Do Mor Do Mar Do Mar DONG Do Not Copy Do Not Copy Do Not Copy Coby Do Not Copy DONG Coby Coby Do Not DONG Distributive and Restorative Justice in the Age of Modern Scientific Research: South Africa as a Case Study Coby CODY Do Not Copy Do Not Do Not DONG Ezinne Adibe Do Not Copy Do Not Copy Do Not Copy DONG Do Not Copy Coby Professor Kara Swanson Do Mot Copi Northeastern University School of Law DONG Winter 2018 Do Not Copy Do Not Copy Do Not Copy Do Not Copy DONG CODY COPY * COPY * CODY

Introduction

Scientific exploration involving indigenous African populations has had a long and often exploitative history, particularly in southern Africa. This paper will highlight the history of this exploration as it relates to such biological resources as medicinal plants and human subjects, as well as cultural objects, such as sculptures. How can distributive and restorative justice be achieved, using South Africa as a model, so that African communities can financially benefit from and control the narrative of scientific research?

Distributive and restorative justice for African peoples means that hundreds of years of exploitation, genocide and other physical and psychic harms, particularly at the hands of foreign powers, can be addressed through just compensation for the use of Africa's natural resources --- including its people and its labor. In this paper, I explore a fairly recent effort by indigenous South Africans (the San community), to receive equitable financial compensation for the use of !Xhoba (Hoodia cactus), a treasured medicinal and spiritual plant used in the development of anti-obesity medications and other Hoodia-based products. While the dominant narrative about the *Hoodia* case presents the San in a sort of David and Goliath battle against a pharmaceutical company and research organization

¹Restorative justice is a "philosophical framework and series of programs for the criminal justice system that emphasize the need to repair the harm done to crime victims through a process of negotiation, mediation, victim empowerment and Reparation." http://law.jrank.org/pages/9840/Restorative-Justice.html

who sought to obtain academic accolades and billions of dollars from a Hoodia patent, the portrait I paint is a more realistic one. Unlike in the David and Goliath myth where David triumphs over Goliath, in my rendition of the story (based on actual facts), the San never receive the money they were to receive as stipulated in a benefit sharing agreement. Essentially, our protagonists are left in the same financial position as where they began prior to the agreement.

The Hoodia case was a good start in the right direction in terms of addressing the unjust enrichment of research institutions and corporations who advance their careers and fatten their bank accounts by patenting inventions derived from indigenous knowledge and biological resources. However, what the Hoodia case does not address or solve is the fact that thousands of sacred cultural objects plundered from African nations are housed in overseas museums such as the British Museum.² The Hoodia case does not address the need for the repatriation of these objects along with other assets of cultural patrimony,³ especially in light of the well-

²Nigeria has repeatedly requested the return of thousands of wood, ivory, and bronze objects stolen by British colonial officers during the punitive expedition of 1897. Some of these bronze objects are on display in the British Museum. (Nafziger, 390).

³See a definition under the Native American Graves and Repatriation Act (I speak of cultural patrimony in this paper as specifically having to do with objects having ongoing historical, traditional, or cultural importance central to African peoples): "An object having ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual Native American, and which, therefore, cannot be alienated, appropriated, or conveyed by any individual regardless of whether or not the individual is a member of the Indian tribe or Native Hawaiian organization and such object shall have been considered inalienable by such Native American group at the time the object was separated from such group." [25 USC 3001 (3)(D)].

documented history of the trans-Atlantic and trans-Saharan institutions of enslavement, in which not only the movement of African bodies occurred --- but also, the movement of sacred cultural objects of expression (e.g., ceremonial objects such as crowns, masks, staffs, and so forth).⁴ The Hoodia case cannot be seen as an isolated struggle to challenge the unbridled exploitation of Africa's intangible and tangible resources to the benefit of the rest of the world. It must be seen within a larger African narrative of cultural displacement and misappropriation, and outright genocide.

I propose four main arguments:

- (1) African peoples should make cultural patrimony claims as Native Americans and Pacific Islanders have done;
- (2) human genetic material (HGM) should be seen within the scope of cultural property, and indigenous Africans must demand that sacred objects, funerary objects, human remains, and other items of cultural patrimony be returned and under their control;
- (3) African peoples have a right to be compensated according to distributive justice principles; and

⁴The display of looted cultural objects in museums is touched upon in the 2018 film, *Black Panther*. While perusing an African exhibit, the character Erik Killmonger probes a white museum attendant about one of the masks on display, asking: "How do you think your ancestors got these? Do you think they paid a fair price? Or did they take it, like they took everything else?"

(4) laws should be consistent with these aims, allowing compensation through criminal, contract and tort law frameworks.

I draw some inspiration from the legal path that Native Americans have traversed in asserting ownership claims over human remains and cultural objects through such federal statutes as the National Graves Protection and Repatriation Act and through such oversight committees and legal funds as the Native American Rights Fund. It is my hope that other African nations use South Africa as a model for legal reform and that African legal professionals and policymakers use the law to bring about greater cultural and political autonomy for African peoples.

I picked South Africa because it is a place where scientists have conducted a significant amount of genomic research⁵ in an effort to paint a comprehensive picture of human history and migration, and because of its history of imperialist policies such as apartheid. South Africa, like the United States, has a history of settler domination over indigenous populations through overt policies of racial and ethnic segregation and redistribution of wealth and natural resources from indigenous peoples to settler populations.

Part I of this paper explores the history of scientific exploration and exploitation of African communities, such as the African Research Study and

⁵ See the Human Genome Project, for example.

apartheid South Africa's chemical and bioweapons program, within the context of the common heritage of mankind argument. Part II details the Hoodia case. Part III explores the legal approaches used by Native Americans and Pacific Islanders to assert property rights over human remains and other cultural items. Here, I explore concepts such as national heritage, national patrimony and cultural patrimony. Finally, Part IV concludes with brief recommendations for African communities, especially in South Africa, to implement legal reforms that allow them to realize distribute and restorative justice as it relates to cultural heritage.

