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Bioprospecting Legislation in the United States: What We Are Doing, What We Are Not Doing, and What Should We Do Next

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BIOPROSPECTING LEGISLATION IN THE UNITED STATES: WHAT WE ARE DOING, WHAT WE ARE NOT DOING, AND WHAT SHOULD WE DO NEXT

EMILY J. STOLFER^{*}

ABSTRACT

Bioprospecting is a growing worldwide effort to protect knowledge and the environment. With its potential economic benefit and technological advancements, bioprospecting will continue to grow as the world advances. Other nations have begun to protect the information available and continue to develop legislation. However, the United States has been hesitant to ratify international treaties or implement its own legislation. This Note examines both domestic and international efforts to protect both indigenous people and the environment. It analyzes the legislation the United States currently has in place but also examines where the United States is lacking. Regarding the United States' failure to implement national legislation, this Note analyzes how two states that have tried to implement local bioprospecting legislation, instead. Finally, this Note makes a recommendation of what the United States or individual states should do in the future.

CONTENTS

I.	INTRODUCTION	101
II.	BACKGROUND.....	104
	<i>A. Convention on Biological Diversity</i>	104
	<i>B. Nagoya</i>	107
	<i>C. Trade-Related Aspects of Intellectual Property Rights</i>	109
	<i>D. U.S. Bioprospecting Legislation and Precedent</i>	111
	1. Edmonds Institute v. Babbitt and National Park Regulation .	111
	2. Utah.....	115
	3. Hawaii.....	117
III.	ANALYSIS	119
IV.	CONCLUSION.....	125

I. INTRODUCTION

In Leonardo DiCaprio's acceptance speech for Best Actor in a Drama at the 2016 Golden Globes, he ended his remarks by stating, "It is time that we recognize your history and that we protect your indigenous lands from corporate interests and people that are out there to exploit them. It is time that we heard your voice and protected this planet for future generations."¹ One of the biggest threats to these

^{*} J.D., expected May 2017. B.A. in Communications and Political Science from John Carroll University. Emily would like to thank her parents, Anne and Greg, for all of their love and support throughout the years. Your love is not quantifiable; thank you for that. Also, thank you to Gregory and Matthew for being awesome siblings and teaching me the importance of bird law. Finally, thank you to my friends for all of the laughter.

¹ NBC, *Leonardo DiCaprio Wins Best Actor in a Drama at the 2016 Golden Globes*, YOUTUBE (Jan. 10, 2016), <https://www.youtube.com/watch?v=ncgFQAISaGo>. For a more in-

lands is bioprospecting. Bioprospecting has many definitions, as stated below, but generally it is “searching wild plants, animals and microorganisms—that is, biodiversity—for genetic and biochemical information.”² Environmental issues have been at the forefront of policy discussions, and with most of the focus on global warming and sustainable green energy, other environmental issues that are just as important get placed on the backburner.³

Bioprospecting has many definitions. The Convention on Biological Diversity (CBD) defines it as “the exploration of biodiversity for commercially valuable genetic and biochemical resources.”⁴ Each definition can vary significantly but contains the same framework.⁵ For example, one definition states, “Bioprospecting involves searching for, collecting, and deriving genetic material from samples of biodiversity that can be used in commercialized pharmaceutical, agricultural, industrial, or chemical processing end products.”⁶ The bioprospecting definitions usually contain the concept of gathering or collecting genetic material found in nature that may be used for value.⁷

depth analysis of indigenous tribes, see Erik B. Bluemel, *Separating Instrumental from Intrinsic Rights: Toward an Understanding of Indigenous Participation in International Rule-Making*, 30 AM. INDIAN L. REV. 55 (2006) [hereinafter Bluemel, *Separating Instrumental from Intrinsic*]; Nancy Kremers, *Speaking with a Forked Tongue in the Global Debate on Traditional Knowledge and Genetic Resources: Are U.S. Intellectual Property Law and Policy Really Aimed at Meaningful Protection for Native American Cultures?*, 15 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1 (2004); Jennifer Amriott, *Investigating the Convention on Biological Diversity’s Protections for Traditional Knowledge*, 11 MO. ENVTL. L. & POL’Y REV. 3 (2003).

² Andrea Aseff, *First Federal Prohibition on Bioprospecting Within a Place of Protection: Time to Spur the Legislative Dialogue*, 22 COLO. J. INT’L ENVTL. L. & POL’Y 189, 190 (2011) (citing 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, 132-33 (1997)).

³ This paper mostly will discuss bioprospecting, which is the legal form of biopiracy, but in some academic literature these terms are used interchangeably. Biopiracy is referred to as “the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions that seek exclusive monopoly control . . . over these resources and knowledge.” *Patents & Biopiracy*, ETC GRP., <http://www.etcgroup.org/issues/patents-biopiracy> (last visited Sept. 20, 2016).

⁴ Lydia Slobodian et al., *Bioprospecting in the Global Commons: Legal Issues Brief 1*, <http://www.unep.org/delc/Portals/119/Biosprecting-Issuepaper.pdf> (last visited Sept. 20, 2016).

⁵ Compare Slobodian et al., *supra* note 4, with Peter G. Pan, *Bioprospecting: Issues and Policy Considerations* iv, LEGIS. REFERENCE BUREAU (2006), <http://lrhawaii.info/lrbrpts/05/biocon.pdf>.

⁶ Pan, *supra* note 5; see also Nuala Moran, *Microbial Wealth: Bioprospecting the Microbial Communities That Colonize Our Bodies is Starting to Throw Up Opportunities for Commercial Exploitation of the Microbiome* 22, CHEMISTRY & INDUS. (2014) (“We can push the gut microbiota in a health-promoting and health-sustaining way . . . We are not talking about probiotics, but products that will be put through clinical trials”) (internal quotations omitted).

⁷ See *Bioprospectors Feel Backlash in Hawaii: Patents on Taro Plant Outrage Some Who See it as a Sacred Symbol*, NBC NEWS (Jan. 21, 2006),

Anything with a commercial value has the opportunity to be exploited without the right protection and especially when the plant or organism in its original state can be extremely profitable.⁸ If companies have unregulated, unlimited access to these resources, the biodiversity they need for new biotechnologies will be destroyed, and “the wonderfully unusual accomplishment of discovering and eradicating in the same instant a new species”⁹ will become a reality. Even though the practice of bioprospecting has been around for over one hundred years,¹⁰ the potential profits that nanotech and biotechnological companies seek from bioprospecting are relatively new due to society’s technological advances.¹¹ For example, in South Africa, the government established the Council for Scientific and Industrial Research (CSIR) to help individuals, including indigenous groups, obtain patents.¹² The San People of South Africa used CSIR to develop the active ingredient in the Hoodia cactus.¹³ However, the CSIR sold the patent information to a British pharmaceutical company, leaving the San People incapable of receiving profits from benefit sharing.¹⁴ Without regulations, both the environment and individuals can be robbed of their rights due to commercial greed.¹⁵

http://www.nbcnews.com/id/10945323/ns/technology_and_science-science/t/bioprospectors-feel-backlash-hawaii/#.V9YMYIUrLIU (explaining key ingredients to medication were found through bioprospecting processes, like drugs for breast cancer and painkillers).

⁸ See Gina Kolata, *In Ancient Times, Flowers and Fennel for Family Planning*, N.Y. Times, Mar. 8, 1994, at C10 (explaining that the Romans used silphium, a plant, “to prevent pregnancies and induce abortions”). Silphium perhaps was effective almost 100 percent of the time, as evident from recent studies of rats ingesting a similar plant. *Id.* Romans used silphium so much that they drove the plant to extinction. *Id.*

⁹ Jim Chen, *Diversity and Deadlock: Transcending Conventional Wisdom on the Relationship Between Biological Diversity and Intellectual Property*, 31 ELR 10625 (2001) (citing BILL BRYSON, *A WALK IN THE WOODS: REDISCOVERING AMERICA ON THE APPALACHIAN TRAIL* 92 (1998)).

¹⁰ See *Edmonds Inst. v. Babbitt*, 93 F.Supp.2d 63, 65 (2000) (“[T]he earliest research permit authorizing collection of microbial samples from Yellowstone was in 1898.”).

¹¹ Genecore International Inc., a profitable biotechnology company, earned “\$13 million in the first quarter of 2004 on \$94 million in Revenue.” *Bioprospecting in Nature Fuels Debate*, NBC NEWS (Jul. 7, 2004), http://www.nbcnews.com/id/5295305/ns/us_news-environment/t/bioprospecting-nature-fuels-debate/#.V89JJ62xnVJ.

¹² Tak Jong Kim, *Expanding the Arsenal Against Biopiracy: Application of the Concession Agreement Framework to Prevent Misappropriation of Biodiversity*, 14 SMU SCI. & TECH. L. REV. 69 (2010).

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *How Does Biodiversity Loss Affect Me and Everyone Else?*, WORLD WIDE FUND FOR NATURE, http://wwf.panda.org/about_our_earth/biodiversity/biodiversity_and_you/ (last visited Sept. 7, 2016) [hereinafter WWF]. Ecosystem surveys are valued to an estimated amount of \$33 trillion per year, which is more than the United States’ and the European Union’s combined GDP for the year. Approximately 50,000 to 70,000 plant species are used in medicine and about 100 million metric tons of aquatic life are harvested every year. A significant loss of biodiversity would greatly damage the international ecosystem.

