

7-1-2015

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Recommended Citation

Ryan D. Levy and Spencer Green, *Pharmaceuticals and Biopiracy: How the AIA May Inadvertently Reduce the Misappropriation of Traditional Medicine*, 23 U. Miami Bus. L. Rev. 401 (2014)

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Pharmaceuticals and Biopiracy: How the America Invents Act May Reduce the Misappropriation of Traditional Medicine

Ryan Levy* and Spencer Green**

For decades, Eastern traditional medicine has been misappropriated by others who claim it as their own and attempt to obtain patent protection for it. As long this practice has existed, the international community has pushed back against it. Several countries and international bodies have created databases of traditional knowledge, hoping to preclude the issuance of patents on that knowledge. Other countries, like Thailand, have extended intellectual property protection to the traditional knowledge stakeholders themselves. However, a recent change to U.S. patent law may have the unintended consequence of helping resolve the issue of biopiracy.

Prior to the passage of the America Invents Act, a foreign invention could only serve as prior art to U.S. patents if the foreign invention itself was patented or if it was described in a printed publication. Because much traditional knowledge was never recorded, U.S. law did not consider it to be prior art. This allowed corporations to obtain patent protection for traditional medicine, even though indigenous peoples had been using it for centuries.

The America Invents Act, however, eliminated the requirement that a public use occur “in this country” to constitute prior art. As a result, public use of traditional knowledge anywhere in the world renders it prior art to all subsequent U.S. patent applications. This article analyzes how this dramatic shift in the

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scope of available prior art affects the patent strategies of companies and provides different remedies to traditional knowledge stakeholders.

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I. INTRODUCTION

In 1995, two Indian immigrants at the University of Mississippi Medical Center obtained a U.S. patent entitled “Use of turmeric in wound healing” (the “Turmeric Patent”).¹ The patent acknowledged that turmeric had been used “in India as a traditional medicine for the treatment of various sprains and inflammatory conditions.”² However, this patent purported to put turmeric to a new use based on “experimental

¹ U.S. Patent No. 5,401,504 col. 1 l. 37-39 (filed Dec. 28, 1993); *see also* Prithwiraj Choudhury & Tarun Khanna, *Bio-Piracy or Prospering Together? Fuzzy Set and Qualitative Analysis of Herbal Patenting by Firms* 24 (Harvard Bus. Sch., Working Paper 14-081, 2014) [hereinafter Choudhury & Khanna, *Bio-Piracy*], available at http://www.hbs.edu/faculty/Publication%20Files/14-081_6cfa4f81-d5cb-44f6-9a0c-1fe7c91f61ef.pdf.

² ‘504 Patent., *supra* note 1 col. 1 l. 37-39 (filed Dec. 28, 1993).

evidence.”³ The inventors claimed a “method of promoting healing of a wound in a patient, which consists essentially of administering a wound-healing agent consisting of an effective amount of turmeric powder to said patient.”⁴ The problem is that turmeric had, in fact, been used in wound healing for millennia.⁵

Because of the widespread use of turmeric for wound healing, particularly in India, this patent had the potential to have significant effects. Indians living in America could infringe the patent by using this home remedy and Indian companies would be subject to liability if they exported goods to the United States that used the remedy.⁶ In response, the Indian Council of Scientific and Industrial Research (CSIR) sought reexamination of the patent.⁷ It demonstrated, through ancient Sanskrit texts and academic publications, that the patented method lacked novelty.⁸ The United States Patent and Trademark Office (USPTO) issued a Reexamination Certificate in 1998 cancelling every claim of the patent.⁹ Thus, with respect to the Turmeric Patent, the patent system corrected itself. A bad patent was issued on traditional medicine, adverse parties utilized the available administrative procedures, and the USPTO cancelled the claims.

However, due to geographic limitations on prior art, patents based on or claiming traditional knowledge are not always invalidated. Many traditional knowledge stakeholders do not have the benefit of printed publications embodying their knowledge. Under pre-America Invents Act (AIA) law, patents on that knowledge remain valid.¹⁰ Moreover, the mere grant of a patent on a method for using turmeric in wound healing brought about significant social harm, despite its later invalidation. A remedy that the Indian people had utilized for thousands of years was now *owned* by the University of Mississippi Medical Center.¹¹ The Indian people were outraged that a patent had been granted on

³ *Id.*

⁴ *Id.* col. 3 l. 4-7.

⁵ Choudhury & Khanna, *Bio-Piracy*, supra note 1, at 23.

⁶ See 35 U.S.C. § 271(a) (2012) (providing that “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”).

⁷ TOBIAS KIENE, THE LEGAL PROTECTION OF TRADITIONAL KNOWLEDGE IN THE PHARMACEUTICAL FIELD 17 (2011).

⁸ *Id.*; ‘504 Patent., supra note 1 Reexamination Certificate (issued Apr. 21, 1998).

⁹ *Id.*

¹⁰ Patents issued before March 18, 2013 are governed by the Patent Act, rather than by the America Invents Act. *Medisim Ltd. v. BestMed, LLC*, 758 F.3d 1352, 1354 n.1 (Fed. Cir. 2014). Under the Patent Act, foreign inventions were not regarded as prior art unless they were “patented or described in a printed publication.” 35 U.S.C. § 102(a) (2006).

¹¹ Choudhury & Khanna, *Bio-Piracy*, supra note 1, at 23.

“something that has been the collective wisdom of a people for centuries.”¹²

The USPTO has received tens of thousands of patent applications relating to traditional uses of Indian and Chinese herbal remedies.¹³ However, a recent change in U.S. patent law will affect whether such patents continue to be granted, whether they are enforced, and how the patent claims are drafted. Prior to the passage of the America Invents Act (AIA),¹⁴ foreign public use, sale, or knowledge of these traditional remedies was not regarded as “prior art” to U.S. patents.¹⁵ As a result, even if traditional remedies had been used for thousands of years outside the United States, they could not be used to invalidate a U.S. patent unless they were published.¹⁶ The AIA changed that by eliminating the “in this country” limitation to those types of prior art.¹⁷

This article addresses how the America Invents Act will affect the patent strategies of pharmaceutical companies seeking U.S. patents based on traditional medicine. It also discusses whether the AIA has created a new avenue through which traditional knowledge stakeholders may invalidate patents based on traditional medicine. Part I provides background on the history of geographic limitations to prior art under U.S. patent law. Part II discusses biopiracy, how it affects traditional knowledge stakeholders, and how Western firms have responded to charges that they expropriated traditional knowledge. Part III discusses the various measures that governmental entities and international bodies have taken in order to combat biopiracy. Part IV identifies and discusses the particular changes to the U.S. patent system under the AIA that may affect pharmaceutical companies’ ability to obtain protection for inventions based on traditional knowledge.