I. Black/African Communities as Scientific Testing Grounds

African Research Survey

"Medical research is a scientific enterprise. It seeks to gain a better understanding of the biological processes in humans and aims to develop new drugs and other treatments, for future therapeutic use." (Kuhse, Schüklenk and Singer, n.d.).

In 1929, at its annual meeting held in South Africa, the president of the British and South African Association for the Advancement of Science, Jan Hofmeyr, proclaimed that "science must harness the great resources of Africa" and "overcome the might of African barbarism and the defiant resistance of African nature." (Tilley, 1). This proclamation is reminiscent of similar proclamations and

beliefs by not just scientists during the second wave of colonialism,⁶ but also, many other persons and groups looking to exert dominance over the African continent and African peoples.⁷

The 1929 proclamation occurred within the timeframe of the "Scramble for Africa," which resulted in the partitioning of the African continent by several European powers: Belgium, Germany, Britain, France, Italy, Portugal and Spain. However, there are countless documented examples pre and post-1929 that expose the abuse and genocide of African communities through the use of science. Author Harriet Washington explores these deplorable events in her book, *Medical Apartheid*. Speaking about these atrocities, Washington asserts that the misuse of science to maim and destroy Black communities was not just isolated to the United States. Speaking on the use of continental African communities as scientific testing grounds, Washington states, "Western physicians, scientists, and pharmaceutical companies need large pools of people for Phase I trials and they

⁶I divide colonialism (whether overt, institutionalized, and the physical occupation of territories or largely covert and physiological), specifically as it relates to the African context, into three periods: The first period is pre-1870 C.E. (includes the Maafa, or "transatlantic slave trade," and Arab slave trade, kwk[etc.]; the second period is 1870-1960; and the third period is 1960-present).

⁷See Dr. Wolfgang U. Eckart's *Medizin und Kolonialimperialismus Deutschland, 1884-1945* for more on genocidal experiments by German scientists on the Herero of Namibia. See also, Benjamin Madley's "From Africa to Auschwitz: How German South West Africa Incubated Ideas and Methods Adopted and Developed by the Nazis in Eastern Europe."

⁸The Scramble for Africa (1870s – 1950s). See Helen Tilley's *Africa as Living Laboratory* for a lengthier discussion about the motivations of European powers in partitioning the African continent. ⁹See Washington's *Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to Present*, generally, for a plethora of examples involving scientific abuses on Black research participants.

have swarmed Africa." (Washington, 389). Such beliefs as to the inferiority of Black/African¹⁰ peoples, the ability of African peoples to withstand pain, and the paternalistic view that non-Africans are better suited to assess the needs of Black/African communities are still widespread.

Chemical and Biological Weapons

The use of chemical and biological weapons by apartheid South Africa on the Black majority, including anti-apartheid activists like Steven Biko, underpins why many in Black/African communities have looked at the scientific enterprise with deep suspicion. As Washington notes, the South African apartheid government engaged in Project Coast, a decades-long chemical and biological warfare programme (CBWP) with the help of U.S. researchers. The details of the program are alarming. Led by a mad-scientist of sorts, Dr. Wouter Basson, 11 the program employed such chemical agents as cyanide to poison anti-apartheid activists and Black citizens of South Africa and neighboring countries.

¹⁰I use Black and African interchangeably, and in some cases together, for anyone who may confuse my use of African to mean any person of any race or ethnicity residing on the continent or asserting themselves to be African. My use of African refers to Black people.

¹¹A cardiologist by trade, Basson's research activities came to light in 1999 when he was arrested in Johannesburg for the illicit sales of ecstasy pills. That same year, Basson was charged with murdering 67 people (all Black) – although he was accused of murdering approximately 300 Black persons. After apartheid was dismantled, Basson refused to face the Truth and Reconciliation Commission and instead went to trial where murder charges were dismissed by apartheid era judge, Judge Willie Hartzenberg (who also granted Basson amnesty). (Washington, 2008). To date, Basson has never faced jail time for his involvement in Project Coast and continues to work as a cardiologist in Cape Town. South Africa.

Basson is just one of many scientists who set aside their Hippocratic oath¹² and acted out their darkest fantasies to harm members of already vulnerable communities. Some of these scientists have never reached the depravity level of Basson. Nonetheless, the harm to communities inflicted by scientific abuse is a persistent concern, especially for vulnerable communities.

Bypassing Ethics

"To get around consent forms and a skeptical public, many researchers are turning their attention to African and other developing countries. I would say the greatest chance for injury is in the Third World, where people don't even know research is going on and don't have a clue."

 Robert F. Murray, Jr. MD, former Chief of the Division of Medical Genetics at Howard University College of Medicine

Following the atrocities of scientific abuse and genocide committed by scientists during World War II, international standards were developed to protect human participants in research. Following the war, many physicians were tried for crimes against humanity based on medical experiments they performed on prisoners of war. The subsequent Nuremberg Code was the first modern code of research ethics. The Code provides ethical safeguards for human participants. For

¹²The Hippocratic maxim is a fundamental principle of medical ethics and derives from ancient Greece (400 B.C.E.). The oath declares: "What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself, holding such things shameful to be spoken about." *Genetic Databases and Biobanks: Who Controls our Genetic Privacy*? Santa Clara Computer & High Tech. L.J. 1.

example, the Code states, "voluntary consent of the human subject is absolutely essential," and specifies the components of such consent.¹³ The Code asserts that the individual who "initiates, directs or engages in the experiment" is responsible for ascertaining the quality of consent.