Biodiversity loss greatly threatens human wellness, especially in developing parts of the world, where water and food sources, the bare necessities of human survival, are sparse.¹⁶ Biodiversity is the underpinning of all life and necessary for human survival.¹⁷ Biodiversity is currently eroding at significant rates (twenty to fifty percent) due to human use,¹⁸ and the erosion is most significant in undeveloped or developing areas.¹⁹ Without biodiversity, our lifeline of food and water will not be able to sustain future populations, which could lead to resource wars, creating a true game of survival of the fittest.²⁰

This Note will address four different ways the United States has tried to regulate bioprospecting internationally and domestically. It will then analyze the pros and cons of the bioprospecting regulations and suggest a federal call to national bioprospecting legislation with a presentation of specific legislation to help protect a state's individual interests, encompassing the public and private property rights of both the government and individuals.²¹

II. BACKGROUND

A. *Convention on Biological Diversity*

The CBD was adopted in 1992 to help conserve biological diversity and establish rules for fair and equitable benefits for sharing genetic resources.²² In the CBD's quest to help preserve biodiversity, the convention addressed the topics above as well as intellectual property rights concerning the biotechnology derived from genetic resources.²³ The CBD noticed that biological diversity is a key asset to our society for both present and future generations.²⁴ Current unregulated practices

¹⁶ Sandra Diaz et al., *Biodiversity Loss Threatens Human Well-Being*, PLOS (Aug. 15, 2006), <http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.0040277> (“[E]cosystem services may decrease the quality of life of these vulnerable population . . . Biodiversity change is therefore inextricably like to poverty.”).

¹⁷ WWF, *supra* note 15.

¹⁸ NEVILLE ASH & ASHGAR FAZEL, *GLOBAL ENVIRONMENT OUTLOOK 4 (GEO-4): ENVIRONMENT FOR DEVELOPMENT 162* (Neville Ash & Asghar Mohammadi Fazel eds., 2007).

¹⁹ *Id.* at 160.

²⁰ INT'L INST. SUSTAINABLE DEV., *CONSERVING THE PEACE: RESOURCES, LIVELIHOODS AND SECURITY 34-35* (Richard Matthew et al. eds., 2002).

²¹ As later presented, each state may have individual interests it would like to protect, especially if the state is particularly rich in biodiversity (for example, Hawaii and Alaska). See *infra* Part II(D).

²² *History of the Convention*, CBD, <https://www.cbd.int/history/> (last visited Oct. 13, 2015); Chen, *supra* note 9, at 10630. Chen states, “If even casual hiking affects the distribution of population of wildlife, purposeful bioprospecting expeditions can leave a deep human footprint. The need for government intervention is far more urgent in the biosphere than in the ionosphere; unlike the supposedly ‘scarce’ but physically inexhaustible electromagnetic spectrum, natural resources can be depleted through unpatrolled exploitation.”

²³ Guri Bang, *Signed But Not Ratified: Limits to U.S. Participation in International Environmental Agreements*, 28 *REVIEW OF POL'Y RESEARCH* 65, 72-73 (2011).

²⁴ *History of the Convention*, *supra* note 22.

continue to deplete the Earth's biodiversity; the CBD only has five of its indicators making sufficient progress while sixteen currently show negative trends.²⁵ Specifically, in the Amazon, up to 8,700 species of trees are endangered due to deforestation, and the proportion of plants that are endangered has increased to one-fifth.²⁶

As of today, 196 countries have signed onto the CBD and its mission.²⁷ However, the U.S. is not a party to the CBD.²⁸ Even though President Bill Clinton signed the CBD in 1993, Congress failed to ratify because it would rather “deal with trade-related issues with environmental implication in the WTO [World Trade Organization] rather than in international environmental regimes.”²⁹ Clinton signed the CBD because the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) did not address the biological diversity concerns highlighted in the CBD.³⁰ Congress's concern was the opposite. Congress thought the CBD did not properly address intellectual property rights, private property rights, or consequences for land use policies.³¹ Although the Senate had a simple majority in favor of the CBD, it did not have the votes to ratify.³² The Senate, moreover, has not voted to ratify since 1994.³³ The U.S. concern of the CBD not addressing intellectual and private property rights shows the controversy between the need for biotechnological advancement and the protection of biodiversity.³⁴ The TRIPS agreement does not address Congress's concerns of land use policies, private property, or financing the project, which Congress stated was similar to the problems it encountered with the Endangered Species Act.³⁵ Congress did not want tougher land-use policies that would interfere with the rights of landowners, specifically ranchers and farmers.³⁶

²⁵ G7 ELMAU PROGRESS REPORT, BIODIVERSITY—A VITAL FOUNDATION FOR A SUSTAINABLE DEVELOPMENT (2015), <http://www.bmz.de/g7/includes/Downloadarchiv/G7-Elmau-Progress-Report-2015-Biodiversity-A-vital-foundation-for-sustainable-development.pdf>.

²⁶ *Half of the Amazonian Tree Species are Endangered*, SCI. DAILY (Feb. 10, 2016), <https://www.sciencedaily.com/releases/2016/02/160210111733.htm>.

²⁷ *List of Parties*, CBD, <https://www.cbd.int/information/parties.shtml#tab=0> (last visited Feb. 13, 2016).

²⁸ Pan, *supra* note 5, at 24.

²⁹ Bang, *supra* note 23, at 72.

³⁰ *Id.* at 73.

³¹ *Id.* at 74.

³² *Id.* at 75.

³³ *Id.*

³⁴ Chen, *supra* note 9.

³⁵ Bang, *supra* note 23, at 75.

³⁶ *Id.*

The CBD helps protect developing countries and indigenous groups through protocols, such as prior informed consent (PIC).³⁷ PIC is a two-step process.³⁸ First, it requires the bioprospector to obtain permission per a nation's protocol.³⁹ Second, the bioprospector must obtain this permission from the specific community where they are extracting materials.⁴⁰ PIC requires an understanding of what the researcher or company is doing within the community.⁴¹ It also requires the bioprospector to enter a written agreement with the community stating that the community understands what will be taking place.⁴² Usually, other benefit-sharing provisions are also discussed during the PIC process and can be put into a contract with the native tribes or landowners. The U.S. does not require PIC, allowing companies to "engage in biopiracy, patent any invention . . . resulting from the research on stolen biological resources and innovations, and prohibit other nations from utilizing their own resources."⁴³ Without PIC protections, individual bioprospectors can independently contract without a landowner's permission and without fully explaining what the bioprospector will do on the land.⁴⁴ This is similar to the problem with fracking, which is loosely regulated.⁴⁵ Similar to bioprospecting, fracking has no comprehensive regulatory regime.⁴⁶ Private actors protect themselves through private laws even though their actions have an adverse effect on the environment and public.⁴⁷ This legally allows companies to extract materials from nature without permission from areas except national parks, such as Utah and certain parts of Hawaii.⁴⁸ But usually, laws derived from the CBD discourage companies from investing in bioprospecting.⁴⁹

³⁷ U.N. DEP'T ECON. & SOC. AFFAIRS, INTERNATIONAL WORKSHOP ON FREE, PRIOR, AND INFORMED CONSENT AND INDIGENOUS PEOPLES: CONTRIBUTION OF THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE PRINCIPLE OF PRIOR AND INFORMED CONSENT 1 (2005).

³⁸ *Id.* at 5.

³⁹ *Id.*

⁴⁰ Sabrina Safrin, *Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life*, 98 A.J.I.L. 641, 649 (2004).

⁴¹ *Id.* at 654-55.

⁴² *Id.* at 654.

⁴³ Laura Grebe, *Requiring Genetic Source Disclosure in the United States*, 44 CREIGHTON L. REV. 367, 369 (2011).

⁴⁴ *Id.* at 384.

⁴⁵ See Shalanda Helen Baker, *Is Fracking the Next Financial Crisis? A Development Lens for Understanding Systemic Risk and Governance*, 87 TEMP. L. REV. 229 (2015).

⁴⁶ *Id.* at 237.

⁴⁷ *Id.* at 254-55 (noting that one of the harms of fracking is the leaking of natural gas and fracking fluid to mix with the water supply).

⁴⁸ *Id.* at 256.

⁴⁹ Safrin, *supra* note 40, at 668. Some argue that due to the decline in biodiversity, there is a need to develop technologies and pharmaceuticals prior to the depletion of the resources. See Aseff, *supra* note 2, at 197.

The CBD sets guidelines for countries to follow when creating legislation to protect both biodiversity and the rights of an area's indigenous people.⁵⁰ The majority of the countries belonging to the CBD are developing countries, which are seeking to protect themselves from corporate exploitation.⁵¹

B. Nagoya

The CBD's most recent attempt for the conservation of biological diversity and benefit-sharing of genetic material between countries is the Nagoya Protocol.⁵² Unlike the CBD, only sixty-eight countries have signed onto the Nagoya Protocol.⁵³ There are three obligations each participating state must meet: (1) access to genetic resources, (2) benefit-sharing, and (3) compliance.⁵⁴ Each obligation has its own rules for nations to follow.⁵⁵ Most countries that have agreed to the CBD also have agreed to the Nagoya Protocol.⁵⁶

To gain access to genetic resources and traditional knowledge,⁵⁷ collectors must obtain prior informed consent from the community or indigenous tribe, and both

⁵⁰ Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J.L. REFORM 433, 473 (2006).