¹² *Id.* at 26.

¹³ Prithwiraj Choudhury & Tarun Khanna, *Codifying Prior Art and Patenting: Natural Experiment of Herbal Patent Prior Art Adoption at the EPO and USPTO* 15 (Harvard Bus. Sch., Working Paper No. 14-079, 2014) [hereinafter Choudhury & Khanna, *Prior Art*], available at http://www.hbs.edu/faculty/Publication%20Files/14-079_9f881e56-002c-4603-a778-5a698184c827.pdf.

¹⁴ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified at 35 U.S.C. §§ 1–390 (2011)) [hereinafter America Invents Act or AIA].

¹⁵ 35 U.S.C. § 102(a) (2006).

¹⁶ *Id.*

¹⁷ See 35 U.S.C. § 102(a) (2012).

II. A BRIEF HISTORY OF GEOGRAPHIC LIMITATIONS ON PRIOR ART

Geographic limitations on prior art have been a long-standing feature of U.S. patent law following passage of the Patent Act of 1836.¹⁸ Before the advent of airplanes and the Internet, which carry products and information rapidly across the world, geographic limitations on prior art enabled American “inventors”—who sought to commercially exploit foreign inventions in this country—to receive patents on that technology, despite not having invented it.¹⁹ Nonetheless, these patents were arguably consistent with the Constitution’s Intellectual Property Clause, which grants Congress the power “to promote the progress of science and the useful arts.”²⁰ These entrepreneurs introduced to the United States new technology that would otherwise be unavailable, thereby promoting the progress of science in this country.²¹ In the modern world, however, geographic limitations on prior art are no longer required to ensure that new technology is made available across seas. Advances in how people trade information globally also reduce the burden of examining patent applications in light of all prior art, wherever it may be found.

The U.S. patent system seeks to do more than simply encourage the introduction of new products into American markets. There are costs associated with granting monopolies to patent holders and removing information from the public domain. To properly balance those costs against the social and economic benefits of the introduction of new technology, the Framers understood the Intellectual Property Clause to embody certain limitations. Patents may not be granted to non-inventors, and inventions in the public domain may not be removed from the public domain.²² Modern patent law reflects those understandings by granting patent protection only to inventors who have “invent[ed] or discover[ed]” technologies²³ that are useful,²⁴ novel,²⁵ non-obvious,²⁶

¹⁸ Patent Act of 1836, ch. 357, 5 Stat. 117, Sec. 7 (1836). (providing that a patent shall only issue if the invention “had [not] been invented or discovered by any other person in this country prior to the alleged invention or discovery thereof by the applicant . . . or described in any printed publication in this or any foreign country.”).

¹⁹ If, however, each of the claim limitations was embodied in a printed publication, a U.S. patent would be denied. *See id.*

²⁰ U.S. CONST. art I, § 8, cl. 8.

²¹ *See* Margo A. Bagley, *Patently Unconstitutional*, 87 MINN. L. REV. 679, 684 (2003) (arguing that geographic limitations on prior art are unconstitutional because they permit the patenting of inventions in the public domain).

²² *Id.*

²³ 35 U.S.C. § 101 (2012).

²⁴ *Id.*

²⁵ 35 U.S.C. § 102 (2012).

and enabled.²⁷ By eliminating geographic restrictions on prior art, the America Invents Act has broadened the scope of prior art in a way that may prevent future patents on traditional knowledge. In doing so, it will help ensure that the U.S. patent system does not prejudice the public or harm traditional knowledge stakeholders.

III. THE PROBLEM OF BIOPIRACY

“Biopiracy” describes circumstances in which “developed countries use biotechnology patents to expropriate the biological [or] genetic heritage of less developed countries.”²⁸ Accusations of biopiracy typically involve the theft of traditional knowledge that is otherwise held by indigenous people.²⁹ The textbook example involves valuable uses of local plants or animals within a particular indigenous community. Corporations may become aware of these uses, then seek to patent and commercialize that knowledge for their own gain.³⁰ Companies often attempt to patent rights in indigenous knowledge or the products and methods derived from that knowledge.³¹ As such, the patentee may receive significant financial compensation for their patent rights, while leaving the indigenous community with no gain.

A. *Biopiracy in the Pharmaceutical Industry*

Due to the medicinal nature of much traditional knowledge, pharmaceutical companies are among the most common perpetrators of biopiracy. Consumers often have allergies to drugs or simply desire to avoid the side effects associated with such medicines.³² As a result, the market for pharmaceutical products based on traditional knowledge is growing, and pharmaceutical companies seek to take advantage.³³ These companies frequently become aware of traditional remedies for common medical problems, then commercialize and patent some variation of

²⁶ 35 U.S.C. § 103 (2012).

²⁷ 35 U.S.C. § 112 (2012).

²⁸ Baruch A. Brody, *Traditional Knowledge and Intellectual Property*, 20 KENNEDY INST. OF ETHICS J. 231 (2010).

²⁹ *Id.*

³⁰ *Id.* at 232.

³¹ Peter Drahos, *Indigenous Knowledge, Intellectual Property and Biopiracy*, 22 EUR. INTELL. PROP. REV. 245 (2000).

³² J. Maheswari, *Patenting Indian Medicinal Plants and Products*, 4 INDIAN J. SCIENCE & TECH. 298, 300 (2011).