The Declaration of Helsinki,¹⁴ while not legally binding, provides ethical guidance for biomedical researchers who work with human subjects. The Declaration sets forth such important principles as respect for individuals and their informed decisions, as well as the need for greater protection for vulnerable populations in the research context.

Another definitive moment in the history of human experimentation, the Tuskegee syphilis study, ¹⁵ inspired explicit standards of conduct towards human research participants. Following the study, which exploited low-income African American men who had syphilis, Congress passed the National Research Act of 1974, ¹⁶ which codified into law that human research participants in federally funded research must be protected. In line with this act, Congress created the

¹³See "The Nuremberg Code." https://history.nih.gov/research/downloads/nuremberg.pdf.

¹⁴In 1964, the World Medical Association issued an aspirational declaration that has inspired legislation and regulations internationally with respect to biomedical research involving human subjects. Massachusetts Continuing Legal Education, Inc. 2012. Research Compliance, Culm MA-CLE 7-1.

¹⁵From 1932-1972, the U.S. Public Health Service conducted research on 400 low-income Black males with syphilis. The researchers monitored the research participants but failed to treat them despite the availability of an effective cure: penicillin (beginning in the 1950s). Massachusetts Continuing Legal Education, Inc. 2012. Research Compliance, Culm MA-CLE 7-1.

¹⁶National Research Act. Public Law 93-348-July 12, 1974. https://history.nih.gov/research/downloads/PL93-348.pdf

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research ("The Commission"). This Commission published the Belmont Report.¹⁷

The Report identified three principles relevant to research with human subjects. These principles are: (1) respect for persons; (2) beneficence; and (3) justice. Under the first principle, research participants must enter into the research voluntarily and have adequate information. Here, the Report asserts two ethical convictions: that individuals should be treated as autonomous agents, and that participants with diminished autonomy are entitled to protection. Diminished capacity in this context includes individuals who lose the capacity for self-determination because of illness, mental disability or other circumstances that negatively impact autonomy. The extent of protection involves a balancing test that weighs the risk of harm to the individual that would result from including them in the research against the likelihood of benefit for participation.

The beneficence principle draws from the Hippocratic maxim of "do no harm." Beneficence, in this context, is an obligation whereby researchers must treat research participants in an ethical manner, respect their decisions, protect them from harm, and make efforts to maintain their well-being. Two general rules arise

¹⁷Protection of Human Subjects; Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 44 FR 23192-01.

¹⁸Id.

from this principle: minimize possible harms and maximize possible benefits. The last principle, justice, focuses on fairness and the distribution of benefits derived from research. In describing this principle, the Report explicitly notes that injustice occurs in a research context when "some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly."¹⁹ Specifically, justice in research demands that the selection of research participants undergo scrutiny to ensure that vulnerable groups (i.e., racial or ethnic "minorities", persons confined to mental institutions, or poor or low-income persons) are not systematically exploited based on easy availability, manipulability, or compromised position.

The policies regarding respect for persons, beneficence, and justice in the Belmont Report influenced a set of federal regulations that govern human subjects research, known as the Common Rule.²⁰ The Common Rule focuses on federally funded research and requires that all human subjects of federally funded research receive informed consent.²¹ Through Institutional Review Boards (IRBs), researchers must meet certain requirements, such as obtaining informed consent from potential research participants. Even after the Board approves a prospective

 $^{21}Id.$

 $^{^{19}}Id$.

²⁰In 1991, more than fifteen federal agencies and departments adopted regulations guiding human subject research. Such regulations include requirements for establishing informed consent, the role of IRBs in reviewing, approving, and monitoring research activities, and the protection of vulnerable populations in research, such as prisoners and children. 45 C.F.R. § 46.

research study, researchers must continue to adhere to guidelines set forth in the Rule. On informed consent, the Rule states:

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. 45 C.F.R. § 46.116.

The basic elements of informed consent, as outlined in the Common Rule, include a description of the research study and its proposed duration, any reasonably foreseeable risks and discomforts to the subject, potential benefits to the

subject or to others as a result of participation, the confidentiality of records identifying the subject, a statement that participation is voluntary and may be revoked at any time by the subject, whether there is compensation that may derive from the research, and in some cases, whether new findings developed during the course of the research may be communicated to the subject. *Id*.

Washington aptly notes that U.S. researchers have bypassed bioethical concerns by traveling to African nations to conduct biomedical research without facing intense scrutiny of their research methods. This is problematic for a number of obvious reasons. Ethical and legal safeguards exist to protect research participants. When foreign researchers can come to African nations to conduct drug trials without having to answer to such oversight agencies as the Food and Drug Administration, these loopholes foster feelings of mistrust and sever the chain of accountability that might otherwise be identifiable.

In South Africa, the Intellectual Property Rights from Publicly Financed Research and Development Act²² sets guidelines for research institutions and those affiliated with such institutions engaged in research and development initiatives that are funded by the Republic. Under the Act, "the people of the Republic,

²²The Intellectual Property Rights from Publicly Financed Research and Development Act, enacted in 2008, allows universities to make intellectual property claims emanating from publicly funded research.

particularly small enterprises and BBBEE²³ entities, have preferential access to opportunities arising from the production of knowledge from publicly financed research and development and the attendant intellectual property." The Act recognizes intellectual property rights for recipients²⁴ of public funds for research and development projects. The Act has disclosure requirements, such as that recipients must identify commercialization opportunities flowing from their research and that recipients must report to the Minister of the Department of Science and Technology on an ongoing basis. However, nowhere in the Act does it mandate that institutions and their affiliates grant co-ownership rights to research participants.²⁵ Therefore, the South African legal system is similar to the United States system in that publicly financed research still gives research institutions the ability to shut out research participants from also holding intellectual property rights.