⁵¹ *List of Parties*, *supra* note 27. See *Lessons from Bioprospecting in India and Nigeria*, CULTURAL SURVIVAL (2000), <https://www.culturalsurvival.org/ourpublications/csq/article/lessons-bioprospecting-india-and-nigeria> (demonstrating that India, for example started the Tropical Botanic Garden and Research Institute (TBGRI) which helped collaborated with the Kani tribe and started a profit sharing program of fifty percent of the licensing fee and two percent royalty on profits). TBGRI knew it did not reach out to all of the members, so they put the profits in a trust. *Id.* The Kani tribe continues to profit from the agreement with the TBGRI. *Id.* Due to the CBD the Kani tribe is allowed to deny such activity today if it wants. *Id.*

⁵² Matthias Buck & Clare Hamilton, *The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity*, 20 RECIEL 47, 47 (2011); see also Vanessa Danley, *Biopiracy in the Brazilian Amazon: Learning from International and Comparative Law Successes and Shortcomings to Help Promote Biodiversity Conservation in Brazil*, 7 FLA. A & M UNIV. L. REV. 2, 302 (2012) ("The Nagoya Protocol's main goal is to ensure that the parties to the agreement are adopting the benefit-sharing provision of the CBD.").

⁵³ *List of Parties*, *supra* note 27.

⁵⁴ *About the Nagoya Protocol*, CBD, <https://www.cbd.int/abs/about/default.shtml/> (last visited Oct. 15, 2015).

⁵⁵ *Id.*

⁵⁶ Dr. Konstantia Koutouki & Katharina Rogalla von Bieberstein, *The Nagoya Protocol: Sustainable Access and Benefits-Sharing for Indigenous and Local Communities*, 13 VT. J. ENVTL. L. 513, 528-29 (2012). The United States has not agreed to the Nagoya Protocol.

⁵⁷ See *Traditional Knowledge Innovations and Practice*, CBD, <https://www.cbd.int/traditional/intro.shtml> (last visited Feb. 22, 2015) ("Traditional knowledge refers to the knowledge, innovations and practices of indigenous and local communities around the world. Developed from experience gained over the centuries and adapted to the local culture and environment, traditional knowledge is transmitted orally from generation to generation.").

parties must agree on the established terms.⁵⁸ How that consent is handled is undefined.⁵⁹ It is up to the individual nations or parties to legislate accordingly.⁶⁰ There are precautions in place to help the traditional knowledge holders or indigenous tribes; such precautions include understanding the bioprospector's proposition or that a community has the right to say "no."⁶¹ The communities also must agree upon benefit sharing.⁶² Not all the words within the Nagoya Protocol are defined.⁶³ For example, utilization is not defined, which could be a weak point in the protocol.⁶⁴ But each country's ability to make its own rules, following the framework of Nagoya, can define the extra terms and change laws that are not having the intended effect.⁶⁵ Bioprospecting legislation should be analyzed annually to see if the legislation has the intended effect.⁶⁶

The last step a nation must take is to make sure bioprospectors are complying with the country's regulations for gathering genetic resources and traditional knowledge.⁶⁷ Regulations include upholding contracts, PIC, and settling any contractual violations or changes a party may want to make to the contract.⁶⁸ Nagoya added extra precautions to protect indigenous and local communities.⁶⁹ Nagoya's additional protections were a significant step in developing international biodiversity policy.⁷⁰ However, a weakness of Nagoya lies within its enforcement mechanisms; enforcement depends on any given nation's willingness to act on it.⁷¹ This leaves communities and nations vulnerable to exploitation by bioprospectors, especially when a nation does not hold the indigenous group in high regard or when there is a lack of enforcement due to a lack of resources.⁷² Nevertheless, the Nagoya

⁵⁸ Buck & Hamilton, *supra* note 52, at 54.

⁵⁹ *See id.*

⁶⁰ *Id.*

⁶¹ *Id.*; *see also* *About the Nagoya Protocol*, *supra* note 54.

⁶² Buck & Hamilton, *supra* note 52, at 55.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ Jorge Cabrera Medaglia et al., *The Interface Between the Nagoya Protocol on ABS and the ITPGRFA at the International Level: Potential Issues for Consideration in Supporting Mutually Supporting Implementation at the National Level*, FNI REPORT (2013), <http://www.fni.no/pdf/FNI-R0113.pdf>.

⁶⁶ *See* Jane Maienschein et al., *Articles, Biology and Law: Challenges of Adjudicating Competing Claims in a Democracy*, 38 JURIMETRICS J. 151, 156 (1998) ("[S]cientific knowledge can change rapidly, which can be a problem for legal and political processes . . . the process of doing science creates a changeable set of specific evidentiary claims.").

⁶⁷ *About the Nagoya Protocol*, *supra* note 54.

⁶⁸ *Id.*

⁶⁹ Buck & Hamilton, *supra* note 52, at 54.

⁷⁰ *Id.* at 60; *see also* Koutouki & Rogalla von Bieberstein, *supra* note 56, at 535.

⁷¹ Koutouki & Rogalla von Bieberstein, *supra* note 56, at 531.

⁷² *Id.* at 531.

Protocol is promising because it overcomes differences in global environmental politics, showing a strong effort for regrowth in not only nature but relations as well.⁷³

C. Trade-Related Aspects of Intellectual Property Rights

The U.S. has decided to use TRIPS instead of the CBD because of its focus on the patenting of new biotechnology discoveries.⁷⁴ The U.S. has many companies that are focused on biotechnologies. The prevalence of biotechnology companies strengthens the economy and, therefore, is important to policymakers.⁷⁵ TRIPS globally recognizes different patents and requires all participating nations to recognize patent rights of genetic and plant resources.⁷⁶ Primarily, developing countries have attempted to put limits on how material for the patents can be acquired.⁷⁷ However, the U.S. and foreign developing countries do not agree so long as they follow the patent process for the country.⁷⁸ The U.S. has continued to favor TRIPS due to its prioritization of intellectual property rights.⁷⁹

TRIPS currently requires countries to issue patents for a patentable product.⁸⁰ The requirement for patents holds true even if the patentable product violated access rules of the country, so long as they “involve an inventive step and are capable of industrial application.”⁸¹ This shows that countries that prioritize the TRIPS agreement over the CBD are not concerned about indigenous peoples’ rights or the need to address the mass biodiversity loss. Rather, such countries are more concerned about patents and commercial innovation based on resources that may have been obtained through unethical means, such as not fully disclosing the extent to which corporations may take from the land or finding loopholes to benefit sharing contracts, which are extremely difficult to enforce.⁸² Innovation in the U.S. has

⁷³ Buck & Hamilton, *supra* note 52, at 61.

⁷⁴ Grebe, *supra* note 43, at 369.

⁷⁵ See Mark Terry, *In Public-Private Deal, New York State Invests \$225 Million and Athenex Invests \$1.62 Billion to Create 1,400 Jobs*, BIOSPACE (Feb. 11, 2016), <http://www.biospace.com/News/in-public-private-deal-new-york-state-invests-225/408642?intcid=homepage-seekercarousel-featurednews-navindex1> (“We have been incredibly impressed by Governor Cuomo’s leadership to attract significant new jobs within New York State . . . [h]is commitment to economic development has successfully permeated an impressive ‘Open for Business’ culture we have not see [sic] anywhere else.”).

⁷⁶ Grebe, *supra* note 43, at 384.

⁷⁷ Safrin, *supra* note 40, at 666-67.

⁷⁸ *Id.* at 667.

⁷⁹ See generally Grebe, *supra* note 43.

⁸⁰ Safrin, *supra* note 40, at 667.

⁸¹ *Id.*

⁸² See Nicola Lucchi, *Understanding Genetic Information as a Commons: From Bioprospecting to Personalized Medicine*, 7 INT’L J. COMMONS 313, 332 (2013) (“‘Patent protection is . . . a two-edged sword.’ On one side, ‘the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery.’ On the other side, ‘that very exclusivity can impeded the flow of information that might permit, indeed spur, invention.’”).

always been favored, especially since it is closely associated with “the American Dream” mentality.⁸³ Thus, not regulating bioprospecting gives corporations room for innovation and exploitation of both goods and people without consequences.

