MISAPPROPRIATION OF GENETIC RESOURCES IN AFRICA

A STUDY OF: *PENTADIPLANDRA BRAZZEANA*, *IMPATIENS USAMBARENSIS*, AND *COMBRETUM MICRANTHUM*

Julie Micalizzi

INTRODUCTION

The implementation of the patent system sought to foster innovation in fields that would yield the most public benefit, by offering the innovator an exclusive property right. A patent imparts on its owner a right to exclude others from making and distributing the claimed invention. Importantly, a patent does not grant the right to make or use the newly claimed invention itself, for if the invention is an improvement on a previously patented item, the whole item, including the original invention and the improvement as an inseparable unit, falls under the umbrella of exclusion associated with the original patent. However, the limited property right is generally overcome by sophisticated licensing agreements between knowledgeable parties wherein the previous patent owner and the owner of the improvement work together to allow the other restricted use of each granted right to make an item with both attributes. However, this limitation is not to diminish the influence of a patented property right alone; in fact, the repercussions of an exclusionary right are especially profound regarding misappropriation.

While the patent system is not meant to reach knowledge already within the public domain—since an exclusionary right on natural elements would hinder, not promote downstream innovation—the patent system is intended to provide avenues of reward for inventions that newly benefit the public. Unfortunately, this means that patent system does not reach the entire body of information referred to as traditional knowledge, which has been discovered and passed down by indigenous groups for generations. Often consisting of plants utilized for their flavorful, aesthetic, or medicinal qualities, traditional knowledge incorporates mostly natural materials within the public domain that indigenous populations utilized for centuries. As such, the information is unpatentable. Because traditional knowledge is already within the public domain, any patentable "improvements" on the traditional knowledge made by third parties would not be considered improvements at all, but rather original inventions. Based on the patent system, the indigenous groups would not have any initial right to the information and would not be entitled to licensing agreements or compensation for subsequent inventions. Not only are the traditional groups unable to obtain an exclusionary right to the information and prevent others from the exploitation and misappropriation of their knowledge, but,

furthermore, the indigenous people are also unable to claim any financial interest or entitlement to licensing agreements over subsequent research done by third parties.

This paper will address three potential cases of misappropriation concerning traditional knowledge and genetic resources of traditional groups in Africa and will explore how the Western patent system enabled, prevented, and corrected misappropriation in the context of these case studies. In all three studies, the patent system failed in misapplying the requirements of patentability and in granting patents for information that is per se unpatentable. However, the unpatentability of these specific instances of traditional knowledge also precludes the indigenous populations from claiming property rights over the information. Without an exclusionary property right, third parties are still able to commercialize the information. While such misappropriation might not be prohibited under patent law, the wrongful taking still is immoral. Though the patent system has evolved in preventing its inherent discrimination, e.g. recognizing public use outside the U.S. as a patent-defeating element, the patent system effectively fails to enable the indigenous groups to claim their own property right over the information or provide any adequate remedy for the traditional communities including recognition or compensation.

I. TYPES OF MISAPPROPRIATION AND THE PATENT SYSTEM

A. DEFINITION

While member states in the World Intellectual Property Organization (WIPO) do not currently agree upon a definition, Black's Law Dictionary offers one potential understanding of misappropriation: "a common-law tort of using the non-copyrightable information or ideas that an organization collects and disseminates for a profit to compete unfairly against that organization, or copying work whose creator has not yet claimed or been granted exclusive rights in work."[1] The elements of misappropriation further require: (1) the party claiming right to the information invested time, money, or effort for its extraction, (2) the competing party seized the information without similar time, money, or effort, (3) and the party claiming right to the information thereby suffered injury.[2] In the patent context, misappropriation involving indigenous populations typically occurs when their traditional knowledge—i.e. their unique cultural practices, rituals, and traditions—becomes the subject of a patented right by another group that is more fiscally and commercially knowledgeable and who retains substantial market power or economic influence. Universities and corporations involved with pharmaceuticals or biotechnology recognize the monetary potential in exploiting certain traditional knowledge and, unrestrained by the patent

[1] World Intellectual Property Organization, *Glossary*, http://www.wipo.int/tk/en/resources/glossary.html#33 (last visited April 4, 2017).
[2] *Id.*

system, gain an exclusionary right and effectively engage in misappropriation of the claimed information.

Though the definition of traditional knowledge is also in contention, it is often understood as "a living body of knowledge that is developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity."[3] Furthermore, traditional knowledge possesses four general traits that serve as the hallmark for the term of art. First, the body of information is all-encompassing including knowledge, know-how, rituals, skills, innovations, practices, and traditions.[4] Traditional knowledge may be cultural and social expressions of the indigenous communities—folklore, poetry, music, dance, textiles, pottery—or it can pertain to environmental factors, agriculture, or medicine, such as therapeutic salves, hunting or fishing techniques, and knowledge about animal migration patterns.[5] Secondly, indigenous groups serving as the guardians of the traditional knowledge passed and continue to pass the information between generations and, thirdly, the groups pass the information in a traditional, often oral, context.[6] Finally, the traditional knowledge forms a significant portion of and often defines the lifestyle of the indigenous communities who safeguard the information.[7] Traditional knowledge, for many indigenous communities, "forms part of a holistic world-view, and is inseparable from their very ways of life and their cultural values, spiritual beliefs and customary legal systems."[8] More than a commercial success, a community's traditional knowledge lies at the heart of its very identity.

Often, traditional knowledge does have a practical element or commercial potential as well as public health and entertainment implications. As a subset of traditional knowledge, genetic resources may offer great benefit to society at large. However, "when others seek to benefit from [traditional knowledge], especially for industrial or commercial advantage, this can lead to concerns that the knowledge has been misappropriated and that the role and contribution of [the traditional knowledge] holders has not been recognized and respected."[9] The Convention on Biological Diversity defines genetic resources as "parts of biological materials that: (1) contain genetic information of value and (2) are capable of reproducing or being reproduced."[10] Examples of genetic resources include matter isolated from plants, animals, or microbes,

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[3] *Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions*, WIPO Publication No. 933(E), 2015, at 13.

[4] *Id.*

[5] *Id*. at 14, 17.

[6] *Id*. at 13.

[7] *Id*.

[8] *Intellectual Property and Traditional Knowledge*, WIPO Publication No. 920(E), 2006, at 1.

[9] *Id.*

[10] World Intellectual Property Organization, *Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions*, WIPO Publication No. 933(E) 1, 18 (2015) (available at http://www.wipo.int/edocs/pubdocs/en/tk/933/wipo_pub_933.pdf).

including medicinal or agricultural crops, and animal breeds.[11] It is precisely the practicality and usefulness of these genetic resources that render them susceptible to commercial exploitation by third parties. Misappropriation "entails the wrongful or dishonest use or borrowing of someone's property."[12] Not only does misappropriation prevent indigenous communities from claiming a property right to the information they have discovered, isolated, and used that now belongs to another entity holding a patent to the traditional knowledge, but moreover, misappropriation leaves the native groups without any financial ownership of their traditional knowledge. The indigenous groups are unable to participate in any of the profit that results from the misappropriation of their traditional knowledge. Furthermore, as a core element of the group's identity, taking of their traditional knowledge and genetic resources without consent or prospective benefit sharing presents not only financial concerns, but moral concerns as well.

Silke von Lewinski, in her book *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge, and Folklore*, characterizes traditional knowledge and genetic resources in a manner distinct from the definitions heretofore discussed. Where it is otherwise understood that both genetic resources and traditional knowledge are interrelated and identifiable as property rights, Lewinski distinguishes the two domains based on the potential for recognition within the patent system.[13] Lewinski argues: "Traditional knowledge is human information, and as such it can be considered as something 'intellectual,' which may lead to protection within the framework of intellectual property rights."[14] On the other hand, genetic resources "may contain important and useful information," but this information "is merely natural, and therefore in principle not 'intellectual' information."[15] In essence, intellectual property and patent protection for genetic resources is not available by virtue of their natural origin—in patentability terms, the material is ineligible subject matter. However, such information may yield potential for a property right when the natural components are "processed by humans," e.g., the useful compound is investigated, the application proves novel, non-obvious, and useful[16]—the requirements necessary to obtain a U.S. patent. Furthermore, where misappropriation of traditional knowledge infringes a property right of another, misappropriation of a genetic resource does not carry such a violation.[17] Instead, as Lewinski contemplates, "the sovereign right in a part of biological diversity [that is violated in misappropriation of genetic

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11 *Id.*

12 *Glossary*, *supra* note 1.

13 See Lewwinski, Silke Von, *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge, and Folklore* 164 *(*Kluwer Law Int'l, 2004).

14 *ID.*

15 *Id*.