²³BBBEE means broad-based black economic empowerment. See the Broad-Based Black Economic Empowerment Act, 2003 (Act No. 53 of 2003).

²⁴The Act states that a recipient is: "means any person, juristic or non-juristic, that undertakes research and development using funding from a funding agency and includes and institution."

²⁵Section 15(2) of the Act states: "Any private entity or organisation may become a co-owner of the intellectual property emanating from publicly financed research and development undertaken at an institution if (a) there has been a contribution of resources, which may include relevant background intellectual property by the private entity or organisation; (b) there is joint intellectual property creatorship; (c) appropriate arrangements are made for benefit-sharing for intellectual property creators at the institution; and (d) the institution and the private entity or organisation conclude an agreement for the commercialisation of the intellectual property."

Common Heritage vs. National and Indigenous Sovereignty

In my view, the belief that Africa's and indigenous peoples' resources are a gift to the world and should be accessible to all because they constitute the common heritage of humankind is dismissive of the history of colonial plunder of such resources and the inequitable allocation of financial benefit from these resources -- indigenous communities generally benefit little in comparison to outsiders who commercialize these resources. As author Shubha Ghosh notes in "Globalization, Patents, and Traditional Knowledge," the problem with the common heritage or public domain position is that the acquisition and exploitation of knowledge is based on bargaining and conquest strength. On the subject of plant genetic resources (PGRs), Keith Aoki states:

Nations with a colonial history of widespread collection of exotic germplasm, such as the U.S. and the European colonial powers, were able to exploit and benefit from the "common heritage" treatment of PGRS. Conversely, the "common heritage" regime over the past five hundred years disadvantaged those countries subject to colonial domination in which PGRS had been located. (Aoki, 10).

The anti-colonial critique of an open access approach to resources posits that the flow of such resources tends to be unilateral ("developed" nations extracting from "developing" nations and selling these resources back to them at a premium). The common heritage position undermines national and/or indigenous

sovereignty claims over stolen and otherwise removed cultural items from the very communities where these materials originate. Indigenous intellectual property rights allow indigenous peoples asserting rights to be subjects, not objects, of property.²⁶

II. Why the Hoodia Case Did Not Go Far Enough

Commodification of indigenous intellectual property is already happening. The problem is the sources of such material do not benefit economically in comparison to those in the business of marketing and selling these materials and products derived from indigenous/traditional knowledge. A notable case involving the tension between indigenous communities and corporate actors who utilize traditional knowledge for commercial gain is the *Hoodia* case.

The San community have used the Hoodia cactus for thousands of years as an appetite suppressant and for other medicinal and ritual uses. After discovering that bio-prospectors had used their knowledge of the plant to develop new drugs and generate large profits, they objected to the commercialization of the plant without just compensation to the community.²⁷ Eventually, the San entered into a

²⁶See Madhavi Sunder, generally, for a discussion on indigenous intellectual property in Martha Ertman and Joan Williams's *Rethinking Commodification: Cases and Readings in Law and Culture* and Keith Aoki's *Seed Wars*.

²⁷In Charles Masango's *Indigenous traditional knowledge protection: prospects in South Africa's intellectual property framework?*: "The South African Council for Scientific and Industrial Research (CSIR) recognizing the enormous potential market for the Hoodia outside South Africa ... placed a patent P57 and sold the licensing rights to an English biopharmaceutical firm, Phytopharm, in 1997. Phytopharm then sold the license to American pharmaceutical giant Pfizer for 25 million dollars'. Throughout the whole process ...the San peoples were completely unaware of what was

benefit-sharing agreement with the researchers and drug company involved in the patent. The benefit sharing agreement stipulated that the San would not receive upfront payments and instead would receive 6% royalty payments and 8% milestone payments. Further, the San would not have any co-ownership right over the patent. The terms of the agreement made it to where the San community's compensation depended on whether the pharmaceutical companies involved in producing Hoodia related drugs made a profit. Upfront compensation would have ensured that the San received compensation no matter what. Additionally, a co-ownership right would have given the community the opportunity to deny or allow others the use of the patent. Thus, providing additional revenue streams for them, such as through licensing fees.

Bioprospecting, Biopiracy and Benefit Sharing

Biopiracy encompasses patent-based and non-patent-based means and misappropriation. The first instance entails the patenting of inventions based on biological resources and/or traditional knowledge.²⁸ Non-patent based biopiracy occurs when other intellectual property control measures, such as deceptive

occurring. In fact, they became aware of it only after the excessive media coverage of Phytopharm's sale of licensing rights to Pfizer (Case Study: Hoodia Cactus (South Africa) 2006)."

²⁸Daniel F. Robinson's Confronting Biopiracy: Challenges, Cases and International Debates.

trademarks, are used. In each instance, the unauthorized extraction of biological resources and/or traditional knowledge occurs. When biopiracy occurs, there is a lack of adequate authorization from and benefit sharing for affected communities. *The Biodiversity Act*

South Africa's 2004 Biodiversity Act was inspired at least by two significant events: the (1) 1992 Convention on Biological Diversity (CBD); and (2) Hoodia case. One of the goals of the Act is to ensure fair and equitable benefit sharing arising from the bioprospecting²⁹ of indigenous biological resources. The CBD specifically carved out protections for indigenous peoples.³⁰

The Hoodia case reflects a challenge that other indigenous communities face, which is gaining access to a system that has historically denied them access. Patent law, as Laura Foster notes, is European at its root and aligned with histories of colonialism.³¹ During the negotiations process, the San, as Foster notes, had to navigate traditional and modern identities. In a particular telling part of the story, Phytopharm, the drug company that CISR licensed their patent to, made the claim

²⁹Under the Act, bioprospecting is defined as "any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation."

³⁰Article 8(j) states that parties to the Convention must: "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote the wider application with approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices."

