generally applicable public land management mandates.¹⁰⁵ Next, environmental protection efforts are evaluated both domestically and internationally as to their applicability to domestic bioprospecting.¹⁰⁶ Finally, the public trust doctrine is discussed as a possible basis for developing a comprehensive genetic resource management strategy.¹⁰⁷

A. *The Public Lands*

No single agency exercises authority over all the public lands.¹⁰⁸ Authority for the management of the public lands follows little logical organization.¹⁰⁹ This is attributable as much to history as to geography or political favoritism.¹¹⁰ One commentator noted "there is no cohesive, logical pattern which can be discerned, and that, indeed, many of the agencies involved carry out functions which are exactly like the functions of other agencies that manage different parts

¹⁰¹ See *infra* Part V (discussing still unresolved issues surrounding bioprospecting activity on public land).

¹⁰² See Marla E. Mansfield, *A Primer of Public Land Law*, 68 WASH. L. REV. 801, 802 (1993).

¹⁰³ See *id.*

¹⁰⁴ See *infra* Part III.A (examining classifications of public lands).

¹⁰⁵ See *infra* Part III.B. (reviewing current public land management mandates).

¹⁰⁶ See *infra* Part III.B.3-4, Part III.C (evaluating domestic and international environmental legislation in bioprospecting context).

¹⁰⁷ See *infra* Part III.D (discussing applicability of public trust doctrine to bioprospecting).

¹⁰⁸ See 5 FRANK P. GRAD, *TREATISE ON ENVIRONMENTAL LAW* § 12.02[1][a] (Matthew Bender, 1998) (discussing piecemeal approach taken with respect to acquisition, disposition and management of public lands).

¹⁰⁹ See *id.*

¹¹⁰ See *id.*

of the public domain."¹¹¹ It is exactly this multilayered administrative structure that makes developing a comprehensive policy for managing genetic resources on the public lands particularly problematic. Each component of the public domain faces different mandates regarding use and management based on their unique historical circumstances.¹¹²

The federal government owns more than one-third of all land in the United States.¹¹³ Authority for the management of these lands is split between the Department of the Interior and the Department of Agriculture.¹¹⁴ The Department of the Interior administers lands held by the National Park Service (80 million acres), Bureau of Land Management (450 million acres), and the Fish and Wildlife Service (88.5 million acres).¹¹⁵ The Department of Agriculture manages its portion through the National Forest Service (187 million acres).¹¹⁶ An understanding of the different policy goals of each of these components is critical to formulating a comprehensive strategy for managing all genetic resources on the public lands effectively.

¹¹¹ See *id.*

¹¹² See *id.*

¹¹³ See *id.* (citing Council on Environmental Quality, *Environmental Quality — First Annual Report* 165-67 (1970)).

¹¹⁴ Authority for the acquisition, use, management and disposition of all lands held by the U.S. finds its source primarily in two places in the Constitution — the “enclave” clause and the “property” clause. See U.S. CONST. art. I, § 8, cl. 17 (providing that Congress has authority “to exercise exclusive legislation in all cases whatsoever . . . over all places purchased by the consent of the legislature of the state in which the same shall be, for the erection of forts, magazines, arsenals, dock-yards, and other needful buildings . . .”); U.S. CONST. art. IV, § 3, cl. 2 (providing that “congress shall have power to dispose of and make all needful rules and regulations respecting territory or other property belonging to United States . . .”). The Enclave Clause provides Congress the exclusive authority over “all places purchased by the consent of the legislature of the state in which the same shall be, for the erection of forts, magazines, arsenals, dock-yards, and other needful buildings.” *Id.* Under the enclave clause, “needful buildings” has been interpreted to include national parks as well. See *Collins v. Yosemite Park & Curry Co.*, 304 U.S. 518, 529 (1938) (providing that authority granted under Enclave Clause has been liberally construed considering it is not sole constitutional basis for sovereign authority over acquired lands). The enclave clause, however, is only triggered when a state has ceded land to the U.S., hence its applicability is limited to a small proportion of all lands held by the U.S. See *Mansfield*, *supra* note 102, at 805.

The property clause, by contrast, does not need the consent of a state to exert authority over land held by the U.S. Interpreting the Property Clause, the Supreme Court has held that “the ‘complete power’ Congress has over public lands necessarily includes the power to regulate and protect the wildlife living there.” *Kleppe v. New Mexico*, 426 U.S. 529, 541 (1976). The Property Clause enables Congress to determine the public good and forward it by legislation regulating the public lands. *Mansfield*, *supra* note 102, at 807.

¹¹⁵ See *GRAD*, *supra* note 108, at § 1202[1] (citing Council on Environmental Quality, *Environmental Quality — Twenty-Second Annual Report* 308 (1992)).

¹¹⁶ See *id.*

1. Wilderness Act Lands

The Wilderness Act of 1964¹¹⁷ provides for the protection of wilderness areas to be left in their pristine state.¹¹⁸ Lands given wilderness status are severely restricted in their use.¹¹⁹ Wilderness lands under the act must be managed to “promote, perpetuate and, where necessary, restore the wilderness character of the land and its specific values of solitude, physical and mental challenge, scientific study, inspiration, primitive recreation, watersheds and water yield, wildlife habitat, natural plant communities, and similar natural and recreational values.”¹²⁰ Thus, in most ways, Wilderness Act lands are burdened with the highest duty of preservation, eschewing permanent improvements and leaving “the imprint of man’s work substantially unnoticeable.”¹²¹

2. The National Parks

In 1872, President Ulysses S. Grant signed into law the act establishing some two million acres as Yellowstone National Park.¹²² This established the

¹¹⁷ Pub. L. 88-577, 78 Stat. 890 (1964) (codified as amended at 16 U.S.C. §§ 1131-1136 (1994)).

¹¹⁸ The statutory definition of wilderness provides an adequate overview of the restricted uses contemplated by lands designated as “wilderness” under the act:

A wilderness, in contrast with those areas where man and his own works dominate the landscape, is hereby recognized as an area where the earth and its community of life are untrammled by man, where man himself is a visitor who does not remain. An area of wilderness is further defined to mean in this Act . . . an area of undeveloped Federal land retaining its primeval character and influence, without permanent improvements or human habitation, which is protected and managed so as to preserve its natural conditions and which (1) generally appears to have been affected primarily by the forces of nature, with the imprint of man’s work substantially unnoticeable; (2) has outstanding opportunities for solitude or a primitive and unconfined type of recreation; (3) has at least five thousand acres of land or is of sufficient size as to make practicable its preservation and use in an unimpaired condition; and (4) may also contain ecological, geological, or other features of scientific, educational, scenic, or historical value.

16 U.S.C. § 1333(c) (1994).

¹¹⁹ See *id.* (prohibiting commercial enterprise, permanent and temporary roads, mechanical transports, structures, installations in designated wilderness areas with limited exceptions).

¹²⁰ See 43 C.F.R. § 8560.0-6 (1998) (providing explication of policy goals of Wilderness Act including goals that ecological succession should be allowed to operate freely, human use allowed consistent with maintenance of wilderness character, and primacy of wilderness values in resolving use conflicts).

¹²¹ 16 U.S.C. § 1131(c) (1994).

¹²² The lands described by the Act were “reserved and withdrawn from settlement, occupancy, or sale under the laws of the United States, and dedicated and set apart as a public park or pleasuring-ground for the benefit and enjoyment of the people.” *Id.* § 21 (1994).

first component of what would grow to a world renowned system of well over 100 parks, monuments and recreation areas.¹²³ Since then, the National Park Service's¹²⁴ original role of promoting, regulating and preserving the parks¹²⁵ as a "public park or pleasuring-ground for the benefit and enjoyment of the people"¹²⁶ has evolved into a mandate to conserve the scenery, natural and historic objects, and wildlife while "provid[ing] for [their] enjoyment [. . .] in such manner and by such means as will leave them unimpaired for the enjoyment of future generations."¹²⁷

Like the Wilderness Act lands, the National Parks' emphasis is primarily on conservation and preservation. Unlike the Wilderness Act lands, however, the Park Service has a recreational mandate as well.¹²⁸ To fulfill this second mandate, the Park Service routinely contracts for concession services, builds roads, and establishes campgrounds and other facilities within park territory.¹²⁹ Additionally it is affirmatively authorized to enter into cooperative research agreements with public or private parties.¹³⁰ While scientific research clearly comports with the parks' conservation imperatives, the question remains whether

¹²³See generally *id.* §§ 21-460kk (1994) (establishing components of National Park System).

¹²⁴The National Park Service was established under the Department of the Interior and delegated the authority to manage the Park System in 1916. *Id.* § 1 (West 1998).

¹²⁵Each of the components of the National Park System are reserved by specific legislative enactment and may contain individually specific mandates and use restrictions. For example, the act establishing Yellowstone National Park in 1872 can be found at *id.* §§ 21-40(c) (1994).

¹²⁶*Id.* § 21 (1994).

¹²⁷*Id.* § 1 (1994). The National Park Service's full mandate is found in the declarations of findings and purpose, enacted in 1970:

Congress declares that the national park system, which began with establishment of Yellowstone National Park in 1872, has since grown to include superlative natural, historic, and recreation areas in every major region of the United States, its territories and island possessions; that these areas, though distinct in character, are united through their inter-related purposes and resources into one national park system as cumulative expressions of a single national heritage; that, individually and collectively, these areas derive increased national dignity and recognition of their superb environmental quality through their inclusion jointly with each other in one national park system preserved and managed for the benefit and inspiration of all the people of the United States

Id. § 1a-1 (West 1998).

¹²⁸See John G. Sprankling, *The Antiwilderness Bias in American Property Law*, 63 U. CHI. L. REV. 519, 560 n.216 (1996) (discussing National Park System's purpose as being founded on "twin pillars of conservation and recreation").

¹²⁹See Mansfield, *supra* note 102, at 843-44 (describing variety of improvements and activities Park Service may engage in to pursue its double mandate of conservation and recreation).

¹³⁰See 16 U.S.C. § 1a-2(j) (1994).

the commercialization of genetic resources found therein represents a “derogation of the values and purposes for which they were established.”¹³¹

3. *The National Forests*

The 187 million acres of the National Forests are managed by the U.S. Forest Service within the Department of Agriculture.¹³² While originally chartered for watershed protection and improved timber production, the Forest Service’s mandate was expanded to include recreation, range, timber, watershed and wildlife and fish as management objectives.¹³³ However, like the Bureau of Land Management lands,¹³⁴ the Forest Service lands are subject to “disparate uses and competing interests” and the statutory mandates do not dictate or prohibit specific uses unless a tract is included in a specialized management regime.¹³⁵ Unlike the National Parks or Wilderness Act lands though, the National Forests may be commercialized under an affirmative grant of authority.¹³⁶

4. *Bureau of Land Management Lands*

The Bureau of Land Management (“BLM”) in the Department of the Interior has the responsibility for managing over 450 million acres of public lands.¹³⁷ These are residual lands that have not been specifically designated to a particular use such as wilderness, national park or national forest.¹³⁸ As the holder of these “residual” lands, the BLM finds its management mandate solely

¹³¹*Id.* § 1a-1 (West 1992).

¹³²*See* Mansfield, *supra* note 102, at 838.

¹³³Originally the National Forests were established in 1897 for “the purpose of securing favorable conditions of water flows, and to furnish a continuous supply of timber for the use and necessities of citizens of the United States.” 16 U.S.C. § 475 (1994). In 1960, Congress expanded the uses of the National Forests stating that “the national forests are established and shall be administered for outdoor recreation, range, timber, watershed, and wildlife and fish purposes.” *Id.* § 528 (1994).

¹³⁴*See infra* Part III.A.4 (discussing mandates affecting Bureau of Land Management lands).

¹³⁵Mansfield, *supra* note 102, at 841.

¹³⁶*See id.* § 475 (1994) (stating that administration of national forests shall be for purposes of “securing favorable conditions of water flows, and to furnish a continuous supply of timber for the use and necessities of citizens of the United States.”).

¹³⁷*See* GRAD, *supra* note 108, § 12.02[1][c].

¹³⁸*See id.*

in the Federal Land Policy and Management Act of 1976 (“FLPMA”).¹³⁹ Generally, the FLPMA dictates that the BLM must observe the principles of multiple use and sustained yield¹⁴⁰ in its formation of plans and management activities.¹⁴¹ Given the wide variety of the lands under BLM control and the uses for which they are suited, the concepts of multiple use and sustained yield provide little clear guidance for the development of management strategies. One commentator has aptly noted that the FLPMA provides “schizophrenic directives to [the BLM to] both encourage mining and preserve land in its natural condition.”¹⁴²

In sum, the vast majority of federally owned lands are administered by three agencies: the National Park Service, the Forest Service, and the Bureau of Land Management.¹⁴³ The Wilderness Act lands and National Parks have the most restrictive mandates regarding conservation and commercial exploitation of their resources.¹⁴⁴ Less restrictive are the mandates of the Forest Service, providing for timber production and watershed protection, but incorporating uses such as recreation, range, wildlife use and preservation of species.¹⁴⁵ Further, the Forest Service must only administer these uses under the multiple-use and sustained-yield principles of the National Forest Management Act, leaving room for the balancing necessary to develop a commercial genetic resource management strategy.¹⁴⁶ The Bureau of Land Management, having no organic mandate, must only administer its non-use designated lands consistent with the FLPMA’s

¹³⁹ 43 U.S.C. §§ 1733, 1736-1739, 1740 (1994); *see infra* Part III.B.1 (examining FLPMA further).

¹⁴⁰ *See* Mansfield, *supra* note 102, at 853 (discussing how unlike dominant uses applicable to Wilderness Act lands or the National Parks — preservation or recreation — “multiple use” requires “the most judicious use of the land for some or all of these resources . . . [,]harmonious and coordinated management . . . without impairment of the productivity of the land, . . . not necessarily the combination of uses that will give the greatest dollar return or the greatest unit output.” By comparison sustained yield “means the achievement and maintenance in perpetuity of a high-level annual or regular periodic output of the various renewable resources of the national forests without impairment of the productivity of the land.” citing 16 U.S.C. § 531 (1985)).

¹⁴¹ *See id.*

¹⁴² Mansfield, *supra* note 102, at 837.

¹⁴³ *See supra* Part III.A (describing public lands managed by various federal agencies).

¹⁴⁴ *See supra* Part III.A.1-2 (discussing restrictive mandates of Wilderness Act lands and National Parks).

¹⁴⁵ *See supra* Part III.A.3 (setting forth management mandates of Forest Service); *see also* National Forest Management Act, 16 U.S.C. §§ 1600-1687 (1994) (detailing management mandates applicable to Forest Service).

¹⁴⁶ *See infra* Part III.B.2 (noting requirements of NFMA).

multiple-use, sustained yield philosophy, again leaving room for development of a commercial genetic resource management strategy.¹⁴⁷ However, as will be examined below, specific provisions of the Federal Land Policy and Management Act, the National Forest Management Act, the National Environmental Policy Act and Endangered Species Act may impact the applicability of bioprospecting agreements on the public lands.¹⁴⁸

B. Public Land Management Mandates

In addition to the basic management mandates affecting the various classifications of federally owned or controlled land, several broader legislative schemes have attempted to provide a more cohesive management policy for them. As discussed, the management of the Wilderness Act lands and the National Parks are governed by their own specific mandates.¹⁴⁹ The remainder are subject to more generally applicable acts like the Federal Land Policy and Management Act, the National Forest Management Act, National Environmental Policy Act, and the Endangered Species Act. In the context of developing a genetic resource management strategy, an examination of each of these mandates is useful.

1. Federal Land Policy and Management Act

In response to this multiplicity of policies and directives governing the management of public lands, Congress passed and the President signed into law the Federal Land Policy and Management Act of 1976.¹⁵⁰ While clarifying the purposes, goals, and administrative authority for the management of public lands, the FLPMA failed to unify responsibility for managing the public lands in a single administrative body.¹⁵¹ It did, however, reaffirm the principles of mul-

¹⁴⁷ See *infra* Part III.B (recounting requirements of FLPMA).

¹⁴⁸ See *infra* Part III.B (discussing public land management mandates).

¹⁴⁹ See *supra* Part III.A (examining specific mandates applicable to Wilderness Act lands and National Parks).

¹⁵⁰ Pub. L. 94-579, 90 Stat. 2744 (1976) (codified at 43 U.S.C. §§ 1701-82).