16 *Id.*

17 *Id*. at 165.

resources], is not an intellectual right, but a material one."[18] Misappropriation of genetic resources is theft, not infringement of intellectual property.[19]

The United Nations Conference on Trade and Development offers yet another variation on the definition: misappropriation "refers to access to and use of genetic resources without prior informed consent and/or mutually agreed terms pursuant to the national access legislation of the country providing the genetic resources and applicable international rules on access and benefit sharing."[20] As an illustration, misappropriation of genetic resources may occur by means of the intellectual property system when "a company sources biological resources from a country without consent, utilizes that resource in [research and development] to develop an invention, and then attempts to patent that invention utilizing the resource without any benefits to the provider, or without mentioning where the resource was obtained."[21] Similar to Lewinski's definition above, misappropriation of genetic resources only becomes relevant in regards to intellectual property rights after research, isolation, development, and usefulness—effectively bringing the material within the purview of patentability. However, as will be discussed in the following section, once the material becomes patentable in the sense of novelty and nonobviousness, wherein research and development takes the ineligible subject matter of plants and naturally-occurring information and transforms it into an invention, such distinguishing features, under U.S. patent law, render the end-result the intellectual property of the inventor. Indigenous groups would not have a claim for intellectual property rights because: (1) the original traditional knowledge is unpatentable and (2) the final information that is patentable is characteristically different from the original source material. Importantly, however, the UN conference suggests potential solutions to the problem of misappropriation, which would be at least morally acceptable in the event the law precludes remedy, informed consent, plans of access and benefit sharing, and disclosure of sourcing.

Even news sites have acknowledged and attempted to define misappropriation in the context of genetic resources; Anthony Barnett comments that the term biopiracy "is being increasingly used by environmental groups to describe a new form of "colonial pillaging" in which western corporations reap profits by taking out patents on indigenous materials from developing countries and turning them into lucrative products."[22] However, as Barnett recognizes, the corporations rarely share benefits of such commercialization with the country of origin[23]—one of the

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[18] *Id.*

[19] *See id.*

[20] U.N. CONFERENCE ON TRADE AND DEV., THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE NAGOYA PROTOCOL: INTELLECTUAL PROPERTY IMPLICATIONS 1 (2014).

[21] *Id.*

[22] Anthony Barnett, *Biopiracy in Africa*, THE GUARDIAN, Sept. 22, 2006, http://www.theguardian.com/world/2006/sep/22/outlook.development.

[23] *See id.*

many characteristics of misappropriation that seems to evoke not only financial and property concerns, but also moral implications.

B. PATENT SYSTEM

For an invention to receive a patent right in the U.S., the invention must pertain to eligible subject matter[24] and must be novel,[25] non-obvious,[26] and useful.[27] However, even with requirements that would suggest a narrow scope for patent eligible inventions, the U.S. definitions of prior art, public use, and inventive step effectively broaden the application of patent laws and enable the misappropriation of traditional knowledge and genetic resources of other countries. Additionally, often it is the case that the requirements for patentability are misapplied to a specific situation yielding patents that should not have been granted at all, i.e. in respect to naturally occurring plants and nucleotide sequences or well-known uses and applications of medicinal herbs. In these instances where public use, printed publications, and ineligible subject matter should have precluded patentability, the indigenous peoples who have held the traditional knowledge and genetic resources would also have been prevented from receiving patent protection. Furthermore, in instances where the patent-holders have transformed naturally-occurring and ineligible subject matter into a novel and nonobvious invention, the indigenous groups would still not have a legal intellectual property right claim to the invention. Such wrongful taking, though not prohibited under the patent legal system, might still elicit a moral claim to compensation or recognition.

1. ELIGIBLE SUBJECT MATTER—ISOLATION OF ACTIVE INGREDIENTS

When determining what constitutes eligible subject matter, courts look to 35 U.S.C. §101 which provides, "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[28] Although hallmark cases regarding eligible subject matter, *Diamond v. Chakrabarty* and *Association for Molecular Pathology v. Myriad Genetics, Inc.*, reaffirmed patent law's general principle that naturally-occurring material is unpatentable, the case studies discussed later in this paper demonstrate that these court rulings might have been misapplied and resulted in the wrongful granting of property rights over natural proteins and plants.

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[24] 35 U.S.C. § 101 (2013).
[25] *See* 35 U.S.C. § 102 (2013).
[26] *See* 35 U.S.C. § 103 (2013).
[27] 35 U.S.C. § 101 (2013).
[28] *See id.*

While *Myriad* is a newer case decided only in 2013, *Chakrabarty* has been U.S. precedent since 1980. In *Chakrabarty*, the Supreme Court of the U.S. held that human-made genetically engineered bacterium capable of breaking down crude oil was an invention eligible for patentability because: (1) it was not naturally occurring[29] and (2) had possessed characteristics markedly different from naturally-occurring bacterium that were direct the result of human ingenuity.[30]Since the 1930 Plant Patent Act, crossing two plant varieties when the resulting hybrid does not occur naturally has expressly enabled the patentability of plants that are asexually produced, according to Congress.[31] Additionally, under the World Trade Organization agreement on Trade-Related Intellectual Property Rights, "it is possible to patent life forms if they have been altered in some way for new and innovative uses."[32] In *Myriad*, the U.S. Supreme Court further refined this principle by holding that a naturally-occurring nucleotide DNA sequence is not patentable because of its isolation from the full DNA molecule. DNA, containing only the protein-coding genes and ability to be produced only in a laboratory setting, however, remains patent-eligible.[33] The difference again lies in the definitions of naturally-occurring matter and human invention. Importantly, *Myriad* expressly outlines what the decision did not seek to resolve—patents claiming novel methods of manipulating genes, new applications of knowledge regarding genes, and the patentability of DNA wherein scientists alter the naturally-occurring nucleotide sequence[34]—which is the subject of one of the following case studies.

Patent law intends to promote creation and allow public access to critical inventions, while incentivizing and compensating the inventors with a temporary exclusionary property right. However, patent law is hesitant to upset the principle that laws of nature, natural phenomena, and abstract ideas are not patentable. Not only is this information already within the public domain, even if not yet isolated or named, but it also ties-up potential downstream innovations. In short, Chakrabarty created a new bacterium whereas Myriad *created* nothing. While Myriad's discovery and isolation of genes related to breast cancer required much effort and resulted in information highly significant and sought after, it is simply not eligible for patent protection.

2. NOVELTY—PRIOR ART AND PRIOR USE

29 *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980).

30 *Id*. at 310.

31 *Id.* at 312.

32 Marilyn Carr & Martha Alter Chen, *Globalization and the Informal Economy: How Global Trade and Investment Impact on the Working Poor*, Women in Informal Employment Globalizing & Organizing 1, 19 (2001) (available at http://natlex.ilo.ch/wcmsp5/groups/public/---ed_emp/documents/publication/wcms_122053.pdf).

33 *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013).

34 *Id*. at 2119-20.

The requirement of novelty for patents filed on or after March 16, 2013 is disclosed in post-AIA 35 U.S.C. § 102(a):

> A person shall be entitled to a patent unless— (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or (2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b).[35]

Thus, all material and knowledge within the public domain, through either printed-publication or public-use for more than 1 year,[36] is unpatentable regardless of geographical location. As written, this would prevent U.S. companies and universities from exploiting indigenous groups' traditional knowledge and genetic resources. At the same time, these limitations would also prevent the indigenous groups from obtaining a patent of material disclosed in a printed publication or in public-use for more than one year.

However, novelty pre-AIA included geographical limitations such that: "A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."[37] Thus, to defeat patent eligibility, prior art outside of the U.S. must be contained in a printed publication whereas within the U.S. the prior art need only be in public use. Thus, U.S. patent law pre-AIA purported to protect oral traditional knowledge and genetic resources only if it were present in the U.S., presumably that of Native Americans. However, patent law failed to provide adequate means of protection for the oral traditional knowledge and genetic resources of indigenous groups outside of the U.S. where the material had not been published in a printed publication, or if the material had been published, was not widely available or searchable. The requirement of pre-AIA novelty especially discriminated "against indigenous communities in other countries because their knowledge is rarely documented."[38] In fact, per the four qualities generally characteristic of traditional knowledge, such indigenous groups generally pass down their traditional knowledge in an oral, and not written, context.

3. NONOBVIOUSNESS—INVENTIVE-STEP

The requirement of nonobviousness for patents filed before March 16, 2013 is disclosed in pre-AIA 35 U.S.C. §103(a):

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35 35 U.S.C. § 102(a) (2013) (post-AIA).

36 35 U.S.C. § 102(b) (2013) (post-AIA).

37 35 U.S.C. § 102(a) (1952) (pre-AIA).

38 Lakshmi Sarma, Note & Comment*: Biopiracy: Twentieth Century Imperialism in the Form of International Agreements*, 13 TEMP. INT'L & COMP. L.J. 107, 130 (1999).

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 , if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.[39]

After the AIA, the change to the language of §103(a) was minimal, reflecting the change from first-to-invent to first-to-file such that the timeframe is not at the time the invention was made, but rather, "before the effective filing date of the claimed invention."[40]

Whereas novelty sought to assure that patents were not granted for information and material already within the public domain, nonobviousness demands the invention be sufficiently removed from prior art—a leap forward or an inventive step. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Supreme Court of the U.S. held that in order to overcome nonobviousness, there must be an inventive concept "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself."[41] In *Graham v. John Deere Co.*, the U.S. Supreme Court described a test to determine nonobviousness: ascertaining the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art.[42] The requirement of obviousness is intended to ensure "whether the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[43] Furthermore, secondary considerations such as commercial success, long-felt but unresolved needs, and failure of others may aid in the nonobviousness determination.[44]

Importantly, nonobviousness looks to the direction of the prior art and is determined in reference to a person having ordinary skill in the art. In *United States v. Adams*, the U.S. Supreme Court held the patent valid and nonobvious because the prior art—suggesting that water-activated batteries were successful only when combined with electrolytes detrimental to the use of magnesium— taught away from the invention.[45] The invention at issue utilized cuprous chloride, which has an interdependent relationship with

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39 35 U.S.C. §103(a) (1952) (pre-AIA).