³¹For a fuller account of the Hoodia case, see Laura Foster's Decolonizing Patent Law: Postcolonial Technoscience and Indigenous Knowledge in South Africa. *Feminist Formations*, 28(3), pp.148-173

that the San were extinct, and as such, the company was unable to negotiate with them regarding benefits from the Hoodia patent. The San were, and are, very much still in existence, but this event underscores how outsiders often craft erroneous narratives about African peoples, especially by situating Africans as backwards or "stuck in the past" and unable to compete in the global economy. Following the benefit sharing agreement between the San, CISR, and Phytopharm, South Africa implemented its Biodiversity Act, which requires (among other requirements):

- (1) a bioprospecting permit in order to engage in a bioprospecting project;
- (2) a benefit-sharing agreement that provides for sharing by the stakeholder in any future benefits that may be derived from the relevant bioprospecting; and
- (3) that all monies arising from benefit-sharing agreements and material transfer agreements be paid into a Bioprospecting Trust Fund managed by the state

Unjust Enrichment: Biomedical Research & the Commercialization of Human Genetic Material (HGM)

Debra L. Greenfield explores the "gold rush" resulting from the commercialization of genomics, whereby such stakeholders as scientific

researchers and biotechnological firms obtain patents on genetic material.³² The Patent Act³³ promotes innovation and progress in the science, but ironically, one could argue that the granting of a substantial number of patents related to processes involving human genetic material (HGM) have hindered scientific progress and collaboration in biomedical research.

<u>Indigenous Communities and Control over Bio-specimens</u>

As author and professor Kara Swanson notes in her book, *Banking on the Body*, the origin of the term *bank* in relation to body banks is not only drawn from financial banking but also represents a transformation in the way society viewed body products as viable means of generating cash flow:

At the origins of the transformation of the body into a source of harvestable property, *bank* was chosen as metaphor for understanding body product exchange. This term...created the context in which Americans learned to think about body products and in which we developed our contemporary laws governing property in the human body.

Biobanks, which serve as repositories for tissue samples, contain valuable

³²See Greenberg v. Miami Children's Hospital: Unjust Enrichment and the Patenting of Human Genetic Material.

³³35 U.S. Code § 101.

collections of bio specimens used by researchers, institutions, and biotech organizations. In a typical scenario, a research institution or hospital sells or licenses the contents of its biobanks to biotech companies, who in turn develop products of commercial value using those resources. As a result of legislation that occurred in the 1980s, institutions and researchers who discover or invent something using federal funds can personally benefit from such discoveries.³⁴

Biobanks contain over 400 million samples and represent billions of dollars in value.³⁵ The use of biobanks triggers ethical and legal considerations regarding access, exclusion, and ownership over genetic material. As it stands, Europe contains the largest biobanks in the world.³⁶ The European model of ownership over genetic material assigns ownership to the state. Here, rights over human genetic material (HGM) exist in the public domain. Unlike the European model, the American model allows biotech companies and research institutions to claim ownership of HGM contained in biobanks.³⁷ Under the American model,

_

³⁴Bayh-Dole Act, the Stevenson-Wydler Act in 1980, and the Federal Technology Transfer Act, in 1986, changed the rules regarding the receipt of profits from federally funded research. The Bayh-Dole Act "allows universities and non-profit institutions to apply for patents on federally-funded inventions and discoveries and provides significant tax incentives to companies investing in academic research. 35 U.S.C. § 200-211 (2004). The Technology Transfer Act allows researchers in government facilities, including scientists at the National Institute of Health, to patent their inventions, and keep up to \$150,000 of the yearly royalties on top of their government salaries. 15 U.S.C. § 3710c(a)(3)(2004). The law allows government researchers to enter into commercial arrangements (known as CRADAs - cooperation research and development agreements) with for profit companies. 15 U.S.C. § 3701-3714 (2004)." Lori B. Andrews, *Harnessing the Benefits of Biobanks*, 33 J.L. Med. & Ethics 22 (2005).

³⁵David J. Jefferson, *Biosociality, Reimagined: A Global Distributive Justice Framework for Ownership of Human Genetic Material*, 14 Chi.-Kent J. Intell. Prop 357 (2015). ³⁶Id.

 $^{^{37}}Id.$

individuals possess virtually no rights over their genetic material. Instead, researchers and institutions derive such professional benefits as making scientific breakthroughs in the way of understanding the epidemiology of disease and developing modalities for treatment as well as public and private funding to further research. Support for the use of human genetic material often focuses on the benefit to society as a result of the scientific enterprise.³⁸

In a 2004 lawsuit, the Havasupai sued the Arizona Board of Regents and Arizona State University (ASU) for using their genetic material outside of the scope of research that they had agreed to.³⁹ Four hundred members of the Havasupai provided DNA samples for use in genetic studies on diabetes. However, these samples were also used in studies unrelated to diabetes without the knowledge and consent of the participants.⁴⁰ Since the lawsuit ultimately resulted in a financial settlement and the return of the tribe's samples, there is was no legal precedent for modifications to the informed consent process that resulted from this case. However, as a result of the disastrous study outcome, many Native American groups withdrew from or declined to participate in genomic research.⁴¹

_

³⁸See *Id*.

³⁹Nanibaa' A. Garrison. *Genomic Justice for Native Americans: The Impact of the Havasupai Case on Genetic Research*. Science, Technology, and Human Values, Vol. 38, No. 2, Special Issue: Entanglements of Science, Ethics and Justice (March 2013), pp. 201-223.

⁴¹See *Id*.