TRIPS sets forth guidelines for individuals filing patents, and each country models its own set of rules to meet its needs.⁸⁴ Each country’s provisions must fall within three categories: (1) intellectual standards, (2) domestic enforcement, and (3) settle disputes amongst its members.⁸⁵ TRIPS binds nations with only its minimum standard requirements, ignoring the requirements of the CBD, so the only way to incorporate the two is either have the WTO incorporate the CBD or have each individual country make the CBD a part of its patent filing processes.⁸⁶ However, the main reason countries like the U.S. prefer the TRIPS agreement is due to the loose standards and enforcement policies for when a dispute occurs between countries.⁸⁷ If an inventor wants a patent approved in a country, the inventor must file it according to that country’s specifications.⁸⁸ The U.S. is no different.⁸⁹ The TRIPS agreement is not bulletproof because developing countries have been copying other countries’ patents.⁹⁰ For example, Brazil copies pharmaceutical patents.⁹¹

Authors have already suggested incorporating PIC into the U.S. TRIPS patent process. Even though naturally-occurring resources cannot be patented, which includes traditional knowledge, “TRIPS effectively allows biopiracy to occur, since products of nature are not protected by TRIPS.”⁹² Scientists can extract the material from a natural substance and turn it into a medical advancement, changing the naturally occurring material into a profitable patent.⁹³ For example, if PIC was included under TRIPS and applied to all possible afflicted parties, not limited to national governments, it could be the gateway into granting property rights to citizens and traditional knowledge benefits to indigenous groups.⁹⁴ Even though the

⁸³ Safrin, *supra* note 40, at 674.

⁸⁴ Nuno Pires de Carvalho, *From the Shaman’s Hut to the Patent Office: In Search of a TRIPS-Consistent Requirement to Disclose the Origin of Genetic Resources and Prior Informed Consent*, 17 WASH. U.J.L. & POL’Y 111, 125-26 (2005).

⁸⁵ *Overview: The TRIPS Agreement*, WORLD TRADE ORGANIZATION (2016), https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm.

⁸⁶ Carvalho, *supra* note 84, at 128.

⁸⁷ *See id.* at 186.

⁸⁸ *See id.* at 126.

⁸⁹ *See id.*

⁹⁰ *See* Erik B. Bluemel, *Substance Without Process: Analyzing TRIPS Participatory Guarantees in Light of Protected Indigenous Rights*, 86 J. PAT. & TRADEMARK OFF. SOC’Y 671, 686-87 (2004) [hereinafter Bluemel, *Substance Without Process*].

⁹¹ *See* Carolyn S. Corn, *Pharmaceutical Patents in Brazil: Is Compulsory Licensing the Solution?*, 9 B.U. INT’L L.J. 71, 71-75 (1991).

⁹² Bluemel, *Substance Without Process*, *supra* note 90, at 684-86.

⁹³ *See id.* at 686.

⁹⁴ *Id.* at 694-95.

U.S. does not allow for substances occurring in nature not to be patented in that form,⁹⁵ this does not mean other nations follow the same guidelines.⁹⁶

Although PIC is mentioned under TRIPS, the protocol is not required in the agreement and, therefore, is not necessary for enforcement unless the rules from the country require it.⁹⁷ Since PIC is not within the agreement part of TRIPS, the U.S. is not required to incorporate it into its patent legislation and has not required it yet.⁹⁸ The U.S. failure to require PIC has the consequence of allowing biopiracy findings—microorganisms or active chemical ingredients with highly profitable potential retrieved through exploiting land or traditional knowledge of an indigenous tribe—to be eligible patent material within the U.S.⁹⁹ Also, if one of the following regulations does not function properly, a researcher may bioprospect on public grounds in the U.S., making all public land open to exploitation.

D. U.S. Bioprospecting Legislation and Precedent

The U.S. has taken some action concerning bioprospecting legislation. The earliest U.S. action was the case of *Edmonds Institute v. Babbitt*, in which Yellowstone National Park initially tried to implement the first bioprospecting agreement within its park.¹⁰⁰ Hawaii and Utah have also enacted, or attempted to enact, legislation to help regulate bioprospecting on public grounds.¹⁰¹ Below are descriptions of such actions.¹⁰²

1. *Edmonds Institute v. Babbitt* and National Park Regulation

Edmonds Institute v. Babbitt is the only case to establish precedent for bioprospecting in the U.S. National Parks.¹⁰³ In 1999, plaintiffs first brought the case challenging the Department of the Interior's authority to enter into a commercial bioprospecting agreement with Diversa Corporation (Diversa)¹⁰⁴ at Yellowstone

⁹⁵ See *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980) (“Congress thus recognized that the relevant distinction was . . . between products of nature, whether living or not, and human-made inventions.”).

⁹⁶ See Bluemel, *Substance Without Process*, *supra* note 90, at 686.

⁹⁷ *Id.* at 693-94.

⁹⁸ Grebe, *supra* note 43, at 389-90; see also Chen, *supra* note 9, at 10639.

⁹⁹ Grebe, *supra* note 43, at 389-90.

¹⁰⁰ *Edmonds Inst. v. Babbitt*, 42 F. Supp. 2d 1, 4 (D.C. Cir. 1999).

¹⁰¹ Eric Goldman, *Utah Passes Nation's First (?) Bioprospecting Regulation*, TECH. AND MARKETING L. BLOG (Mar. 10, 2010), http://blog.ericgoldman.org/archives/2010/03/utah_passes_nat.htm.

¹⁰² See *infra* notes 106-81.

¹⁰³ *Edmonds Inst.*, 42 F. Supp. 2d at 9.

¹⁰⁴ See *id.* at 2. Diversa Corporation is a San Diego based biotechnology company. The plaintiffs in the case were Edmonds Institute (a nonprofit public interest organization), Alliance for the Wild Rockies (a nonprofit organization to preserve native biodiversity), International Center for Technology Assessment (a nonprofit organization focused on the ethical issues in the biotechnology industry), and Phil Knight, a resident of Bozeman, Montana. *Id.* at 9.

National Park.¹⁰⁵ The Cooperative Research and Development Agreement (CRADA) was the first bioprospecting legislation entered into on behalf of the parks.¹⁰⁶ Prior to CRADA, park services received no benefit from any derivative park products.¹⁰⁷ The Yellowstone-Diversa CRADA included benefit-sharing practices and revenues if Diversa commercially benefited from any research deriving from the microorganisms collected from Yellowstone.¹⁰⁸ Also, Diversa agreed to make annual payments of around \$20,000 to Park Services and provide research equipment for the park to use.¹⁰⁹

Prior to CRADA, any researcher could remove specimen from the park with a permit and develop it if he or she wished.¹¹⁰ Yellowstone already has examples of unique genetic material with commercial application, such as *thermos aquaticus*, a heat-resistant bacterium.¹¹¹ The environmental impact assessment is especially important because of the potential to exploit natural resources for commercial gain.¹¹² A court makes the distinction between commercial and research activity in stating that, “There is an undeniable reality that commercial activity is qualitatively different than scientific and educational activity of a similar nature, due to the very different forces and motivations that drive them.”¹¹³ Due to the profitable nature of bioprospecting, exploitation is bound to happen unless there are safeguards in place

¹⁰⁵ *Id.* at 4.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* at 5. Yellowstone has had commercial derivative products, such as the Taq polymerase, that are profitable. *Id.* The Taq polymerase patent sold for an estimated \$300 million and generates about \$100 million a year. *Id.* The current patent holder offered to contribute to the park; however, Yellowstone denied because it was uncertain about the legality of the transaction. *Id.*

¹⁰⁸ *Id.* at 2-3, 5 (“The Park has indicated that it will receive royalties of between .5% and 10% depending upon the nature of the raw material and the final product.”).

¹⁰⁹ *Id.* at 5.

¹¹⁰ Todd Weaver, *Bioprospecting in the National Parks: Edmonds Institute v. Babbitt*, 42 JURIMETRICS J. 61, 67 (2001).

¹¹¹ Safrin, *supra* note 40, at 682 (citing Adair, *supra* note 2, at 141); *see also* Chelsea DeWeese, *Mysterious Microbes: How Yellowstone’s Thermophiles Affect All of Us*, YELLOWSTONE Q. (Spring 2015).

¹¹² *See* Aseff, *supra* note 2, at 201-02 (“Protected public land and natural resources provide raw material for the bioprospectors, while patent law opens the door for commercial exploitation, inevitably raising concerns about line drawing and the ‘Tragedy of the Commons’ dilemma.”).

¹¹³ *Edmonds Inst.*, 42 F. Supp. 2d at 13; *see also* Lonie R. Boens, Note, *Edmonds Institute v. Babbitt: Bioprospecting on Federal Lands, Public Loss or Public Gain?*, 4 GREAT PLAINS NAT. RESOURCES J. 50, 58 (1999) (“The commercial component of bioprospecting is driven by self-interest profit incentives which have the potential to overshadow the more altruistic conservation component of the industry. The lure of extensive profits subjects bioprospecting to abuse.”).

prior.¹¹⁴ Thankfully, the National Park Service has such protection through legislation.¹¹⁵

The *Edmonds* court defined bioprospecting as “a relatively new method of natural resource exploitation . . . that targets microscopic resources—the genetic and biochemical information found in wild plants, animals, and microorganisms.”¹¹⁶ This is a very narrow definition, and even though the court alluded to the fundamental understanding of “timber harvesting, mining, hunting, and grazing,”¹¹⁷ it purposely did not include it because those activities are using the materials themselves as the commercial gains and not the scientifically-derived material.¹¹⁸ The court also pointed to the lack of a definitive policy statement of bioprospecting through regulations or less formal means.¹¹⁹

In *Edmonds*, the plaintiffs brought suit because the National Park Service failed to provide public notice of the changes brought by the agreement and did not perform an environmental impact assessment of the agreement, which is required by law.¹²⁰ The plaintiffs alleged that human intrusion around features like the thermal geysers disrupted the aesthetic enjoyment of the park.¹²¹ Plaintiffs also alleged the Park Service violated the Federal Technology Transfer Act (FTTA), the National Park Service Organic Act (NPSOA), the Yellowstone National Park Organic Act (YOA), the National Environmental Policy Act (NEPA), and the public trust doctrine.¹²² The court only decided that the plaintiffs proved the agreement between Diversa and Yellowstone was against public interest of the Park and that the Yellowstone-Diversa CRADA would be suspended on completion of an environmental assessment or an environmental impact statement.¹²³

The D.C. District Court heard *Edmonds Inst. v. Babbitt* again, deciding whether the Department of the Interior’s “entry into a research agreement with a private biotechnology company for the ‘bioprospecting’ of microbial organisms from . . .