40 35 U.S.C. §103(a) (2013) (post-AIA).

41 *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012).

42 *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17 (1966).

43 *Id.* at 3.

44 *Id.* at 17.

45 *United States v. Adams*, 383 U.S. 39, 52 (1966).

magnesium.[46] On the other hand, as an example of obviousness, in *Hotchkiss v. Greenwood*, the U.S. Supreme Court held the substitution of clay or porcelain in doorknobs where the prior art disclosed use of metallic knobs was obvious and not patentable.[47] The Court determined the improvement was the work of a mechanic and not an inventor:

> Unless more ingenuity and skill in applying the old method of fastening the shank and the knob were required in the application of it to the clay or porcelain knob than were possessed by an ordinary mechanic acquainted with the business, there was an absence of the degree of skill and ingenuity which constitute essential elements of every invention.[48]

To determine who constitutes a person of ordinary skill in the art, the Federal Circuit offered several factors in their decision for *Daiichi Sankyo Co, LTD v. Apotex Inc.*, including: the educational level of the inventor, the type of problems encountered in the art, prior art solutions to those problems, rapidity with which innovations are made, sophistication of the technology, and educational level of active workers in the field.[49]

The intent of patentability requirements is to ensure information already within the public realm or already utilized by groups of people are not wrongfully taken and exploited by entities with greater financial resources and commercial market power. The requirements, however, effectively preclude indigenous groups from claiming intellectual property rights to their traditional knowledge and genetic resources. Such traditional knowledge and genetic resources are often undocumented, in public-use for generations, and typically encompass natural materials. Interestingly, as the following three case studies illustrate, much of the misappropriation does not occur as the exploitation of patentable indigenous knowledge; rather, misapplication of the patentability requirements accounts for much of the failure of the patent system to protect the indigenous groups' traditional knowledge and genetic resources. Of course, this again precludes the indigenous groups themselves from claiming intellectual property rights of their traditional knowledge and genetic resources when it is naturally occurring, previously published, in public use, or utilized as a source for a patentable invention that is markedly different from the original material. Thus, to curtail misappropriation, the patent system must be reorganized so as to protect a special subset of public knowledge when that public is an indigenous group.

II. CASE STUDY I: *PENTADIPLANDRA BRAZZEANA*

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[46] *Id.* at 50.

[47] *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248, 264 (1851).

[48] *Id.* at 267.

[49] *Daiichi Sankyo Co., Ltd. v. Apotex, Inc*., 501 F.3d 1254, 1256 (Fed. Cir. 2007).

The West African plant *pentadiplandra brazzeana*, the fruit of which Gabon locals refer to as *j'oublie*,[50] is host to the protein brazzein reported to be 500 to 2000[51] times sweeter than sugar.[52] Recognizing the commercial market-potential for low-calorie sugar alternatives in a country plagued by obesity, the University of Wisconsin-Madison through its Wisconsin Alumni Research Foundation (WARF) sought to harness the concentrated sugar-like sweetness and low-glycemic qualities of brazzein.[53] While WARF recognizes that traditional communities indigenous to the region of natural growth have consumed the berries associated with *pentadiplandra brazzeana* "for thousands of years,"[54] WARF holds numerous patents associated with brazzein and claims the protein as "an invention of UW-Madison research."[55] At the same time, despite the well-established documentation of the traditional communities in Gabon use of brazzein, it does not appear that a specific traditional community, organization, or government within West Africa has claimed the use of *j'oublie* as their intellectual property, or specifically accused WARF of misappropriation. Since the concept of misappropriation implies that a traditional community has asserted rights over the traditional knowledge and deems the use of the materials as a taking, without such knowledge of who is harmed, it would be difficult for WARF to obtain prior informed consent or engage in access and benefit-sharing. At the same time, perhaps without knowledge of their own exploitation, it might be impossible for an indigenous group to alert WARF and other institutions to the perceived misappropriation.

In the 1980s, ethnobotanist Claude-Marcel Hladik, utilizing information a Gabonese assistant provided him, supplied UW-Madison researcher Göran Hellekant with berries from *pentadiplandra brazzeana*, urging him to study their sweet quality. [56] Upon watching natives of the region eat the *j'oublie* berries, researcher Hellekant allegedly decided, "there

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[50] Robert Ostergard et al., *Between the Sacred and the Secular: Indigenous Property, International Markets, and the Modern African State*, 44 THE J. OF MOD. AFR. STUD. 309, 317 (2006).

[51] Julia Rojahn, *Fair Shares or Biopiracy: Developing Ethical Criteria for the Fair and Equitable Sharing of Benefits from Crop Genetic Resources*, EBERHARD KARLS UNIVERSITÄT TÜBINGEN 1, 15 (2010) (available at http://d-nb.info/1001988825/34).

[52] Magdalena Kaihuzi, *LDCs in a Globalizing World: A Strategy for Gender-Balanced Sustainable Development*, in United Nations Conference on Trade and Development: Trade, Sustainable Development and Gender 347, 356 (1999) (available at http://unctad.org/en/docs/poedm_m78.en.pdf).

[53] *Variants of the Sweet Protein Brazzein with Improved Characteristics*, Wisconsin Alumni Research Foundation, 1,1 (available at https://www.warf.org/documents/technology-summary/P02087US.pdf).

[54] *Natur Research Ingredients to Launch Cweet™ New Natural Intense Sweetener Worldwide*, Wisconsin Alumni Research Foundation (Nov. 5, 2007), http://www.warf.org/news-media/news/releases-and-announcements/natur-research-ingredients-to-launch-cweet-new-natural-intense-sweetener-worldwide.cmsx.

[55] Kaihuzi, *supra* note 51 at 356.

[56] Baruch A. Brody, *Intellectual Property, State Sovereignty, and Biotechnology*, 20 KENNEDY INST. OF ETHICS J. 51, 53 (2010).

was something of value there."[57] Between 1989 and 1994, Hellekant and the UW-Madison researchers discovered the sweetness of the fruit was of a proteinaceous nature,[58] isolated the protein through purification and named it brazzein, and identified its naturally occurring amino acid sequence.[59] Results of the targeted research indicated lucrative physical and molecular qualities that suggest the protein would be promising as a sugar substitute—its solubility in water and heat stability, its sweetness profile that is very close to sucrose, its low glycemic index and low caloric nature, and its lack of aftertaste that is a lingering side effect characteristic of most other sugar substitutes.[60] Beginning in 2003, Hellekant and fellow researchers from UW-Madison began to create mutants of the brazzein protein consisting of varying amino acid sequences to determine critical regions responsible for the overall sweetness of the molecule[61] and confirmed the results by studying electrophysiological responses in rhesus monkeys and human psychophysical to the mutant proteins.[62] Studies determined that different mutations at specific positions made the new protein either significantly sweeter than wildtype brazzein or removed its sweetness altogether.[63]

In their publications, the researchers only vaguely disclosed the geographical source of the samples analyzed to isolate and research brazzein and failed to describe how the samples were actually acquired including any permissions gained by government or traditional groups:

> In the 1980s, our attention was attracted to a West African plant, *Pentadiplandra brazzeana* (Hladik *et al.*, 1984). We obtained a small sample of smoke-dried berries in which we tentatively identified a sweet tasting protein, pentadin (van der Wel *et al.*, 1989). From a new and fresher sample of the berries' pulp we identified and isolated the major sweet principle of *P. brazzeana*, which we named brazzein (Ming and Hellekant, 1994).[64]

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57 *Trade Related Intellectual Property Rights (TRIPs) and Farmers' Rights*, UK Parliament (1999) (available at http://www.publications.parliament.uk/pa/cm199900/cmselect/cmenvaud/45/45ap08.htm).

58 H. van der Wel et al., *Isolation and Characterization of Pentadin, the Sweet Principle of Pentadiplandra brazzeiana Baillon*, 14 CHEM. SENSES 75,75 (1989).

59 Ding Ming & Göran Hellekant, *G. Brazzein, a New High-Potency Thermostable Sweet Protein from Pentadiplandra brazzeana B.*, 355 FEBS LETTER 106, 106 (1994).

60 Wisconsin Alumni Research Foundation, *supra* note 53.

61 Zheyuan Jin et al., *Critical Regions for the Sweetness of Brazzein*, 544 FEBS LETTERS 33, 33 (2003).

62 Zheyuan Jin et al., *Monkey Electrophysiological and Human Psychophysical Responses to Mutants of the Sweet Protein Brazzein: Delineating Brazzein Sweetness*, 28 CHEM. SENSES 491, 491 (2003).