Indigenous African groups and affiliate organizations could rightfully assert that human genetic material (HGM) is a part of cultural patrimony, with lineal descent established through a variety of means --- one such way is through existing DNA science --- oral and written documentary evidence, and quite obviously geographic location (as in the case of human remains, funerary objects and sacred objects). As Native Americans have raised similar objections to the possession of Native American cultural property and demanded the return of human remains and cultural items, indigenous peoples in South Africa can raise similar objections and demands within a legal context.

The Role of the United States

It is important to explore both South African and United States intellectual property laws, as many researchers doing work in South Africa (and on the African continent in general) come from the United States. Some U.S. researchers conduct their research on the continent then file patents and other IP-related applications in the United States.⁴²

According to U.S. patent law, for an invention or process to have patentability it must conform to certain statutory requirements.⁴³ The United States

⁴²See authors, Harriet Washington, Shubha Ghosh, and Abena Dove Osseo-Asare for more on this topic.

⁴³There are four basic conditions that an invention must meet to qualify for patent protection. The invention must be in a statutory subject matter category, useful, novel, and non-obvious from the

Patent and Trademark Office (USPTO), the agency that grants patents, does not conduct any review of the source of biological material in patent applications.⁴⁴ The United States could look to South Africa for legal guidance on the issue of identifying the source of biological material in patent applications. Under South African law, patent applicants must: (1) disclose whether the invention for which they are seeking protection is "based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use;" and (2) furnish proof of title or authority to make use of such research or knowledge.⁴⁵

To address the lack of ethical review in U.S. patent applications with regards to biological material, the Carvalho Requirement⁴⁶ has been advanced. Here, U.S. researchers would have to disclose the source of genetic material. Such a requirement would obligate researchers to be transparent with regards to their use of raw materials (biological material) or tools used in the invention process.

III. The Native American & Pacific Islander Legal Approach

Native American Graves Protection and Repatriation Act

prior art to a person of ordinary skill in the art at the time the invention was made. 35 U.S. Code § 101.

<sup>101.

44</sup>David J. Jefferson, Biosociality, Reimagined: A Global Distributive Justice Framework for

Ownership of Human Genetic Material, 14 Chi.-Kent J. Intell. Prop 357 (2015). ⁴⁵See the Patents Amendment Act 2005: http://www.wipo.int/wipolex/en/text.jsp?file id=179614

⁴⁶See Nuno Pires de Carvalho, Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution, 2 WASH. U. J. L. & POLY 371, 374 (2000).

The Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S. § 3001, provides a comprehensive legal framework to protect indigenous heritage by requiring the repatriation of Native American⁴⁷ human remains and other cultural items from museums⁴⁸ and federal agencies. NAGRPA does not protect remains on municipal and private lands, only federal or tribal lands.⁴⁹

Pursuant to section 5 [providing for required inventories by museums of human remains and associated funerary objects], the cultural affiliation of Native American remains and associated funerary objects with a particular Indian tribe or Native Hawai'ian organization is established, then the Federal agency or museum, upon the request of a known lineal descendant of the Native American or the tribe or organization...shall expeditiously return such remains and associated funerary objects. 25 U.S. § 3001.

Under NAGPRA, cultural items belonging to or affiliated with a particular "Indian tribe or Native Hawai'ian organization" consist of all materials subject to

⁴⁷Native American refers to a "tribe, people or culture that is indigenous to the United States," and

the Act therefore, describes Indian tribes and Native Hawai'ian organizations. U.S.C. § 3001(9). ⁴⁸Under NAGPRA, a museum is defined as "any institution or State or local government agency (including any institution of higher learning) that receives Federal funds and has possession of, or control over, Native American cultural items." (Nafziger, Patterson, Renteln 428).

⁴⁹See *Castro Romero* v. *Becker*, 256 P.3d 349 (5th Cir. 2001) (case involving remains found on municipal land). See also *Bonnichsen* v. *United States*, 357 F.3d 962 (9th Cir. 2004) (case involving a demand for the repatriation of Kennewick Man's remains by Native American tribes from the Columbia Plateau. The court held that oral traditions and other accounts given by the tribes were insufficient to establish a special and significant genetic or cultural link to Native Americans, and thus, Kennewick Man's remains were determined not to be Native American human remains "within the meaning of NAGPRA.").

an object-by-object inventory or summary. 43 C.F.R. 10.1(3) (1998). These cultural items include funerary objects, sacred objects, or "objects of cultural patrimony."⁵⁰

NAGPRA is closely related to such legislation as the National Museum of the American Indian Act,⁵¹ the Archaeological Resources Protection Act of 1979 (ARPA),⁵² and the National Heritage Preservation Act.⁵³ While NAGPRA does not provide a basis of recovery of monetary damages for individuals as evidenced in *Castro*, Indian tribes or Hawaiian organizations may seek injunctive relief through NAGPRA or the National Preservation Act, 16 U.S.C. § 470.

Under NAGRPA, there are two routes for resolving disputes arising from the possession of Native American human remains and cultural items by museums and federal agencies: NAGRPA's Review Committee and federal court jurisdiction. The Review Committee is a seven-person advisory group, consisting of three members nominated by a national museum and scientific organization,

⁵⁰There is some debate as to what all cultural patrimony entails. See Nafziger, Patterson, Renteln 428-29 for further discussion.

⁵¹The National Museum of the American Indian Act 20 U.S.C. § 80q-80q-15 (2002), "requires the Smithsonian Institution to inventory Native American remains and return identifiable remains to the tribes." *Id* at 427.