¹⁵¹ See GRAD, *supra* note 108, § 12.02[3][a] (noting lack of overall planning authority and coordination was noted by Public Land Law Review Commission, which recommended establishment of inter-agency planning coordination, . . . or establishment of new federal department of natural resources to combine responsibilities of Department of Interior with those in Department of Agriculture.)

multiple-use and sustained-yield,¹⁵² making them applicable to all public lands administered by the BLM and the Forest Service.¹⁵³ The Wilderness Act lands and National Parks, by contrast, are governed only by the organic statutes creating them.¹⁵⁴ Resource uses and management practices are specifically limited by these statutes and other generally applicable environmental legislation, thus the FLPMA's principles do not apply to these two types of public lands.¹⁵⁵

2. National Forest Management Act

Enacted at the same time as the FLPMA, the National Forest Management Act (NFMA)¹⁵⁶ attempted to reduce the Forest Service's unbridled discretion in managing the National Forests.¹⁵⁷ In addition to incorporating the disclosure procedures of the National Environmental Policy Act¹⁵⁸ and the multiple-use,

¹⁵²The FLPMA expands the definition of multiple use and sustained yield in the following manner:

The term "multiple use" means the management of the public lands and their various resource values so that they are utilized in the combination that will best meet the present and future needs of the American people; making the most judicious use of the land for some or all of these resources or related services-over areas large enough to provide sufficient latitude for periodic adjustments in use to conform to changing needs and conditions; the use of some land for less than all of the resources; a combination of balanced and diverse resource uses that takes into account the long-term needs of future generations for renewable and nonrenewable resources, including, but not limited to, recreation, range, timber, minerals, watershed, wildlife and fish, and natural scenic, scientific and historical values; and harmonious and coordinated management of the various resources without permanent impairment of the productivity of the land and the quality of the environment with consideration being given to the relative values of the resources and not necessarily to the combination of uses that will give the greatest economic return or the greatest unit output.

43 U.S.C. § 1702(c) (1994). Accordingly sustained yield "means the achievement and maintenance in perpetuity of a high-level annual or regular periodic output of the various renewable resources of the public lands consistent with multiple use." *Id.* § 1702(h) (1994).

¹⁵³GRAD, *supra* note 108, § 12.02[3][a]. As discussed in Part III.A. *supra*, the lands administered by the Forest Service under the Department of Agriculture include the National Forest lands while those administered by the Bureau of Land Management under the Department of the Interior include all the "residual" lands not included in Wilderness areas, National Parks, or National Forests, etc.

¹⁵⁴*See id.*

¹⁵⁵*See Mansfield, supra* note 102, at 269 (arguing that Wilderness areas and National Parks have more restrictive use mandates in their organic statutes subject only to provisions of more generally applicable environmental statutes such as National Environmental Policy Act and Endangered Species Act).

¹⁵⁶National Forest Management Act of 1976, Pub. L. 94-588, 90 Stat. 2949 (1976) (codified at 16 U.S.C. §§ 472a, 521b, 1600-14).

¹⁵⁷*See Michael A. Padilla, The Mouse That Roared: How the National Forest Management Act Diversity of Species Provision is Changing Public Timber Harvesting*, 15 UCLA J. ENV'T. L. & POL'Y 113, 115 (1997) (discussing how NFMA fundamentally changed the way Forest Service managed National Forests which under Organic Act of 1897 gave Service wide discretion in its management practices).

¹⁵⁸*See infra* Part III.B.3 (examining National Environmental Policy Act).

sustained-yield objectives of the FLPMA,¹⁵⁹ the NFMA provided a critical substantive regulatory mandate incorporating the preservation and enhancement of the diversity of plant and animal species in its land management decisions.¹⁶⁰

Even while the Forest Service has promulgated regulations that seek to focus and clarify its preservation of diversity mandate,¹⁶¹ the delicate balancing act of incorporating preservation of species diversity with multiple-use, sustained-yield principles has spawned extensive litigation.¹⁶² As the effect of the NFMA's diversity of species requirement is already affecting National Forest land use decision making,¹⁶³ its existing mandate will have to be considered when developing a genetic resource management strategy.

3. *The National Environmental Policy Act*

The National Environmental Policy Act of 1969 (NEPA)¹⁶⁴ was enacted, in part, to mandate that federal agencies consider the consequences of their actions on the environment.¹⁶⁵ NEPA is generally applicable to all federal actions and agencies.¹⁶⁶ Generally, the Act requires environmental impact statements to be filed in instances that involve "major federal actions significantly affecting the quality of the human environment."¹⁶⁷ If a federal action is determined not to have a significant effect, the responsible agency must provide a reviewable envi-

¹⁵⁹ See *supra* Part III.B.1 (reviewing multiple-use and sustained yield approaches of FLPMA).

¹⁶⁰ See *id.* at 118 (discussing so-called "diversity of species requirement" of NFMA embodied in 16 U.S.C. § 1604 (g)(3)(B) (1994) which commands the Forest Service to "provide for the diversity of plant and animal communities . . . within the multiple-use objectives of a land management plan adopted pursuant to this section . . .").

¹⁶¹ See, e.g., 36 C.F.R. § 219.27(g) (1998) (interpreting NFMA's diversity requirement to require preservation of diversity "so that it is at least as great as that which would be expected in a natural forest . . .").

¹⁶² See Padilla, *supra* note 157, at 123 (discussing plethora of complex litigation surrounding old growth redwoods in Pacific northwest and spotted-owl which applied not only provisions of Endangered Species Act, but NFMA diversity of species requirements as well).

¹⁶³ See Padilla, *supra* note 157, at 119-50 (detailing Forest Service's development and implementation of long range management plans promulgated under NFMA); Wilkinson, *supra* note 74, at 681 (commenting on impact of NFMA "[t]he Forest Service, sometimes on its own initiative, sometimes moving haltingly, sometimes dragged kicking and screaming, seems to have embraced this new kind of management. The agency seems increasingly to be imbued with the primacy of biodiversity as a management goal.").

¹⁶⁴ Pub. L. No.91-190, 83 Stat. 852 (1970) (codified as amended at 42 U.S.C. § 432-4347 (1994)).

¹⁶⁵ See 4 GRAD, *supra* note 108, § 9.01[h].

¹⁶⁶ See *id.*

¹⁶⁷ 4 GRAD, *supra* note 108, § 9.02[1][a][II] (citing NEPA § 102(2)(C)).

ronmental record of its findings and provide adequate opportunity for public participation in the determination.¹⁶⁸

The Council on Environmental Quality, established by the Act¹⁶⁹ and given subsequent authority to promulgate regulations¹⁷⁰ has defined "major federal action" to include actions "with effects that may be major and which are potentially subject to Federal control and responsibility."¹⁷¹ Considering the "significance" of the federal action contemplated, the courts have provided factors to examine including: (1) the degree to which public health and safety is affected, (2) the uniqueness of the area affected, (3) the highly controversial nature of the effects, (4) the precedential effect for similar actions, (5) the effect related to other actions that may have a cumulative effect, (6) the extent of its affect on endangered species, and (7) whether the proposed action would violate the requirements of other applicable environmental protections.¹⁷²

Considering both the breadth and the forward-looking nature of these interpretations, it is conceivable that bioprospecting agreements on public lands, (although perhaps a *de minimis* incremental intrusion into the ecosystem) may fall within the Act's scope, thus requiring environmental impact statements. This is particularly the case when the cumulative effects of multiple agreements are considered. Unrestricted access to a genetic source about which little is known or which may be particularly sensitive to perturbation in its environment may have significant deleterious effects on the long term viability of the population. In this respect, though NEPA may impose a burden requiring the consideration of environmental effects federal action may have, the Act itself is largely toothless, providing no substantive environmental mandate but merely the adequate consideration of effects within its scope.

¹⁶⁸ See *id.* (citing *Hanly v. Mitchell*, 471 F.2d 823, 836 (2d Cir. 1973), which provides that before threshold determination is made, the public must be given an opportunity to submit relevant facts which might bear upon the agency's decision whether an environmental impact statement is required)

¹⁶⁹ See NEPA §§ 201-207, 42 U.S.C. §§ 4341-4347 (1994).

¹⁷⁰ See 4 GRAD, *supra* note 108, § 9.01[3][a] (citing Executive Order No. 11514, Protection and Enhancement of Environmental Quality, 35 Fed. Reg. 4247 (Mar. 5, 1970), revised by Executive Order No. 11991, 42 Fed. Reg. 26967 (May 25, 1977)).

¹⁷¹ *Id.* § 9.02[1][a][1] (citing CEQ Regulations, 40 C.F.R. § 1508.18, 43 Fed. Reg. 56004 (Nov. 29, 1978)).

¹⁷² See *id.* § 9.02[1][a][1] (citing, for example, *Burbank Anti-Noise Group v. Goldschmidt*, 623 F.2d 115 (9th Cir. 1980), *cert. denied*, 450 U.S. 965 (1981)).

4. *The Endangered Species Act*

Generally, the Endangered Species Act¹⁷³ (ESA) requires the federal government to improve the condition of various species of fish, wildlife, and plants in the United States as a member of the international community.¹⁷⁴ The Act specifically mentions various existing international agreements and contemplates future agreements such as the as-yet-unratified United Nations Conference on the Environment and Development's Convention on Biological Diversity, thus developments in the international arena may find domestic application in concert with the ESA.¹⁷⁵ The applicability of the ESA turns on the determination that a given species of flora or fauna is endangered or threatened.¹⁷⁶ This assessment must be based on the present or threatened destruction of habitat, overutilization for commercial recreational or scientific purposes, disease or predation, inadequacy or existing regulatory mechanisms, or other human-made factors affecting its continued existence.¹⁷⁷ Additionally, designation of critical habitat must be based upon the best available scientific data.¹⁷⁸ Factors to be considered in making the determination of critical habitat may include space for individual and population growth, food, water, air, light, minerals, or other nutritional or physiological requirements, cover or shelter, sites for breeding, reproduction, rearing of young, germination or seed dispersal and general considerations regarding the historical, geographical or ecological distributions of a species.¹⁷⁹

Before taking any action, the ESA requires federal agencies to consult with the U.S. Fish and Wildlife Service to determine whether an endangered or threatened species may be present in the area of proposed action.¹⁸⁰ If so, the agency

¹⁷³Endangered Species Act of 1973, Pub. L. 93-105, 87 Stat. 884, (1973) (codified at 16 U.S.C. §§ 1531-44).

¹⁷⁴SEE W. JACK GROSSE, *THE PROTECTION AND MANAGEMENT OF OUR NATURAL RESOURCES, WILDLIFE AND HABITAT* 83 (2d ed. 1997).

¹⁷⁵The ESA already contemplates the existence of international agreements such as the North American Migratory Bird Treaty, the Migratory and Endangered Bird Treaty with Japan, the Convention on Nature Protection and Wildlife Preservation in the Western Hemisphere, the International Convention for the Northwest Atlantic Fisheries, the International Convention for the High Seas Fisheries of the North Pacific Ocean, the Convention on International Trade in Endangered Species of Wild Fauna and Flora and specifically "other international agreements" generally. 16 U.S.C. § 1531(4) (1994).

¹⁷⁶See 16 U.S.C. § 1533 (1994).

¹⁷⁷See GROSSE, *supra* note 174, at 93 (discussing 16 U.S.C. § 1533(b)(1)(A)).

¹⁷⁸See *id.*

¹⁷⁹See *id.* at 94.

¹⁸⁰See *id.* at 102 (citing 16 U.S.C. § 1536).

must prepare a biological assessment to determine what effects, if any, the proposed action is likely to have on the species.¹⁸¹ Finally, if the agency determines that an endangered or threatened species is likely to be affected, the Fish and Wildlife Service must be formally consulted.¹⁸² It is then incumbent upon the Fish and Wildlife Service to determine whether the proposal would result in a violation of the Act by publishing a biological opinion.¹⁸³

On its face, the ESA seems particularly on point with respect to the promulgation of bioprospecting agreements and the development of a genetic resource management strategy. This is especially the case in ecologically sensitive areas with populations of largely unknown or rare species. Once a species or critical habitat has been designated, the Endangered Species Act may prove to be an essential tool in the management of genetic resources on public lands. However, the controversial nature of the broad scope of the Act may preclude its application in the genetic resource context.¹⁸⁴

C. The Public Trust Doctrine

The public trust doctrine embodies the proposition that some kinds of property should not be held in exclusively private hands, but rather should be open to the public or at least subject to the "public right" or "jus publicum."¹⁸⁵ In recent years, the public trust doctrine has been used increasingly to provide a

¹⁸¹ See *id.*

¹⁸² See *id.* (citing 16 U.S.C. § 1536(b)).

¹⁸³ See *id.* at 104 (citing 16 U.S.C. § 1536(c)).

¹⁸⁴ See Dana Clark & David Downes, *What Price Biodiversity? Economic Incentives and Biodiversity Conversion in the United States*, J. ENV'T. L. & LITIG. 9, 14 n.10 (1996) (discussing controversy over stringency of Act's regulations as evidenced by Congressional attempts to halt listing of species, and wrangling over renewal of Act which has continued since 1992); Katherine Bouma, *Endangered Species Act Also Struggling to Stay Alive*, ORLANDO SENTINEL, Dec. 29, 1997, at A6 (recounting six years of continuous attacks Act and Fish and Wildlife Service have undergone in Congress since Act's renewal came up in 1992, including moratorium on listing new species and lack of funding for its implementation since 1988).

¹⁸⁵ See GEORGE C. COGGINS, PUBLIC NATURAL RESOURCES LAW § 8.07 (1998) (elaborating that while state public trust doctrines stem from Roman law, they more directly spring from 1892 Supreme Court decision *Illinois Central Railroad v. Illinois*, 146 U.S. 387 (1892) which recognized modern public trust doctrine as a limitation on state legislature's discretion to convey trust lands); Rose, *supra* note 251, at 713 (contending that notion of public property has longstanding tradition in modern western law, stemming from Roman civil law and its subsequent influence on European law); Richard J. Lazarus, *Changing Conceptions of Property and Sovereignty in Natural Resources: Questioning the Public Trust Doctrine*, 71 IOWA L. REV. 631, 635 (1986) (chronicling introduction of Roman notion of "res communes" or common to all, first into thirteenth century English common law, then into nineteenth century American law).

basis for the preservation and regulation of natural resources.¹⁸⁶ The courts have extended the doctrine well beyond its ancient traditions of insuring public access to air, running water, the sea and seashore¹⁸⁷

As applied in recent years, courts have used the public trust doctrine as a tool to correct perceived imperfections in governmental natural resource decision making.¹⁸⁸ The doctrine has been used more recently to support claims for the preservation of natural areas, parks, historical areas, cemeteries, archeological sites, remains, and works of art.¹⁸⁹ The doctrine, in various forms, has been used to limit the alienation of public resources by legislatures with insufficient public notice.¹⁹⁰ It has also been used in the counter-majoritarian role where there has been a failure of representation-reinforcement, denying interested parties sufficient access to the political process.¹⁹¹

The expanding nature of this doctrine has been criticized as being undemocratic, giving a technically non-competent judiciary veto authority over decisions made by specialized administrative agencies on highly complex issues.¹⁹² It has also been criticized as allowing over-valuation of public trust uses while derogating private property rights.¹⁹³ However, proponents have argued that the doctrine finds its true roots in the recognition that the preservation of public access — and its beneficial effect on commerce — results in social benefit through its democratizing effect.¹⁹⁴ In this manner, the public trust doctrine can be viewed as a tool not unlike the Fifth Amendment's takings clause, providing

¹⁸⁶ See William D. Araiza, *Democracy, Distrust, and the Public Trust: Process-based Constitutional Theory, The Public Trust Doctrine, and the Search for a Substantive Environmental Value*, 45 UCLA L. REV. 385, 387 (1997) (noting that in last 25 years, public trust doctrine has enjoyed tremendous renaissance, and provided source of judicial authority for natural resource preservation).

¹⁸⁷ See *id.*

¹⁸⁸ See *id.* at 400 (discussing seminal article by Joseph L. Sax, *The Public Trust Doctrine in Natural Resource Law: Effective Judicial Intervention*, 68 MICH. L. REV. 471 (1970)); Lazarus, *supra* note 185, at 643 (noting impact that modern resurrection of public trust doctrine has had on environmental law while questioning its validity).

¹⁸⁹ See *id.* at 402 (reviewing recent expansion of doctrine and its increasing importance in natural resource law jurisprudence).

¹⁹⁰ See *id.* at 399 (elaborating Sax's view of various courts' application of doctrine before 1970, describing result as "democratization" of natural resource decision making).

¹⁹¹ See *id.*

¹⁹² See *id.* at 403 (describing parade of horrors envisioned by critics of public trust doctrine as doctrine departs from its traditional basis in navigation and waterways). See generally Lazarus, *supra* note 185 (discussing pitfalls associated with expansion of doctrine).

¹⁹³ See Araiza, *supra* note 186, at 403.