63 *Id.*

64 Göran Hellekant & Vicktoria Danilova, *Brazzein a Small, Sweet Protein: Discovery and Physiological Overview*, 30 CHEM. SENSES i88, i88 (2005).

In what appears to be the first publication in the series of scientific papers that would eventually lead to the isolation and study the specific protein brazzein, Hladik describes the initial finding of Central African plants.[65] Though written in French, a crude translated abstract describes the geographical source of the study: "The different species of rain-forest plants developing starchy tubers were studied around Makokou (N.E. Gabon) and in the Lobaye River district (S.W. Central African Republic)."[66] Without a complete English translation, it is unknown whether Hladik interacted with the traditional communities of Gabon and Central Africa during the initial survey of the land and the acquisition of the berries. In subsequent publications, the researchers, including Hladik and Hellekant, refer to the initial procurement of the berries: "The fruits were collected in Gabon (voucher specimen in the Paris Herbarium: A.Hladik no. 4139),"[67] but again fail to specifically describe permissions and interactions with local communities. As a trend, in another subsequent scientific publication, the researchers disclose the source of the materials by a quick and vague reference to geographic location: "Fruits of *Pentadiplandra brazzeana* from West Africa were used."[68]

Importantly, however, Hellekant does acknowledge that the sweet properties of *j'oublie* were well-known to the traditional groups of West Africa and Gabon: "Indigenous people have known brazzein for centuries. It is consumed either raw or in a cooked form (Hladik and Hladik, 1988) and used as a sweetening agent in drinks and food."[69] Furthermore, Hladik and Hellekant recognize that the very basis of their study, the sweet nature of brazzein, has been well-known by traditional communities of the area: "Under a thick epicarp, these berries contain one to five reniform seeds surrounded by a thick soft layer of red pulp which is locally known, especially in Gabon, for its strong sweet taste."[70] Even with this recognition, Hellekant and the University of Wisconsin-Madison claim the discovery of the sweet protein brazzein as a result of their own scientific research and study: "We have discovered a new high-potency thermostable sweet protein, which we name brazzein, in a wild African plant *Pentadiplandra brazzeana*."[71]

Resulting from UW-Madison's extensive research into the brazzein protein, WARF has acquired eight utility U.S. patents,[72] two patents granted by

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65 Annette Hladik et al., *Les plantes `a tubercules de la for^et dense d'Afrique Centrale*. 39 Revue d'Ecologie (Terre et Vie) 249 (1984) (available at http://documents.irevues.inist.fr/handle/2042/55168).

66 *Id.*

67 van der Wel, *supra* note 57 at 75.

68 Ming, *supra* note 58 at 106.

69 Hellekant, *supra* note 63 at i88.

70 van der Wel, *supra* note 57 at 75.

71 Ming, *supra* note 58 at 106.

72 U.S. Patent No. 8,501,910 (active until 2028); U.S. Patent No. 7,812,122 (active until 2029); U.S. Patent No. 7,153,535 (expired due to nonpayment of fees); U.S. Patent No. 6,274,707 (expired due to nonpayment of fees); U.S. Patent No. 5,741,537 (expired lifetime 1995); U.S. Patent No.

Germany, and two from South Africa.[73] Of the U.S. patents, four expired due to passing of the 20-year term, two expired due to nonpayment of fees, and two remain active for at least another 10 years.[74] The patents claim a variety of structures and uses including: the isolated protein containing the naturally occurring amino acid sequence,[75] the recombinantly produced protein,[76] the isolated DNA sequence that codes for the protein,[77] a method of increasing the sweetness of the protein by altering the amino acid sequence,[78] use of brazzein as a sweetener in foods and beverages,[79] mixing the brazzein sweetener with other sweeteners,[80] and multiple synthetically created protein mutations wherein the amino acid sequence of the naturally-occurring brazzein are altered manually thereby changing the sweetness.[81]

5,527,555 (expired lifetime 1994); U.S. Patent No. 5,346,998 (expired lifetime 1993); U.S. Patent No. 5,326,580 (expired lifetime 1993).

[73] S. Afr. Patent No. 1994/01061 and S. Afr. Patent No. 1995/03888.

[74] '910 Patent; '122 Patent; '535 Patent; '707 Patent; '537 Patent; '555 Patent; '998 Patent; '580 Patent .

[75] '580 Patent ("A sweet protein containing an amino acid sequence substantially the same as that shown in SEQ ID NO:1, the protein being essentially free of Pentadiplandra brazzeana plant material other than Brazzein").

[76] '580 Patent ("A sweet protein containing an amino acid sequence substantially the same as that shown in SEQ ID NO:1, wherein the protein has been produced recombinantly and is essentially free of Pentadiplandra brazzeana plant material other than Brazzein"); '555 Patent ("A sweet protein containing an amino acid sequence according to SEQ ID NO:4 amino acid residues 2-54, wherein the protein has been produced recombinantly and is essentially free of Pentadiplandra brazzeana plant material other than Brazzein").

[77] '998 Patent ("The DNA sequence essentially according to SEQ ID NO: 2, wherein the DNA sequence is located outside of a Pentadiplandra brazzeana Baillon cell, and the DNA sequence codes for essentially the protein of SEQ ID NO: 1, wherein the DNA sequence is essentially free of Pentadiplandra brazzeana plant material other than Brazzein"); '555 Patent ("A DNA sequence according to SEQ ID NO:5 bases 4-162, wherein the DNA sequence is located outside of a Pentadiplandra brazzeana Baillon cell, and the DNA sequence encodes the protein of SEQ ID NO:4 residues 2-54, wherein the DNA sequence is essentially free of Pentadiplandra brazzeana plant material other than Brazzein").

[78] '537 Patent ("A method of increasing the sweetness of a composition selected from the group consisting of foods and beverages comprising the step of adding a sufficient amount of Brazzein protein to the composition, so that the composition has an increased sweetness, wherein the Brazzein protein has been produced in a recombinant host cell and said protein has been isolated").

[79] *Id.* (A composition comprising a food or beverage and a Brazzein protein produced and isolated from a recombinant host cell).

[80] '555 Patent ("A composition comprising the protein of claim 1 mixed with another sweetener obtained from other than Pentadiplandra brazzeana Baillon").

[81] '707 Patent ("A synthetically produced peptide having a different sweetness potency or sweetness temporal profile from naturally occurring Brazzein comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 12, SEQ ID NO: 13 and SEQ ID NO: 14"); '535 Patent ("A synthetically produced peptide having a different sweetness potency from naturally occurring Brazzein, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 5"); '122 Patent ("A peptide consisting of: SEQ ID NO: 2 wherein the Xaa at position 53 is selected from the group consisting of Phe, Trp or His; SEQ ID NO: 3 wherein the Xaa-Xaa at positions 1 and 2 is selected from Ile-Ile or Gly-Pro; wherein the peptide has a different sweetness potency from naturally occurring Brazzein"); '910 Patent ("A peptide having a different sweetness potency from naturally occurring Brazzein, comprising the amino acid sequence of SEQ ID NO: 2 where Xaa is not Tyr").

Subsequent work for the UW-Madison has focused on eliminating the need to collect the berries from *pentadiplandra brazzeana* in West Africa, instead has enabled the production of brazzein in laboratories by means of transgenic organisms.[82] In 1998, UW-Madison sold exclusive rights for the use of brazzein as an extracted sweetener, however produced, to NeKtar Worldwide, who intended to extract large quantities of the protein from corn maize genetically modified to express brazzein.[83] In a press release, NeKtar and ProdiGene announced their promising partnership in a lucrative commercial market for sugar alternatives.[84] President and CEO of NeKtar described: "Since this natural, plant-based sweetener can be extracted from corn in a conventional milling operation while preserving the value of the other corn products, Brazzein is expected to be extremely cost-effective to produce."[85] Interestingly, the press release acknowledged the general source of the critical protein and the traditional knowledge of the berry as a sweetener: "The Brazzein protein is from a West African plant where it has been consumed locally for many years."[86] Without much other press after 1998, it would appear that the ProdiGene incident wherein the biotech company was required to pay millions of dollars for contamination of conventional crops, might have halted the production of brazzein.[87]

In 2007, UW-Madison granted American corporation Natur Research Ingredients exclusive license[88] to manufacture and distribute a brazzein-based substitute sweetener under the trademark Cweet.[89] As of April 7, 2016, Cweet has yet to offer a commercially available brazzein product for consumer purchase.[90] Nevertheless, Cweet hosts a website describing the benefits of sugar alternatives derived from brazzein including its zero-calorie nature, low glycemic index, similarity to sucrose, and heat stability.[91] Furthermore, Cweet itself acknowledges the source of its product and the traditional knowledge of indigenous groups that encompassed its sweetness, "derived from brazzein, a protein extracted from the West African fruit of the climbing plant Oubli (*pentadiplandra brazzeana*

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82 Fariba M. Assadi-Porter et al., *Brazzein, a Small, Sweet Protein: Effects of Mutations on its Structure, Dynamics and Functional Properties*, 30 CHEM. SENSES i90, i90 (2005).

