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Appropriation Without Benefit-Sharing: Origin-of-Resource Disclosure Requirements and Enforcement Under TRIPS and the Nagoya Protocol

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Abstract

Since the late twentieth century, there have been many instances of foreign entities appropriating a country's biological resources without sharing with that country the benefits of its patents that are associated with those resources. This appropriation without benefit-sharing (AWBS) has led to calls that patent applicants should disclose the geographical origins of biological resources used in their inventions in order for patent offices to better assess the patentability of these inventions. This Comment investigates whether international law mandates disclosure and whether there can be an effective system to enforce disclosure by focusing on two treaties: the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Nagoya Protocol. The Comment argues that under TRIPS there are two situations that likely trigger mandatory origin-of-resource disclosures and that under the Nagoya Protocol, patent offices may effectively enforce the disclosure requirements to combat AWBS.

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I. INTRODUCTION

The neem tree is a distinctive plant that is tied to the culture and history of India.[1] Throughout the country's history, the people of India have used extracts of the neem tree for many practical purposes, ranging from cleaning teeth to killing insects.[2] In 1959, Western countries were alerted to "the wonders [of the neem tree] . . . when a German entomologist reported that neem trees were spared during a locust swarm that devoured all other foliage."[3]

Around the late twentieth century, a U.S. chemicals corporation, W.R. Grace (Grace) became interested in the neem tree. After experimenting on neem seeds imported from India,[4] Grace isolated azadirachin, an active ingredient responsible for the neem tree's pesticide qualities.[5] In 1990, Grace filed a patent application for a stabilized solution of azadirachtin in the U.S. Patent and Trademark Office (USPTO).[6] On its application, Grace failed to mention that the neem seeds on which it experimented originated in India.[7] As patents generally provide the patentee with a monopoly for a limited period of time, nondisclosure might have delayed potential challenges to its patent. In 1992, the USPTO approved the application.[8]

Although Grace did not pursue a similar patent in India,[9] Grace's U.S patent had adverse economic effects on the South Asian country[10]: "W.R. Grace began processing twenty tons of neem seed per day. As a result, neem seed prices in India skyrocketed from 300 rupees per ton to an average of 3500 rupees per ton."[11]

Grace did not share the economic proceeds of its azadirachtin invention with the people of India.[12] Many believed that Grace should have done so because

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1 *See* Lorna Dwyer, *Biopiracy, Trade, and Sustainable Development,* 19 COLO. J. INT'L ENVTL. L. & POL'Y 219, 226–27 (2008); Emily Marden, *The Neem Tree Patent: International Conflict over the Commodification of Life*, 22 B.C. INT'L & COMP. L. REV. 279, 283 (1999).

2 *See* Marden, *supra* note 1, at 283. *See also* David Conforto*, Traditional and Modern-Day Biopiracy: Redefining the Biopiracy Debate*, 19 J. ENVT. L. & LITIG. 357, 390 (2004).

3 Marden, *supra* note 1, at 283.

4 *See* Grace Issues Statement About Patent for Neem Pesticide, PR NEWSWIRE (Sept. 14, 1995.).

5 *See* Marden, *supra* note 1, at 283.

6 *See* Dwyer, *supra* note 1, at 226–27; Marden, *supra* note 1, at 283–84.

7 *See* U.S. Patent No. 5,124,349 (issued June 23, 1992).

8 *See id.*

9 *See* Marden, *supra* note 1, at 283.

10 *See* Conforto, *supra* note 2, at 390.

11 *Id.*

12 *See* Marden, *supra* note 1, at 287.

they believed that "Indians provided the raw material—an assiduously cultivated understanding of the neem tree's properties—and that therefore they are the rightful beneficiaries of any commercial development."[13]

The case of the neem tree is an example of a foreign entity appropriating another country's biological resources without sharing with that country the benefits of its patents that are associated with those resources. Some commentators have called this phenomenon patent-based biopiracy, which is defined as "[t]he patenting of (often spurious) inventions based on biological resources and/or traditional knowledge that are extracted without adequate authorization and benefit sharing from other (usually developing countries), indigenous or local communities."[14] To avoid the negative connotation of the word "biopiracy," this Comment will call this phenomenon appropriation without benefit sharing or AWBS for a more neutral connotation.