¹⁹⁴ See *id.* at 434 (positing public trust doctrine as public property doctrine).

a mechanism whereby the highest "use" of property can be achieved despite private agreements or under-inclusive legislative decisions to the contrary.¹⁹⁵

The public trust doctrine therefore provides a somewhat ambiguous but potentially significant tool conceptually toward developing a comprehensive management strategy for genetic resources on public lands. In this manner, the judiciary may fulfill a critical role insuring both democratization in the process as well as assisting in checking legislative and administrative decision making that may be compromised by under-representation or conflicts of interest.¹⁹⁶ While judicial oversight of legislative and administrative decisions ex-post facto is clearly an undesirable result,¹⁹⁷ the availability of a judicial remedy should provide not only incentive to develop policy through legislative means, but also provide a decisional safety net at the margin of resource management decisions.¹⁹⁸ The principles behind the public trust doctrine, therefore, may provide a conceptual framework for the development of cogent genetic resource management strategy in harmony with the evolution of the common law.

D. International Agreements for Protection of Genetic Resources: The Biodiversity Treaty

The United Nations' Conference on Environment and Development: Convention on Biological Diversity (Biodiversity Treaty)¹⁹⁹ represents the global

¹⁹⁵ See *id.* at 22 (discussing role of judicial review and public trust doctrine as a pure property theory).

¹⁹⁶ One commentator explained the basis for the role of the judiciary as a resource decision making safety net to protect the public interest as follows:

The idea is that there is a substantive value underlying the public trust doctrine — namely, that there is substantial worth in the unorganized public's custody of a resource — and that the nature of this value as inhering in a diffuse group makes judicial intervention necessary, given the difficulty of effectuating that interest in the political-administrative process.

Araiza, *supra* note 186, at 436.

¹⁹⁷ See generally *supra* Part V (explicating goals of genetic resource management strategy which include economic efficiency — precluded by perennial judicial oversight); *infra* Part VI (analyzing current regulatory framework in context of goals articulated in Part V and concluding that proactive legislative policy would be more efficient than reactive judicial response).

¹⁹⁸ Cf. COGGINS, *supra* note 185, at § 8.07 (concluding that public trust doctrine in federal natural resource law has had little impact and is unlikely to be construed as limitation on congressional discretion as it has been on state legislative action); LAZARUS, *supra* note 185, at 674 (arguing that "with the emergence of the modern police power, the public trust doctrine retains little importance in promoting governmental authority to protect and maintain a healthy and bountiful environment.").

¹⁹⁹ United Nations Conference on Environment and Development: Convention on Biological Diversity, art. 3, 31 I.L.M. 818 (1992) [hereinafter Biodiversity Treaty].

community's attempt to provide a framework for the preservation of biodiversity. The Convention's objectives embrace the conservation of biodiversity, sustainable use, and fair and equitable sharing of benefits — which includes appropriate access to genetic resources and technology.²⁰⁰

The Biodiversity Treaty provides an international framework for the formulation of individual national legislation designed to serve the convention's objectives.²⁰¹ While the convention explicitly acknowledges that sovereign states have a right to exploit their own biological resources,²⁰² the principles embodied in the treaty attempt to address the fundamental issues surrounding the preservation and use of biodiversity on an international scale.²⁰³ Even though the convention sought to address fundamental inequities in the exploitation of the southern hemisphere's biological resources by the north,²⁰⁴ the Biodiversity Treaty's principles find ready applicability within a sovereign nation in the formulation of a comprehensive plan for managing genetic resources.

Rather than focusing on an individual species or its critical habitat, the Biodiversity Treaty attempts to create a comprehensive framework for both preservation and sustainable use by adopting a genetic portfolio approach.²⁰⁵ Further, the Biodiversity Treaty attempts to address shortcomings of both regulatory and market-based approaches by proscribing identification and monitor-

²⁰⁰ See *id.* at 823.

²⁰¹ See *id.*

²⁰² See *id.* at 824.

²⁰³ See *id.*

²⁰⁴ President Ali Hassan Mwinyi of Tanzania stated the issue concisely:

[M]ost of us in developing countries find it difficult to accept the notion that biodiversity should [flow freely to industrialized countries] while the flow of biological products from the industrialized countries is patented, expensive and considered the private property of the firms that produce them.

This asymmetry reflects the inequality of opportunity and is unjust.

Report of the United Nations Conference on Environment and Development, at 36, U.N. Doc. A/CONF.151/26/Rev.1 (1993). See Craig D. Jacoby & Charles Weiss, *Recognizing Property Rights in Traditional Biocultural Contribution*, 16 *STAN. ENV'T L.J.* 74, 90 (1997) (arguing that "use of biocultural contributions by biotechnology companies . . . to create commercial products [is another] example of the traditional colonial paradigm of exchanging natural resources for manufactured goods.").

²⁰⁵ A genetic portfolio approach attempts to preserve a diversity of genetic material rather than a single species or habitat. See Stone, *supra* note 41, at 614-15 (discussing ambiguity embodied in adopting methods of measurement of biodiversity in context of Biodiversity Treaty). Recall that the applicability of the protections of the ESA turns on the determination that an individual species or its habitat is threatened. The Biodiversity Treaty, by contrast, recognizes the intrinsic value in biodiversity and articulates its preservation as a goal. See *supra* Part III.B.4 (discussing mechanics of Endangered Species Act).

ing, impact assessment, and both in-situ²⁰⁶ and ex-situ²⁰⁷ conservation.²⁰⁸ Additionally, it calls for the integration of sustainable use and development, economically and socially sound incentive programs, and public education.²⁰⁹ Perhaps most controversially, it couples access to genetic resources with a quid pro quo technology transfer goal.²¹⁰ Incorporated in these goals are the protection of intellectual property rights²¹¹ as well as insuring that the benefits of derivative technology inure to the nation charged with the conservation of the genetic resources.²¹²

²⁰⁶ Under the Biodiversity Treaty "in-situ conservation" means:

the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

Biodiversity Treaty, *supra* note 199, at 823.

²⁰⁷ As defined in the treaty, "ex-situ conservation means the conservation of components of biological diversity outside their natural habitats." *Id.*

²⁰⁸ *See id.*

²⁰⁹ *See id.*

²¹⁰ Article 16 (1) provides:

Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes . . . to provide and/or facilitate access for and transfer to other Contracting Parties or of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

Biodiversity Treaty, art. 16, § 1, *supra* note 199, at 829. The Bush administration refused to sign the treaty in 1992 claiming that the "prerequisite" of the transfer of intellectual property rights incorporated in the treaty resulted in a "seriously flawed" document. U.S. DEPARTMENT OF STATE, CONVENTION ON BIOLOGICAL DIVERSITY, DEPARTMENT OF STATE DISPATCH, June 1, 1992. Opponents of the treaty, however, supported adoption of the treaty after the Clinton administration issued its interpretations of the treaty in 1993. OTP BIOTECHNOLOGY REPORT, *supra* note 2, at 106. This support was based upon State Department "Statements of Understanding" explaining the U.S. interpretation of the treaty that reaffirmed a strong commitment to protection of U.S. intellectual property rights and the voluntary nature of technology transfer terms negotiated into agreements. *Id.* See generally President's Message to the Congress Transmitting the Convention on Biological Diversity, 29 Weekly Comp. Pres. Doc. 2417 (Nov. 19, 1993) (stating that administration will "strongly resist any actions . . . that lead to inadequate levels of protection of intellectual property rights") [hereinafter Message to Congress on the Biodiversity Treaty]; U.S. DEPARTMENT OF STATE, RATIFICATION SOUGHT FOR THE CONVENTION ON BIOLOGICAL DIVERSITY, U.S. DEP'T OF STATE DISPATCH (Apr. 18, 1994) [hereinafter STATE DEP'T DISPATCH ON RATIFICATION] (discussing concerns raised by industry regarding intellectual property rights and detailing administrations specific interpretations of provisions of treaty. The Secretary went so far as to state that "no implementing legislation or changes in U.S. regulations or existing federal-state relationships will be needed to fulfill the domestic requirements [of the treaty] . . .").

²¹¹ *See* Biodiversity Treaty, *supra* note 199, at 828

²¹² *See id.*

As yet unratified, the Biodiversity Treaty has no binding effect on the United States.²¹³ However, in the context of developing a comprehensive strategy for managing biological resources, the treaty goes a long way toward providing a blueprint for a comprehensive management plan. No legislation in the United States had attempted to unify the goals of species preservation, habitat protection, scientific investigation, sustainable technological development, protection of intellectual property rights, and ensuring that the benefits of native genetic resources are equitably shared by the population. To this end, the Biodiversity Treaty represents not only the first international attempt at managing biological resources, but represents a fundamental paradigm shift in viewing the unique and diverse concerns that are evolving around the issue of genetic resources and bioprospecting.²¹⁴

IV. INTELLECTUAL PROPERTY PROTECTION

Intellectual property protection provides the final veneer on the complex regulatory framework applicable to bioprospecting activities in the United States. It is through the intellectual property protection scheme that the biotechnology industry creates and preserves the value of its efforts.²¹⁵

Protection of intellectual property in the United States finds its basis in the Constitution. The Constitution specifically authorizes Congress to issue patents and copyrights for a limited time to inventors and authors "To promote the Progress of Science and useful Arts."²¹⁶ The basic rationale for the constitutional basis for the intellectual property protection is that such protection provides incentives for invention and innovation.²¹⁷ In the context of bioprospecting, a

²¹³ See OTP BIOTECHNOLOGY REPORT, *supra* note 2, at 106 n.109.

²¹⁴ See STATE DEP'T DISPATCH ON RATIFICATION, *supra* note 210 (describing treaty as an "unprecedented effort by nations of world to take action now to deal with biodiversity loss before its too late . . .").

²¹⁵ See OTP BIOTECHNOLOGY REPORT, *supra* note 2, at 97 ("The ability to control discoveries through the establishment of intellectual property rights is fundamental to the competitiveness of the biotechnology.").

²¹⁶ U.S. CONST. art. I, § 8, cl. 8.

²¹⁷ See Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024 n.31 (1989) (quoting Thomas Jefferson's rejection of notion of natural law basis for patents). Jefferson wrote:

Inventions then cannot, in nature, be a subject of property. Society may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may produce utilities, but this may or may not be done according to the will and convenience of society, without claim or complain from anybody.

Id.

patent is the ultimate goal of the prospector and the greatest source of value attributable of the successful product or technology.²¹⁸ Thus a brief foray into the contours of intellectual property law must inform any discussion of bioprospecting.

A. The Patent Act

The Patent Act²¹⁹ provides the statutory framework for protection of intellectual property. Anyone who invents a “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent.”²²⁰ To receive a patent, an invention must qualify as patentable matter, exhibit utility, novelty, and non-obviousness.²²¹ If a patent is granted, the patentee receives the right to exclude others from using the patent, offering or selling products made with the patent, and to stop the importation of products made by that process for a period of twenty years from the time of application.²²²

Historically, living products such as bacterium were thought to be unpatentable.²²³ In 1980, however, the U.S. Supreme Court in *Diamond v. Chakrabarty*,²²⁴ extended patent protection to a human-made, genetically engineered bacterium.²²⁵ Though the Court still declined extending patent protection to laws of nature, physical phenomena, abstract ideas, or products of nature such as naturally occurring minerals, plants and animals,²²⁶ this decision is credited with significantly accelerating the growth of the biotechnology industry, then in its infancy.²²⁷

²¹⁸ See *supra* Part II.A (revealing how biotechnology companies use biosprospecting and tremendous market potential for highly successful products).

²¹⁹ 35 U.S.C. §§ 1-293.

²²⁰ *Id.* § 101 (1994).

²²¹ See *id.* §§ 101-103 (1994).

²²² See *id.* § 154 (1994) (discussing rights that inure to holders of U.S. patents).

²²³ See *Oddi, supra* note 259, at 301 (discussing non-patentability of strain of bacteria decided in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)).

²²⁴ 447 U.S. 303 (1980).

²²⁵ See *Diamond*, 447 U.S. at 310 (holding that live human-made microorganism is patentable subject matter).

²²⁶ See *id.*, 447 U.S. at 309 (specifying laws of nature, physical phenomena, abstract ideas, newly discovered minerals and plant matter, and other manifestations of nature are not patentable subject matter under Patent Act).

²²⁷ Until the *Diamond* decision, it was thought that only process- and method-based transformations of biologicals were patentable. The court in *Diamond* however, broadly extended the statutory definition of

As a result of *Diamond* and other decisions,²²⁸ the Patent Office and the courts have extended the patent monopoly to a host of biotechnology products.²²⁹ With the immense commercial success of PCR technology,²³⁰ the recent Diversa-Yellowstone Agreement,²³¹ and the prospect of future cooperative-research and development agreements between the United States and private industry, the allocation and scope of intellectual property protection to products and technologies developed as a result of these agreements should be examined with great scrutiny during the development of genetic resource management strategy.

patentable subject matter to "include anything under the sun that is made by man." *Id.* at 309. The Court described the bacterium as a "nonnaturally occurring manufacture or composition of matter — a product of human ingenuity 'having a distinct name, character [and] use.'" *Id.* at 310 (citation omitted) (alteration in original). This protection was critical to the development of the biotechnology industry in at least two ways. First, this afforded protection to organisms made through techniques of gene-splicing — the introduction of foreign DNA, which when integrated into the host organism's DNA, gives the host and its offspring a non-naturally occurring desired ability or trait. This was the situation in *Diamond* that gave the bacterium *Pseudomonas* the ability to metabolize hydrocarbons — oil-eating bacteria. Secondly, it allowed protection to organisms created for the purpose of synthesizing otherwise naturally occurring compounds, such as taxol. This is the technique used in the case of the *Thermus aquaticus* and the PCR method of DNA amplification. The biotechnology uses both of these methods routinely. See *supra* Part II.A (explaining how biotechnology industry uses genetic resources to develop beneficial products and technologies).

²²⁸The patentability of certain biotechnological processes still faced significant hurdles after *Diamond*. In *In re Durden*, 763 F.2d 1406, 1410 (Fed. Cir. 1985), the appellate court held that a chemical process "otherwise obvious in view of issued patent, was not patentable simply because either or both the specific starting material employed and the product obtained, were novel and unobvious." The Office of Technology Policy explained the problem after *Durden*:

[T]he company might seek patents for both the starting product (e.g., a recombinant gene or host cell) and for the process used to produce the end product. While the patent for the starting product might be granted, the industry felt that claims for the patentability of processes were being unfairly denied on the basis of *Durden* — by characterizing the recombinant expression of the protein as an obvious process.

OTP BIOTECHNOLOGY REPORT, *supra* note 2, at 98.

These problems in patenting biotechnology processes led to legislative action. The response was the Biotechnology Process Patent Act, Pub. L. 101-41 (1995) (codified at 35 U.S.C. § 103(b)). This act defined "biotechnology process" and largely provided a concrete standard for a process' patentability. See OTP BIOTECHNOLOGY REPORT, *supra* note 2, at 99.

²²⁹See *supra* Part II.C (discussing recent biotechnology developments).

²³⁰See *supra* Part II.C (chronicling development and commercial success of PCR technology for amplification of DNA strands giving rise to "DNA fingerprinting" industry).

²³¹See *supra* Part II.C.2 (describing agreement between Diversa Corporation and Yellowstone National Park which authorizes sampling of park microbes and commercial development of products and technologies).

V. DEVELOPING A GENETIC RESOURCE MANAGEMENT STRATEGY:
CONCEPTUALIZING THE ISSUES

The development of genetic resources found on the public lands presents a number of unique problems not typically encountered in the context of resource management. Indeed, perceiving genetic information as a resource at all bespeaks the conceptual problems associated with developing a management strategy. In order to evaluate current regulatory structure and posit solutions or alternatives, the goals of any management strategy must be determined from not only the particular characteristics of genetic resources, but also in the particular context of their location on public lands. Before any goals can be developed, several conceptual hurdles must be examined and surmounted. Primarily, the nature or character of the resource must be conceptualized — are genetic resources more like flora and fauna, renewable, fugitive and amenable to husbandry? Or are they more akin to mineral resources, that may be owned, exploited, and exhausted to the exclusion of others? Next, to what degree do genetic resources exhibit the characteristics of public goods? And, can their “use” be managed in light of the traditional problems associated with public goods? Third, what role should the effect of labor have on the development or management of the resource? By what do we measure “improvement” of a genetic resource? These issues are discussed below in an effort to determine the goals of genetic resource management.

A. *Animal, Vegetable, or Mineral?*

One of the primary problems in developing a genetic resource management strategy is conceptualizing the character of the resource itself.²³² Genetic

²³² See, e.g., Stone, *supra* note 41, at 596-600 (arguing that in one respect rights in genetic resources should be conceptualized as information — a public good that allows free access and non-rivalrous use — while at the same time a source of genetic material — forest, fishery or wild land — takes on characteristics more typical of a privatizable good with rivalrous uses, i.e., land devoted to biodiversity preservation may be incompatible with other uses such as human development); Asebey & Kempenaar, *supra* note 57, at 707-09 (discussing gradual shift away from common heritage doctrine view of genetic resources toward more sovereignty-based schemes exemplified by Biodiversity Treaty); Kadidal, *supra* note 57, at 228-31 (recounting migration of common heritage doctrine from United Nations Convention on Law of Sea through International Undertaking on Plant Genetic Resources to its tacit rejection in Biodiversity Treaty). The common heritage doctrine would provide that the genetic components of natural diversity should be considered the common heritage of humankind, affording free access and use to all. Asebey & Kempenaar, *supra* note 57, at 708. The doctrine has been criticized as allowing the industrialized, technologically

information contained within organisms on public land can't be seen, measured, metered, or fenced. What and where is the resource? Does it lie within the boundaries of the public lands, some number of living organisms, or is it the intangible information on a strand of DNA? Complex organisms like buffalo contain more genetic information than simpler organisms like bacterium, yet thousands of species of bacteria have adapted to the harshest environments on earth. How do we value buffalo compared to bacteria? Modern biotechnological techniques like PCR allow the ready replication DNA — the repository of this genetic information. Should we act to preserve vast areas of habitat and species diversity or is a library of genetic material a more effective strategy?