⁵²The Archaeological Resources Protection Act of 1979 (ARPA), 16 U.S.C. § 470aa-470mm (1994) "reasserts federal control over archaeological resources on federal and tribal lands and provides stiff penalties for persons who knowingly excavate, remove, or engage in transactions involving those resources without a federal permit. *Id.*

⁵³The National Historic Preservation Act, 16 U.S.C. § 470 et seq. (2000) declares that: "(1) historic properties significant to the Nation's heritage are being lost or substantially altered; (2) the preservation of this irreplaceable heritage is in the public interest; and (3) the increased knowledge of our historic resources, the establishment of better means of identifying and administering them, and the encouragement of their preservation will improve the planning and execution of Federal and federally assisted projects and will assist economic growth and development." *Id* at 274.

three nominated by the indigenous community, and one member chosen by the other six members.⁵⁴ The Committee uses three types of evidence in its decision-making process: osteological (physical anthropological), spiritual, and contextual.⁵⁵

The push for the return of Native American remains to tribal communities for reburial gathered significant steam in the 1970s and 1980s, when an Indian burial rights movement challenged the use of ancestral remains as scientific resources. The post-World War II period saw a greater sensitivity among the international community to human rights issues and the dignity of the human being. From this, there were calls for new rights to be vested in national patrimonies, as nations asserted a need for the protection of cultural heritage. Indigenous populations in South Africa should adopt a stance similar to Native Americans in their quest for cultural and political sovereignty. Current South African legislation is not explicit enough with regard to the repatriation of cultural items. Nor are the current South African laws specific to the preservation of indigenous peoples' cultural property, with the exception of the Traditional Knowledge Bill, which uses a *sui generis* approach to traditional knowledge and seeks to confer IP rights to traditional knowledge holding communities instead of to the state. The second significant is successful.

_

⁵⁴The Review Committee's responsibilities include (but are not limited to): (a) appointment of a chair; (b) monitoring the inventory and identification process; (c) reviewing and making findings related to the identity or cultural affiliation of cultural items; (d) resolution dispute facilitation; and (e) consulting with Indian tribes, Native Hawai'ian organizations and museums. Nafziger et al. ⁵⁵ *Id*.

⁵⁶See *Id*.

National Heritage Resources Act

Post-second wave colonialism, African nations began to assert, with probably greater authority, a desire to establish and protect national heritage. One such act along these lines is the National Heritage Resources Act (NHRA).⁵⁸ The Act provides for the protection of cultural objects and sites considered as part of the national estate⁵⁹ and grants authority to protect and conserve such heritage resources as graves and burial grounds, movable objects (including those of scientific and technological interest), archaeological, paleontological and geological sites, historical settlements and townscapes, and placements, buildings and structures to the Council of the South African Heritage Resources Agency

⁵⁸ The purpose of the 1999 National Heritage Resources Act (NHRA) is to "introduce an integrated and interactive system for the management of the national heritage resources; to promote good government at all levels, and empower civil society to nurture and conserve their heritage resources so that they may be bequeathed to future generations; to lay down general principles for governing heritage resources management throughout the Republic; to introduce an integrated system for the identification, assessment and management of the heritage resources of South Africa; to establish the South African Heritage Resources Agency together with its Council to coordinate and promote the management of heritage resources at national level; to set norms and maintain essential national standards for the management of heritage resources in the Republic and to protect heritage resources of national significance; to control the export of nationally significant heritage objects and the import into the Republic of cultural property illegally exported from foreign countries; to enable the provinces to establish heritage authorities which must adopt powers to protect and manage certain categories of heritage resources; to provide for the protection and management of conservation-worthy places and areas by local authorities; and to provide for matters connected therewith."

⁵⁹ See 3(1), which states: "For the purposes of this Act, those heritage resources of South Africa which are of cultural significance or other special value for the present community and for future generations must be considered part of the national estate and fall within the sphere of operations of heritage resources authorities."

(SAHRA). Per section 42(1)[a], the Council has the authority to negotiate and agree with a "provincial authority, local authority, conservation body, person, or community" through a heritage agreement to manage a heritage resource.

IV. Conclusion

Recommendations

I realize that topic of indigenous property rights is quite layered and that there are a number of multilateral and bilateral agreements and international conventions and charters in place that affirms indigenous rights and call for the protection of cultural resources. I won't address them in detail in this paper. My aim in this paper was to focus on some the problems faced by indigenous African communities in relation to property rights over objects of cultural patrimony within a historical context of scientific exploration and exploitation. To that aim, I briefly address some concerns that I have in regard to existing South African laws. South Africa has some of the most progressive and comprehensive intellectual property laws in the world. For example, the patent system has admirable disclosure requirements with respect to indigenous resources and traditional knowledge. In

⁶⁰See the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS), the Convention on Biodiversity (1992), the UNESCO Convention Concerning for the Protection of the World Cultural and Natural Heritage (1972), the UNESCO Convention for the Safeguarding of the Intangible Cultural Heritage (2003), and the UN Declaration on the Rights of Indigenous Peoples, among others.

examining another statute, the National Heritage Resources Act, I identified some areas for improvement.

National Heritage Resources Act

The National Heritage Resource Act only mentions "indigenous" in two instances. The Act was not intended to grant particular legal standing to indigenous groups to assert claims of ownership on indigeneity grounds (Indigenous groups possess equal status regarding claims to heritage objects and sites as any other interested party). Instead, NHRA asserts national patrimony over heritage resources.

The Act also does not mandate the repatriation of heritage resources (unlike the Native American Graves Protection and Repatriation Act) in possession outside of South Africa. On the restitution of heritage objects, the Act states:

When a community or body with a *bonafide* interest makes a claim for the restitution of a movable heritage resource which is part of the national estate and is held by or curated in a publicly funded institution, the institution concerned must enter into a process of negotiation with the claimants regarding the future of the resource."⁶²

⁶¹Indigenous is mentioned here in the Act: to describe "living heritage" as including "*indigenous* knowledge systems," 2(xxi)[g] and in the context of the identification, assessment, and management of heritage resources as needing to take account of all "relevant cultural values and *indigenous* knowledge systems." 5(7)[a].

⁶²⁴¹⁽¹⁾.