Since the late twentieth century, AWBS has become a common international occurrence.[15] The rise of a lucrative biotechnology industry in countries such as the U.S. has contributed to this phenomenon.[16] The strengthening of IP systems in developed countries, including the U.S, and the expansion of IP protections to biological materials and their derivatives may have also played a role in triggering AWBS.[17] Increasingly, commentators and the international community have argued that in AWBS cases, patent-holders should share the benefits and proceeds of their inventions with the countries providing the biological resources.[18]

However, benefit sharing cannot occur if patent-holders do not disclose the geographical origins of the biological resources that they used for their inventions. In fact, many cases of AWBS have persisted because of an information problem that exists at the patent application stage. On their applications, those engaging in AWBS often do not identify the geographical origins of biological materials. When patent offices approve the applications, these patent-holders could enjoy the fruits of their products for a long period without encountering a challenge. The case of the neem tree fits here. As Grace did not state that its neem tree seeds originated

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13 *See id.* at 287.

14 DANIEL F. ROBINSON, CONFRONTING BIOPIRACY: CHALLENGES, CASES, AND INTERNATIONAL DEBATES 21 (2010).

15 *See id.* at 46–76.

16 *See* Conforto, *supra* note 2, at 358.

17 *See* Dwyer, *supra* note 1, at 227.

18 *See, for example*, Paul Kuruk, *Regulating Access to Traditional Knowledge and Genetic Resources: The Disclosure Requirement as a Strategy to Combat Biopiracy*, 17 SAN DIEGO INT'L L.J. 1 (2015); Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution*, 2 WASH U.J.L. & POL'Y 371, 374–75(2000); Marden, *supra* note 1, at 292–93.

in India in its patent application, a challenge to its patent could not occur immediately.[19] Only after three years was a challenge mounted.[20]

At least two other possible instances of AWBS revolve around nondisclosure: one involving the camu camu plant, between a Japanese cosmetics company and Peru,[21] and another involving Ballia barley, between a Japanese beer company and India.[22] There may be more examples of AWBS involving nondisclosure that the international community has not identified yet.

Disclosure at the patent application stage is essential because it gives prompt notice to those who want to challenge the patent. As inventions have to be "novel" in order to be patentable,[23] disclosure could serve as a way for governments and others to verify the patentability of products.[24] In fact, "[m]andatory disclosure in biotechnological patent applications of any geographical source and indigenous knowledge source would allow countries and communities to review patent applications and file claims to block patents before the grant."[25] By having a voice in patentability, people of countries with high biodiversity could have a property right in the invention, as international treaties have recognized a country's property right in its natural resources.[26]

A disclosure requirement might also facilitate "fair and equitable benefit-sharing."[27] By enforcing such disclosure requirements, patent offices of various nations could block applications of inventors who have not agreed to share the economic and scientific benefits of their products with other countries.[28] Mandatory disclosure of the source of the biological materials on patent

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19 *See* Marden, *supra* note 1, at 286 (showing a challenge occurred three years after the patent was granted)

20 *See id.*

21 *See* Section VII, *infra.*

22 *See* Section VII, *infra.*

23 Agreement on Trade-Related Aspects of Intellectual Property Rights Part II, § 3, art. 27, ¶ 1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS].

24 *See generally* Dwyer, *supra* note 1.

25 Maggie Kohls, *Blackbeard or Albert Schweitzer: Reconciling Biopiracy*, 6 CHI.-KENT J. INTELL. PROP. 108, 132 (2007).

26 *See id.*; Marden, *supra* note 1, at 281 ("Article 15 of the CBD [Convention on Biological Diveristy], for example, recognizes a limited sovereign property right in genetic material found within a nation's boundaries.").

27 *See* Conference of the Parties to the Convention on Biological Biodiversity, Tenth Meeting, Nagoya, Jap., Oct. 18–29, 2010, 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, Oct. 29, 2010, U.N. Doc. UNEP/CBD/COP/DEC/X/1 (Oct. 29., 2010) [hereinafter Nagoya Protocol].