The value of bioprospecting is derived ultimately from the genetic information contained in the DNA of the biological inhabitants of the public lands.²³³ The 'use' of the resource by a bioprospector occurs in two distinct ways — rivalrous extraction and non-rivalrous replication.²³⁴ Though the sampling is usually a *de minimus* extraction,²³⁵ unrestricted sampling of exceedingly rare specimens from sensitive ecosystems could imperil the continuing survival of those organisms.²³⁶ Thus, the problems associated with managing the genetic resource

wealthy, northern hemisphere countries to inequitably exploit the genetic wealth of the technologically poorer developing nations of the southern hemisphere. *Id.* The move away from the common heritage doctrine in characterizing genetic resources toward sovereignty-based schemes is epitomized in the language of the United Nations Conference on Environment and Development's Convention on Biological Diversity:

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other states or of areas beyond the limits of national jurisdiction.

Biodiversity Treaty, *supra* note 199, art. 3, at 824.

²³³ See *supra* Part II.A (discussing how biotechnology companies use naturally occurring biological materials for genetic information they contain).

²³⁴ See *supra* notes 16-20 and accompanying text (describing generally process by which small sample of organic material is obtained from nature then replicated by synthesis in laboratory through chemical or biological means); Stone, *supra* note 41, at 597 (explaining rivalrous extraction in context of raw material like tree bark or lumber — "its use is rival: If I appropriate the [raw material], it is not available for you" — as opposed to non-rivalrous replication — "once copied . . . the value is shifted from the original specimen to the associated process. In that process the use of the information is non-rivalrous . . . my enjoyment of Shakespeare's plays does not conflict with your enjoyment of the same information.").

²³⁵ See Asebey & Kempenaar, *supra* note 57, at 706 (explaining in detail process by which a typical sample of 500 grams undergoes screening for identification of possibly beneficial compounds); Wilkinson, *supra* note 74, at US1 (describing amount of material required for screening and laboratory synthesis as a "few tablespoons" of collected material. Yellowstone Research Chief John Varley claims the average backpacker will carry away more soil in the soles of his hiking boots than researchers will take back to the laboratory).

²³⁶ See *supra* notes 32-35 and accompanying text (recounting problems that have arisen in international bioprospecting activities and specifically collection of *Maytenus buchananni* by National Cancer Institute).

are analogous to those incident to managing the population of any imperiled animal species — habitat must be preserved, a healthy breeding population must be maintained and rivalrous extractive uses such as hunting or scientific sampling must be carefully limited to insure the continued survival of the species.²³⁷

Recognition of this “endangered species” approach, however, fails to acknowledge a critically different characteristic of genetic resources: the species to be sampled is only identified as a potentially valuable source of genetic information *ex-post*.²³⁸ Subsequent screening identifies promising prospects that are then investigated further.²³⁹ Though value may be extracted once the prospector finds the needle in the haystack, the value of the resource lies as much in the haystack as in any particular needle.²⁴⁰ To this end then, management of the genetic resource finds a stronger analogy in total ecosystem management strate-

²³⁷ These are precisely the values incorporated into the Endangered Species Act, discussed *supra* Part III.B.4.

²³⁸ See *supra* Part II.A. (describing screening process for collected samples).

²³⁹ See *id.*

²⁴⁰ One expression of this recognition is found in the Preamble to the Biodiversity treaty:

The Contracting Parties, [are] Conscious of the intrinsic value of biological diversity and of the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of biological diversity and its components . . . [and] Not[e] further that the fundamental requirement for the conservation of biological diversity is the in-situ conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings

Biodiversity Treaty, *supra* note 199, at 822-23.

While the Biodiversity Treaty addresses diversity in the context of bioprospecting head-on, earlier acts by Congress began to recognize the intrinsic value of biodiversity as early as the acts creating Yellowstone and the National Park System 125 years ago. For example, the National Parks’ mandate is to “conserve the scenery and the natural and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations.” 16 U.S.C. § 1 (1994). Another example of this creeping consciousness can be found in this eloquent definition from the Wilderness Act of 1964:

A wilderness . . . is hereby recognized where the earth and its community of life are untrammled by man . . . retaining its primeval character and influence. . . which is protected and managed so as to preserve its natural conditions which . . . is of sufficient size as to make practicable its preservation and use in an unimpaired condition and [] may also contain ecological, geological, or other features of scientific, educational, scenic or historic value.

Id. § 1131(c) (1994). Finally, the National Forest Management Act of 1976 contains an affirmative mandate to

provide for diversity of plant and animal communities based on the suitability and capability of the specific land areas in order to meet overall multiple use objectives, and . . . to provide . . . for steps to be taken to preserve the diversity of tree species similar to that existing in the region controlled by the plan.

Id. § 1604(g)(3)(B) (1994).

gies rather than in single species conservancy.²⁴¹ Greater value derives from the greater total number of species rather than simply the greater number of a particular species.²⁴² In this way, the issues that arise in the context of managing genetic resources are similar to those of preserving wilderness, open space, or a rain forest — identification of wild land areas, acquisition of contiguous parcels for preservation on a large scale, and access and use restrictions.²⁴³

Both the “endangered species” model and the “rain forest” model fail to adequately address all the characteristics of genetic resources. Unlike these models, genetic resources also have a rivalrous or quasi-extractive character as well.²⁴⁴ The identification and development of commercially successful products and technologies derived from genetic resources find a great deal of their value in their patentability.²⁴⁵ Once a developer has discovered a beneficial product and

²⁴¹ See Oliver A. Houck, *On the Law of Biodiversity and Ecosystem Management*, 81 Minn. L. Rev. 869 (1997) (commenting “One of the more rational conclusions to emerge from America’s experience with the Endangered Species Act is that we need to manage ecosystems and protect biological diversity on a scale larger than individuals on the brink of doom.”); Stone, *supra* note 41, at 598 (analogizing genetic resources to wildlife preserve — a non-rivalrous use that justifies some exclusionary rules in some circumstances).

²⁴² The Biodiversity Treaty states as its first objective the “conservation of biological diversity” defined as “the variability among living organisms from all sources. . . [and] includes diversity within species, between species and of ecosystems.” Biodiversity Treaty, *supra* note 199, at 823. Stone points out that there exists “honest differences” in just what maximizing biodiversity means. While he starts with the general proposition typical of the rainforest ideal of biodiversity, more species is better, he points out that one view would favor preservation of areas like grasslands which tend to harbor fewer species but of a higher taxonomic order (such as mammals) which generally holding more genetic information being more complex organisms. Stone, *supra* note 41, at 614-15. At the extreme, he reminds us that disturbance ecology or the destabilization of ecosystems exposes life to new stresses that foster the generation of new species with traits adapted to the changing or changed ecosystem. *Id.*

²⁴³ One commentator has noted some consensus developing in the scientific community toward decision making constructs for biodiversity and ecosystem conservation. These principles are:

- (1) Species well distributed across their native range are less susceptible to extinction than species confined to small portions of their range,
- (2) Large blocks of habitat containing large populations of a target species are superior to small blocks of habitat containing small populations,
- (3) Blocks of habitat close together are better than blocks far apart,
- (4) Habitat in contiguous blocks is better than fragmented habitat,
- (5) Interconnected blocks of habitat are better than isolated blocks, and dispersing individuals travel more easily through habitat resembling that preferred by the species in question, and
- (6) Blocks of habitat that are roadless or otherwise inaccessible to humans are better than roaded and accessible habitat blocks.

Houck, *supra* note 241, at 878-79.

²⁴⁴ See Stone, *supra* note 41, at 605 (discussing impact of intellectual property protection on biotechnology).

²⁴⁵ See *supra* Part II.A. (describing how biotechnology industry uses genetic resources to develop beneficial products and technologies).

a means to synthesize it in the lab, patent protection creates rights of exclusion usually found only in the exploitation of rivalrous resources such as mineral reserves or other non-renewable resources. Strong intellectual property protection may create monopoly problems and create disincentives to innovate. Likewise, weak protection raises the possibility that over-exploitation may occur and again create a disincentive to innovate for fear of losing development costs by being second to market (or first to market with no barriers to entry for that matter).²⁴⁶ Thus, the mechanism for allocating exclusive rights, their pricing, the period of exclusivity, and affirmative duties to exploit the "claim" color the development of a management resource strategy for genetic resources as well.

B. Jus Publicum, Inalienability and the Free-Rider

One problematic consideration in developing the goals of any genetic resource management strategy is recognition and resolution of ownership issues.²⁴⁷ If one can own the genetic information contained in organisms found on the public lands, should that interest be freely alienable (as in timber sales) or completely inalienable (as in public trust lands)? If there is no traditional property interest recognized in these derivative products and technologies, will simple market-based incentives adequately address preservation, distribution of benefits and costs and innovation incentive issues?

With respect to genetic resources found on the public lands, the question becomes simply whether the federal government owns the genetic information contained in organisms found there or whether this resource is owned by no one at all — or perhaps by all equally. If the federal government has a recognizable property interest in products derived from genetic resources on public lands, then the development of a management strategy must incorporate an analysis of

²⁴⁶Lord Mansfield characterized this problem in the following way:

The rule of decision in this case is a matter of great consequence to the country. In deciding it we must take care to guard against two extremes equally prejudicial: the one, that men of ability, who have employed their time for the service of the community, may not be deprived of their just merits, and the reward of their ingenuity and labor; the other, that the world may not be deprived of improvements, nor the progress of the arts to be retarded.

Sayre v. Moore, 102 Eng. Rep. 139, 140 (1785) (Lord Mansfield, C.J.).

²⁴⁷The term "ownership issues" here is used to describe what traditional ownership rights — i.e., the right to exclude, use, transfer, and destroy — if any, should be ascribed to genetic resources found on the public lands, and to whom they should be allocated.

the alienability of that interest.²⁴⁸ If the interest is to be owned by no one, then a management strategy must address the problems of privatization and monopoly.²⁴⁹ Either approach must address the free-rider problem²⁵⁰ associated with maintaining the resource on public land.

In one sense, the genetic information contained in organisms found on the public lands fits the definition of public property or *jus publicum* with ownership in the federal government.²⁵¹ Economists contend that pure public goods have

²⁴⁸If the government, as steward of the genetic resource on the public land, held some interest in the genetic information contained therein, the conditions under which that interest can be sold, if at all must be considered. If the interest can be alienated, then this problem transmutes into a pricing and externality problem. See *supra* Part VI (elaborating further on problems surrounding inalienability). There are, however, a number of justifications for the inalienability of this interest. One situation where an inalienability rule may be justified is where the alienation of an interest from one party to another has a deleterious effect on a large number of "third" parties. Ordinarily, this problem may be internalized by having the seller simply pay the would-be injured parties. However, where transaction costs may be high, or the number of injured parties may be large, the valuation of the injury may be excessively high or even non-monetizeable, a rule barring the alienation of the interest may be the most economically efficient solution. See Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1111 (1972) (claiming that inalienability rules can be justified where "significant externalities [or] costs to third parties" occur or where for moralistic reasons "external costs do not lend themselves to collective measurement which is acceptably objective and non-arbitrary."); Susan Rose-Ackerman, *Inalienability and the Theory of Property Rights*, 85 COLUM. L. REV. 931, 933 (1985) (arguing that economic efficiency, specialized distributive goals, and responsible democracy justify inalienability rule in certain contexts).

²⁴⁹On the flip-side of inalienability lay the problems of privatization and monopoly. The privatization problem is simply that if an alienable interest is underpriced (or its price does not adequately internalize all social costs with its alienation, or free) over exploitation will occur as buyers race to maximize their own benefit. See generally JOSEPH E. STIGLITZ, *ECONOMICS OF THE PUBLIC SECTOR* 88 (1986) (explaining how underpricing creates incentives for over-exploitation). As privatization occurs through the intellectual property protection scheme, the rights of exclusion and remedies for imitation may create an effective monopoly on the beneficial good or technology resulting in higher costs and lower benefit to society. See *id.*

²⁵⁰The "free rider" problem occurs typically in contexts where public goods are consumed by a group. While all would benefit from supplying the good, no one individual has incentive to do so, since only a fraction of the benefit will be enjoyed by the individual who bears the total cost. See Calabresi & Melamed, *supra* note 248, at 1107 (describing problem as "free loader" problem); Rose-Ackerman, *supra* note 248, at 933 (explaining problem in context of provision of urban parkland); STIGLITZ, *supra* note 249, at 100 (describing free-rider problem as "the reluctance of individuals to contribute voluntarily to the support of public goods.").

²⁵¹The public trust doctrine embodies the proposition that some kinds of property should not be held in exclusively private hands, but rather open to the public or at least subject to the "public right" or "jus publicum." See Carol Rose, *The Comedy of the Commons: Custom, Commerce and Inherently Public Property*, 53 U. CHI. L. REV. 711, 713 (1986) (contending that notion of public property has longstanding tradition in modern western law, stemming from Roman civil law and its subsequent influence on European law). Alternatively, genetic resources may be characterized as *jus regium* or property of the state. There is a difference between *jus regium* — alienable only within the constitutional discretion of a democratic government — and *jus publicum* — alienable only by the government as effective trustee for its citizens. However, for the purpose of this Article, no such distinction will be made.

two critical properties: (1) it is not *feasible* to ration their use, and (2) it is not *desirable* to ration their use.²⁵² An examination of the nature of the genetic resource reveals that this is just the case: it would be prohibitively expensive if not impossible to exclude the public from nearly one-third of the land in the United States,²⁵³ and if biotechnological innovation contributes to overall social welfare, then it would be *undesirable* to exclude researchers from the resource.²⁵⁴ Thus the public genetic resource has the essential characteristics of a public good.

If this interest is freely alienable, there is a risk that improvers who develop successful products from the genetic resource may fail to adequately internalize the maintenance cost of the resource resulting in higher economic rents to the improver of the resource.²⁵⁵ In this respect the alienability of the government's interest becomes reduced, in part, to a pricing problem.²⁵⁶ The ability to correctly allocate or internalize the cost of maintaining the resource from which the improver derived her product eliminates the problem of the free-rider.²⁵⁷ However, even if the cost of maintaining the resource can be calculated, the benefits

²⁵²SEE STIGLITZ, *supra* note 249, at 99.

²⁵³See Part III.A (examining nature and extent of federal public lands).

²⁵⁴See Part II.A (reviewing some of biotechnology's contribution to human well being).

²⁵⁵By analogy, consider the impact of a trespasser who steals apples from a farmer's orchard and uses them to make and sell apple pies. Arguably the trespasser has improved the apples through the addition of his labor in harvesting them, transforming them into a marketable form, and selling them. Because the trespasser may only face farmers in the apple pie market, the trespasser may sell his pies at the market price, and having not incurred any costs in growing the apples, keep the extraordinary economic profit. In a similar fashion, the trespasser may choose to use her cost advantage to under cut her competition, driving them from the competitive market place. This analogy can be replicated in the case of traditionally public resources such as: ocean fisheries, timber harvesting, and mineral resources. See Rose-Ackerman, *supra* note 248, at 932 (discussing subjects of property rights analysis in context of internalizing externalities). In discussing the close relationship between property rights and externalities, Demsetz explained the situation this way:

Externality is an ambiguous concept . . . [T]he concept includes external costs, external benefits, and pecuniary as well as nonpecuniary externalities. No harmful or beneficial effect is external to the world. Some person or persons always suffer or enjoy these effects. What converts a harmful or beneficial effect into an externality is that the cost of bringing the effect to bear on the decisions of one or more of the interacting persons is too high to make it worthwhile . . . "Internalizing" such effects refers to a process, usually a change in property rights, that enables these effects to bear (in greater degree) on all interacting persons.

Harold Demsetz, *Toward a Theory of Property Rights*, 57 AM. ECON. ASS'N 347, 348 (1967), reprinted in 1 LAW AND ECONOMICS 341, 342 (Jules Coleman & Jeffrey Lange eds., 1992).

²⁵⁶See Demsetz, *supra* note 255, at 348 (explaining that "Some costs and benefits are not taken into account by users of resources whenever externalities exist, but allowing transactions increases the degree to which internalization takes place.")