³³ See Chika A. Ezeanya, *Contending Issues of Intellectual Property Rights Protection and Indigenous Knowledge of Pharmacology in Africa South of the Sahara*, 6 J. PAN AFR. STUD. 24, 29 (2013).

those remedies for their own benefit. The USPTO receives literally thousands of patent applications that relate in some way to traditional knowledge.³⁴

Below are a few of the most well-known instances of pharmaceutical biopiracy. These examples reflect the complexity of the issues, the varying cultural perceptions on the commercialization of traditional medicine, and the limits of the patent system's ability to resolve these conflicts.

i. Kwao krua

The Thai herb kwao krua had been used for over 100 years and its medicinal uses had been documented in Thai writings as early as 1931.³⁵ More recently, however, certain plant-produced hormones have been discovered in the plant.³⁶ These hormones have been used in modern medicine to enhance male sexual performance, enlarge and firm breasts, and firm the skin.³⁷ A company based in South Korea holds a U.S. patent on an extract from kwao krua for some of these purposes.³⁸

The concern for the Thai people is that the steps for extraction disclosed in the patent do not differ from the methods that practitioners of traditional medicine have used for nearly a century.³⁹ Unfortunately, publications discussing this practice were not considered as prior art to the U.S. patent.⁴⁰ Threats of legal action have disrupted local producers of kwao krua and the plant has been harvested quickly for commercial purposes, which does not allow time for the plant's regrowth.⁴¹ Due to the grant of intellectual property protection in this traditionally used plant and its extract, indigenous peoples' customs relating to the plant's ordinary production and use have been disturbed.⁴²

ii. Hoodia

The San people of the Kalahari Desert in South Africa have been using Hoodia, a local plant, as an appetite-suppressant since ancient

³⁴ Choudhury & Khanna, *Prior Art*, *supra* note 1, at 15.

³⁵ DANIEL F. ROBINSON, CONFRONTING BIOPIRACY: CHALLENGES, CASES AND INTERNATIONAL DEBATES 55 (2010).

³⁶ *Id.*

³⁷ *Id.*

³⁸ U.S. Patent No. 6,673,377 (filed Aug. 28, 2000).

³⁹ ROBINSON, *supra* note 35, at 55.

⁴⁰ *See id.*

⁴¹ *Id.* at 59.

⁴² *See id.*

times.⁴³ Suppressing their appetite by consuming Hoodia allowed them to engage in longer hunting expeditions and carry fewer supplies, increasing the productivity of the hunts.⁴⁴ Pursuant to an international treaty, the Convention on Biodiversity (CBD), the San people have received royalty payments for the sales of drugs containing Hoodia by multinational pharmaceutical companies.⁴⁵ However, serious questions remain about the fairness and propriety of such profit-sharing agreements.⁴⁶ Moreover, the United States is not a party to the CBD, so profits gained through the exploitation of the U.S. patents on Hoodia result in no benefit to the San people.⁴⁷ Thus, numerous patents that incorporate the San people's indigenous knowledge of Hoodia have been granted in both the United States and Europe, with little or no benefit from the sales of products protected by those patents to the San people.

iii. Madagascar rosy periwinkle

The commercialization of the healing properties of the Madagascar rosy periwinkle is another example of a pharmaceutical company reaping the rewards of Eastern medicinal plants. The plant had been long used in traditional medicine by the indigenous communities of Madagascar, among others.⁴⁸ Inspired by the use of this plant in traditional medicine, Eli Lilly & Company⁴⁹ isolated two extracts that give the plant its healing properties: vinblastine and vincristine.⁵⁰ Those extracts are now used in drugs the company markets for the treatment of cancer.⁵¹ Eli Lilly receives around \$100 million each year from these drugs, but the indigenous peoples of Madagascar do not share in the profits.⁵²

⁴³ Fritz Dolder, *Traditional Knowledge and Patenting: The Experience of the Neemfungicide and the Hoodia Cases*, 26 BIOTECHNOLOGY L. REP. 583, 587 (2007).

⁴⁴ *Id.*

⁴⁵ Saskia Vermeulen, *Contextualizing 'Fair' and 'Equitable': The San's Reflections on the Hoodia Benefit-Sharing Agreement*, 12 LOC. ENV'T 423, 428 (2007).

⁴⁶ See generally *id.* (discussing the San people's perceptions of the fairness of the Hoodia Benefit Sharing Agreement); see *infra* Part I.C.

⁴⁷ *List of Parties*, CONVENTION ON BIOLOGICAL DIVERSITY, <http://www.cbd.int/information/parties.shtml> (last visited Mar. 29, 2015) (listing the parties to the CBD).

⁴⁸ Michael Hassemer, *Genetic Resources*, in INDIGENOUS HERITAGE AND INTELLECTUAL PROPERTY, 151, 168 (ed. Silke von Lewinski 2004).

⁴⁹ Eli Lilly & Company has approximately 39,000 employees worldwide, markets products in 125 countries, and had net sales of over \$23 billion in 2013. *Key Facts*, ELI LILLY & CO., <http://www.lilly.com/about/key-facts/Pages/key-facts.aspx> (last visited Mar. 29, 2015).

⁵⁰ Hassemer, *supra* note 48 at 168.

⁵¹ *Id.*

⁵² *Id.*

Despite the perceived misappropriation of Malagasy culture, Malagasy healers never used the rosy periwinkle for the uses to which Eli Lilly is putting it. They used it primarily in treating diabetes.⁵³ Because Eli Lilly used the plant to produce new compounds, for new medicinal uses, they may be able to obtain patent protection even under the America Invents Act.⁵⁴ However, the expanded scope of prior art under the new Section 102 will not be without impact on Eli Lilly's ability to patent these sorts of inventions. Consideration of the Malagasy use may force companies like Eli Lilly to narrow their patent claims, directing them only at the new innovation. Accordingly, even where prior art may not entirely bar new patents, its consideration may affect the reach of new patent claims.

B. *Negative Consequences of Biopiracy*

The greatest criticism of the expropriation of indigenous medical knowledge by for-profit companies is that it is simply unfair.⁵⁵ These critics argue that pharmaceutical companies are permitted to realize millions of dollars in sales from some traditional remedies with little or no payment to the actual indigenous knowledge holders.⁵⁶ Critics of the Turmeric Patent leaned heavily on the perceived unfairness of patenting a remedy that had been used to heal wounds in India for hundreds of years.⁵⁷ It was also an issue in Eli Lilly's use of the Madagascar rosy periwinkle, which generates \$100 million in sales for the company annually.⁵⁸ Ironically, the patenting of traditional knowledge may cause the sale of products embodying traditional knowledge to the traditional knowledge holders at monopoly prices.⁵⁹ Such sales, however, would

⁵³ *Id.*

⁵⁴ The AIA would consider medicinal uses of the plant that were known to the public to be prior art. 35 U.S.C. § 102 (2012).

⁵⁵ See e.g., Lester I. Yano, *Protection of the Ethnobiological Knowledge of Indigenous Peoples*, 41 UCLA L. REV. 443, 445 (arguing that permitting drug developers to profit off indigenous knowledge without compensating indigenous practitioners "is unfair and hypocritical."); David Conforto, J. ENVTL. L. & LITIG. 357, 365 (acknowledging the perceived unfairness of geographic restrictions on prior art). *But see generally* Jim Chen, 37 MCGEORGE L. REV. 1 (arguing that biopiracy is only a perceived problem, not an actual problem, and that the "biopiracy narrative" is false).