¹¹⁴ See Aseff, *supra* note 2, at 190, 201.

¹¹⁵ The National Park Service Organic Act provides that the purposed of the parks are “to conserve the scenery and the natural and historic objects and the wild life therein . . . by such means as will leave them unimpaired for the enjoyment of future generations.” 54 U.S.C. § 100101 (2016) et. seq; see also *Edmonds Inst. v. Babbitt*, 93 F. Supp. 2d 63, 69-70 (D.C. Cir. 2000).

¹¹⁶ *Edmonds Inst.*, 42 F. Supp. 2d. at 6.

¹¹⁷ *Id.* at 5-6.

¹¹⁸ *Id.* at 11-12 (“[D]efendants concede, the collection of microbial samples, while not rising to the level of strip mining or timber harvesting, does involve some intrusion into delicate ecosystems around Yellowstone’s thermal features.”).

¹¹⁹ *Id.* at 9.

¹²⁰ *Id.*

¹²¹ *Id.* at 11-12.

¹²² Weaver, *supra* note 110, at 62.

¹²³ See *Edmonds Inst.*, 42 F. Supp. at 20; see also *Alaska Wildlife Alliance v. Jenson*, 108 F.3d 1065, 1074 (9th Cir. 1997) (“[C]ommercial fishing is statutorily prohibited only in the Park’s designated wilderness areas.”).

Yellowstone” was arbitrary and capricious.¹²⁴ The arbitrary and capricious standard is “‘highly deferential’ and presumes the validity of agency action.”¹²⁵ When construing the language of the statutes in question, the court stated, “CRADA is consistent with Congressional intent regarding cooperative scientific research agreements with units of the National Park System.”¹²⁶

The court wrote that CRADA was not against the intent of the statute because the “‘commercial use’ flowing from such research is limited to applications or products generated from the scientific study of the resources, not the resources themselves.”¹²⁷ The court also recognized a park’s ability to construe the regulations to meet the park’s own requirements.¹²⁸ Even the Solicitor recommended the essence of CRADA be placed within the permit process for research itself in order to help regulate the commercial benefits from products derived as a result of research throughout the National Park System.¹²⁹ This addition would remove the arbitrary and capricious standard so long as Park System gives equal opportunity for organizations to apply for the CRADA after they have applied for a permit. Because only approximately forty to fifty of the research permits are for microbial research, the CRADA agreements would be less than or equal to the amount of permits for a given year.¹³⁰

Both of the *Edmonds* decisions provide parks the flexibility to engage in potential commercial benefits of the parks, but the cases set precedent that the researchers or companies cannot obtain profits from harvesting or mining the raw material.¹³¹ If the profits came from “the resources themselves,”¹³² then the plaintiffs would have won due to the prioritization of protecting the parks and the biodiversity within them. The profit from the microbial samples come from the research and the genetically modified results from the samples, unlike timber and mineral extraction where the organic resources are the goods themselves.¹³³

These cases are important because of the financial benefits involved in the CRADA Act, providing the parks financial benefits and resources.¹³⁴ National Parks

¹²⁴ *Edmonds Inst. v. Babbitt*, 93 F. Supp. 2d 63, 64 (D.C. Cir. 2000).

¹²⁵ *Id.* at 67 (quoting *United Transp. Union v. Lewis*, 711 F.2d 233, 252 (D.C. Cir. 1983)).

¹²⁶ *Id.* at 68.

¹²⁷ *Id.* at 72.

¹²⁸ *Id.*; see *Weaver*, *supra* note 110, at 71-72.

¹²⁹ See *Edmonds Inst. v. Babbitt*, 42 F. Supp. 2d 1, 8 (D.C. Cir. 1999) (“Any specimen collected under this permit . . . may not be used for commercial purposes unless the permittee has entered into a cooperative research and development agreement (CRADA) with the [relevant agency of the Department of Interior.]”) (quoting Pls.’ Reply Brief, Ex. 1).

¹³⁰ *Id.* at 7.

¹³¹ See *Adair*, *supra* note 2 at 131 (discussing the benefits of the U.S. resources in the field of biotechnology and if they should be used).

¹³² *Edmonds Inst.*, 93 F. Supp. 2d at 72.

¹³³ See *Aseff*, *supra* note 2, at 201 (“[N]on-naturally occurring organisms . . . are patentable . . . Under current U.S. law, genetically modified organisms obtained through bioprospecting are patentable.”).

¹³⁴ *Edmonds Inst.*, 42 F. Supp. 2d at 5.

have the potential to benefit greatly from the agreement, providing Yellowstone up to ten percent (10%) of future profits Diversa might make from bioprospecting profits.¹³⁵ Yellowstone has lawfully issued permits to companies, and the park continues to issue permits to this day.¹³⁶

2. Utah

Utah is the first state to pass bioprospecting legislation after *Edmonds Institute v. Babbitt*, and the laws passed with almost no opposition within the state's legislature.¹³⁷ The only other state to attempt to pass bioprospecting legislation is Hawaii, but the legislation failed due to relations with Hawaii's indigenous population, addressed below.¹³⁸ Unlike Hawaii, Utah went for a more economic tone while attempting to adapt to the CBD.¹³⁹ Utah requires registration prior to bioprospecting.¹⁴⁰ The state defines bioprospecting as "the removal from a natural environment for research or commercial use of naturally occurring microorganism, plant or fungus, or information concerning a naturally occurring microorganism's, plant's, or fungus' physical or genetic properties."¹⁴¹ The definition encompasses more than the D.C. District Court's definition in *Edmonds* or Hawaii's definition, and this shows Utah's ability to incorporate the international views of bioprospecting into its statute. Keeping the definition broad and the statute vague or "skeletal" allows for the Act to be molded so that it may be more effective in the future.¹⁴²

Another key difference between Utah and Hawaii is that Utah has far fewer indigenous people.¹⁴³ The bill was enacted stating that Utah owned its resources and not the people.¹⁴⁴ Thus, companies have to enter into a contract with Utah and not with individual parties.¹⁴⁵ Utah's approach has worked for some CBD nations, as well.¹⁴⁶ Because companies must set terms with the state, Utah can enforce "criminal

¹³⁵ *Id.*

¹³⁶ See DeWeese, *supra* note 111, at 12-13.

¹³⁷ UTAH CODE ANN. §§ 65A-14-101, 201, 202, 301 (2016); see also William M. Fischer, *The Utah Bioprospecting Act of 2010: (Unintentional) State-Level Implementation of the United Nations Convention on Biodiversity*, 10 J. TELECOMM. & HIGH TECH. L. 197, 200 (2012).

¹³⁸ See Fischer, *supra* note 137, at 205-06. See generally A NATION RISING: HAWAII MOVEMENTS FOR LIFE, LAND, AND SOVEREIGNTY (Noelani Goodyear-Ka'ōpua et al. eds., 2014).

¹³⁹ See Fischer, *supra* note 137, at 199-201.

¹⁴⁰ *Id.* at 201.

¹⁴¹ *Id.* (quoting UTAH CODE ANN. § 65A-14-102 (2016)).

¹⁴² *Id.* at 202.

¹⁴³ See *id.* at 205.

¹⁴⁴ See *id.* at 202.

¹⁴⁵ See *id.* at 201.

¹⁴⁶ Like Utah, Brazil also requires that bioprospectors negotiate directly with the country, instead of individual parties. Brazil also requests that all of the activities involving genetic information and the traditional knowledge be recorded. Further, Brazil has enacted penalties

penalties, including payment of restitution, ‘proportional to the economic interests the state may have under [the Act].’¹⁴⁷ Through enforcing risks, Utah has the ability to regulate the bioprospectors and offers a means to deter individual companies from breaking their contracts.