83 Biopiracy, *RAFI's Sixth Annual Update* (Rural Advancement Foundation International Communique) May/June 2000 at 1, 3 (available at http://www.etcgroup.org/files/publication/327/01/com_biopiracy.pdf).

84 *NeKtar Worldwide and ProdiGene to Develop Natural Intense Sweetener in Corn,* SeedQuest (Seed Quest) April 22, 1998 (available at http://www.seedquest.com/News/releases/usa/ProdiGene/N1641.htm.)

85 *Id.*

86 *Id.*

87 *See Generally* Jeffrey Fox, *Puzzling Industry Response to ProdiGene Fiasco*, 21 NATURE BIOTECHNOLOGY 1, 3-4 (2003).

88 Wis. Alumni Res. Foundation, *Exclusive License Agreement Template*, (2015) (available at http://www.warf.org/media.acux/627e8a4b-6170-4bf1-a50f-ae35bfa7cdb1).

89 Wis. Alumni Res. Foundation, *supra* note 53.

90 Telephone Interview with Stephen Felderstein, Vice President National Sales, Natur Research Ingredients, (April 7, 2016).

91 Cweet Natur Research Ingredients, *Cweet Natural Intense Sweetener Attributes*, http://www.cweet.com/attributes.html (last visited Apr. 6, 2017).

Baillon), which has been consumed by local natives…for centuries."[92] Though the website claims "Cweet" is a registered trademark of Natur Research Ingredients,[93] a search completed through the USPTO website on April 7, 2016 finds that the trademark for "Cweet" is dead by cancellation as of February 20, 2015.[94]

With a U.S. sweetener market that exceeds $2 billion and annual world-wide sales that top $100 billion, the economic implications for a new sweetener are vast.[95] UW-Madison does not have any plans for access and benefit-sharing with the traditional communities in West Africa and Gabon who first utilized *pentadiplandra brazzeana* berries for their unique sweetness.[96] The traditional groups have not received any compensation for use of their traditional knowledge and genetic resources.[97] However, Loren Miles, CEO of Natur Research Ingredients, Inc., has stated that "because the brazzein plant is native to Africa, we are exploring establishing a foundation that will contribute to humanitarian causes in Africa once production and distribution has started."[98] Still, neither the UW-Madison nor ProdiGene recognize any intellectual or material property claim that the Gabonese people may have to the use of brazzein as a sugar substitute.[99]

Since all of the patents were filed prior to March 16, 2013, the relevant statutes that apply are pre-AIA. Under the novelty requirement then, prior public use by traditional groups in Gabon and other areas of Africa would not defeat the property right of UW-Madison as it did not occur within the U.S. Furthermore, since there is no evidence the traditional knowledge was written in any sort of printed publication, brazzein would satisfy the requirement of novelty. However, if these patents were to have been sought after the AIA was passed into law, then the traditional communities could have defeated the patent by showing of public use since the AIA eliminates the geographical restriction. Still, this change does not necessarily enable the traditional groups themselves to claim exclusive patent rights over the sweetness of brazzein. If the public use occurred for more than a year prior to filing of a patent, which is required in the definition of traditional knowledge to have been passed through generations, then those who have utilized the material as a part of their traditional knowledge and genetic resources for centuries would additionally fail to satisfy the novelty requirement of patentability. Therefore, though UW-Madison would be unable to gain a patent over the knowledge, the researches and university

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92 Cweet Natur Research Ingredients, *Cweet Natural Intense Sweetener About*, http://www.cweet.com/about.html (last visited Apr, 6, 2017).

93 Cweet Natur Research Ingredients, *Cweet Natural Intense Sweetener*, http://www.cweet.com/ (last visited Apr. 6, 2017).

94 USPTO. *Trademark Electronic Search System (TESS)*. April 7, 2016. Serial Number 78829311. http://tsdr.uspto.gov/#caseNumber=78829311&caseSearchType=US_APPLICATION&caseType=DEFAULT&searchType=statusSearch

95 Select Committee on Environmental Audit, *supra* note 56.

96 Kaihuzi, *supra* note 51 at 356.

97 Ostergard, *supra* note 49 at 317.

98 Wis. Alumni Res. Foundation, *supra* note 53.

99 Ostergard, *supra* note 49 at 317.

would still be able to study the protein and commercialize its use as an alternative sweetener. The traditional groups would not be able to claim *j'oublie* as their intellectual property under U.S. patent law or claim any resulting financial right to the commercial profits of third parties.

Outside of determining public use and publication, as a naturally-occurring substance and nucleotide sequence, even under a *Chakrabarty* framework, brazzein should not have been considered patent eligible material at an initial stage. The researchers at UW-Madison, similar to those in *Myriad*, simply engaged in discovery and isolation of a natural element; they did not invent anything markedly different from that which was already found in the fruit of *j'oublie*. Though *Myriad* expressly did not decide this scenario, perhaps once the researchers began altering the nucleotide sequence of brazzein to scientifically manipulate its structure and create a material even sweeter than that which was naturally-occurring, the result would be patentable both as satisfying the requirement eligible subject matter and the non-obviousness inventive step. However, not only does this invention account for less than half of the patents granted to UW-Madison, but furthermore, this would additionally preclude traditional groups from claiming a property right. First and foremost, the original and naturally-occurring source of the sweetness would not be patentable itself and secondly, with the inventive step achieved by UW-Madison, traditional communities would not have a claim to this modification and invention.

Overall, while the patent system might have failed in granting patents to UW-Madison over ineligible and naturally-occurring subject matter and might have been discriminatory against indigenous groups without written traditional knowledge prior to the passing of the AIA, the patent system does not offer any means by which the traditional groups could claim exclusive right to their traditional knowledge and genetic resources when it involves a naturally-occurring plant. Even though such a case might constitute an immoral and wrongful taking, it is not prohibited under U.S. patent law.

III. CASE STUDY II: *IMPATIENS USAMBARENSIS*

Tanzania's Usambara Mountains, located just south of Mount Kilimanjaro, are a "green island" rising above the surrounding dry plain and home to unique biodiversity, including *impatiens usambarensis* and *impatiens walleriana* (also known as Busy Lizzies).[100] Multinational biotech giant Syngenta holds one utility U.S. patent[101] and one patent granted by the E.P.O.[102] for a cross between these two plant varieties, which result in a trailing quality. Syngenta also has a pending U.S. patent application for the

[100] Jay McGown, *Out of Africa: Mysteries of Access and Benefit Sharing*. THE EDMONDS INST. in cooperation with THE AFR. CTR. FOR BIOSAFETY 1, 24 (2006) (available at http://www.edmonds-institute.org/outofafrica.pdf).

[101] U.S. Pat. No. 7,807,905 (active until 2026).

[102] Eur. Pat. No. 1711049.

method of crossing the two plants to result in the hybrid.[103] Although Syngenta recognizes the trailing hybrid occurs naturally in Tanzania[104] and that the invention relates to such plants belonging to the African group of ornamental *impatiens,*[105] the company claims all trailing growth habit crosses of *impatiens usambarensis* and *impatiens walleriana* as its intellectual property including all plants,[106] sexually or asexually produced,[107] their means of reproduction—e.g. seeds,[108] ovules, embryos, and pollen[109]—and even putting the floral arrangements in hanging baskets or other "ornamental arrangements."[110] Paralleling that of brazzein, it does not appear that a specific traditional community, organization, or government within East Africa has claimed the use of *impatiens usambarensis* as their intellectual property or specifically accused Syngenta of misappropriation. However, Maurizio Dioli does argue that knowing the scientific name of the plant used by Syngenta to create a commercial hybrid enabled Usambara communities to assert their rights to royalties, but Dioli does not disclose who, how, or when these assertions were made.[111]

Syngenta does not disclose the manner by which it obtained *impatiens usambarensis* or that the plant originated in East Africa.[112] In fact, Syngenta classifies *impatiens usambarensis*, the source of its claimed invention, Spellbound, as insignificant: "*I. usambarensis* is a rather robust, up to 2 m tall, upright growing plant which is native of the Usambara Mountains in Tanzania. *I. usambarensis* has no commercial significance."[113] Syngenta admits the hybrids are "naturally occurring," but claims the "crosses of cultivated plants generally do not yield viable seeds."[114] Though Syngenta discloses the procedure for crossing the plants: "In a preferred embodiment of the invention the naturally occurring interspecific hybrid *I.*

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103 U.S. Pat. No. 2010/0313287A1 ("A method of introgressing a trailing growth habit into a plant of the species Impatiens walleriana comprising the steps of…").

104 Tanya Wyatt, *Invisible Pillaging: The Hidden Harm of Corporate Biopiracy*, in Invisible Crimes and Social Harms 161, 166-8. (2014).

105 U.S. Pat. No. 7,807,905 ("The instant invention relates to an Impatiens plant having a trailing growth habit during its vegetative and generative growth phase. The invention particularly relates to such plants belonging to the African group of ornamental Impatiens. The invention further relates to pollen, seed and sexual as well as asexual progeny of such plants, to methods for obtaining Impatiens plants with a trailing growth habit, to methods for propagating said plants and to uses of said plants").

106 *See id.* ("The Impatiens plant obtained by growing the seed of claim 1").