⁵⁶ See e.g., Yano, *supra* note 55.

⁵⁷ See Choudhury & Khanna, *Bio-Piracy*, *supra* note 1, at 25-26.

⁵⁸ Hassemer, *supra* note 48, at 168.

⁵⁹ Martin Khor, *IPRs, Biodiversity, and the Theft of Indigenous Knowledge*, 28 INTERDISC. SCI. REVIEWS 7, 8 (2003).

have to occur within the United States to obtain the benefit of the monopoly a U.S. patent would provide.⁶⁰

The most egregious examples of the exploitation of traditional knowledge can occur when individuals and companies are prevented from utilizing knowledge that they had been using for centuries. An American patent does not preclude exportation of the patented invention to foreign countries, but it does prevent importation of products embodying the claimed invention to the U.S.⁶¹ Due to the threat of legal action, many such entities in countries that serve as the source of traditional knowledge have been precluded from using that knowledge.⁶² For instance, despite a history of the use of kwao krua by the indigenous people of Thailand, threats of legal action have disrupted local production of the herb.⁶³

In India, individuals and companies had been using extract from neem trees for centuries to repel insects and bacterial diseases.⁶⁴ Once a patent on a variation of this extract was granted to W.R. Grace & Co., the company sought to force Indian companies producing neem-based products to license its technology.⁶⁵ Local companies feared that this patent would preclude them from exporting goods to the U.S. market and would drive up the price of neem seeds.⁶⁶ By depriving Indian companies of their ability to export certain neem-based products to the world's largest economy, the neem patent deprived Indian people of their ability to exploit their indigenous knowledge within the world economy.⁶⁷ This led to a worldwide campaign to cancel the patent.⁶⁸ By allowing for patent protection on inventions derived from traditional knowledge, the

⁶⁰ See 35 U.S.C. § 271(a) (2012) (limiting patent infringement to infringements “within the United States” or importation “into the United States.”)

⁶¹ *Id.*

⁶² This use preclusion extends to personal uses only to the extent that patented methods are being used inside the United States. The primary impact is with respect to commercialization of traditional knowledge because products embodying the patents would be shipped to the U.S.

⁶³ ROBINSON, *supra* note 35, at 59.

⁶⁴ Itsuki Shimbo et al., *Patent Protection and Access to Genetic Resources*, 26 NATURE BIOTECHNOLOGY 645, 645 (2008).

⁶⁵ *Id.*

⁶⁶ Shayana Kadidal, *Subject-Matter Imperialism? Biodiversity, Foreign Prior Art and the Neem Patent Controversy*, 37 IDEA 371, 376-77 (1997). *But see* Emily Marden, *The Neem Tree Patent: International Conflict Over the Commodification of Life*, 22 B.C. INT'L & COMP. L. REV. 279, 285 (articulating that effects of the neem patent on Indian farmers are unclear and that the patent may help Indian farmers because W.R. Grace processes its seeds in India).

⁶⁷ Jonathan B. Warner, *Using Global Themes to Reframe the Bioprospecting Debate*, 13 IND. J. GLOBAL LEGAL STUD. 645, 651-652 (2006).

⁶⁸ Shimbo, *supra* note 64.

use of the traditional knowledge itself amongst indigenous people may be eroded.⁶⁹

Not only is the patenting of these traditional remedies unfair to the indigenous knowledge holders, it is also unfair to the public, who grants the “inventors” of these remedies the right to exclude others.⁷⁰ The grant of patent protection to inventors is based on a *quid pro quo* with society. Inventors agree to disclose their discoveries to the public through the patent’s specification and, in return, the public grants them an exclusive right to exploit those discoveries for a limited time. In this way, both the inventor and the public benefit from the protections that patent law provides. This paradigm breaks down, however, when the discovery to be disclosed is already known to the public. If the invention has been used publicly for thousands of years, there is no benefit to the public in granting the patentee the exclusive right to exploit it. When well-known traditional knowledge is patented, there can be no *quid pro quo*, and the public does not get the benefit of its bargain.

C. *Royalties Paid to Indigenous Knowledge Stakeholders*

In response to the backlash that companies face due to their misappropriation of traditional knowledge and pursuant to the Nagoya Protocol under the Convention on Biological Diversity (CBD), which requires benefit-sharing agreements with indigenous people, companies will occasionally pay royalties to indigenous knowledge stakeholders. While this scenario is fairer than it would be if no royalties were paid, it is accompanied by its own unique set of problems. Conceptions of fairness are culturally defined and indigenous peoples are often concerned with social, environmental, and spiritual concerns that are not accounted for by most profit-sharing agreements.⁷¹ Therefore, while the payment of royalties may be perceived as “fair” by the pharmaceutical companies that are exploiting traditional knowledge, such arrangements may not be perceived as fair by the indigenous people themselves.⁷²

The CBD sought to resolve a fundamental dispute regarding the ownership of genetic resources by declaring that states’ sovereign rights over natural resources extend to genetic resources.⁷³ This model requires a “government-to-government approach,” even though private actors

⁶⁹ Khor, *supra* note 59, at 8.

⁷⁰ *See supra* Part I.

⁷¹ Vermeylen, *supra* note 45, at 425-26.

⁷² *See id.*

⁷³ Matthias Buck & Claire Hamilton, *The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*, 20 REV. EUR. COMMUNITY & INT’L L. 47, 47 (2011).

ordinarily conduct transactions in genetic resources and traditional knowledge.⁷⁴ The CBD has raised the level of protection for sovereign rights to genetic resources, but has not augmented the level of protection for the traditional knowledge holders themselves.⁷⁵ Moreover, because each member government has interpreted the provisions of the CBD differently, standards governing the obligations of the parties and the fairness of benefit-sharing agreements vary dramatically.⁷⁶

A prime example of how these benefit-sharing agreements under the CBD fail to compensate most traditional knowledge holders is in the treatment of the San people of Southern Africa.⁷⁷ The San's traditional knowledge relating to consuming Hoodia as an appetite suppressant is the subject of a benefit-sharing agreement through South Africa's Council for Scientific and Industrial Research (CSIR).⁷⁸ Through the benefit sharing agreement, the CSIR has permitted companies such as Pfizer and Unilever to commercially exploit Hoodia.⁷⁹ The San never granted prior informed consent for the commercialization of their traditional knowledge.⁸⁰ Thus, the San began in a disadvantaged bargaining position and did not obtain an equitable benefit-sharing agreement. In fact, the vast majority of San people had never even heard of the benefit-sharing agreement.⁸¹ Under the benefit-sharing agreement, the CSIR was to pay the San peoples eight percent of the "milestone payments" made by licensees during the drug's clinical development.⁸² After the drug's development was completed, the San would receive a six percent royalty on the marketing of the drug.⁸³

To make matters worse, the very existence of a benefit-sharing agreement disturbed long-standing San values regarding egalitarianism.⁸⁴ To facilitate the negotiation of a benefit-sharing agreement, the San were pressured to elect leaders, thus changing the nature of group-decision making that had previously prevailed in San culture.⁸⁵ Most of the San

⁷⁴ *Id.* at 48.