Utah regulates and implements its legislation through its administrative rule-making body, the Department of Natural Resources (DNR).¹⁴⁸ For a company to have access to Utah’s resources, the company must first register with the state.¹⁴⁹ After registration, a license is granted, and the parties have to enter a contract with Utah.¹⁵⁰ Once granted, bioprospectors must provide information concerning the activity and the sites on which parties plan to bioprospect.¹⁵¹ The license is valid for twelve months and can be renewed after the period expires.¹⁵²

Utah’s DNR would discuss the royalty programs derived from bioprospecting through “good faith negotiations.”¹⁵³ The state would receive any benefits a company may produce from future bioprospecting products or receive royalties from the extraction of such goods, like oil around the Salt Lake.¹⁵⁴

Authors have pointed out that the bill’s vagueness could have a detrimental effect on protecting the biodiversity of the land itself, calling for a more concrete set of rules.¹⁵⁵ However, because it is the first bill of its time, vagueness might come in handy, especially because the overall objectives of the bill are set forth both in the legislative history and the original purpose in the bill. Critics argue that the bill was poorly drafted and question Utah’s ability to regulate without clear and convincing guidelines.¹⁵⁶ However, ambiguity in the law allows Utah to test different approaches to see what works, and although the bill enacts the state’s rights within bioprospecting, there is room to address private property rights, which could be a job for future legislation.¹⁵⁷ Utah is taking steps in the right direction and sets a

to protect this information. See Stephen Jenei, *Brazilian Government Published Bill on Bioprospecting/Biopiracy*, PATENT BARISTAS (Feb. 15, 2008), <http://www.patentbaristas.com/archives/2008/02/15/brazilian-government-published-bill-on-bioprospectingbiopiracy/>.

¹⁴⁷ Fischer, *supra* note 137, at 201 (quoting UTAH CODE ANN. § 65A-14-301 (2016)).

¹⁴⁸ See *id.* (citing UTAH CODE ANN. § 65A-14-104 (2016)); UTAH ADMIN. CODE r. 652-150 (2011).

¹⁴⁹ See Fischer, *supra* note 137, at 201.

¹⁵⁰ See *id.*

¹⁵¹ See *id.*

¹⁵² See *id.* (citing UTAH CODE ANN. § 65A-14-201 (2016)).

¹⁵³ *Id.* (quoting UTAH CODE ANN. § 65A-14-202 (2016)).

¹⁵⁴ See *id.* at 201-02. Due to the extreme habitats of the state, “research showed that organisms unique to Utah had great potential for profitable products and processes.” *Id.* at 203.

¹⁵⁵ See *id.* at 222.

¹⁵⁶ See Goldman, *supra* note 101.

¹⁵⁷ See Fischer, *supra* note 137, at 217, 222; see also Bang, *supra* note 23, at 74.

framework that other states can copy to include bioprospecting rights on their own soil.

3. Hawaii

Hawaii has a lot to offer bioprospectors, including its wealth of traditional knowledge, unique biodiversity, and promotion of the biotechnological sector.¹⁵⁸ But because of its rich information and history, Hawaii should be worried about the stripping of these resources for any biotechnological advances that may be in high demand. Hawaii attempted to enact its own laws to protect against bioprospecting and the “tremendous loss of biodiversity.”¹⁵⁹ Hawaii’s Constitution provides that “[a]ll public natural resources are held in trust by the State for the benefit of the people,”¹⁶⁰ so through this language, Hawaii attempted to put its resources in a trust for the state.¹⁶¹ However, Hawaii’s solution in creating a public trust ignores the private interest of the people indigenous to Hawaii who have a special connection to the state’s land and resources.¹⁶²

In its draft legislation, Hawaii defined bioprospecting as “the collection, removal, or use of biological and genetic resources of any organism, mineral, or other organic substance found within the public lands of the State and the state marine waters for scientific research or commercial development.”¹⁶³ Hawaii attempted to functionally adopt the CBD’s guidelines and rules by making it a part of its new legislation.¹⁶⁴ Hawaiian indigenous people make up twenty-three percent (23%) of the population.¹⁶⁵ The indigenous people have a significant amount of knowledge and a history with the land.¹⁶⁶ The legislature has had some problems in the past deciding whether to give native Hawaiians special rights and protection when it comes to the patentability and extracting of resources and use of their traditional knowledge.¹⁶⁷ The indigenous population of Hawaii should be wary of bioprospecting because it “has harmed many of the estimated 300 million indigenous people worldwide.”¹⁶⁸

¹⁵⁸ See Sarah K. Kam, Comment, *Biopiracy in Paradise?: Fulfilling the Legal Duty to Regulate Bioprospecting in Hawai’i*, 28 U. HAW. L. REV. 387, 388 (2006).

¹⁵⁹ S.B. 151, 24th Leg, Reg. Sess. (Haw. 2007).

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² “Bioprospecting has adversely affected environments and indigenous peoples throughout the world, including the extinction of natural species and the unauthorized appropriation of traditional knowledge.” Kam, *supra* note 158, at 388.

¹⁶³ Haw. S.B. 151.

¹⁶⁴ Fischer, *supra* note 137, at 199-200.

¹⁶⁵ Sara K. Goo, *After 200 Years, Native Hawaiians Make a Comeback*, PEW RESEARCH CTR., <http://www.pewresearch.org/fact-tank/2015/04/06/native-hawaiian-population/> (last visited Sept. 22, 2016).

¹⁶⁶ *Id.*

¹⁶⁷ Kam, *supra* note 158, at 399.

¹⁶⁸ *Id.* at 397.

Through these problems and the loose interpretation of the CBD, Hawaii has had trouble enacting any proactive legislation to help establish rights within the state.¹⁶⁹

In its enactment, Hawaii's legislation faced more difficulties than Utah's because the Hawaiian legislation could not only focus on the economic benefits like Utah's.¹⁷⁰ Hawaii must focus more on the preservation of biodiversity and traditional knowledge of native Hawaiians when enacting bioprospecting legislation.¹⁷¹ Hawaii has different values for bioprospecting legislation, which can make enacting and enforcing the legislation much more difficult compared to Utah's plan above.¹⁷² Hawaii's history and cultural diversity make it more difficult to agree on how to protect the biodiversity and knowledge of the land.¹⁷³

However, Hawaii did not fail completely. In 2009, Hawaii started and continues to limit activity in the Papahānaumokuākea Marine National Monument.¹⁷⁴ In order to manage and minimize human impact, the state initiated a permitting program, requiring all activities in the Monument (with limited exceptions) to obtain a permit.¹⁷⁵ This small step shows Hawaii's commitment to preserving its biodiversity.¹⁷⁶ Indeed, this prohibition of bioprospecting without a permit in the Monument shows the state's commitment.¹⁷⁷ However, this legislation only protects

¹⁶⁹ Fischer, *supra* note 137, at 199-200 (“The Hawaiian statute failed, in part due to its lack of efficiently stringent benefits-sharing arrangements with the Hawaiian people.”).

¹⁷⁰ *Id.*

¹⁷¹ *Id.* at 212.

¹⁷² *Id.* at 225. Hawaii's interest to protect Native Hawaiian rights and knowledge is a state constitutional value. But there is disconnect between Native Hawaiians and the rest of the population. See Kenneth R. Conklin, *Kahana Valley Giveaway—Just More of the Same*, HAW. REP. (Feb. 5, 2009), <http://www.angelfire.com/big09a/KahanaGiveawayToEvilEmpire.html>.

¹⁷³ See generally NOELANI GOODYEAR-KA'OPUA, *A NATION RISING: HAWAIIAN MOVEMENTS FOR LIFE, LAND AND SOVEREIGNTY* (2014). Hawaii's struggle between indigenous rights and public domain or public resources, shows the tension with which most international bioprospecting legislation has struggled. Indigenous people have known properties of certain organic material for hundreds of years while companies now are trying to figure out ways of extracting the those properties and commercializing them. See, e.g., Anupam Chander & Madhavi Sunder, *The Romance of the Public Doman*, 92 CALIF. L. REV. 1331 (2004).

¹⁷⁴ *Resource Protection*, PAPAHAANAUMOKUAKEA MARINE NAT'L MONUMENT, <http://www.papahanaumokuakea.gov/resource/> (last visited Feb. 12, 2016).

¹⁷⁵ *Permitting*, PAPAHAANAUMOKUAKEA MARINE NAT'L MONUMENT, <http://www.papahanaumokuakea.gov/permit/> (last visited Feb. 12, 2016).

¹⁷⁶ *Id.*

¹⁷⁷ See Aseff, *supra* note 2, at 189-90. This does not mean that research in the area has stopped. Four new species of deep-water algae recently were found and sampled between 2013-2015. See *News and Events: New Algae Species Discovered in Hawaii's Deep Waters*, PAPAHAANAUMOKUAKEA MARINE NAT'L MONUMENT, http://www.papahanaumokuakea.gov/news/new_species_algae.html (last visited Feb. 12, 2016).

the northwest Hawaiian islands and does not protect the rest of Hawaii from the possible effects of bioprospecting.¹⁷⁸

III. ANALYSIS

The U.S. would have much to gain through bioprospecting legislation. It is one of the biggest nations in world with varying climates, from arctic conditions in Alaska to tropical temperatures in Hawaii and Florida. The U.S. also has reserved a lot of land for federal parks, started by Theodore Roosevelt to help preserve the nation's lands.¹⁷⁹ The National Park Service manages 79.6 million acres over 58 national parks, with the largest being Wrangell-St. Elias National Park and Preserve in Alaska covering 13.2 million acres and the smallest being Thaddeus Kosciuszko National Memorial in Pennsylvania covering 0.02 acres.¹⁸⁰ The parks receive over 292 million visitors every year,¹⁸¹ showing that they are a national treasure and should be preserved.