107 *See id.* ("The invention further relates to pollen, seed and sexual as well as asexual progeny of such plants, to methods for obtaining Impatiens plants with a trailing growth habit, to methods for propagating said plants and to uses of said plants").

108 *See id.* ("A seed of Impatiens line JN215, wherein a representative sample of seed was deposited under deposit number NCIMB 41210").

109 *See id.* ("Pollen, ovule or embryo of the plant according to claim 2").

110 *See id.* ("A specific embodiment of the invention is the use of a plant according to the invention for creating an ornamental arrangement in a hanging basket").

111 Maurizio Dioli, *How to Combine Responsible Species Description, Biodiversity Protection, and the Activities of Amateur Botanists*, 84 CACTUS AND SUCCULENT J. 233, 235-7 (2012).

112 McGown, *supra* note 100 at 23.

113 U.S. Pat. No. 7,807,905.

114 *Id.*

usambarensis x *I. walleriana* is crossed with *I. walleriana* and sexual progeny of the F1 plants resulting from said cross are obtained by self-pollination,"[115] Syngenta fails to make the connection that since both parent plants are found as natural fauna in East Africa and are able to self-pollinate, the resulting hybrids are a product of nature. Indeed the crosses occur naturally in the Usambara Mountains, albeit rarely.

Syngenta instead proclaims that "after many years of research" it has produced a variety of impatiens that "can achieve, at maturity, trails of 70cm masses of large flowers throughout the summer until the first frost."[116] A Syngenta representative revealed that the company obtained the seeds from *impatiens usambarensis* in 1982 from the Royal Botanic Gardens in Edinburgh, which had cultivated the seeds from "a wild collection from Tanzania."[117] Furthermore, the company admitted Syngenta paid nothing for the seeds: "We got them in 1990 before the international convention came into force. In any case our paperwork shows that when we received the seeds, nobody knew exactly which country they came from."[118]

Spellbound offers a great deal of commercial potential where, just in the U.S., impatiens represented the fourth largest annual ornamentals market in 2004, worth $148 million. In the UK, retail prices for Spellbound range from £2-£10 each.[119] The Spellbound variety of impatiens also is lucrative on the global scale, already sold in Canada, France, Germany, and Italy. [120] Syngenta, itself, has provided much commercial anticipation with television, radio, and newspaper advertising as well as its own mascot—a blonde doll named Lizzie the Spellbound Fairy.[121] Syngenta even sent some of its customers on free trips to Disney World, promoting the magical element of their Spellbound plant variety.[122] Though the magic occurs naturally in the Usambaras—a pocket of endemic biodiversity rising above the surrounding dry landscape—the trailing growth habit indicative of the hybrid is highly sought after by gardeners and general consumers.[123] Despite the popularity of *impatiens walleriana*, the upright nature prevented its use in hanging baskets, which Syngenta sought to change.[124]

Syngenta, while making a profit on Spellbound, has not shared any benefit with the local communities of Tanzania who housed the trailing hybrid of impatiens as a part of their traditional knowledge and genetic

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115 *Id.*

116 U.N. EDUC., SCI., AND CULTURAL ORG., INTERNATIONAL CONFERENCE ON BIOETHICS CONFERENCE PROCEEDINGS at 50 (2009) (available at http://unesdoc.unesco.org/images/0018/001841/184159e.pdf).

117 Barnett, *supra* note 21.

118 *Id.*

119 McGown, *supra* note 100 at 23-4.

120 *Id.*

121 *Id.*

122 *Id.*

123 *Id.*

124 Barnett, *supra* note 21.

resources.[125] While no benefit sharing agreements have been developed with the country of origin, the Convention on Biological Diversity notes: "it is important to recognize that wild material is seldom 'plucked' out of the wild and introduced, but rather is accompanied by a long process of research and development—more especially where new products are involved." [126] However, ActionAid has a contrasting opinion, asserting: "This appears to be a classic case of biopiracy…Here we have a large multinational taking out a patent on a plant that grows naturally in a part of Africa. The Tanzania communities will not receive one penny."[127]

Regarding the types of misappropriation, this case study appears to fall squarely within the realm of ineligible and naturally-occurring subject matter. Whereas the researchers studying brazzein eventually engaged in a process that might have constituted an inventive step and resulted in a material, perhaps, markedly different than that which was found in nature; here, it is very clear that hybrids claimed by Syngenta are unaltered plants. Thus, the patent system again seems to fail insofar as it granted a patent that should not have been allowed under the requirements of patentability. This seems especially clear since this case does not even involve isolation of a nucleotide sequence from the surrounding DNA, but merely plucking a plant from the ground and isolating it from its surrounding landscape. As with brazzein, even if the traditional groups managed to write down their knowledge and even if this case occurred post-AIA such that public use that occurred outside the U.S. was recognized as a patent-defeating element, thereby precluding Syngenta from obtaining a patent, overall, the plant is not patentable general and even the traditional communities would not be able to assert an exclusive property right. Furthermore, though the patent system might not offer a remedy for the misappropriation, morally it might seem that Syngenta should acquire prior informed consent or access and benefit sharing with the traditional communities. However, without a specific group claiming the plants and asserting misappropriation, it is difficult to determine that misappropriation exists.

IV. CASE STUDY III: *COMBRETUM MICRANTHUM*

Home to the dry regions of Western Africa and in particular Senegal, *combretum micranthum* or kinkéliba is a familiar plant harvested for use in tea and medicine.[128] The plant is well-known among traditional

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[125] U.N. Educ., Sci., and Cultural Org., *supra* note 116 at 50.

[126] ASIA-PACIFIC ECON. COOPERATION, SEMINAR ON GENETIC RESOURCES AND PROTECTION OF TRADITIONAL KNOWLEDGE ACCESS AND BENEFIT-SHARING IN PRACTICE: TRENDS IN PARTNERSHIPS ACROSS SECTORS 18 (2008) (available at http://mddb.apec.org/Documents/2008/IPEG/SEM2/08_ipeg_sem2_015.pdf).

[127] Barnett, *supra* note 21.

[128] Edward Hammond, Biopiracy Continues: A Compilation of Some Recent Cases, Third World Network 1, 10 (2013) (available at http://www.twn.my/title2/biotk/misc/Biopiracy%20Compilation_10%20Dec2012.doc).

groups of West Africa for its use in food and pharmacopeia, [129] and widely regarded for a myriad of purposes ranging from tea, to treating fevers, to assisting in weight loss, to managing diabetes.[130] Rutgers University holds one U.S. utility patent,[131] one Canadian patent,[132] and one patent granted by the E.P.O.[133] claiming several chemicals isolated from kinkéliba leaves that have potential use as anti-diabetic agents.[134] Rutgers also holds a pending U.S. patent application[135] claiming the extracted compounds medicinal uses in the treatment of hepatitis C virus, which causes persistent liver infections and affects an estimated 170-200 million people worldwide.[136] Rutgers proclaims, "Scientists have developed a proprietary method of extracting and purifying a novel type of piperidine flavan alkaloids from the leaves of Combretum micranthum (kinkéliba) and a procedure for the preparation of total piperidine flavan alkaloids (TPFA) that possess anti-diabetic properties."[137] Paralleling that of the previous two case studies, it does not appear that a specific traditional community, organization, or government within West Africa claimed the use of *combretum micranthum* as their intellectual property or specifically accused Rutgers of misappropriation.

While Rutgers concedes much of the plant's role in the traditional knowledge of Senegal communities, Rutgers asserts the application to diabetes is novel and subject to patentability.[138] Rutgers acknowledges, "Kinkéliba is a highly regarded medicinal plant in Africa, with roots, bark, fruit and leaves being used…[i]n its native Sub-Saharan Africa, the fresh and brewed leaves of kinkéliba have a long established history as being safe multi-functional agents that are consumed regularly for a broad range of health, prophylactic, curative, and anti-disease benefits."[139] Furthermore, Rutgers recognizes, "*Combretum* is the largest genus with 350 spp. and is widely used in traditional African medicine." [140] Additionally:

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[129] WORLD INTELLECTUAL PROPERTY ORGANIZATION, ASSEMBLIES OF MEMBER STATES OF WIPO GENERAL REPORT 1, 79 (2015) (http://www.wipo.int/edocs/mdocs/govbody/en/a_54/a_54_13.doc).

[130] Hammond, *supra* note 128 at 11.

[131] U.S. Pat. No. 8,642,769.

[132] Can. Pat. No. 2798509.

[133] Eur. Pat. No. 2566326.

[134] U.S. Pat. No. 8,642,769 ("A piperidine-flavan alkaloid compound of formula…" and "11. A pharmaceutical composition derived from a species of the kinkéliba (*Combretum micranthum*) family, the composition comprising at least one piperidine-flavan alkaloid compound of formula…").

[135] U.S. Pat. No. 2013/0302279.

[136] *Id.* ("The present invention relates to a novel use of any one of the naturally occurring plants, mushrooms, plant and mushroom extracts, and specific polyphenols or alkaloids that exhibit properties as HCV NS5B polymerase inhibitors.")