²⁵⁷See Calabresi & Melamed, *supra* note 248, at 1107 (explaining in context of public good like urban park, collective valuation and imposition of "benefits" tax on all citizens will eliminate free-rider problem).

of free access to the genetic information found on the public lands may be diminished by an improver's ability to privatize their interest through the patent system.²⁵⁸

Patent law gives the improver a monopoly market position creating further market distortions — lower production, higher prices, less competition, restricted access to the technology and lower social benefit.²⁵⁹ Such free access to the resource and the lure of monopoly profits however, create strong incentives to innovate.²⁶⁰ The possibility of privatizing a public resource may inadvertently lead not only to more market inefficiencies as individual entities rush to stake out their property interest, but also imperil the very resource itself.²⁶¹

A property ownership scheme that provides for the inalienability of the government's interest (as in public trust lands), may create disincentives to innovate.²⁶² Preventing the government from completely alienating its interest in the genetic resource and its derivative products and technology allows the gov-

²⁵⁸ See *supra* Part II.A (recounting how genetic information is used to create beneficial products and technologies by biotechnology industry).

²⁵⁹ This seemingly facile statement grossly oversimplifies the raging debate regarding the complex economics of patents. One commentator describes the search for a consistent economic theory of patents as akin to searching for a unifying scientific theory of the universe. See A. Samuel Oddi, *Un-Unified Economic Theories of Patents — The Not-Quite-Holy Grail*, 71 NOTRE DAME L. REV. 267 (1996) (describing and summarizing five competing perspectives on patent economics). However, simplified, this view does seem to reflect the prevailing views. See Steven N.S. Cheung, *Property Rights and Invention*, in 8 RESEARCH IN LAW AND ECONOMICS 5, 8-11 (1986) (discussing prevailing theories of Plant and Arrow which tend to find that "the patent system creates scarcity by granting monopoly rights" (Plant) and that "underinvestment in invention will result with or without a patent system, and that this problem can best be mitigated by expanded government investment in innovative activities" (Arrow)).

²⁶⁰ Most commentators seem to agree that under any theory, innovation is encouraged by a patent system. The debate tends to revolve around whether the net benefit to society is increased or decreased by the existence of a patent system. See Oddi, *supra* note 259, at 277-86 (describing basic premises of "reward theory," "patent-induced theory," "prospect theory," "race-to-invent theory," and "rent-dissipation theory" of patent economics, all of which, tend to encourage invention).

²⁶¹ "Underpricing" typically results in classic overexploitation or the familiar tragedy of the commons. See Rose, *supra* note 251, at 712 ("No one wishes to invest in something that may be taken from them tomorrow, and no one knows whom to approach to make exchanges. All resort to snatching up what is available for 'capture' today, leaving behind a wasteland."); see also *supra* Part II.A (recounting story of how entire adult population of *Maytenus buchanii* was harvested by zealous researchers).

²⁶² All other things equal, if the government retains some form of ownership interest in the derivative products from genetic resources found on the public lands, simply having to account to another owner lowers the return the improver would realize, if for no other reason by increase transaction costs creating if not a disincentive to innovate, an incentive to poach the resource. See Cheung, *supra* note 259, at 10-12 (arguing generally that, other considerations aside, "inventions pose problems in appropriating or capturing returns . . . because of the presence of transaction costs," and that mechanisms like royalty payments "inhibit marginal use.").

ernment to recapture the improver's externalized cost of maintenance by charging royalties or other forms of economic rent. The mere fact that the government becomes a perpetual stakeholder in new products and technology delays the improver's return of developmental capital, thus slowing down the rate of innovation. This may provide such a disincentive that few improvers will undertake the development of beneficial products or technology.

Further, if the government charges excessive rent, a poaching problem may arise.²⁶³ Regardless, the potential availability of the same specimens from adjoining private lands, may simply move the market out of the public sector and into the private sector. Ironically, the effort to recover enough economic rent to maintain the public resource may not only result in loss of revenue to the government (as steward of the resource), but also create a market incentive for private landowners to preserve their own genetic resources.²⁶⁴

The final issue with respect to inalienable government interests involves increased transaction costs.²⁶⁵ If the government rents the genetic information to an improver, valuing the rent beforehand will likely result in an inaccurate price due to market uncertainty.²⁶⁶ Overpricing has the potential to discourage innovation,²⁶⁷ while underpricing externalizes the cost of preserving and maintaining the resource.²⁶⁸ On the other hand, if the government values the rent based upon market performance *ex post*, the true cost of preserving and main-

²⁶³ Considering the small amount of genetic material required to begin screening for potentially useful compounds or traits, poaching is a very real and intractable possibility. See Julia Flynn, *Novo Nordisk's Mean Green Machine*, *Bus. Wk.*, Nov. 14, 1994 (advocating for collection of samples by employees of biotechnology companies while on vacation).

²⁶⁴ Here the government imposition of onerous rent obligations creates in effect a supply shock, restricting supply of the commodity, with a concomitant rise in the market price presenting heretofore unavailable economic opportunities to those landowner's with valuable biodiversity. See generally ARTHUR A. THOMPSON, JR., *ECONOMICS OF THE FIRM: THEORY AND PRACTICE* 181 (4th ed., Prentice-Hall 1985) (explaining that technological change can enhance market power of suppliers of essential components — in this case, biodiversity).

²⁶⁵ See Douglas W. Allen, *What Are Transaction Costs?*, in 14 *RESEARCH IN LAW AND ECONOMICS* 1,3 (1991) (defining transaction costs as "the resources used to establish and maintain property rights. They include the resources used to protect and capture . . . property rights, plus any deadweight costs that result from any potential or real protecting and capturing.").

²⁶⁶ *Ex-ante* pricing uncertainty results in part from the nature of the resource, nature herself. In contrast to an engineer, who may be presented with a problem and design a solution, bioprospecting, in many ways, starts with a potential solution in search of a problem. Since in many cases biological "solutions" may find many problems, their marketability, efficacy and value may be unknown at the time of their invention.

²⁶⁷ See generally THOMPSON, *supra* note 264, at 186 (discussing factors that affects firm's ability to innovate).

²⁶⁸ See Stone, *supra* note 41, at 581-82 (explaining relationship between underpricing, externalization and resource overexploitation).

taining is known. Royalty payments and enforcement mechanisms, however, impose continuing obligations on the licensor and licensee to enforce the bargain.²⁶⁹ Here, the cost of enforcing the bargain actually raises the cost of developing products and technologies from the genetic resource, creating additional disincentive to negotiate and comply with reporting requirements.

The other alternative, non-ownership of the genetic information found on public lands,²⁷⁰ raises the possibility of failing to adequately internalize the cost of maintaining the resource creating free-rider problems.²⁷¹ A non-ownership model effectively allows a first-possession overexploitation scenario to occur. A management scheme that affords the opportunity to effectively privatize ownership interests in the resource again raises the spectre that the monopoly power imbued by the patent system will result in either higher prices and lower production,²⁷² or, in the case of inadequate internalization of externalities, underpricing and overconsumption.²⁷³ Again, as with any privatizeable resource, a race to establish rights may result in overutilization of the resource to its demise.²⁷⁴

²⁶⁹ See Cheung, *supra* note 259, at 11 (discussing effect of royalty based transaction costs on patent economics).

²⁷⁰ The basic problem of publicly accessible privatizeable unowned resources is the so-called tragedy of the commons, whereby a failure to allocate property rights among a communal asset (or recognize an inalienable common right) creates disincentives to maintain the resource. Without an allocation of property rights among the users of the "commons" the costs incurred by one individual to maintain the commons necessarily results in benefits to the other users of the resource. Because there is no mechanism for the maintainer to recapture the portion of costs that do not result in a proportionate increase in his own benefit, there is no incentive to maintain the commons at all. If the maintainer were able to exclude all others, his efforts would enure completely to himself. Likewise if he were granted the right to seek compensation from the other users for his cost of maintaining the commons, all users would be better off. Fortunately in the context of public lands, some mandate exists for the maintenance of these lands by the government. Thus, the problem is not cast so much in terms of a tragedy of the commons, but rather who and how should someone be forced to internalize the cost of this maintenance.

²⁷¹ One analogy for this scenario is the settlement of the Louisiana Purchase through homesteading. All of the citizens of the United States paid for the purchase price that Thomas Jefferson tendered to Napoleon, but only a few were able to privatize the land. These pioneers effectively externalized a portion of the acquisition cost of the land on to other non-homesteading taxpayers. See Dean Lueck, *The Rule of First Possession and the Design of Law*, J.L. & ECON. 393, 415 (1995) (examining impact first possession rules have on rent dissipation).

²⁷² See STIGLITZ, *supra* note 249, at 85 (recapitulating effects of monopolistic behavior).

²⁷³ See Stone, *supra* note 41, at 581 (arguing that privatizeable wild biological resources tend to be underpriced and overconsumed due to imperfect pricing).

²⁷⁴ A classic example is unowned fishing stocks. Each fisherman that captures part of the resource creates a negative externality on every other fisherman. As each fisherman depletes the resource there is less for all the others creating a classic overexploitation scenario. See STIGLITZ, *supra* note 249, at 179-85; Stone, *supra* note 7, at 582 (arguing that subsidization of ocean fisheries exceeds value of catch, creating incentives that result in resource depletion).

C. Locke May Hold the Key

The duality of interests described above is critical to formulating the goals of a management strategy. The federal government has enormous sunk costs in maintaining the diversity of genetic resources on public lands — namely the costs the federal government has expended and will spend to fulfill its obligation to preserve and maintain public resources like the national parks for future generations. Likewise, a private sector improver sinks enormous costs into developing methods to bring beneficial products and technologies to market.²⁷⁵ However, without the continuing existence of the genetic resource from which to forage for possibly appropriable products and technologies, there would be no opportunity for development at all. In a pure private sector development process, an innovator would bear the full cost of research and development including the search for, and acquisition of, materials and technologies.²⁷⁶ In the bioprospecting context, a would-be innovator is able to externalize the cost of maintaining genetic diversity on to the public.

In the private sector, innovation through great industry is encouraged and rewarded in large part by intellectual property protection, namely, the grant of the patent monopoly.²⁷⁷ Though great effort and expense is expended in the development of beneficial products and technologies from bioprospecting on the public lands,²⁷⁸ the burden of supporting and maintaining the genetic resource in the public sector is borne by the public sector.

Typically, there are several methods the government may use to internalize these negative externalities: penalties, subsidization, regulation, or allocation of property rights.²⁷⁹ Onerous access fees to compensate the government for its stewardship of genetic resources may prove untenable or ineffective.²⁸⁰ If access

²⁷⁵ See Part II.A (discussing high development cost of biotechnology products).

²⁷⁶ See STIGLITZ, *supra* note 249, at 159-61 (describing private sector development).

²⁷⁷ See *supra* Part V (discussing policies and goals of patent system).

²⁷⁸ See *supra* Part II.A. (elaborating upon typical cost of research and development of products derived from genetic resources); Part V (reviewing intellectual property protection in United States).

²⁷⁹ See STIGLITZ, *supra* note 249, at 184 (surveying various attempts to mitigate externalities).

²⁸⁰ See Asebey & Kampenaar, *supra* note 57, at 727-28 (explaining how Merck/InBio Agreement is structured as contract for collection services, recognizing that access fees and restriction would prove futile in an area as vast as Costa Rican rainforest); STIGLITZ, *supra* note 249, at 189 (arguing that fines as opposed to subsidies tend to reduce output of externality creating activity, but fiscal or political limitations may prevent effective subsidization).

fees are too high or the cost of effective exclusion from the resource is too high, incentives for poaching arise — a strong likelihood where a few grams of the resource is all that is needed to launch an industry. Likewise uncertainty in pricing the contribution may lead to significant overvaluation or undervaluation problems. Finally, royalty-type agreements or taxation schemes that attempt to recapture this value carry with them increased transaction costs and create market distorting avoidance incentives. A delicate balance must be achieved to maintain adequate incentive to innovate yet recognize the contribution of the government's stewardship of these genetic resources.²⁸¹

Locke's original idea that all natural resources — “all good things that nature hath provided”²⁸² — were held in common ownership may find particular relevance in the context of public genetic resources. A common property scheme²⁸³ may provide a solution that avoids the overexploitation problems of an entirely privatizeable resource and the externality problems of alienating a wholly owned government resource.²⁸⁴

²⁸¹ Even in 1690, Locke recognized the tension between innovation (“appropriation”) and rights held by the government (through “compact and agreement”) with respect to the utilization of property:

Though the things of nature are given in common, yet man, by being master of himself and proprietor of his own person and the actions or labor of it, had still in himself the great foundation of property; and that which made up the great part of what he applied to the support or comfort of his being, when invention and arts had improved the conveniences of life, was perfectly his own, and did not belong in common to others.

.....

[But] men . . . by laws within themselves, regulated the property of the private men of their society, and so, by compact and agreement have by common consent given up their pretences to their natural common right . . . and so by positive agreement settled a property amongst themselves in distinct parts and parcels of the earth.

.....

Now of those good things which nature hath provided in common, everyone had a right, as hath been said, to as much as he could use, and property in all he could effect with his labour; all that his industry could extend to, to alter from the state nature had put it in, was his.

JOHN LOCKE, *THE SECOND TREATISE OF CIVIL GOVERNMENT* 23-24 (J.W. Gough, ed., Basil Blackwell 1948) (1690).

²⁸² *Id.*

²⁸³ Or quasi-common scheme with the government acting as trustee for the public.

²⁸⁴ A common scheme could result from explicit private contracting or with the facilitation of the government to the exclusion of outsiders. As one commentator noted “[e]qual sharing of access to the asset avoids the explicit costs of measuring and enforcing individual effort” thus minimizing the externalization of maintenance costs but avoiding the tragedy of the commons incident to a first possession scheme. Lueck, *supra* note 271, at 406.

D. The Goals of a Genetic Resource Management Strategy

A consideration of the issues described above results in three general goals which any comprehensive management strategy should address — preservation, equitable distribution of costs and benefits, and incentives to innovate.²⁸⁵

Fundamentally, the value of any renewable natural resource is contingent upon its continued existence. To that end, the maintenance and preservation of that resource is paramount. The value of genetic resources on public lands derives largely from the diversity of species from which screening for favorable compounds and traits can take place.²⁸⁶ Therefore, the maximization of biodiversity²⁸⁷ should be the criteria by which to evaluate the preservationist goal.

Secondly, preservation for future generations comes at great cost to the public at large.²⁸⁸ Further as the value of genetic resources is realized, and concomitant with the development of a management strategy, activities taken to preserve the resource — such as habitat and species location and classification, and habitat acquisition and management — the federal government will incur

²⁸⁵These goals represent essentially a Benthamite utilitarian approach — that the aggregate benefit to society as a whole should be maximized by the policy goals enunciated. However, implicit within this assumption as it pertains to this Article is a consideration and recognition of *future* members of society essentially unrepresented in the policy development process. Thus preservation, for example, reflects from a utilitarian perspective the substantive value of husbandry of the resource. See STIGLITZ, *supra* note 249, at 66-69 (elaborating distinctions between utilitarianism and Rawlsianism social welfare economics).

²⁸⁶See *supra* Part II.A (explaining how biotechnology industry uses biodiversity to create beneficial products and technologies).

²⁸⁷Maximization of biodiversity is a term subject to considerable debate:

Biological diversity has been defined as 'the variety of life and its processes. It includes the variety of living organisms, the genetic difference among them, the communities and ecosystems in which they occur, and the ecological and evolutionary processes that keep them functioning, yet ever changing and adapting.' Biodiversity is usually further described at four levels: genetic, species, community or ecosystem, and landscape or regional. 'Each of these levels can be further divided into compositional, structural, and functional components of a nested hierarchy. Composition includes the genetic constitution of populations, the identity and relative abundances of species in a natural community, and the kinds of habitats and communities distributed across the landscape.' The difficulty of converting these definitions to a legal concept should be apparent.

Houck, *supra* note 241, at 873 n.12; Stone, *supra* note 41, at 614-15 (arguing that evolutionary distance between species should be adopted as measure of biological diversity).

²⁸⁸The 1999 anticipated budget for the Department of the Interior — responsible for administering the National Park System — is over \$8.4 billion. *Budget of the United States Government Fiscal Year 2000, Table 4.1* (visited Feb. 20, 1999) <<http://www.access.gpo.gov/usbudget/fy2000/hist.html>> (copy on file with *Environs*).

even greater costs. Arguably, the opportunity cost of not undertaking classification and identification activities which may yield significant beneficial information such as a long-awaited cure for disease, may greatly eclipse any current budgetary number and must enter the cost calculus. As such, a management strategy for genetic resources must attempt to recapture that cost in proportion to the benefit the private sector derives from its utilization.²⁸⁹ Further, since the public has undertaken to preserve these valuable resources, their efforts should not be merely repaid for their stewardship, but also reap some degree of benefit from the beneficial products and technologies so derived.²⁹⁰

Finally, the value of these genetic resources is derived from their ability to be developed and improved to the benefit of society at large.²⁹¹ Genetic information in the information age finds value in its application — at least in a utilitarian construct. Thus to inhibit biotechnological innovation is to undermine the basis for the husbandry of the resource.²⁹² Any management scheme, therefore, must attempt to create and maintain incentives for improvers to develop useful products and technologies that result in social benefit. It is in the context of these general goals that the current regulatory framework is evaluated and a comprehensive strategy proposed.²⁹³

²⁸⁹ See generally Adair, *supra* note 14, at 134 (arguing that United States government should adopt a compensation seeking approach to bioprospecting).