There are two distinct, overarching concerns throughout bioprospecting regulation literature. First, bioprospecting needs to be regulated to protect biodiversity.¹⁸² Second, we must make sure indigenous people's rights and knowledge are protected.¹⁸³ The common denominator and threat in both of these aspects is commercialization and capitalism and how they can corrupt the indigenous peoples and the ecosystem.¹⁸⁴ Due to the potential profitability of these resources, companies are going to want access to ecosystems that could be biotechnological gold.¹⁸⁵

After looking at all the options that states and the federal government have—and have not—taken to protect against bioprospecting, it is difficult to assemble a coherent structure that includes the nurturing nature of the CBD and the patentability aspirations of the WTO while respecting federal and state rights. A common thought throughout the literature, on both an international and national scale, is for the U.S.

¹⁷⁸ See Andrea Aseff, *Hooray for No Bioprospecting in the NWHI!*, KAHEA BLOG (Jun. 24 2009, 6:52 PM), <http://kahea.org/blog/hooray-for-no-bioprospecting-in-the-nwhi>.

¹⁷⁹ Ross W. Gorte et al., *Federal Land Ownership: Overview and Data*, CONGRESSIONAL RESEARCH SERV. (Feb. 8, 2012), <https://fas.org/sgp/crs/misc/R42346.pdf>.

¹⁸⁰ *Frequently Asked Questions*, NAT'L PARK SERV., <http://www.nps.gov/aboutus/faqs.htm> (last visited Dec. 4, 2015).

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ Traditional knowledge in the United States is not in danger because the natural resource itself cannot be patentable. However, the knowledge could expedite the patent process if researchers use it in attempts to extract and remake a chemical that can lead to a new drug or technology. See David R. Downes, *How Intellectual Property Could be a Tool to Protect Traditional Knowledge*, 25 COLUM. J. ENVTL. L. 253 (2000).

¹⁸⁴ *Id.*

¹⁸⁵ See *id.* at 254-55 (“Traditional knowledge has been used in many industries as a starting point for new product development, in sectors such as specialty food, beverages, pharmaceuticals, agriculture, horticulture, and personal care and cosmetics; and it remains a significant resource for many commercial research and development programs.”).

to include prior informed consent as a part of the patentability process.¹⁸⁶ But that still does not address the argument of who owns the biological material, which is where Congress's original concern of property rights comes into play.¹⁸⁷

One of the main focuses for federal legislation is that it must incorporate the CBD ethics into the TRIPS process, which would allow the U.S. to focus on patentability and innovation through the WTO lens.¹⁸⁸ The U.S. has stood by the TRIPS agreement, and any deviation would go against the pro-corporation mentality for the prioritization of the patent process.¹⁸⁹ This is consistent with the American dream and fostering creativity and innovation of which the U.S. is a leader.¹⁹⁰ Because the TRIPS recommends incorporating PIC into a country's regulations for the patent process, the U.S. could easily alter its patent process to match the protocol. It would be more beneficial, though, for the WTO to amend its rules; however, the implementing body, the Council of TRIPS committee, has no authority to do so.¹⁹¹ Thus, countries that have not ratified the CBD have no incentive, other than good will, to incorporate this extra step in their patent processes, which would make the U.S. patent process more burdensome.

Without patents requiring disclosure of the genetic material or PIC, the U.S. patent process is incomplete when compared to other countries.¹⁹² By not specifically requesting the location an organic material was found, the process is negligent to the fact that materials could be found in a different place. Because there are multiple areas on the globe that could potentially have the ecosystem to support the microbial material, companies could make false claims on their applications. Further, there is no way to quickly and adequately test the legitimacy of where a microbial was found, especially when each sample is random and there is no guarantee of finding the same microbial needed for reproducing the genetic material from which the patent was derived.¹⁹³ Also, the time and resources it would take to confirm the patent application are costly and counterintuitive.¹⁹⁴

¹⁸⁶ See Chen, *supra* note 9; Pan, *supra* note 5.

¹⁸⁷ See Bang, *supra* note 23, at 73.

¹⁸⁸ See *id.*; Chen, *supra* note 9, at 10637.

¹⁸⁹ Chen, *supra* note 9, at 10641 ("Plainly put, it is the Convention on Biological Diversity and not TRIPS or UPOV that winks at biopiracy.").

¹⁹⁰ See *id.* at 10635.

¹⁹¹ BITA AMANI, STATE AGENCY AND THE PATENTING OF LIFE IN INTERNATIONAL LAW: MERCHANTS AND MISSIONARIES IN A GLOBAL SOCIETY 223 (2009) ("They can only occur through waiver or amendment by its members but advisory opinions concerning members' interpretation of TRIPS may be provided.").

¹⁹² See Kabir S. Bavikatte & Morten W. Tvedt, *Beyond the Thumbrule Approach: Regulatory Innovations for Bioprospecting in India*, LEAD (2015), <http://www.lead-journal.org/content/15001.pdf>.

¹⁹³ See *Edmonds Inst. v. Babbitt*, 42 F. Supp. 2d 1, 11 (D.C. Cir. 1999) ("[M]icrobes present in a wide array of ecosystems and 'systematically sample[]' the sites in order of their uniqueness and genetic diversity.").

¹⁹⁴ See Grebe, *supra* note 43, at 369.

Even though there are possible ways get around this potential requirement in the patent process, the requirement could nevertheless be beneficial. If the results are not completely accurate, the data derived from such legislation would allow an administrative body to track where potential profitable biodiversity is located.¹⁹⁵ Through the data, the U.S. would be able to protect areas susceptible to bioprospecting more adequately.

The U.S. patent process does require that the information on the material, like general location, be disclosed within the patent process, along with a detailed explanation of the patent itself, including how to make it.¹⁹⁶ A PIC would not be hard to implement under the U.S. patent process, and most researchers and companies would not have a problem enacting it, especially if corporations already had agreements, like CRADA between Yellowstone and Diversa.¹⁹⁷ However, bioprospecting on private lands or with indigenous people would require more time and resources.¹⁹⁸ The PIC is the easiest way to instill protection and more regulation of the areas where bioprospectors are collecting the information.

In theory, however, once an organism is extracted from an area, additional samples of the same resource should not be needed, especially since the patentable material needs to be a product of human innovation and not nature.¹⁹⁹ Changing patent regulation is not enough because that still does not regulate bioprospecting on public lands without other regulations to help aid the process.²⁰⁰ But not all biotechnology companies have the same access to the same microbial material, especially in areas where permits are required, such as Yellowstone and the Papahānaumokuākea Marine National Monument.²⁰¹ Plus, certain companies may have an advantage over their competitors. For example, arguably Diversa, through the CRADA agreement with Yellowstone, has an advantage over competitors even though the agreement took eight years after the environmental impact assessment.²⁰² With biotechnology's profitability potential, companies want to invest in research and development.²⁰³ Legislation and a more comprehensive program to combat bioprospecting can only help. Not only should the federal government regulate all national parks and monuments, but each individual state also should set up requirements to help regulate bioprospecting, like Utah.

¹⁹⁵ See Pan, *supra* note 5.

¹⁹⁶ See Chen, *supra* note 9, at 10637.

¹⁹⁷ See Bluemel, *Substance Without Process*, *supra* note 90, at 698.

¹⁹⁸ See Bluemel, *Separating Instrumental from Intrinsic*, *supra* note 1, at 59.

¹⁹⁹ See AMANI, *supra* note 191, at 86.

²⁰⁰ See *id.* at 89-90.

²⁰¹ See DeWeese, *supra* note 111.

²⁰² See Weaver, *supra* note 110.

²⁰³ Thomas A. Kursar, et al., *Securing Economic Benefits and Promoting Conservation through Bioprospecting*, 56 BIOSCI. 12 (2006) ("The estimates of expenditures in these areas clearly indicate that substantial benefits can be obtained from participation in preclinical research, even if no product makes it to market. Many billions in research funds are granted annually to scientists in academia by the US government . . . and by nonprofit institutions . . .").

One of the benefits for states or the federal government in enacting bioprospecting legislation is the possible economic benefit, such as those on which Utah's legislation focused.²⁰⁴ Biotechnological advances potentially can be a billion dollar investment for a state.²⁰⁵ But greed also could be a motivating factor behind Utah's legislation. Further, Utah only addresses public lands.²⁰⁶ If states or the federal government are only worried about the potential commercial benefit, they may overlook the reason why most bioprospecting bills are passed in the first place—to protect biodiversity loss and traditional knowledge for everyday uses.

If the U.S. enacted a similar bill, it would only protect its lands and people and set the standard for U.S. corporations and their bioprospecting practices in other parts of the world. This isolated effect is especially true because the U.S. did not sign either the CBD or the Kyoto agreement.²⁰⁷ The U.S. government purposely does not ratify certain agreements, so it has an excuse not to be held accountable.²⁰⁸ Even if other nations put pressure on the U.S., the U.S. government does not bend to the international community.²⁰⁹ This shows a lack of leadership on environmental issues, especially when the U.S. has the potential to impact those issues.²¹⁰

Because the U.S. did not sign the CBD or Kyoto agreement, the U.S. government has free reign to enact legislation how it sees fit, which may be a reason why no comprehensive, federal legislation has been enacted.²¹¹ Due to this inaction, states like Utah and Hawaii have taken the initiative to help protect their resources from the biotechnical world even though each state has enacted different forms of such legislation.²¹² Utah established a comprehensive framework that is still pretty new and vague.²¹³ Although Fischer, a critical scholar on the topic, calls for open debate and policy initiatives, there are clear strategies that the U.S. should have already

²⁰⁴ See Fischer, *Utah Bioprospecting Act*, *supra* note 137, at 212-13.