⁷⁵ *Id.* at 56.

⁷⁶ *Id.* at 55-56.

⁷⁷ *See supra* Part II.A.iii.

⁷⁸ Vermeulen, *supra* note 45, at 427.

⁷⁹ World Health Organization, *Protecting Traditional Knowledge: the San and Hoodia*, 84 BULL. OF THE WHO 345 (2006). *See also* Ezeanya, *supra* note 33, at 30 (discussing the sublicensing of Hoodia to Pfizer).

⁸⁰ Vermeulen, *supra* note 45, at 427.

⁸¹ *Id.* at 429.

⁸² Leon Marshall, *Africa's Bushmen May Get Rich from Diet-Drug Secret*, Nat'l Geographic News (Apr. 16, 2003), available at http://news.nationalgeographic.com/news/2003/04/0416_030416_san1.html.

⁸³ *Id.*

⁸⁴ Vermeulen, *supra* note 45, at 431.

⁸⁵ *Id.*

people were not consulted regarding the benefit-sharing agreement and cared less about monetary compensation than they did about non-monetary benefits, such as access to education and land.⁸⁶ They also expressed concerns that the money would be wasted and misused by public officials.⁸⁷ These people's interests were not represented. Not only did the majority of the San people *not* gain any tangible benefit from the benefit-sharing agreement, the benefits that were gained came at the expense of their traditional mode of decision-making.

IV. PUSHBACK FROM THE INTERNATIONAL COMMUNITY

Unsurprisingly, the perceived unfairness of allowing companies to expropriate traditional knowledge for their own commercial gain has been met with strong international resistance. Countries with vast traditional knowledge have sought to protect that knowledge either by publishing it in English or by granting property rights in that knowledge to the indigenous people. Additionally, international treaties, such as the CBD, have sought to address the problem by providing some protections for indigenous knowledge stakeholders. This Part explores the two major ways that countries rich in traditional knowledge seek to prevent the misappropriation of that traditional knowledge, as well as suggestions that have been made by the World Intellectual Property Organization (WIPO).

A. *Traditional knowledge databases*

The most obvious and effective means of preventing the grant of patents based on traditional knowledge is to ensure that the traditional knowledge will be considered as prior art. At the most basic level, if those opposing the issuance of a patent can demonstrate that the “invention” is already known to the public, the invention is ineligible for patent protection either because it is not novel or because the invention's improvement over the prior art would have been obvious to person of ordinary skill in the art.⁸⁸ One of the reasons that patents based on traditional knowledge have been granted under U.S. law—despite their obviousness or lack of novelty—is that foreign “public use” did not qualify as prior art.⁸⁹ Foreign prior art must have been published in English to be considered by the USPTO and federal courts.⁹⁰ In response,

⁸⁶ *Id.* at 430.

⁸⁷ *Id.*

⁸⁸ *See* 35 U.S.C. §§ 102–103 (2012).

⁸⁹ 35 U.S.C. § 102 (2006).

⁹⁰ 37 C.F.R. § 3.26 (2014).

various governments and international organizations have created traditional knowledge databases that serve as a published written record of the traditional knowledge.

The most inclusive of these databases is WIPO's "Centralized Access to Search and Examination" (CASE) database. While not specifically directed at traditional knowledge, CASE facilitates communication amongst patent offices worldwide.⁹¹ This allows patent examiners to view patent applications in other participating jurisdictions and share their own examination results.⁹² For instance, if a patent application based on medical uses of indigenous Australian plants is filed in the United Kingdom's Intellectual Property Office, the UK patent examiner can access the database to determine whether any similar applications had been filed with IP Australia.⁹³ In this way, the scope of available prior art and the accessibility of that prior art are both improved.

WIPO's PATENTSCOPE Search System provides patent attorneys, inventors, and researchers a free and accessible way to search patent documents from over thirty participating countries and organizations.⁹⁴ In addition to WIPO's databases, China, India, the Republic of Korea, Bioversity International, Peru, the Philippines, the Inuit of Nunavik, and the Dene in Canada have all established databases directed specifically towards traditional knowledge.⁹⁵ These databases consist of English language documents that have recorded traditional knowledge.

These traditional knowledge databases have had a measurable impact on the subject matter of patents that have been granted. For instance, following the EPO's adoption of India's traditional knowledge database, new patents based on herbal formulations were ninety-six percent more likely to be a mix of herbal and synthetic formulations.⁹⁶ This trend is likely the result of patent applicants seeking to avoid the prior art. Synthetic formulations are more likely to be novel than herbal ones. Therefore, if a patent applicant can improve upon traditional herbal

⁹¹ WIPO CASE—Centralized Access to Search and Examination, WIPO, <http://www.wipo.int/case/en/> (last visited Mar. 29, 2015).

⁹² *Id.*

⁹³ IP Australia is Australia's administrative body that "administers intellectual property rights and legislation relating to patents, trademarks, designs and plant breeder's rights." IP AUSTRALIA, *About Us*, <http://www.ipaustralia.gov.au/about-us/> (last updated Mar. 20, 2015).

⁹⁴ WIPO, PUB. NO. L43/8E, PATENTSCOPE SEARCH: THE USER'S GUIDE 1-2 (2013), available at http://www.wipo.int/edocs/pubdocs/en/patents/434/wipo_pub_l434_08.pdf.

⁹⁵ WIPO, PROGRESS REPORT ON THE STATUS OF TRADITIONAL KNOWLEDGE AS PRIOR ART 33 (2001) [hereinafter WIPO, PROGRESS REPORT], available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_2/wipo_grtkf_ic_2_6.pdf.