²⁹⁰ The notion is that the public has an ongoing equity interest in the products and technologies so derived rather than merely a right of reimbursement.

²⁹¹ Stone cites moral suasion as a rationale for the pure existence value of his hypothetical penguins — a species having no commercial value — arguing that “the world is a better planet for having the penguins, or alternatively, that the penguins have a right to exist.” Stone, *supra* note 41, at 588. Henry Thoreau, in the manner of Stone’s notion of pure existence value, offers another argument against solely improvement-based valuations of genetic resources:

We need the tonic of wildness — to wade sometimes in marshes where the bittern and the meadow hen lurk, and hear the booming of the snipe; to smell the whispering sedge where only some wilder and more solitary fowl builds her nest, and the mink crawls with its belly close to the ground. At the same time that we are earnest to explore and learn all things, we require that all things be mysterious and unexplorable, that land and sea be infinitely wild, unsurveyed and unfathomed by us because unfathomable. We can never have enough of Nature.

HENRY DAVID THOREAU, WALDEN 216 (Sherman Paul ed., Houghton Mifflin Co., 1960) (1854).

²⁹² Notwithstanding other justifications for preserving *biological diversity* on other bases, this applies to the concept of a public genetic resource, using biodiversity as a proxy for measuring and maintaining the genetic resource.

²⁹³ See *infra* Part VI, Part VII (evaluating current regulatory framework and proposing comprehensive management strategy).

VI. ANALYSIS OF THE CURRENT REGULATORY FRAMEWORK AND CONCERNS

The adequacy of the current regulatory framework can best be measured by the degree to which it achieves the goals of such a system. As discussed above, the primary goal of any renewable resource management strategy should provide for the preservation of that resource.²⁹⁴ Next, some mechanism should provide for adequate cost sharing and equitable distribution of benefits from successful derivative products and technologies. Finally, any management strategy should preserve adequate incentives for private innovation. It is in the context of these goals that the current regulatory framework will be examined.

A. *Preservation of Indigenous Genetic Resources*

The commercial value of bioprospecting comes from the wide variety of naturally occurring organisms in the environment and the genetic diversity contained therein.²⁹⁵ The primary goal of any attempt to regulate bioprospecting must then act to preserve that wealth of diversity that affords us its bounty. To that end, the preservation of genetic resources on public lands means the preservation of the biodiversity on public lands. Pragmatically, two questions are presented: what do we mean by biodiversity?²⁹⁶ And, does our current domestic regulatory framework adequately protect and preserve that diversity on the public lands?

The bare meaning of 'biodiversity' implies a diversity of life. Suggested meanings of biodiversity range from simple species diversity, to measures of genetic diversity, and even to ecosystem diversity.²⁹⁷ Others have suggested that the measure should be the range of variation between organisms — that biodiversity should stand as a proxy for some degree of exoticness.²⁹⁸ The Biodiversity Treaty offers the following definition encompassing all three: "Biological diversity' means the variability among living organisms form all sources including, inter alia, terrestrial, marine, and other aquatic ecosystems and the

²⁹⁴ See *supra* Part V.D. (explicating fundamental goals of public genetic resource management strategy).

²⁹⁵ See *supra* Part II, V.D. (discussing value of bioprospecting in context of biodiversity).

²⁹⁶ See Stone, *supra* note 41, at 614 (surveying but not concluding on number of meanings given to ambiguous term "maximizing biodiversity").

²⁹⁷ See *supra* Part V.D. (noting disparity among various definitions of biodiversity).

²⁹⁸ See *id.*

ecological complexes of which they are part; this includes diversity within species, between species, and of ecosystems."²⁹⁹ Even this definition has been criticized as giving no real guidance for policy makers.³⁰⁰ More fundamentally, the meaning of biodiversity in the context of bioprospecting embraces uncertainty. In this sense, like wilderness, we may bound it but not yet know it. That which we seek most to preserve is that about which we know least, perhaps even knowledge of its very existence.³⁰¹ In the context of bioprospecting then, preservation should focus not only the results of nature's continuing experimental efforts at adaptation, but on the preservation of nature's laboratory itself. To that end, biodiversity preservation should encompass the broadest possible ecosystem-based approach; it should embrace the simple notion that a fully functioning ecosystem — land, air, water, flora, and fauna — will be the most productive laboratory for the generation and preservation of unique organisms. Only such a broad view will force policy makers to adequately consider the value of ecosystem diversity on the public lands.³⁰²

Though lacking an element of quantified objectivity, the notion of valuing biodiversity parallels the paradigm shift accompanying the "wilderness" movement.³⁰³ Application of this broad definition yields some obvious hierarchical preferences as well as crude but useful tools for policy makers. Fundamentally, a "more is better" approach becomes universally applicable to assessing biodiversity. More species, generally is better than lesser, with the greater number and variety of species being present offering the greatest opportunity to support higher taxonomic categories of life containing more genetic information. More geography

²⁹⁹ Biodiversity Treaty, *supra* note 199, at 823.

³⁰⁰ See Stone, *supra* note 41, at 614 (contending that "even among biologists the term is too open-ended to signal clear guidance for policy makers.").

³⁰¹ Consider that current interest in Yellowstone's geothermal features stems from two basic understandings: (1) the environment or ecosystem is unique; and (2) the number of species in that ecosystem is both large and unknown. See *supra* Part II (discussing unique geothermal features of Yellowstone and current interest in bioprospecting there).

³⁰² To be useful to a genetic resource management strategy, the definition would have to identify small invisible spaces like Yellowstone's geysers and thermal features or Carlsbad Caverns underground lightless ecosystem as well as the teeming masses of species that populate the everglades or the delicate prairie grassland ecosystem of the great plains that supports fewer, but more complex organisms.

³⁰³ See Sprankling, *supra* note 128, at 559 n.210 (illustrating gradual shift in federal policy from exploitation to preservation beginning around time of designation of Yellowstone as National Park in 1872).

affords greater and more varied habitat, as well as a more intricate, integrated, and sustainable web of life.

The second management principle that can be distilled from a broad definition of biodiversity is simply that “Whole is better than half, but half is better than none.”³⁰⁴ The greatest efforts, therefore, should be placed on preserving healthy, intact ecosystems whenever possible to encourage the greatest biodiversity.

The third management principle that comes from the broad definition of biodiversity is that “nature is better than nurture.” In the lexicon of the Biodiversity Treaty, in-situ preservation should take precedence over ex-situ preservation whenever possible to preserve the dynamism of adaptation in the ecosystem.³⁰⁵

With this broad concept of biodiversity in mind, and the management principles so derived the question remains: does our current domestic regulatory framework adequately protect and preserve that diversity on the public lands? As noted in Section III, there is no single mandate or regulatory scheme for the management of the major ideological or ecological blocks of the public domain — wilderness areas, national parks, national forests, and residual federal lands.³⁰⁶ These mandates at best reflect a tension between preservation and use,³⁰⁷ and at their worst, reflect a bias toward use and commercialization.³⁰⁸ If the goal is preserving and maximizing biodiversity, these management mandates yield disparate results.

The Wilderness Act lands perhaps serve the goal of preserving biodiversity best. The efficacy of the Wilderness Act in preserving biodiversity can be assessed by resorting to the biodiversity management principles discussed above. First the Act is fundamentally preservationist in strategy.³⁰⁹ It is premised on the “more is better” principle with respect to the characteristics of wilderness de-

³⁰⁴ See *Minnesota v. Dickerson*, 508 U.S. 366, 382 (1993) (paraphrasing Justice Scalia’s comment “that half a constitutional guarantee is better than none.”) (Scalia, J., concurring).

³⁰⁵ The Biodiversity Treaty, for example provides that while signatory countries should “adopt measures for the ex-situ conservation of components of biological diversity,” ex-situ conservation efforts are “predominantly for the purpose of complementing in-situ measures.” Biodiversity Treaty, *supra* note 199, art. 9, at 825. More plainly, the best way to preserve meat is to feed the cow rather than buy a freezer.

³⁰⁶ See *supra* Part III (listing major components of public domain and their statutory management schemes).

³⁰⁷ See *supra* Part III (discussing, for example, dual mandates of National Parks to preserve parks in their natural state for future generations while at same time providing for their use and enjoyment by people today).

³⁰⁸ See *supra* Part III (elaborating on Bureau of Land Management’s schizophrenic mandates to encourage logging, grazing, and mining, while also preserving land in its natural state).

³⁰⁹ See *supra* Part III.A.1 (reviewing preservationist focus of Wilderness Act).

scribed in the statutory definition,³¹⁰ embracing the notion of the “earth and community of life, untrammled by man.”³¹¹ Secondly, the Act as a preservationist tool focuses on habitat identification and acquisition, encouraging the preservation of large amounts of functioning wild ecosystems.³¹² Next, the Act recognizes that “whole is better than half, and half is better than none” by focusing on identifying and preserving the vanishing primaeval wilderness, even in extremely small isolated components.³¹³ Finally, lands under the Act implicitly follow the “Nature is better than nurture” principle. The Act conspicuously subordinates traditional human recreational and commercial values to that of pure preservation.³¹⁴ Thus, the core principles behind biodiversity preservation incorporated into the Wilderness Act adequately serve the goals of biodiversity preservation with respect to those lands.

The National Parks also provide a high level of protection for the resources found there. However, a critical distinction can be drawn in the *type* of mandate the national parks are given. Specifically, the National Park Service is to conserve the scenery and wildlife of the parks while providing for their enjoyment.³¹⁵ Yet they are to do this while still leaving them “unimpaired for the enjoyment of future generations.”³¹⁶ Neither mandate provides for the maximization and preservation of biodiversity as defined above.³¹⁷ The question for the national parks

³¹⁰ 16 U.S.C. § 1131(c) (1994).

³¹¹ *Id.*

³¹² See *supra* Part III.A.1 (examining policy goals of Wilderness Act: primacy of wilderness values over human usage and allowance of ecological succession to operate freely).

³¹³ See Sprankling, *supra* note 128, at 561 n.217 (identifying a dozen designated wilderness areas that fall far short of 5,000-acre statutory design of Wilderness Act, but nonetheless qualify as “of sufficient size to make practicable its preservation and use in an unimpaired condition” 16 U.S.C. § 1131(c) (1994)).

³¹⁴ The definition provides that wilderness under the Act is “where man himself is a visitor who does not remain . . . [is] without permanent improvement or human habitation, . . . [and] with the imprint of man’s work substantially unnoticeable” *Id.* § 1131(c) (1994).

³¹⁵ See *supra* Part III.A.2 (explaining National Parks preservation and recreation mandates).

³¹⁶ 16 U.S.C. § 1 (1994).

³¹⁷ See Sprankling, *supra* note 128, at 560 n.216 (claiming that because our National Park System is premised on twin pillars of conservation and recreation, human use becomes inconsistent with preservation at some point); see also Department of Interior, U.S. Geological Survey, New USGS Study Targets Weeds, Jan. 12, 1998, available in 1998 WL 4799 (D.O.I.) (explaining that invasive non-native plants cultivated or transported by human activity imperils habitat of two-thirds of all threatened and endangered species, that national parks can no longer keep pace with new invasions, and that all public lands suffer, to some extent, from invasive nonindigenous species.).

then becomes one of prioritization — public recreational use³¹⁸ versus biodiversity preservation.³¹⁹ While beyond the scope of this Article, the increased impact that public use has had on certain units of the National Parks has already prompted proposals by park operators and interest groups to propose serious public access restrictions.³²⁰ Absent a legislative voice in this arena, critical use-versus-

³¹⁸In the context of the National Parks, at least, most commercial and consumptive uses such as mining, logging, grazing, hunting and fishing are expressly forbidden or restricted. Because each park is controlled by its own authorizing statute, permitted resource uses within the parks vary. Mansfield, *supra* note 102, at 842. For example, the Organic Act creating the Park Service authorizes timber sales only “in those cases where in [the Secretary’s] judgment the cutting of such timber is required in order to control the attacks of insects or diseases or otherwise conserve the scenery or the natural or historic objects in any such park.” 16 U.S.C. § 3 (1994). The Organic Act likewise allows the Secretary to

grant the privilege to graze livestock within any national park, monument, or reservation herein referred to when in his judgment such use is not detrimental to the primary purpose for which such park, monument, or reservation was created, except that this provision shall not apply to the Yellowstone National Park.

Id. § 3. Yellowstone’s authorizing statute is fairly restrictive, mandating “the preservation, from injury or spoliation, of all timber, mineral deposits, natural curiosities, or wonders, within the park, and their retention in their natural condition.” *Id.* § 22 (1994). Hunting and fishing are also severely limited within the park:

All hunting, or the killing, wounding, or capturing at any time of any bird or wild animal, except dangerous animals, when it is necessary to prevent them from destroying human life or inflicting an injury, is prohibited within the limits of said park; nor shall any fish be taken out of the waters of the park by means of seines, nets, traps, or by the use of drugs or any explosive substances or compounds, or in any other way than by hook and line, and then only at such seasons and in such times and manner as may be directed by the Secretary of the Interior.

Id. § 21 (1994). *Cf.* *Sierra Club v. Watt*, 566 F. Supp. 380, (D. Utah 1983) (finding that Congressional intent to allow leasing of “locatable” mineral resources in Lake Mead National Recreation Area was neither in violation of Organic Act nor park statute).

³¹⁹*See, e.g.,* George Wuerthner, *Gone Stray: at Channel Island National Park — One of the Most Biologically Rich Lands in the Country — The Parks Service Is under Fire for Allowing the Degradation of Resources*, NATIONAL PARKS, Nov. 1997, at 22 (claiming that grazing and browsing animals, introduced by Fish and Wildlife Service, have resulted in soil loss and habitat degradation, driving many Channel Island species toward extinction).

³²⁰*See* Russel Clemings, *Yosemite: What to Sacrifice?*, FRESNO BEE, Dec. 28, 1997, at A1 (discussing focus of Yosemite National Park’s General Management Plan that attempts to alleviate multiple threats of air pollution, over-crowding, and traffic congestion by proposing to eliminate most cars from valley by 2001, two campgrounds, employee housing facilities, two orchards and several bridges). The author also discussed historic tension between competing directives to preserve Yosemite and to provide recreation — as evidenced by past activities such as feeding park garbage to bears for tourist entertainment, Camp Curry “firefall” where bonfire cinders atop Glacier Point were swept over precipice for delight of tourists on valley floor, and tunnel carved through base of Giant Sequoia in Mariposa Grove which allowed visitors to drive their cars through tree. *See id.*; *see also* Jon Margolis, *With Solitude for All: How the Park Service Is Trying to Preserve Nature’s Fragile Beauty in the Face of Traffic-jam Popularity*, AUDUBON, Jul. 17, 1997, at 46 (describing challenge facing Park Service to alleviate adverse impacts of visitors on all parks. Problems to be addressed

preservation choices may be subject to inconsistent application across the park system.³²¹

The multiple-use, sustained-yield approach mandated for the National Forests contemplates both commercialization *and* protection of their resources.³²² With such broad and diverse objectives, some legislative guidance must be provided in order to prioritize biodiversity preservation amongst competing uses. Explicitly establishing biodiversity maximization as a permissible goal for the management of National Forest lands would permit the Forest Service to include certain areas in specialized management regimes, thus avoiding conflict with incompatible uses.³²³ Again, a clear legislative voice is needed to establish biodiversity preservation and maximization among the hierarchy of objectives for the Forest Service.

The residuary nature of the BLM lands makes biodiversity preservation and maximization particularly difficult. These lands encompass such diverse landscapes and contemplate such diverse uses,³²⁴ that any legislative scheme incorporating biodiversity preservation and maximization as a management goal must also provide the necessary directives by which to prioritize management goals. Since the uses contemplated by the FLPMA mandate are much broader than the other two large bodies of public lands already discussed, its more likely that consumptive and extractive uses such as grazing, logging or mining will

by Park Service's efforts include air and surface traffic at Grand Canyon, traffic so severe at Rocky Mountain that endangered bighorn sheep can't reach their salt licks, air quality in West Yellowstone so poor from excessive snowmobiling that park official compares it to Denver, water traffic including noise and pollution by personal watercraft in Olympic, and encroachment by park structures on brown bear habitat at Alaska's Katmai Preserve. The author cautions that change in administration or policy could seriously shift focus of these preservation efforts, recalling less-than-pristine preservationist perspectives of previous administrations typified by this comment by former Interior Secretary James Watt given while advocating more tourist facilities in Grand Canyon: "I don't like to paddle and I don't like to walk."