The Act simply requires negotiation for repatriation. The Act does not go far enough in asserting that legal ownership over cultural property belongs to the nation, and where appropriate, to indigenous South Africans. A mandatory repatriation clause with a specific time frame (such as 90 days) is needed. Given South Africa's (and other African nations) history of foreign exploitation, including the looting of cultural objects, African governments must explicitly demand the return of these objects, much in the same way Native Americans have. This will change the narrative for future generations with regard to Africa's reclamation of cultural and political sovereignty to one that positions African voices at the forefront and illustrates pro-active and resilient efforts to achieve such sovereignty.

<u>Unjust Enrichment: The Need for Legal Professionals to Craft Creative Strategies</u> <u>to Address this Problem</u>

The South African contract law of unjust or unjustified enrichment recognizes condictiones.⁶³ Condictiones may be used to obtain restitution where one party deliberately confers a benefit on another (transfer). However, there is no legal ground for obtaining restitution. A "particular domain of the application of

⁶³Condictio (plural: condictiones) refers to an action or summons. (Berger, 405).

condictio is an unjust enrichment when a person acquires something from another's property at the latter's expenses, without any legal ground or dishonestly."⁶⁴

According to United States contract and tort law principles, unjustified enrichment, a prima facie case for unjust enrichment entails the following elements:

(a) a benefit conferred upon the defendant by the plaintiff; (b) awareness, appreciation, or knowledge by the defendant of the benefit; and (c) acceptance or retention of the benefit by the defendant under such circumstances as to make it inequitable for the defendant to retain the benefit without payment to the plaintiff. 65

It will be important for legal professionals, especially Black/African legal professionals, to research the laws regarding unjust enrichment in their locale to determine if a strong claim of unjust enrichment can be made regarding the appropriation and commercialization of indigenous African heritage resources. Similarly, legal professionals should explore creative legal strategies that might be used to provide indigenous African communities with: (1) restitution for the theft of cultural objects; (2) the repatriation of identified objects and human remains; and (3) reparations for harms inflicted on African peoples from the first-wave of colonialism to the present.

 $^{64}Id.$

⁶⁵Greenfield, 217.

Bibliography

- Andrews, L. B. *Harnessing the Benefits of Biobanks*, 33 J.L. Med. & Ethics 22 (2005).
- Aoki, K. (2008). Seed wars. Durham, NC: Carolina Academic Press.
- Berger, A. (2004). *Encyclopedic dictionary of Roman law*. Clark (N.J.): The lawbook exchange.
- Ertman, M. and Williams, J. (2005). *Rethinking commodification*. New York: Eurospan.
- Foster, L. (2016). Decolonizing Patent Law: Postcolonial Technoscience and Indigenous Knowledge in South Africa. *Feminist Formations*, 28(3), pp.148-173.
- Garrison, N. A. Genomic Justice for Native Americans: The Impact of the Havasupai Case on Genetic Research. Science, Technology, and Human Values, Vol. 38, No. 2, Special Issue: Entanglements of Science, Ethics and Justice (March 2013), pp. 201-223.
- Genetic Databases and Biobanks: Who Controls our Genetic Privacy? Santa Clara
 Computer & High Tech. L.J. 1.
- Ghosh, S. Globalization, Patents, and Traditional Knowledge, Columbia Journal of Asian Law 2003 Fall; 17(1), pp. 73-120 (2003).

- Greenfield, D. L. Greenberg v. Miami Children's Hospital: Unjust Enrichment and the Patenting of Human Genetic Material, 15 Annals of Health Law, 213-249 (2006).
- Ismail, Z. & Fakir, T. (2004). *Trademarks or trade barriers? Indigenous knowledge* and the flaws in the global IRP system. International Journal of Social Economics, 31(1/2/), pp. 173-194.
- Jefferson, D. J. Biosociality, Reimagined: A Global Distributive Justice

 Framework for Ownership of Human Genetic Material, 14 Chi.-Kent J.

 Intell. Prop 357 (2015).
- Kuhse, H., Schüklenk, U. and Singer, P. (2015). *Bioethics*. 3rd ed. John Wiley, p.445.
- Madley, B. (2005). From Africa to Auschwitz: How German South West Africa Incubated Ideas and Methods Adopted and Developed by the Nazis in Eastern Europe. *European History Quarterly*, 35(3), pp. 429-464.
- Masango, C. (2010). Indigenous traditional knowledge protection: prospects in South Africa's intellectual property framework?. *South African Journal of Libraries and Information Science*, 76(1).
- Massachusetts Continuing Legal Education, Inc. 2012. Research Compliance, Culm MA-CLE 7-1.
- Nafziger, J., Paterson, R. and Renteln, A. (2010). *Cultural law*. Cambridge: Cambridge University Press.

- National Research Act NIH History. National Institute of Health. (2017). https://history.nih.gov/research/downloads/PL93-348.pdf.
- Osseo-Asare, A. (2014). Bitter roots: The search for healing plants in Africa.

 University of Chicago Press.
- Patents Amendment Act, 2005 (South Africa). World Intellectual Property Organization. http://www.wipo.int/wipolex/en/text.jsp?file_id=179614.
- Pires de Carvalho, N. Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution, 2 WASH. U. J. L.& POLY 371, 374 (2000).
- Protection of Human Subjects; Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 44 FR 23192-01.
- Robinson, D. (2012). Confronting biopiracy. London: Earthscan.
- Swanson, K. (2014). Banking on the body: The market in blood, milk, and sperm in Modern America. Harvard University Press.
- Tilley, H. (2001). Africa as a living laboratory. University of Chicago Press.
- Washington, H. (2008). Medical apartheid. New York: Anchor Books.
- "What is the Human Genome Project?" National Human Genome Research Institute. (2012).