²⁰⁵ See *id.* at 202.

²⁰⁶ *Id.* at 200.

²⁰⁷ See Bang, *supra* note 23, at 75.

²⁰⁸ See *id.* at 73.

²⁰⁹ See *id.* at 72.

²¹⁰ See CPR Member Scholars, *Reclaiming Global Environmental Leadership: Why the United States Should Ratify Ten Pending Environmental Treaties* (2012), http://www.progressivereform.org/articles/international_environmental_treaties_1201.pdf (“All of the concerns expressed in the mid-1990s about U.S. participation in the CBD have long since been disproved by the experience of other countries . . . CBD has grown to include virtually every country in the world, including all of the closest U.S. allies, demonstrates that the fears that have blocked U.S. ratification are unfounded.”).

²¹¹ See Fischer, *supra* note 137, at 199.

²¹² See *id.* at 217-18 (“Like Hawaii’s attempt, Utah appears to be following this trend with its Bioprospecting Act of 2010, whose equitable benefits-sharing and informed consent licensing regimes mimic much of the CBD.”).

²¹³ See *id.* at 224-25 (“A more unified policy formula, encompassing relevant national and international law, and related experiences . . . will ensure the future effectiveness of the Utah Bioprospecting Act.”).

incorporated into its federal policy and requested that states follow with assisting legislation for the protection of biodiversity.²¹⁴

If the federal government continues to remain inactive on this question, states should protect themselves and their resources. Utah took steps to make this a reality, and Hawaii has desperately tried to come up with a balance between native Hawaiians' rights and the rights of rest of its population.²¹⁵ Each state should tailor its bioprospecting laws on the state's individual needs. The need for bioprospecting in Alaska, which is rich in arctic biodiversity, would be different than the needs in a more commercially developed state like New York.²¹⁶

The drawback would be that each state would need to enact its own regulation, which may not be a priority for the state's legislature, especially since it is not a federal priority. Even though companies would have to follow the individual rules of each state, if the states follow a contract formula for private and state actors, the varying pieces of legislation among the states would incorporate a well-known area of law with the new rules and regulations of bioprospecting.²¹⁷ Even though a comprehensive federal plan may be easier, companies doing business in multiple states already have to adapt themselves to the needs of individual states.²¹⁸ Plus, if they are investing money into the research and development of a microorganism for potential profits, they can surely invest in a lawyer.

However, a comprehensive federal framework could create regulations that would easily transfer from state to state. All states would have to do is ratify or adopt the federal legislation. The dilemma between federal and state action only calls for a "continued emphasis on piecemeal bioprospecting diverts attention from more valuable remedies for the biodiversity crisis."²¹⁹ Even though both are possible options, the reality is that something should be done about bioprospecting. Other countries that have bioprospecting frameworks are also part of the CBD, putting the U.S. in a league of its own for creating and enforcing its laws.²²⁰ Federal and most state governments have still not answered Congress's problems and aspects about bioprospecting.²²¹

There has been little conversation in the U.S. as to protecting indigenous tribes' rights and traditional knowledge when it comes to bioprospecting, as well as identifying personal property rights, which is a fundamental right.²²² Property owners

²¹⁴ See *id.*; see also CPR Member Scholars, *supra* note 210.

²¹⁵ However, even Hawaii's protection of Papahānaumokuākea Marine National Monument is an effective start to a more comprehensive regime that encompasses all of Hawaii's goals. See Conklin, *supra* note 172; Fischer, *supra* note 137.

²¹⁶ See Lief P. Christoffersen & Eric J. Mathur, *Bioprospecting Ethics & Benefits, A Model for Effective Benefit-Sharing*, 1 INDUS. BIOTECH. 4 (2005).

²¹⁷ See Fischer, *supra* note 137, at 219.

²¹⁸ See *id.* at 225.

²¹⁹ Chen, *supra* note 9, at 10627.

²²⁰ See *id.* at 10626.

²²¹ See Bang, *supra* note 23, at 72.

²²² See U.S. CONST. amend. V ("No person shall be . . . deprived of life, liberty or property, without due process of law . . ."); Bluemel, *Substance Without Process*, *supra* note 90, at 675.

with a vast amount of acreage would benefit from PIC and the opportunity to receive economic benefits from biotech companies, like in Utah the system has initiated.²²³ Contract law could help bridge the knowledge gap between indigenous and private owners' cooperation with biotechnical companies.²²⁴ A contract between the bioprospectors and the landowners (either private parties or indigenous groups) would help enforce the rights of the landowners and provide protection against the bioprospecting actions varying from the agreement.²²⁵ The indigenous tribes or private property owners would have grounds for legal action if a part of the contract was not followed or not included within the contract, which could also bring economic compensation for use of their land.²²⁶

The downside to bringing contract theory into the bioprospecting debate is the lack of knowledge concerning the contracts and certain loopholes corporate attorneys may draft to exploit the other party. However, unless heavily incentivized, the more legal jargon written into a contract for land use, the wearier a person will be to sign the contract due to the binding nature of the legal document. Plus, clauses that would allow an indigenous tribe or individuals to cancel the contract if they are unhappy with a bioprospector's actions can potentially rectify the issue of corporations using the contract for exploitation of the land.

The other problem, other than rights to the land, is rights to the information that indigenous communities have known and have passed down for generations. Most of the literature suggests that indigenous tribes should be compensated for their knowledge and the resources their lands provide.²²⁷ Although the literature provides helpful recommendations, the suggestions fail to consider that those communities need protection from the outside world. Even though indigenous communities keep to themselves, the potential exploitation for commercial use of an indigenous tribe's resources or knowledge calls for a greater protection from the government of the indigenous community. Indigenous tribes want the profit-sharing benefits, but they do not want those benefits to come at the expense of their land or traditions.²²⁸ Indigenous communities have a source of pride and respect for their land and the need to take care of it.²²⁹ Thus, a bioprospector wanting to research a certain plant within the indigenous community's property needs to be regulated with the

²²³ See Fischer, *supra* note 137, at 207.

²²⁴ Indigenous peoples are not the only marginalized group that could benefit. The poor, who also have links to traditional knowledge, also could be potential beneficiaries of profits derived from bioprospecting innovations. See Maria-Costanza Torri, *Beyond Benefit-Sharing Agreements: Bioprospecting for the Poor?*, 8 INT'L J. TECH. MGMT. & SUSTAINABLE DEV. 2 (2009).

²²⁵ See Fischer, *supra* note 137, at 210-11.

²²⁶ See *id.*

²²⁷ See Tak Jong Kim, *Article Expanding the Arsenal Against Biopiracy: Application of the Concession Agreement Framework to Prevent Misappropriation of Biodiversity*, 14 SMU SCI. & TECH. L. REV. 69 (2010); Pollyana E. Folkins, Note, *Has the Lab Coat Become the Modern Day Eye Patch? Thwarting Biopiracy of Indigenous Resources By Modifying International Patenting Systems*, 13 TRANSNAT'L L. & CONTEMP. PROBS. 339 (2003).

²²⁸ See Kim, *supra* note 227, at 88.

²²⁹ See *id.*

indigenous community on a case-by-case basis. The bioprospector will probably be interested in any traditional knowledge a community may have with the plant to help expedite the research process, which should include additional compensation and credit prior to any profits made from the potential bioprospecting finding. The relationship should also include, if the resource is valuable, any profits from use of the extracted chemical that may be used in new biotechnology or medication.

There is limited discussion on preventing the outside world's meddling into indigenous communities. There is also limited discussion on allowing the indigenous communities to co-own patents, which the traditional knowledge helped drive. Without a dialogue between the indigenous communities, the government, and potential profit seekers, the indigenous communities will continue to be marginalized for lack of information and care concerning the indigenous interests and interests of the land.

IV. CONCLUSION

Preserving the world's biodiversity is important for present and future generations. Creating new biotechnological advances to cure the world of ailments is also important for these generations. The U.S. needs to enact legislation that can do both. The lack of regulation will only hurt biodiversity and people in the long run. The U.S. must prioritize regulations to guard against biopiracy and help researchers find materials that might lead to other miracles.²³⁰ Even if there is no federal action, individual states can legislate their own bioprospecting rules to regulate according to their needs. Only through trial and error will a government know what does and does not work, but inaction on bioprospecting will not protect biodiversity.²³¹ Maybe now that a celebrity is promoting action, something may get done.²³²

²³⁰ Corliss Karasov, *Who Reaps the Benefits of Biodiversity?*, 109 ENV'T HEALTH PERSP. 12 (2001) ("Bioprospecting is not solely driven by interest in money . . . the hope that cures to cancer, AIDS, and other diseases are hidden in some endangered habitat still fuels the enthusiasm for bioprospecting . . . No chemist could ever dream up the chemistry of Taxol . . . the drug for fighting breast and other cancers that is derived from the bark of the Pacific yew tree . . .").

²³¹ See Fischer, *supra* note 137, at 208-09.

²³² Chances of change increase if Leonardo DiCaprio wins an Oscar for *The Revenant* in 2016.