28 *See id.* at art. 17. For further discussion, see Sections VI and V, *infra.*

applications would mean more accountability and make it less likely that companies are able to patent biological inventions without first consulting with the countries from which the biological resources were taken.

The purpose of this Comment is to investigate whether international law mandates disclosure of the geographical origins of biological resources on patent applications and whether such a disclosure requirement could be enforced. Two important treaties that bind many countries and govern IP rights and the usage of biological resources are the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Nagoya Protocol of the Convention on Biological Diversity (Nagoya Protocol). Commentators have argued that the Nagoya Protocol does not require patent applicants to disclose the geographical origins of their biological resources.[29] They have also asserted that TRIPS mandates disclosure only when the "sources of those resources are unique," but they have not elaborated more on this issue.[30]

Because some countries might not believe that TRIPS and/or the Nagoya Protocol adequately protect their natural resources, they have advocated that the WTO amend TRIPS to mandate disclosure in all circumstances.[31] Some nations have taken the initiative to enact their own domestic laws requiring that patent applicants disclose the geographical sources of any biological materials used in their inventions.[32]

In many cases, TRIPS and the Nagoya Protocol may be sufficient to solve the AWBS problem without amendments to international law or the enactment of sweeping national disclosure regulations. There are strong arguments that, under TRIPS, patent applicants must disclose the origins of biological resources on their applications in two circumstances: (1) when "the source of [a] biological resource [is] unique" (under Article 29),[33] and (2) when a quality, characteristic, or reputation of the biological resources that contributed to the development of an invention is "essentially attributable" to a geographic region (under Article 22).[34]

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29 *See* Riccardo Pavoni, *The Nagoya Protocol and WTO Law*, *in* THE 2010 NAGOYA PROTOCOL ON ACCESS AND BENEFIT-SHARING IN PERSPECTIVE 186, 201–204 (Elisa Morgera, Matthais Buck, & Elsa Tsioumani, eds., 2013).

30 Carvalho, *supra* note 18, at 381. *See also* Committee on Trade and Environment, Report of the Meeting Held on 24–25 of November 1997, WTO Doc. WT/CTE/M/16 at ¶ 90 (Dec. 19, 1997) [hereinafter WT/CTE/M/16]

31 *See* Jacques de Werra, *Fighting Against Biopiracy: Does the Obligation to Disclose in Patent Applications Truly Help?*, 42 VAND. J. TRANSNAT'L L. 143, 145–49 (2009).

32 *See generally* Thomas Henninger, *Disclosure Requirements in Patent Law and Related Measures: A Comparative Overview of Existing National and Regional Legislation on Intellectual Property and Biodiversity*, in TRIGGERING THE SYNERGIES BETWEEN INTELLECTUAL PROPERTY RIGHTS AND BIODIVERSITY 293 (Alexander Werth and Susanne Reyes-Knoche eds., 2010), https://perma.cc/68LM-LNGU.

33 Carvalho, *supra* note 18, at 381.

34 *See* TRIPS, *supra* note 23, at art. 22.

Pursuant to Article 17 of the Nagoya Protocol, a country could enact an effective checkpoints system to enforce these minimum disclosure mandates. In fact, had such a system existed—during the neem tree controversy and during the possible AWBS cases involving camu camu and Ballia barley, these cases could have resulted in the disclosure of the origins of the resources and the enactment of benefit-sharing agreements among the providers and users of biological resources.

Section II of the Comment argues that international law should eliminate AWBS. Section III describes the two important international treaties involving IP and biological resources, TRIPS and the Nagoya Protocol. Section IV emphasizes the importance of disclosure in combating AWBS. Section V shows that under TRIPS, Article 29 and Article 22 likely require a patent applicant to indicate the origins of their resources when two conditions are present. Section VI describes a national checkpoints system under the Nagoya Protocol and shows how this system would operate as a mechanism to enforce the required disclosures of TRIPS. Finally, Section VII will demonstrate how this new regime could be applied to the neem tree controversy and the possible AWBS cases of camu camu and Ballia barley.