³²¹ See Weston Kosova, *Alaska: the Oil Pressure Rises (Oil Drilling in the Arctic National Wildlife Refuge)*, AUDUBON, Nov. 1997, at 66 (discussing both Clinton Administration's ban on oil drilling in Arctic National Wildlife Refuge while continuing preparation for private oil exploration on nearby ecologically sensitive 23.4 million-acre National Petroleum Reserve-Alaska).

³²² See *supra* Part III.A.2 (reviewing mandates applicable to National Parks).

³²³ See *id.* Part III.A.2 Biodiversity preservation and maximization may be impossible in areas where extractive or consumptive uses such as grazing or logging disrupt habitat. *Id.* See also Peter M. Vitousek et al., *Biological Invasions as Global Environmental Change*, AM. SCIENTIST, Sept. 1996, at 468 (asserting that introduction of non-native species into ecosystems — including introduction into national parks as result of human activities — is one of most significant threats to biodiversity).

³²⁴ See *supra* Part III.A.4 (discussing lands under Bureau of Land Management authority).

come into conflict with any goal of biodiversity maximization and preservation.³²⁵ The legislature must speak with clarity to provide the necessary framework to identify critical habitat and establish preservation and management regimes for them.

Applying the tools that NEPA and the ESA provide toward the goal of preservation and maximization of biodiversity on public lands may be somewhat problematical. The primary problem is the narrow focus of these acts.

NEPA only requires an evaluation of the impacts on the environment in instances that involve "major federal actions significantly affecting the quality of the human environment."³²⁶ The problems that NEPA poses as a biodiversity preservation tool is that it focuses on the human environment, only applies to major federal actions with significant effects and ultimately only requires the consideration of these effects. As such, it may not provide a strong tool to insure the preservation and maximization of biodiversity on the public lands.

The ESA also would likely provide little assistance toward biodiversity preservation. The unitary nature of the act limits its applicability toward achieving such a broad goal.³²⁷ The applicability of the ESA depends upon the listing of a species as endangered.³²⁸ The goal of preserving and maximizing biodiversity focuses on the sustained presence and viability of a multiplicity of species, many of which may not be endangered, and thus fall outside the Act's protections. To insure the applicability of the ESA, some species unique to the area sought to be preserved would have to be identified and listed as endangered, or that the area in question is critical habitat for a listed species.³²⁹ Since this ad hoc species-by-species approach will only intervene to protect individual species and only if

³²⁵ Extractive or consumptive uses are fundamentally at odds with preservationist goals. While multiple use and sustained yield can be achieved with renewable consumptive uses such as grazing or silviculture, once indigenous habitat is destroyed and biodiversity is lost, it cannot be renewed. *See generally* Worldwatch Institute, *State of the World, 1998, republished in part in* BALTIMORE SUN, Jan. 14, 1998, at 2A (claiming that world is losing 1,000 species per year, up from natural rate of extinction of one to three species per year as result of habitat loss and degradation and incidental introduction of non-native species); Sprankling, *supra* note 128, at 580 (claiming that grazing on remote grassland and rangeland wilderness imperils ecological integrity of land including elimination of plant species, acceleration of erosion and increased soil aridity.)

³²⁶ *See supra* Part III.B.3 (explaining how NEPA only ultimately require government to adequately consider effects of its actions, rather than dictating what those actions should be).

³²⁷ *See supra* Part III.B.4 (noting that ESA only applies to species officially designated as endangered).

³²⁸ *See supra* Part III.B.4 (explaining how ESA only protects individual threatened species rather than entire ecosystems).

³²⁹ *See supra* Part III.B.4 (discussing applicability of ESA to listed species and how it can act to preserve critical habitat).

they are threatened, it causes the federal government to intervene reactively in the process much later and to less effect than a proactive biodiversity preserving mandate would.³³⁰

To ensure preservation and maximization of biodiversity as the first goal of a comprehensive genetic resource management strategy for the public lands, Congress must clearly provide for its achievement. Current public land management mandates address the problem only obliquely. The Wilderness Act preserves biodiversity by severely restricting access and use.³³¹ The National Parks are conflicted by dual strategies for preservation and recreation.³³² The National Forests and BLM lands are conflicted between extractive, consumptive, and preservationist goals despite sustained yield objectives.³³³ Finally, NEPA and the ESA are too narrow to serve the goal of biodiversity preservation.³³⁴ As the first step of a comprehensive management strategy, Congress must provide the mandate, mechanism and method for prioritizing the competing uses for the public lands.

B. Equitable Distribution of Benefits and Costs

[M]ost of us in developing countries find it difficult to accept the notion that biodiversity should [flow freely to industrialized countries] while the flow of biological products from the industrialized countries is patented, expensive and considered the private property of the firms that produce them. This asymmetry reflects the inequality of opportunity and is unjust.³³⁵

³³⁰Considering the interconnectedness of ecosystems, it is entirely plausible that the valuable microbes of Yellowstone's thermal features (or any small or microscopic organism) may have been completely obliterated before their existence was even known. At the time we determine that a species is threatened, it is possible if not probable, that the lower links on the food chain have already been lost. See Katherine Bouma, *Endangered Species Act Also Struggling to Stay Alive in its 24 Years, the Law Has Been Altered and Weakened. Wrangling in Congress Is Expected to Continue This Year*, ORLANDO SENTINEL, Dec. 29, 1997, at A6 (claiming that although only one percent of species ever listed under the ESA have become extinct, ESA "does nothing to keep species from declining before they are in imminent need of protection.").

³³¹See *supra* Part III.A.1 (noting Wilderness Act's preservation imperative requires extreme use restrictions).

³³²See *supra* Part III.A.2 (stating that National Parks face recreation and preservation mandates).

³³³See *supra* Part III.A.3-4 (revealing that National Forests and BLM lands face ambiguous use mandates).

³³⁴See *supra* Part III.B.3-4 (examining how both NEPA and ESA are reactive and address only singular issues).

³³⁵See Report of the United Nations Conference on Environment and Development, at 36, U.N. Doc. A/CONF151/26/Rev.1 (1993).

These sentiments were expressed by President Ali Hassan Mwinyi of Tanzania. President Bill Clinton expressed a differing view of the Biodiversity Treaty noting that the United States “strongly resist any actions . . . that lead to inadequate levels of protection of intellectual property rights.”³³⁶ These comments reflect the universality and the polarity of the fundamental conflicts that arise in the context of the commercial development of genetic resources found on the public lands: who should pay and who should benefit.

The various fiefdoms of the public lands face a wide variety of management mandates.³³⁷ Assuming that sufficient biodiversity preservation mandates can be meaningfully imposed on the public lands, without more, citizens through their taxes effectively bear the entire burden of preservation.³³⁸ Additionally, if a private improver is able to obtain access to the “public” genetic resource and consequently commercialize derivative technologies, the private improver has effectively externalized the cost of preservation to the public at large.³³⁹ Considering the protections for intellectual property given to the improver,³⁴⁰ the result becomes that an improver can effectively privatize a public good, externalizing part of its cost of development to the public, and then charging the public monopoly rents for the product of that beneficial derivative technology.

This simplified hypothetical presents a number of inquiries, however the problems presented by it may be instructive. First, what ultimately is the externalized cost of preservation to the improver? Second, what is the benefit that society will enjoy from this derivative technology? Finally, what should be done, if anything, to correct this distributional inequity?

³³⁶ Message to Congress on the Biodiversity Treaty, *supra* note 210.

³³⁷ See *supra* Part III (discussing various management mandates applicable to public domain).

³³⁸ See *supra* Part III (detailing how Department of Interior and Department of Agriculture are responsible for administration of vast majority of public land holdings).

³³⁹ Demsetz explains this classic “tragedy of the commons” problem:

Suppose that land is communally owned. Every person has the right to hunt, till or mine the land. This form of ownership fails to concentrate the cost associated with any person’s exercise of his communal right on that person. If a person seeks to maximize the value of his communal rights, he will tend to overhunt and overwork the land because some of the costs of his doing so are borne by others. The stock of game and the richness of the soil will be diminished too quickly.

Demsetz, *supra* note 255, at 354.

³⁴⁰ In this context, for simplicity, intellectual property protection is assumed to be in the form of a patent — an exclusive right to control the use and exploitation of the product or process developed for a fixed period of time — though any form of intellectual property protection providing similarly “strong” protection would equally apply.

Each of these inquiries is mired in uncertainty. The first two present intractable economic problems, while the third presents an intractable political problem. In the case of Yellowstone, the cost of preserving a species³⁴¹ should reduce simply to the pro rata portion of the park's operational cost devoted to preservation of the species in question.³⁴² The budget of the National Park Service, which includes Yellowstone, for example, is \$1.8 billion per year.³⁴³ Considering the first goal of a resource management strategy — its preservation in perpetuity — the cost of merely running the National Parks at their present funding level in perpetuity may be as high as \$27.6 trillion in present value terms.³⁴⁴ Initially, this presents the “numerator” problem — how can the true cost³⁴⁵ of preservation efforts be separated from the other mandates of the National Parks, such as recreation?

Next, the “denominator” problem presents itself. In order to accurately determine the cost of preserving one particular species, one must determine how many species in the aggregate are being preserved and in what numbers. Even if one may determine what proportion of park expenditures could be attributable to biodiversity preservation — the numerator — the sheer number of species (known and unknown), their population sizes, the nature of their habi-

³⁴¹For purposes of this discussion, the “cost of preserving a species” encompasses all manner of the direct financial cost of maintaining and managing habitat, restricting access to sensitive areas, scientific study, and the administration and policing of access to habitat areas.

³⁴²Hypothetically, if the budget of Yellowstone National Park were \$100 million, of which \$50 million were devoted to preservationist objectives and there were only 50,000 species to be preserved, the annual cost of preserving the species at its present level and in its present location is only \$1000 annually.

³⁴³National Park Service, *NPS FY 1999 Budget Proposal Addresses Critical Park Infrastructure, Resource Preservation Needs* (visited Feb. 20, 1999) <http://www.nps.gov/pub_aff/courier/budget.htm> (copy on file with *Environs*). The entire 1998 fiscal year budget for the Department of the Interior was approximately \$7.2 billion. *Budget of the United States Government Fiscal Year 2000, Table 4.1* (visited Feb. 20, 1999) <<http://www.access.gpo.gov/usbudget/fy2000/hist.html>> (copy on file with *Environs*).

³⁴⁴This value represents the present value of a \$1.8 billion outlay in perpetuity. The present value of a stream of payments represents the sum of money that one would have to invest today at an assumed interest rate — the discount rate — in order to generate those payments in perpetuity. See generally EUGENE F. BRIGHAM, *FINANCIAL MANAGEMENT: THEORY AND PRACTICE* 94 (4th ed. 1985) (explaining subtleties of calculating time value of money). The present value of a perpetual income (or outlay) stream is simply the amount of the payment divided by the assumed discount rate. *Id.* at 102. Here, the discount rate was assumed to be 6.5%, or approximately the average rate of return on the 30-year treasury bond. Associated Press, *Bonds Edge Lower* (visited Feb. 20, 1999) <<http://www.nytimes.com/aponline/f/AP-Bonds.html>> (copy on file with *Environs*); Yahoo!Finance, *30 Year Treasury Yield Index* (visited Feb. 20, 1999) <<http://quote.yahoo.com/q?s=^TYX&dc=5ym>> (copy on file with *Environs*).

³⁴⁵“Cost” in this context includes not only direct financial costs, but also opportunity costs in the economic sense.

tat, etc. conspire to obscure the abstraction of the denominator, thus inhibiting this most basic valuation scheme. Very quickly the economic notion of pricing an externality is fraught with uncertainty and arbitrariness.

To compound matters, equitably allocating preservation costs to the improver,³⁴⁶ requires a comparison of the benefit the technology provides to society at large.³⁴⁷ This again involves a valuation inquiry best resolved post hoc if at all.³⁴⁸

C. Incentives for Innovation

The wealth of genetic information in the world has been analogized to a great library of information ranging from the common and mundane to the exotic and exceedingly rare.³⁴⁹ Though this vast library of the world's knowledge may contain many answers to problems not yet conceived, locating the answers from among the myriad volumes requires great effort and industry.³⁵⁰ Though the cost of acquiring, organizing, and indexing the collection is high, the cost to access this vast resource of knowledge must not be so high that no one will seek solutions there. If the cost of accessing the library is too high, would-be patrons (as the financial benefactors of the library) may question the value of maintaining the collection and paying librarians when they receive so little apparent benefit.

³⁴⁶ Accurate allocation of the cost of preserving the resource would allow full internalization of these costs to the improver.

³⁴⁷ This notion may best be understood as a "gravity of the benefit" concept: the cost of preserving the biodiversity from which the beneficial derivative technology comes is allocated in proportion to the social benefit derived from it. Over simplified, if the total preservation cost of biodiversity were known and only two successful technologies were developed from it — one, a cure for a common previously incurable fatal illness, and one, a cure for a relatively rare acute discomfort — the "gravity of the benefit" would allocate the greatest proportion of the preservation cost to the holder of the derivative technology which cures the fatal illness — in proportion to its relative social benefit, the cure for a common fatal illness.

³⁴⁸ For example, the development of a marginally effective vaccine to a disease may seem to prove extremely valuable when first developed. However, if a more effective and cheaper vaccine is produced relatively soon after the first is developed, the value of the benefit that the ineffective vaccine may have been grossly over-estimated ex ante. The point is that any ex ante cost shifting mechanism may be wildly inaccurate considering the pricing problems inherent to the externality of preservation costs.

³⁴⁹ See Stone, *supra* note 41, at 615 (stating that genetic resources are fundamentally different from other biological resources — their value is derived not from their rivalrous consumptive use as raw materials, but rather from their non-rivalrous aspect as information as in a library). See also Richard A. Epstein, *Property Rights in cDNA Sequences: A New Resident for the Public Domain*, 3 U. CHI. L. SCH. ROUNDTABLE 575, 576 (stating that "the payoff from research and development comes not in ownership of the specific thing, but in the use of the key ideas and plans to produce a line of similar products.").

³⁵⁰ See *supra* Part II.A (outlining high cost in time and resources necessary to bring a product derived from genetic or biological resources to market).

Like the library, genetic resources have value aside from their pure existence value.³⁵¹ The commercial value of genetic resources lay in the uses to which this information may be employed.³⁵² Often the cost of developing beneficial products from genetic resources involves tremendous investments of time and resources.³⁵³ The peril to the developer of the genetic resource lies in the possibility that a rival will simply wait for the developer to perfect the product and then enter the market with an identical or similar product.³⁵⁴ If we assume that these products are truly beneficial to society, the problem of creating incentives for innovation³⁵⁵ reduces to a question of attracting and protecting capital investment in biotechnology.

This problem manifests itself in two ways. First, in classical economic fashion, competition in the market place will ultimately drive down the market price as each rival competes for increased market share.³⁵⁶ If there are low barriers to market entry (relatively low costs of imitation and production³⁵⁷) and high research and development costs (relatively high fixed costs), competition may preclude the original innovator from recapturing her sunk costs of development. As a result, the innovator will make below-normal profits.³⁵⁸ As a result, the owners of the innovating firm can receive a better return on their investment somewhere else in the market, and the enterprise will be terminated.³⁵⁹ The owners

³⁵¹ See Stone, *supra* note 41, at 589 (arguing by analogy that penguins which have no commercially exploitable use or market-value, still have an existence value derived from a moral base rather than an economic one).

³⁵² See *id.* at 597 (comparing distinction between traditional extractive uses for biological resources, such as harvesting bark of cinchona tree to extract quinine, with non-extractive, non-rivalrous uses of biological information, such as discovering beneficial compound that can be synthesized).

³⁵³ See *supra* Part II.A (describing typical development costs of pharmaceuticals, etc.).

³⁵⁴ See generally THOMPSON, *supra* note 264, at 183-87 (discussing economic impact of technological change on firm under various conditions).

³⁵⁵ "Incentives for innovation" as used throughout this Article encompasses the full range of economic incentives — tax subsidies, loan subsidies, patents, trade secret protection, direct governmental investment, anti-trust immunity, co-operative research and development agreements, etc.

³⁵⁶ THOMPSON, *supra* note 264, at 183-87.

³⁵⁷ See, e.g., Stone, *supra* note 41, at 605 (arguing that although Chinese had a thousand-year technological monopoly on silk manufacturing — silkworms — all it took to expropriate technology to west was two Nestorian monks smuggling some eggs in their pockets in 552 A.D.).