⁹⁶ Choudhury & Khanna, *Prior Art*, *supra* note 1, at 30.

remedies by introducing some synthetic component, that applicant is more likely to avoid the novelty and non-obviousness issues that are associated with deriving an invention from traditional knowledge. By forcing patent applicants to consider a broader range of prior art, traditional knowledge databases have spurred innovation. Not only do databases preclude patents based on existing traditional knowledge, they force inventors to improve upon traditional remedies through additional innovation.

B. Sui Generis: Granting property rights in traditional knowledge

While establishing traditional knowledge databases is focused on preventing third parties from obtaining intellectual property protection for traditional knowledge, some countries have affirmatively provided for intellectual property protection to traditional knowledge stakeholders. This sort of system, which creates new categories of intellectual property rights for traditional knowledge, has been characterized as a *sui generis* regime.⁹⁷ Thailand, for example, has extended intellectual property protection to traditional Thai medicine through the Act on Protection and Promotion of Traditional Thai Medicinal Intelligence.⁹⁸ Under this statute, the rights holder has the sole right to produce, distribute, or improve upon the medicine.⁹⁹ Anyone seeking to use Thai traditional medicine for commercial benefits is required to apply to “obtain benefits” and must pay fees for their use of the traditional medicine.¹⁰⁰

While this law will likely deter or prevent some of the types of misappropriation described in this article, it opens the door to domestic misappropriation of traditional medicine and alienates the indigenous people themselves. Indigenous Thai peoples, such as the Karen, hold views regarding traditional medicines, and the herbs that create them, that are fundamentally incompatible with intellectual property protection.¹⁰¹ The Karen people reject the viewpoint that natural

⁹⁷ See J. Janewa OseiTutu, *A Sui Generis Regime for Traditional Knowledge: The Cultural Divide in Intellectual Property Law*, 15 MARQ. INTELL. PROP. L. REV. 147, 150–51 (noting that legislatures in countries that possess vast traditional knowledge may seek to create *sui generis* rights to protect that traditional knowledge).

⁹⁸ Act on Promotion and Protection of Traditional Thai Medicinal Intelligence, B.E. 2542 (1999) (Thai.), *translation available at* http://www.wipo.int/wipolex/en/text.jsp?file_id=179713.

⁹⁹ *Id.* § 34.

¹⁰⁰ *Id.* § 19.

¹⁰¹ This article takes no position on whether such views are preferable to well established patent regimes, such as that in the United States. For more information on the cultural differences relating to intellectual property protection, see generally OseiTutu *supra* note 97.

resources, such as herbs, should be considered resources at all.¹⁰² They believe that plants and animals have spirits and should be respected like humans are.¹⁰³ Thus, medicines should not be hoarded and should not be traded for a profit.¹⁰⁴ If medicinal herbs are abused through commercial exploitation, practitioners of traditional Karen medicine would perceive this as an abuse of the herbs' spirit and internalize that harm.¹⁰⁵

Ironically, by refusing to grant patents on such knowledge, the U.S. patent system may be more consistent with traditional Karen values than the Thai system. The Act on Protection and Promotion of Traditional Thai Medicinal Intelligence may enable local practitioners of traditional medicine to claim a monopoly on the use of certain remedies. The law's requirement that users of traditional medicine pay royalties is inconsistent with the Karen people's beliefs relating to the use of these herbs. From the Karen's perspective, commercialization and the grant of exclusive rights over the medicinal use of certain herbs would be an abuse of the herb's spirit and would cause a spiritual injury to indigenous medical practitioners themselves.¹⁰⁶ Rather than protecting traditional knowledge stakeholders, as they purport to do, these types of laws can be adverse to the interests of indigenous peoples if they do not carefully consider local religion and customs. By contrast, the AIA would not allow a patent on this traditional knowledge and consequently would preserve the spiritual integrity of Karen medicine.

C. *WIPO Progress Report on the Status of Traditional Knowledge as Prior Art*

Although WIPO has not undertaken to attempt to solve the issue of biopiracy, it has made suggestions to member states that seek to resolve whether traditional knowledge should qualify as prior art.¹⁰⁷ WIPO's Progress Report on the Status of Traditional Knowledge as Prior Art identifies two particular problems in establishing traditional knowledge as prior art.¹⁰⁸ First, the definition of prior art in many jurisdictions excludes most traditional knowledge.¹⁰⁹ For example, U.S. patent law effectively excluded most traditional knowledge as prior art before the

¹⁰² Daniel F. Robinson, *Legal Geographies of Intellectual Property, 'Traditional' Knowledge and Biodiversity: Experiencing Conventions, Laws, Customary Law, and Karma in Thailand*, 51 GEOGRAPHICAL RES. 375, 379 (2013).

¹⁰³ *Id.*

¹⁰⁴ *Id.* at 378 & 380.

¹⁰⁵ *See id.* at 379.

¹⁰⁶ *Id.*

¹⁰⁷ WIPO, PROGRESS REPORT, *supra* note 95, at 21–23.

¹⁰⁸ *Id.* at 14.

¹⁰⁹ *Id.*

enactment of the America Invents Act.¹¹⁰ Second, on a practical level, traditional knowledge may be difficult for patent examiners to discover.¹¹¹ Traditional knowledge, even when it is recorded in databases or other writings, is often not arranged in an orderly manner.¹¹² It is difficult to search, which diminishes its value to patent examiners looking for prior art.

To address these issues, WIPO suggests that IP offices and traditional knowledge documentation initiatives “build bridges” to enable more effective communication.¹¹³ To facilitate this bridge-building, WIPO suggests that member nations begin by establishing more efficient classification systems.¹¹⁴ While the International Patent Classification (IPC) system is extremely effective and is used on ninety-five percent of all patent documents, a more detailed system is needed for traditional medicine.¹¹⁵ One such example is India’s Traditional Knowledge Resource Classification (TKRC) system.¹¹⁶ A more detailed and organized system for arranging traditional knowledge would allow people to find the relevant prior art that they are looking for.

V. CHANGES IN THE SCOPE OF “PRIOR ART”

Some of the most widely debated reforms under the America Invents Act are contained in the new Section 102. One of the primary goals of the America Invents Act was to bring the U.S. patent system in line with the rest of the world.¹¹⁷ Section 102 served as one of the primary vehicles for accomplishing that goal, in part, by eliminating geographic restrictions on public use, sale, or knowledge as prior art.¹¹⁸ This dramatic shift in the scope of prior art to the U.S. patent system is likely to have unforeseen consequences in the context of biopiracy and the protection of traditional knowledge. Public knowledge, sale, or use of traditional knowledge outside the United States may now serve as prior

¹¹⁰ See *supra* Part II.