[137] Rutgers University, *Anti-Diabetic Agents from Leaves of Combretum Micranthum Rutgers University*, (last visited Apr. 6, 2017) (available at http://techfinder.rutgers.edu/tech/Anti-Diabetic_Agents_from_Leaves_of_Combretum_micranthum_(Kinkeliba)).

[138] Hammond, *supra* note 128 at 11.

[139] Rutgers University, *supra* note 137.

[140] U.S. Pat. No. 8,642,769.

> *Combretum micranthum* is an ethnomedicinal plant widely used in West Africa to treat many diseases. In traditional medicine, kinkéliba is used for the treatment of wounds and sores, guinea worm infestations, diuretic and digestion [1, 3-5]. In the fresh form, the leaves are used to reduce fevers, especially malaria fever [3, 4, 6] and as anti-inflammatory agent [7]. The bark of C. micranthum has high antioxidant capacity and antibacterial activity, and this is directly related to its high content of polyphenolic content [8]. It is reported that kinkéliba branches are used in local handicraft and are an important material for building material for stools, beds, tool handles, etc. [9]. A tea, made from steeping the leaves in boiling water, is a traditional tonic drink in tropical savannah countries such as Senegal, Mali and Burkina Faso and it is believed to be a general aid to weight loss and has detoxifying properties and 'healthy benefits.'[141]

However, despite all the knowledge and use of kinkéliba by traditional groups of West Africa, Rutgers argues "there is no specific information confirming any application nor any studies documenting its validity and/or underlying reason for its purported uses" and that the compound "has not been systematically studied to determine its origin at a molecular or chemical constituent level."[142] Thus, Rutgers' purported invention "represents such an effort to fulfill the foregoing need based on the discovery that kinkéliba tea possesses an interesting anti-diabetic effect, which could be a combination of glucose-lowering and weight loss effects when the tea is used in a traditional manner."[143] Rutgers' invention, at least in part, intends to validate uses of the compound already known in traditional medicine.

The remaining intent behind the invention purports to exploit new bioactive compounds for development as new therapeutic agents for the treatment of diabetes.[144] In a novel regard, Rutgers declares, "Our scientists have identified and isolated specific compounds from kinkéliba leaves that result in a significant glucose-lowering functionality and can be administered in efficacious dosages as a dietary supplement or food additive."[145] Rutgers cites animal studies involving the isolated compounds of *Combretum micranthum*, which demonstrate "decreased fasting plasma glucose levels, increased glucose tolerance, lower plasma insulin levels", decreased liver expression of a gene indicating antidiabetic activity, and anti-

141 *Id*.

142 *Id*.

143 U.S. Patent No. 8,642,769 ("In another aspect the present invention relates to validation of some use of the plants in traditional medicine").

144 U.S. Patent No. 8,642,769 ("In another aspect the present invention sought to identify the structures of the novel bioactive compounds. In another aspect the present invention sought to exploit these new compounds for the development of new therapeutic agents for treatment of diabetes and/or other diseases or disorders").

145 Rutgers University, *supra* note 137.

inflammatory action.[146] To be sure, these findings suggest vast medicinal implications and commercial application for treatment of "diabetes, metabolic disorders, [and] weight loss."[147] Rutgers also lists several advantages to using kinkéliba including that it has been well documented as a as a safe medical use, has an established safety profile, is a readily available source, is rich in antioxidants, and has distinct attributes and functionality as compared to other common teas.[148] The claim of kinkéliba as a readily available source is particularly troubling since it seems to suggest continued access and taking of the plant from the natural landscape home to the traditional communities. This not only ensures continued misappropriation of the original genetic resource, but could compromise biodiversity in the area. It would seem much of the advantages stem from having a long history of use as traditional knowledge with the indigenous communities to that region.

However, it is this trait which theoretically precludes Rutgers from asserting an intellectual property right. Indigenous groups have long been aware and have utilized kinkéliba as a treatment for diabetes prior to Rutgers' patent application. Edward Hammond, in his publication on biopiracy, highlights one such example of indigenous use of kinkéliba preceding the patent application filed by Rutgers:

> For instance, in 2006, an African study on use of traditional remedies for diabetes was published in Diabetes & Metabolism. The Guinean researchers surveyed 397 diabetes patients at Conakry University Hospital, of whom 131 (33%) said they used traditional treatments. Asked to identify the plants they used, they collectively identified 31 species. Of these, kinkéliba was the third most frequently cited plant, used by 19% of the respondents. This indicates that use of kinkéliba in Guinea to treat diabetes not only exists, but is also commonly known.[149]

Rutgers dismisses potential concern for misappropriation of the genetic resource by hollowly stating its claims to intellectual property are "distinct from validating traditional uses and applications of medicinal plants which would overlap with Traditional Knowledge (TK) related issues."[150] At the same time, in light of this use by traditional groups, Rutgers does have a benefit-sharing plan. However, in this plan, Rutgers only *asks* that commercial companies licensing the University patents share benefits, but does not disclose its own intention to share profits with the indigenous peoples of the region: "As [Rutgers] does not commercialize products, but rather licenses the rights to commercialize an invention to a private sector

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146 *Id.*
147 *Id.*
148 *Id.*
149 Hammond, *supra* note 128 at 11.
150 *Id*. at 12.

company, [Rutgers] requests that the private sector company must be committed to adhering to a benefit sharing policy based upon the commercialization of a patent, invention or discovery."[151] Thus, as Hammond argues, Rutgers' benefit-sharing policy is essentially meaningless, lacking implementation and workability.[152] Furthermore, the policy "falls short of any reasonable interpretation of compliance of either the Convention on Biological Diversity or its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits".[153]

Regarding types of misappropriation, here, there are similar concerns regarding potential ineligible and naturally-occurring subject matter and public use outside the U.S. being irrelevant pre-AIA. However, this case study of kinkéliba also demonstrates a failure of the patent system to account for available printed publications, which should have defeated Rutgers's patent claim to the use of kinkéliba for treatment of diabetes. Unfortunately, this is another instance of the patent system not working as the statutes dictate and thus, in the case that proper novelty and nonobviousness requirements were applied, the University as well as the traditional communities utilizing the medicinal qualities of kinkéliba would be precluded from claiming exclusive property rights. Additionally, without a conceivable property right given to the traditional groups and without any specific group claiming misappropriation, the case does not seem to fall into any definition of misappropriation, which requires the improper use of another's property presumably when the victim claims a wrongful taking.

V. RECOMMENDATIONS

Importantly, the first recommendations would be to take steps to ensure the patent system worked correctly such that the requirements of eligible subject matter, novelty, and nonobviousness were properly applied to applications and resulted in the denial of patent grants for material that is naturally occurring, had been in public use, and had been published. Furthermore, it is crucial that the patent system is not inherently discriminatory against indigenous populations outside of the U.S. The passing of the AIA helped reverse the institutional bias by expanding public use as a patent-defeating element even if it occurred outside the U.S. and by not relying solely on international printed publications when traditional knowledge is rarely written. Such precautions will ensure the patent system does not *harm* the traditional groups by enabling misappropriation through granted patents to universities and corporations outside of the indigenous

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151 Rutgers University, *Agreement on Benefit Sharing Policy Related to African and International Inventions,*(last visited Apr 17, 2017) (available at http://www.pricklyresearch.com/webdump/Rutgers_Africa/Agreement%20on%20Benefit%20Sharing%20Policy%20Recommended%20by%20NUANPP%20at%20Rutgers%20Related%20to%20African%20or%20International%20Inventions.pdf).

152 Hammond, *supra* note 128 at 13.

153 *Id.* at 10.

populations. However, if such material is unpatentable by other entities, the material will also be unpatentable by the traditional communities as well. Thus, the patent system must be transformed in such a way as to *protect* the traditional knowledge and genetic resources of indigenous groups. Not only must wrongful patents to other entities be defeated, but for the traditional communities, patents must be enabled. Furthermore, simple procedures such as required disclosure of sources, mechanisms to spread awareness, written and searchable libraries of traditional knowledge, acknowledgement of property rights, prior informed consent, and access and benefit sharing agreements would help safeguard the knowledge and prevent wrongful misappropriation.