³⁵⁸ As used in this context, "profit" means the economic profit of the firm in the long-run — a return to the owners of an enterprise of sufficient magnitude to induce the enterprise to remain in business. See THOMPSON, *supra* note 264, at 293-97 (examining different concepts of "profitability" and long term effect on firm profitability in an industry reliant upon innovation).

³⁵⁹ See *id.*

of the firm will take their capital and vote with their feet seeking new opportunities elsewhere.

The second problem grows out of the first. If investors see a likelihood of below-normal returns in an industry, no single firm will be able to attract enough capital to fund research and development. Accordingly, innovation in the sector will cease, denying society of the benefits of the widespread use and distribution of the beneficial product.³⁶⁰ Therefore, under an incentive to invent theory, too little invention will occur unless some mechanism can step in to correct this market failure and insure an adequate return to the developer, improver or inventor of the novel product.³⁶¹ Thus, in order to retain and encourage adequate incentives to invent, a regulatory scheme for genetic resources must seek to create conditions where firms can generate at least normal profits.

Presently, the patent system attempts to provide this incentive by granting the inventor exclusive rights in inventions and discoveries "To promote the Progress of Science and useful Arts."³⁶² By creating a property right in the invention, the current patent system allows inventors to use their monopoly power to extract above-market prices from consumers, arguably bringing their private benefits in line with the social value of their invention.³⁶³ In addition to monopoly rents, a variety of remedies are available to the patent holder whose patent has been infringed.³⁶⁴

In the context of products developed from public genetic resources, the sunk-costs include not only a private component (research and development) but also a public component (maintenance of the public resource at the public's expense). The cost of preserving the resource (genetic diversity found on public land) is external to the inventor. This allows the inventor to claim additional economic rent on the patented invention. In short, the developer of a product from genetic resources found on the public lands is able to externalize the costs

³⁶⁰ See *id.* at 183-87 (discussing problem of capital flight).

³⁶¹ See Eisenberg, *supra* note 217, at 1025 (asserting that under incentive to invent theory "too few inventions will be made in the absence of patent protection because inventions once made are easily appropriated by competitors of the original inventor who have not shared in the costs of invention"); see also *id.* at 1025, n.31 (providing that in a competitive market without patent protection, sale price will be driven down near the marginal cost of production precluding any return on the sunk costs of research and development).

³⁶² U.S. CONST. art. I, § 8, cl. 8.

³⁶³ See Eisenberg *supra* note 217, at 1026-33 (citing studies that suggest that rate of return from investments in research and development are significantly higher than returns available on other investments)

³⁶⁴ See *id.* at 1021 (describing remedies available to patent holders such as enjoining even innocent infringers from using patented invention or even suppressing all use of invention entirely).

of maintaining the public lands on which the genetic resource is found.³⁶⁵ It appears, then that the current patent system adequately provides an adequate rate of return to the innovator.³⁶⁶

VII. DEVELOPING A COMPREHENSIVE MANAGEMENT STRATEGY FOR FUTURE AGREEMENTS

What are the best methods to pursue the goals of a comprehensive management strategy for genetic resources on public lands? Carrot-like incentives are self-enforcing, yet may externalize the cost of their imposition. Stick-like regulations create market distortions and avoidance incentives as well as breeding disdain for the object of their protection.³⁶⁷ Ex-ante schemes risk uncertainty, while ex-post schemes increase transaction and enforcement costs.³⁶⁸ Intellectual property protection is fraught with the dangers of creating too much monopoly power at the expense of favoring innovation while compulsory licensing schemes may do little but increase transactions costs while reducing innovation and market supply.

A. *The Office of Biotechnology Policy*

First, the myriad questions informing the policy debate needs to be focused in one forum. While the fledgling biotechnology industry needed little policy or regulatory attention in 1980, today the industry has grown to such an extent that one agency — the Office of Biotechnology Policy — should be created to

³⁶⁵ See Demsetz, *supra* note 255, at 348 (explaining ambiguous concept of “externality” as an effect whose cost is too high to bring to bear on decisions of one or more interacting persons, generally including external costs, external benefits, both pecuniary and otherwise. By way of example, the author demonstrates that when person is conscripted into military service, taxpayer avoids or externalizes additional costs that would be required to provide incentives to attract a volunteer soldier).

³⁶⁶ But see Eisenberg, *supra* note 217, at 1033 (contending that because estimated median social rate of return to investment in research and development was 56% while median private rate of return was 25%, current incentive system may be resulting in underinvestment in research and development).

³⁶⁷ Consider, for example, the controversy surrounding the ESA’s protection of species like the snail darter and the spotted owl. See e.g., Brad Knickerbocker, *Saving Species, Ruffling Some Feathers*, CHRISTIAN SCIENCE MONITOR, Dec. 31, 1998, at USA3 (recounting conflict that has surrounded the ESA since its enactment 25 years ago); Paul Raeburn, *Save the Species — But Add Incentives*, BUS. WEEK, Jan. 18, 1999, at 63 (discussing maelstrom that ESA created when protection of endangered snail darter threatened to halt construction of Tellico Dam in Tennessee).

³⁶⁸ See *supra* Part V (examining economic issues unique to genetic resources).

act as the clearinghouse for issues surrounding the industry's development — particularly as they apply to genetic resources on the public lands. As Senator Gore stated in 1991, the United States needs a coherent effort at policy development to keep pace with technological developments.³⁶⁹ That need has only increased as the policy questions surrounding biotechnology has heightened with the growth of the industry.³⁷⁰ As the fractious mandates applicable to the public lands and the litigious mandates applicable to natural resource preservation demonstrate, one agency to collect, evaluate and develop comprehensive policy must be the first step.

The Office of Biotechnology Policy should be located within the Department of the Commerce. The Office would serve as a coordinating agency and information clearing house to evaluate the various legal and ethical issues that surround the use of biotechnology. Necessarily the Office would coordinate with the Office of Technology Policy within the Department of Commerce, the Environmental Protection Agency, and relevant public land management agencies that within the Departments of the Interior and Agriculture.

B. The Preservationist Imperative

The next step must be to develop among the various public land management mandates clear management priorities with respect to the preservation of biodiversity. Contrary to the belief of the last two administrations³⁷¹ present natural resource law either inadequately addresses preservation of biodiversity directly or addresses loss of species in a reactive, piece-meal fashion.³⁷² Thus a policy statement prioritizing biodiversity preservation among the various competing management mandates for the public lands should be the first goal of a new management agency specifically created for and charged with that task — the Biodiversity Preservation Agency.

The Biodiversity Preservation Agency would be located within the Department of the Interior where the majority of land management agencies are al-

³⁶⁹ See Gore, *supra* note 1, at 19 (advocating need for new biotechnology policy).

³⁷⁰ See OTP BIOTECHNOLOGY REPORT, *supra* note 2, at 6 (relating how growth of biotechnology industry has been accompanied by increasing concerns regarding policy development).

³⁷¹ Message to Congress on the Biodiversity Treaty, *supra* note 210; STATE DEP'T DISPATCH ON RATIFICATION, *supra* note 210.

³⁷² See *supra* Part VI.A. (discussing regulatory framework of public lands as applied to genetic resources).

ready located.³⁷³ The BPA's function would be to locate critical habitat, classify organisms and develop specific long range management plans for the preservation and enhancement of biodiversity on public lands. The BPA would be the primary agency responsible for coordinating "access" to the biological resources by the private sector.

C. The Biofund

To promote equitable cost sharing for the maintenance of the public lands, a self-enforcing, incentive-based approach should be used. A tax credit³⁷⁴ for contributions to the maintenance and preservation of biodiversity preserves should be created.³⁷⁵ These contributions may be used as a proxy for access fees, restricting the availability of public genetic resources and information.

³⁷³ A notable exception is the U.S. Forest Service within the Department of Agriculture. Ultimately, the Forest Service would be better located within the Department of the Interior, however, that discussion is beyond the scope of this Article.

³⁷⁴ Section 174 of the Internal Revenue Code already provides for a *deduction* from gross income of certain research and development costs that would otherwise be capitalized. I.R.C. § 174(a) (1999). Deductibility of § 174 expenses is limited to amounts "reasonable under the circumstances." *Id.* § 174(e) (1999). While deductions from gross income provide incentives to innovate in that they lower taxable income, this is only attractive to those companies that actually have taxable income. As discussed in Part II, *supra*, many biotechnology companies incur many years of losses before a profitable product can be brought to market. Thus, for a company not generating profits, the § 174 research and development expense deduction is only useful in that they may increase losses which may be carried back or carried forward to offset taxable income in previous or future years. The current tax code allows these excess losses to be applied to the two tax years preceding the year in which the loss was incurred, and to the twenty years subsequent to the year in which the loss was incurred. I.R.C. § 172(b)(1)(A)(i-ii) (1999).

A *tax credit*, by contrast, is a direct credit against tax liability rather than merely against gross income. In this way cash contributions today can be used to offset future tax liability on a dollar for dollar basis — one dollar contributed reaps one dollar less in tax later. The deductions contemplated by § 174, however, merely shelter taxable income — each dollar expensed under § 174 yields a net tax benefit of only the highest marginal rate that the income of the taxpayer is subject to. For corporations with taxable incomes between \$75,000 and \$10,000,000, the marginal rate is 34%, thus the tax savings for each dollar of § 174 expense yields only 34 cents in tax savings. I.R.C. § 11(b)(C) (1999).

Considering the time value of money, a progressive schedule could be developed to incentivize the contribution process if necessary, e.g., \$1 contributed today would be worth \$1, if used as a tax credit today, or \$1.05 next year, or \$1.10 in year two, \$1.17 in year three, etc. Alternatively, and perhaps more elegantly, contributions to this "Biofund" could be included in the statutory definition of a § 174 research and development expenses, and thus not perturb the current § 172 net operating loss carry back-carry forward provisions.

³⁷⁵ A centralized "Biofund" from which funding prerogatives would revolve would provide the greatest opportunity for the preservation and management of all public genetic resources as the centralization of policy development in a single agency would.

This scheme would have a twofold effect. First, a company seeking to develop products from genetic resources on the public lands could accrue tax credits that could be used to lower tax liability if and when the company develops a profitable product. Progressive marginal tax rates on individuals and corporations creates a strong incentives to use nominal current cash surpluses to ward off high marginal taxes later.³⁷⁶ With the removal of the specter of future royalty payments, and the cost of enforcing them, the potential for profitability is raised as is the possibility for higher marginal taxes.

Second, with contribution as a prerequisite to access to the resources, this scheme creates a quasi-communal property scheme — only contributors have access. This helps prevent rent dissipating racing, as well as allowing flexibility in financial commitment.

This scheme would place the burden of balancing capital deployment on the managers of the entities actually engaged in the development of derivative technologies — those with perhaps the most accurate assessment of the technology's potential and also those subject to shareholder removal — creating self-enforcing checks and balances.

To avoid-poaching problems, these funds should be used to fund scientific identification, inventory and study of potentially useful resources ostensibly carried out by the Biodiversity Preservation Agency.³⁷⁷ Searching for the genetic needle in the biodiversity haystack is one of the most laborious tasks of developing products from genetic resources.³⁷⁸ Creating a one-stop shop for biodiversity would increase the cost-effectiveness of private sector development.³⁷⁹

D. Distributional Goals

To promote equitable distribution of the beneficial derivative products, several approaches may be used. First, for products that may have limited markets but socially beneficial uses — such as a cure for a very rare disease — direct

³⁷⁶For corporations, the lowest marginal tax rate is 15% for taxable incomes below \$50,000. I.R.C. § 11(b)(1)(A) (1999). The rates quickly rise however, so that corporations with taxable income between \$75,000 and \$10,000,000 face a 34% marginal rate. *Id.* § 11(b)(1)(D).

³⁷⁷This is similar to the approach taken by INBio in Costa Rica. *See supra* Part II.B (discussing Merck/INBio agreement for bioprospecting).

³⁷⁸*See supra* Part II.A (examining extensive sampling and sorting required to identify potentially useful naturally occurring compounds and organisms).

³⁷⁹This approach would create more incentives to shelter future profits by supporting preservation and study.

subsidy and redistribution may be the only method to bring these solutions with limited markets to those who may need them.³⁸⁰ Secondly, patent life should be adjusted downward to encourage greater licensing and production during the early years of the patent. Genetic resources and the pharmaceuticals and chemicals derived from them often find different, unintended uses, and spawn more derivative technology.³⁸¹ A shorter patent life encourages the development of these secondary technologies, creating incentives in the form of competitive advantage to those firms who wish to continue to innovate.³⁸² It also encourages the widespread distribution of the benefits of the technology to the society which bears a portion of the cost of maintaining the genetic resources on the public lands from which it derives. It would be one of the first goals of the Office of Biotechnology Policy to evaluate and recommend a patent life — perhaps necessitating a new class of patent (the public biotechnology patent) — with a term uniquely suited to the complex economics of biotechnology developed from public genetic resources.

Finally, to maintain adequate incentives to innovate, patent protection should be maintained for products derived from genetic resources. A patent provides the opportunity to capitalize on the addition of innovation to the genetic resource and provides adequate time to develop efficient production tech-

³⁸⁰This is the situation of the so-called "orphan drug." These situations may be less subject to social economics and more correctly in the realm of distributive justice. In discussing "other justice reasons" for creating effective entitlements such as these, Calabresi and Melamed distinguish these types of situations that involve distributional preferences:

[T]hose preferences [for creating entitlements] which cannot be explained in terms of . . . relatively few broadly accepted distributional preferences [such as equality], or in terms of efficiency are termed justice reasons. The difficulty with this locution is that it sometimes is taken to imply that the moral gloss of justice is reserved for these residual preferences and does not apply to the broader distributional preferences or to efficiency preferences.

Calabresi & Melamed, *supra* note 248, at 1105. Here, society can choose to value the innovation (that may ultimately have derivative effect) by subsidizing the innovator, effectively internalize the cost of the afflicted's suffering, though less based on an efficiency or equality basis but rather on a moralist or "justice reason."

³⁸¹Consider for example, the entire industry spawned by the advent of PCR technology. See *supra* Part II (discussing development of PCR technology). See, e.g., Robin Herman, *The 'Lifestyle' Phenomenon: Pills to Enhance Well-Being*, INT'L HERALD TRIB., Nov. 18, 1998, at 21 (recounting how viagra, wildly successful treatment for impotence, began humbly as treatment to increase blood flow to heart, and finally how propecia, successful hair restoration treatment, began as treatment for enlarged prostate); David N. Leff, *Serendipity Taps Hormone to Treat Dementia*, BIOWORLD TODAY, Apr. 8, 1998, available in 1998 WL 7882436 (discussing how minoxidil, now lucrative hair restoration treatment, originated as treatment for hypertension, and how female hormone estrogen is being used to combat dementia in Alzheimer's patients).

³⁸²See THOMPSON, *supra* note 52, at 177 (noting that "a sounder, longer-lasting competitive edge can be achieved via technological superiority and innovation because technology-based competitive advantages are harder for rivals to overcome.").

niques for the new technology (which again can be patented). In order to promote responsible development of pharmaceuticals and other health care products, a mechanism for the tolling of the patent life may be appropriate where extensive testing is necessary to insure safety. Additionally, for products like orphan drugs, direct subsidy of research, development and production should be encouraged to the extent politically and socially tenable.

Fundamentally, this framework removes the need for formal bioprospecting agreements entirely if adequate safeguards and incentives are put in place. Myriad individual agreements run risk of negotiating away critical policy objectives and developing a dangerous ad hoc approach to public genetic resource management. Ideally, self-interest influencing or corrupting the negotiation process would be eliminated by a coordinated policy-based approach. More pragmatically, it avoids the uncertainties and extra costs associated with both ex-ante and ex-post valuation schemes.

VIII. CONCLUSION

The rapid growth of the biotechnology industry has shown the great potential that lay in the vast genetic resources of our planet.³⁸³ Few fundamental technological changes that have the potential to reshape and influence human destiny occur within one's lifetime. Fire, tools, agriculture, and industry have fundamentally reshaped the world in which we live.³⁸⁴ Unlocking the mysteries that lie in the genetic code of the millions of organisms that inhabit the earth may prove to be the most wide reaching revolution humans have encountered to date.

With the continued decrease in wilderness and greatly increased loss of species, we stand on the eve of the twenty-first century with the opportunity to both pioneer and plan for the future. By coordinating public land management mandates, equitably allocating biodiversity preservation costs, providing access to its technological benefits, and creating incentives for innovation, we have the ability to serve the needs of the present and provide for growth in the future. As the biotechnology industry has matured and as we move toward the twenty-first century, the time to plan so that we may pioneer later, has come.

³⁸³ See OTP BIOTECHNOLOGY REPORT, *supra* note 2, 6 (detailing benefits and identifying potential of biotechnology industry in twenty-first century).

³⁸⁴ See generally 2001: A SPACE ODYSSEY (Metro-Goldwyn-Mayer-United Artists, 1968) (depicting impact technology has had on destiny of human race).