¹¹¹ WIPO, PROGRESS REPORT, *supra* note 95, at 14.

¹¹² *Id.* at 4.

¹¹³ *Id.* at 21.

¹¹⁴ *Id.* at 22.

¹¹⁵ *Id.* at 22-23.

¹¹⁶ *Id.* at 23.

¹¹⁷ Mark Schafer, Note, *How the Leahy-Smith America Invents Act Sought to Harmonize United States Patent Priority with the World, A Comparison with the European Patent Convention*, 12 WASH. U. GLOBAL STUD. L. REV. 807, 807 (2013).

¹¹⁸ The new Section 102 made other major changes to the U.S. patent system to bring it in line with the rest of the world, including, significantly, transitioning to a first-to-file system for determining priority. This article does not address those other changes because they are less significant to the issue of biopiracy than the changing scope of prior art.

art to U.S. patents. Thus, applicants seeking U.S. patent protection based in part upon traditional knowledge may have more difficulty prosecuting and maintaining patents due to the changes to Section 102, which effectively renders most traditional knowledge ineligible for patent protection in the United States.

A. *Substantive changes to U.S. patent law under the America Invents Act*

Under the 1952 Patent Act, a person could not obtain a patent if “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.”¹¹⁹ By the plain language of the statute, the only foreign art that could serve as a bar to a U.S. patent were patents and printed publications. U.S. courts applied this requirement strictly, rejecting challenges to the novelty or non-obviousness of U.S. patents based on a foreign public use of the invention.¹²⁰ In the context of biopiracy, this rule presented a significant challenge to those attempting to protect the interests of traditional knowledge stakeholders. Traditional knowledge is rarely published, so it rarely served as prior art to U.S. patents.

The disputes surrounding the patentability of compounds derived from the neem tree embodied this very problem. In the early 1990s, American researchers found a way to improve upon a traditional Indian pesticide derived from the neem tree by making it suitable for long-term storage.¹²¹ Although this improvement, arguably, would have been obvious to Indian farmers, under Section 102 foreign knowledge could only serve as a bar to a U.S. patent if it was published prior to the “invention” by the U.S. applicant.¹²² In 1995, a coalition of 225 groups and over 100,000 individual farmers filed a petition with the USPTO seeking to invalidate the patent.¹²³ Although a similar patent¹²⁴ was invalidated by the European Patent Office (EPO),¹²⁵ the U.S. patent

¹¹⁹ 35 U.S.C. § 102(a) (2006).

¹²⁰ See, e.g., *E. I. du Pont de Nemours & Co. v. Berkley & Co.*, 620 F.2d 1247, 1265 (8th Cir. 1980) (holding that evidence of an invention’s use in France was inadmissible to show the obviousness of an American patent).

¹²¹ See U.S. Patent No. 5,124,349 (filed Oct. 31, 1990).

¹²² Emily Marden, *The Neem Tree Patent: International Conflict over the Commodification of Life*, 22 B.C. INT’L & COMP. L. REV. 279, 284 (1999).

¹²³ *Id.* at 286.

¹²⁴ Eur. Patent No. 0436257 (filed Dec. 20, 1990) (issued Sept. 14, 1994) (revoked Mar. 8, 2005), available at <https://register.epo.org/application?number=EP90250319&lng=en&tab=legal>.

¹²⁵ *Id.*

remains valid because pre-AIA law continues to apply to patents granted before the AIA took effect.¹²⁶ These differing results are likely explained by the difference between the EPO, which is permitted to consider foreign knowledge, and the old Section 102, which excluded such knowledge if it was not published.

Since the passage of the America Invents Act, however, the scope of prior art under the U.S. patent system has been brought in line with the European system. The new Section 102 removed the “in this country” limitation that used to apply to the “public use” and “on sale” bars. It also added the phrase “available to the public” to “clarify the broad scope of relevant prior art.”¹²⁷ U.S. law no longer requires publication for foreign prior art to block a U.S. patent. Prior art for patents issued under the American Invents Act “will no longer have any geographic limitations.”¹²⁸

The changes to Section 102 also included the addition of “or otherwise available to the public” as a broad category of prior art. While Congress indicated that the purpose of the phrase “available to the public” was “to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it must be publically available,” there was no guidance as to what type of prior art was covered by this phrase and not the remainder of Section 102(a)(1).¹²⁹ One interesting postulation as to the different prior art covered by “or otherwise available to the public” is that the clause could include orally transmitted information that had yet to be physically recorded.¹³⁰ Though appearing inadvertent, this change to Section 102 by the AIA may further assist in the use of traditional knowledge as prior art.

In hypothetically considering the neem-related patents as being subject to the post-AIA patent rules, testimony regarding the hundreds of years of public use of the neem tree as a pesticide, orally transmitted information regarding its effectiveness, and foreign public use of the neem tree would all be admissible to show that the American “invention” lacks novelty or is obvious.¹³¹

¹²⁶ Philip Schuler, *Biopiracy and Commercialization of Ethnobotanical Knowledge*, in POOR PEOPLE'S KNOWLEDGE 159, 162 (J. Michael Finger & Philip Schuler eds. 2004).

¹²⁷ H.R. REP. NO. 112-98, at 42-43 (2011), reprinted in 2011 U.S.C.C.A.N. 67, 72-73.

¹²⁸ *Id.* at 42.

¹²⁹ S. REP. NO. 111-18, at 6 (2009).

¹³⁰ Joshua D. Sarnoff, *Derivation and Prior Art Problems with the New Patent Act*, 2011 PATENTLY-O PAT. L.J. 12, 27 (2011).

¹³¹ The availability of this type of evidence may be determined by the particular proceeding in which the validity of the patent is being determined. See *supra* Part III.B.

B. *Limitations of the administrative process*

Through the increasingly adversarial model of the USPTO's administrative system, the patent system as a whole has a tendency to correct itself. As in the case of the Turmeric Patent, third parties may participate in the administrative process and obtain cancellation of invalid patents.¹³² However, geographic limitations on prior art present a substantial obstacle to the USPTO's ability to perform that function. Moreover, although the new Section 102 drastically expands the scope of available prior art, the practical limitations of the USPTO and the restrictions placed on the administrative system limit the impact these changes will have on the issuance of new patents.