Maurizio Dioli, in his journal article *How to combine responsible species description, biodiversity protection, and the activities of amateur botanists*, argues it was the revelation of the scientific name—*impatiens usambarensis*—which enabled the indigenous communities to assert their rights to the royalties.[154] Masked behind the commercial name "Spellbound," the alleged misappropriation is unknown not only to consumers buying the products, but to the very victims of biopiracy. Dioli further emphasizes: "Undescribed species are therefore of significant advantage for large bio-engineering firms because they allow exploitation of a specific substance produced by or genetic trait of a plant, claiming it to be the work of their own research or to be of unknown identity and origin."[155] Additionally, unknown sourcing prevents indigenous communities from receiving future royalties and from asserting property rights in litigation proceedings without "*corpus delicti"* or proof of crime.[156]

Regarding a potential solution to such a predicament, Dioli suggests botanical knowledge and identification of scientific species are crucial for documenting the chain of research.[157] Not only does this hold corporations and researchers accountable for the plants acquired and studied, but it furthermore, allows indigenous communities to recognize their genetic resources and assert a property right. At the same time, indigenous groups often are unaware of the scientific name for a species of plant as they are regarding a corporation's commercial trademark. To this end, Dioli argues it is amateur botanists—free to travel to remote locations off-limits to official botanists—that "are the only practical tool available that could help the official botanical institutions of such countries to rapidly and inexpensively increase their botanical knowledge and simultaneously limit bio-piracy."[158] As an example, since 2000, amateur botanists have discovered well over 60% of all new *aloe taxa*.[159]

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154 Dioli, *supra* note 111 at 235-237.
155 *Id.* at 237.
156 *Id.*
157 *Id.*
158 *Id.*
159 *Id.*

At an Assembly of the Member States of WIPO, the Delegation of Guinea spoke of their immense repertoire of traditional knowledge, genetic resources, and folklore, which must "be promoted within a regulated framework in order to enable access thereto and share the benefits arising from related exploitation."[160] Both the Access and Benefit-Sharing Capacity Development Initiative and the Nagoya Protocol to the Convention on Biological Diversity vocalize a similar concern, recognizing the misappropriation suffered by Guinea.[161] Traditional knowledge, which once held a vital share of the national economy in their corresponding countries, had been "endangered" due to a lack of regulatory and intellectual property protection.[162] The Delegation offered *combretum micranthum* as exemplary of the international property system failing—where local communities had utilized for generations the genetic resource for the very same medicinal properties that Rutgers sought to commercially exploit.[163] The Delegation contemplated:

> If that trend continued unchecked, indigenous communities in Guinea would be gradually stripped of their property without recompense, hence the urgent need to define appropriate international mechanisms allowing for the rational exploitation of those resources for the benefit of the communities which owned them, with a view to contributing to poverty reduction and alleviating rural exodus.[164]

To reconcile this problem, the Delegation suggests a 2015 convention on traditional knowledge, genetic resources, and folklore like that held in the United Republic of Tanzania in 2013.[165] The Tanzanian conference "contributed significantly to increasing awareness among senior decision makers of the need to invest in intangible assets for the development of a knowledge based economy."[166] Similarly, the Delegation hopes to adopt a binding international legal instrument for protection of its intellectual property.[167]

As Kofi Busia notes, in his journal article titled *Overview of Traditional Medicine in the Economic Community of West African Member States*, traditional medicine is the main source of healthcare for the indigenous peoples of West Africa with estimates that between 70-80% of West

[160] World Intellectual Property Organization, *supra* note 129 at 79.
[161] *Id.*
[162] *Id.*
[163] *Id.*
[164] *Id.*
[165] *Id.*
[166] *Id.*
[167] *Id.*

Africans use traditional medicine to manage disease. [168] Unfortunately, insufficient political and legal infrastructure and regulation perpetuates health disparities among the native populations. Busia highlights that intellectual property, as a relatively new concept, "delays the development of frameworks for the protection of traditional knowledge and access to biodiversity in majority of Member States."[169] Busia outlines the results of a situational analysis conducted by the West African Health Organization intended to assess the level of development of traditional medicine in the Member States:

> In the sub-Region, Cote d'Ivoire carried out a survey among [traditional medicine practitioners] that has recorded more than 2,000 traditionally used plants. In 2007, Ghana developed a national policy on protection of [intellectual property rights] which was reviewed in 2008. In 2006 and 2007 Nigeria developed national legislation and Bill on [intellectual property rights] whereas Mali organized a series of national and sub-Regional workshops for the protection of traditional medical knowledge... Ghana developed a database on Ethnobotanical Floristic Studies and Traditional Medicine Pharmacopoeia in 2000 and Senegal developed a database of THPs in 2003. Benin and Mali reported to have established in 1999 and 2004 databases related to 7,500 THPs and [traditional medical knowledge] and access to biological resources respectively. [170]

It is the dissemination of information, the accessibility and consolidation, as well as the legal protection and regulatory frameworks needed to safeguard traditional knowledge and genetic resources. Busia explains, this is an area "where WAHO will collaborate with WHO…to support member states develop national policies and regulatory frameworks, carry out national inventories of medicinal plants to ensure that indigenous knowledge is used correctly and continuously over generations, obtain patents protection, [and] establish databases…to document formulations used in traditional medicine to prevent misappropriation."[171] Taking inspiration from India, documenting an indigenous groups' traditional knowledge and genetic resources in a forum accessible internationally is the first step to preventing misappropriation insofar as it serves as an assertion to their property right. However, databases put the responsibility of the disclosure on the indigenous groups who are often less technologically and financially capable and may prevent later patentability due to the disclosure and documented public use. Furthermore, as the three case studies demonstrate, corporations and universities are quick to not only devalue the original source of their research

[168] Kofi Busia & Ozzy Kasilo, *Overview of Traditional Medicine in ECOWAS Member States*, The African Health Monitor World Health Organization for Africa, Aug. 2010 (available at http://ahm.afro.who.int/issue13/HTML/article2.html).
[169] *Id.*
[170] *Id.*
[171] *Id.*

even in the rare instances where sourcing is disclosed, but additionally, the entities tend to express entitlement to the study of the natural materials. While the corporations and universities clearly recognize at least some use by the traditional groups, which would indicate the sweetness, trailing qualities, or medicinal properties of plants a part of their traditional knowledge and genetic resources, the corporations and universities do not suggest that these materials and uses are thereby the property of the traditional groups. Not only does this mentality prevent external entities from seeking prior informed consent by the traditional communities for use of their property, but it also seems to eliminate any perceived responsibility to engage in benefit-sharing with the original holders of the traditional knowledge and genetic resources. Acknowledgement of any property right by the indigenous groups, whether or not it may be patentable, is a large step in preventing misappropriation.

Finally, aside from failure of the patent system to: properly apply limitations of ineligible subject matter to naturally-occurring materials, recognize public use outside of the U.S. pre-AIA as a means to defeat novelty, thoroughly search printed publications of traditional groups and studies outside of the U.S. where such use and knowledge is disclosed by the written word—these shortcomings merely render the material unpatentable to both universities and corporations as well as the traditional communities themselves. In order to prevent misappropriation on a larger scale and allow traditional groups to have their own claims to their property, elements of traditional knowledge and genetic resources should not only be patent defeating, but patent enabling for those who have knowledge of and are engaged in its use. The conclusions of these case studies should not be that no property right exists and the information is already within the public realm, but rather that the knowledge and use belongs to the traditional groups that harbor the materials and knowledge as a part of their identity.

CONCLUSION

Under Lewinski's definition, none of the case studies discussed would fall within the parameters of misappropriation; all three revolve around natural and unpatentable material incapable of misappropriation and not deserving of an intellectual property right, which requires novelty, nonobviousness, and something markedly different than that occurring in nature. This distinction parallels the rights acknowledged by the U.S. patent system.

While all the case studies highlight a failure of the patent system to correctly apply its requirements and instead resulted in the granting of patents over unpatentable material, overall, the patent system would not recognize any property right over the information: *impatiens usambarensis*, falls squarely within the definition of ineligible subject matter as naturally-occurring plant; *combretum micranthum* should have been unpatentable due to a disclosure of its anti-diabetic use in a printed publication; *pentadiplandra brazzeana* perhaps with the most research, development, and isolation might fall within the parameters of a property right if looking at the

changes to the amino acid sequence, but might even surpass misappropriation if deemed novel and markedly different from that occurring in nature such that the traditional communities would still be unable to lay meaningful claim to the invention. Since misappropriation entails the improper use of information belonging to another and the indigenous communities lack any property right, these case studies would not fall into definitions of misappropriation that are not sensitive to the particularities of traditional knowledge. Even if the patent system had not misapplied its requirements and had not granted patents to third parties, the corporations and universities would have still been able to commercialize the information without a property right by the traditional communities. While such exploitation of the knowledge might not be prohibited under patent law and might not constitute certain understandings of misappropriation, as Lewinski acknowledged, the taking is still wrongful and immoral—it is theft.

Though the patent system has made significant changes to infrastructure so as to not entail inherent discrimination against indigenous populations outside the U.S., the system still has many shortcomings. Fortunately, with the passing of the AIA, public use outside of the U.S. is now recognized under patent law and serves as novelty-defeating element. This allows indigenous groups to invalidate patents granted to third parties without having to rely on printed publications when traditional knowledge is predominately oral. However, such public use over the course of centuries—as is required by the definition of traditional knowledge—also defeats the indigenous groups' claim to a property right over the information. Furthermore, traditional knowledge is rarely manipulated to produce something markedly different from that found in nature; as ineligible subject matter, the patent system precludes the patentability of nearly all genetic resources. Additionally, once a third party transforms the information into something patentable, something markedly different from that occurring in nature, the property right belongs only to the researchers. Without any property right recognized by the indigenous groups, use of the information is not misappropriation under patent law and there need not be licensing agreements or other compensation.

Thus, the patent system must not only help to defeat patents which claim elements of traditional knowledge, but the patent system must be reorganized so as to enable the patentability of traditional knowledge by the traditional groups despite the limitations of public use, printed publications, novelty, nonobviousness, and ineligible subject matter. Morality dictates that traditional groups have some avenue to either claim the property right or have some combination of benefit sharing, informed consent, or recognition of their contribution.