Federal regulations place limits on the availability of particular types of documentation and when those documents may be presented by third parties. Pre-issuance third party submissions are limited to patents, published patent applications, or other printed publications.¹³³ Thus, before the USPTO has issued a patent, third parties may only submit evidence of public use if that use is contained in a printed publication.¹³⁴ In a post-grant review,¹³⁵ third parties may offer evidence of prior public use or sale.¹³⁶ However, a post-grant review may be sought only within nine months of the issuance of the patent.¹³⁷ Following that nine-month period, a third party may initiate an *inter partes* review,¹³⁸ but only patents and printed publications may be considered as prior art.¹³⁹ This leaves a narrow nine-month window after the issuance of the patent in which third parties may submit evidence of public use of the invention to the USPTO.

¹³² See *supra* Part I.

¹³³ 35 U.S.C. § 122(e) (2012).

¹³⁴ See *id.*

¹³⁵ Post-grant review is an administrative proceeding to determine the validity of a recently granted patent.

¹³⁶ See 35 U.S.C. § 321(b) (2012) (permitting third parties to “request to cancel as unpatentable one or more claims of a patent on *any ground* that could be raised under paragraph (2) or (3) or subsection 282(b) (relating to invalidity of the patent or any claim)”) (emphasis added).

¹³⁷ § 321(c).

¹³⁸ *Inter partes* review is an administrative proceeding through which a third party can challenge the validity of one or more patent claims. It is available after the time period for a post grant review has lapsed.

¹³⁹ 35 U.S.C. § 311(b) (2012) (“A petitioner in an *inter partes* review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under Section 102 or 103 and only on the basis of prior art consisting of patents or printed publications”).

C. Federal Court Practice

Due to the short period in which a patent may be challenged at the administrative level based on public use or sale, the courts are likely to be the forum in which the AIA's changes to Section 102 will invalidate new patents. Courts will consider both oral and documentary evidence in determining whether there has been a public use or sale of products embodying the patent. For instance, in *Trans-World Mfg. Corp. v. Al Nyman & Sons, Inc.*, the Federal Circuit upheld the sufficiency of evidence supporting a jury verdict of obviousness based on both oral and documentary evidence.¹⁴⁰ The jury relied both on photographs of the prior art and the testimony of one of the inventors himself.¹⁴¹

While documentary evidence may be difficult to come by in cases involving traditional medicine, oral evidence is still available. At trial, cross-examination of inventors may reveal the obviousness or lack of novelty of the claimed invention, as it did in *Trans-World Mfg. Corp.* Additionally, those with personal knowledge of how the traditional medicine was used may testify as to those facts. The fact that this type of evidence is available at trial, but is largely unavailable at the administrative level, means that the new Section 102 will have a greater impact in patent litigation than in the issuance of new patents.

However, the trend toward accelerated litigation schedules for patent cases may make the timely acquisition of such evidence difficult. In one of the more aggressive district courts, the Western District of Tennessee, invalidity and unenforceability contentions are due within ninety days after an answer is filed.¹⁴² In the Eastern District of Texas, a popular forum for patent disputes, invalidity and unenforceability contentions are due within thirty-five days of the initial case management conference.¹⁴³

As of the drafting of this article, there has yet to be a patent invalidated by prior art that only became applicable by the removal of the geographic limitation from Section 102. Because the post-AIA version of Section 102 applies to patents issued from applications having, at any time, at least one claim with an effective filing date on or after March 16, 2013, there should soon be an increase in attention to the broader availability of prior art.

Despite the challenges of putting evidence of foreign public use before the USPTO and the difficulties faced in litigation, it is axiomatic that a patent is essentially useless if it will be invalidated upon litigation.

¹⁴⁰ *Trans-World Mfg. Corp. v. Al Nyman & Sons, Inc.*, 750 F.2d 1552, 1559 (Fed. Cir. 1984).

¹⁴¹ *Id.* at 1560.

¹⁴² W.D. Tenn. LPR 3.5 (2014).

¹⁴³ E.D. Tex. P.R. 3-3 (2014).

Therefore, pharmaceutical companies seeking patents relating to traditional knowledge are likely to consider the scope of foreign public knowledge, use, and sale in drafting their patent claims, even if that information will never be presented to the USPTO.

VI. CONCLUSION

After the passage of the America Invents Act, U.S. patent law theoretically should refuse protection to a larger number of “inventions” based on traditional knowledge. However, practical considerations significantly limit the effect that the AIA will have on the patentability of traditional knowledge. The American regulatory system is likely to narrow the practical—as opposed to the statutory—scope of prior art. Even if oral traditions in South Africa may qualify as prior art under the statute, they will not have that effect at the administrative level unless the patent examiner knows of those traditions. Additionally, as demonstrated by pharmaceutical companies’ responses to traditional knowledge databases, these companies are likely to move towards combining remedies derived from traditional knowledge with more synthetic elements, thus avoiding novelty and non-obviousness issues.

When the invention is known to the public before the issuance of a patent, there is no need to encourage innovation or disclosure, so there is no justification for the grant of patent protection. The America Invents Act provides the beginnings of a solution both for this foundational problem of U.S. patent law and for the injustice that can result from the misappropriation of traditional knowledge. It cannot, however, solve this problem entirely.

One solution would be to eliminate some of the evidentiary restrictions in administrative procedures, thereby permitting witness testimony regarding foreign public uses. That could be accomplished by eliminating those restrictions in *inter partes* review or by extending the time period for post-grant review, which contains fewer evidentiary restrictions. However, this change would add to the USPTO’s already considerable workload. It would also change the nature of the proceedings such that they may become full adversarial trials bearing closer resemblance to litigation in the federal courts than administrative proceedings. Individual district courts could also decide to amend litigation schedules through local patent rules in a way that would provide defendants with more time to locate invalidating foreign prior art. Both of these potential solutions would prolong an already lengthy and expensive patent litigation process, which would not serve the

parties, the courts, or the USPTO well. As is often the case, the law cannot provide a perfect solution to this problem.

Due to practical and procedural constraints on the availability of foreign prior art, the impact that the America Invents Act's expansion of the scope of prior art will have remains somewhat unclear. What is clear is that the statute now permits traditional knowledge stakeholders to introduce evidence of foreign public use in their efforts to invalidate controversial patents. This possibility alone may be enough to deter companies from drafting patent claims that cover traditional knowledge, while allowing them to seek protection for their own innovations.