II. THE CASE AGAINST AWBS

AWBS has its advocates and its critics. Supporters of AWBS have argued that AWBS should be allowed to continue because it contributes to medical and scientific innovation.[35] These advocates underscore the value of AWBS in facilitating the development of medicine, as AWBS can make previously obscure natural resources available for scientific study, which can lead to new cures for diseases.[36] Supporters of AWBS have also asserted that if inventors must compensate the country in which the raw resources were found, then "[p]harmaceutical companies, agribusiness and bio-tech firms would be forced to buy information and germplasm from rights holders and might well encounter refusals to deal."[37]

On the other hand, it is impossible to ignore the fact that AWBS has significant negative externalities.[38] For one, AWBS can result in economic harms.[39] By patenting biological resources or drugs derived from them, companies may prevent those in countries where the resources were found from selling these

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35 *See* Paul J. Heald*, The Rhetoric of Biopiracy*, 11 CARDOZO J. INT'L & COMP. L. 519 (2003).

36 *See id.* at 531 (Explaining that as "four-fifths of all drugs have their basis in natural plant resources . . . a cure for cancer may well be found in the rain forest.").

37 *Id.* at 531–32.

38 *See, for example,* Conforto, *supra* note 2, at 390; Dwyer, *supra* note 1, at 228–29; ROBINSON, *supra* note 14, at 102–05.

39 *See* Dwyer, *supra* note 1, at 228–29; ROBINSON, *supra* note 14, at 102–05.

resources.[40] For example, in the late 1990s, an American company that acquired a patent on yellow Mexican beans stopped trade of yellow beans between the U.S. and Mexico.[41] Similarly, in the pharmaceuticals industry, a company with a patent on drugs derived from a biological resource may also compete in the market of the country where the material is found.[42] Since IP systems create strong market protections for those with patent rights, those committing AWBS can take advantage of those rights to maximize their economic welfare to the detriment of others.

AWBS can have also adverse social and environmental effects.[43] People often feel slighted when a corporation of a foreign country patents products based on their natural resources without obtaining express permission from their local government because they have emotional attachments to certain raw resource.[44] This slight can breed mistrust between locals and future researchers, which can then lead to less collaboration between that nation and scientists of another country.[45] In cases where the level of collaboration has not decreased, AWBS can lead to overexploitation of a biological resource, which may lead to eventual loss of that material in the environment. As shown in some African countries, overharvesting of the hoodia plant for the isolation of a biochemical has led to the "destruction and fragmentation of the hoodia populations."[46] Thus, despite some positive effects, AWBS causes significant problems that the international community needs to address.

III. THE RELEVANT LAW: TRIPS AND THE NAGOYA PROTOCOL

There are two important treaties regarding IP and the access and use of biological materials: TRIPS and the Nagoya Protocol of the Conservation of Biological Diversity. This Section will discuss both of these conventions in regards to how they relate the AWBS.

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40 *See* Dwyer, *supra* note 1, at 364–65; Robinson, *supra* note 14, at 103.

41 *See* ROBINSON, *supra* note 14, at 103.

42 *See id.* at 105 ("This has occurred in cases such as the plao noi example, whereby a trademarked and patented Japanese product has been developed from Thai traditional knowledge and sold back to the Thai market in direct competition with herbal remedies that use plao noi as a peptic ulcer treatment.").

43 *See id.* at 108–14.

44 *See id.* at 109 ("Culture affront is usually felt in circumstances whereby prior informed consent has not been sought of local or indigenous 'provider groups' groups.").

45 *See id.* at 113–14.

46 *Id.* at 113.

A. TRIPS

In 1994, "multilateral trade negotiations . . . culminated in the signing of the Agreement Establishing the World Trade Organization."[47] TRIPS accompanied the emergence of the World Trade Organization (WTO).[48] Parties to TRIPS agreed that TRIPS was necessary due to "three fundamental reasons: the increasing economic significance [of intellectual property rights] and hence the need for protection of the property protected by these rights, the deficits in traditional international protection of these rights, and the questionable nature of unilateral and bilateral protection."[49]

In the late twentieth century, IP rights became an increasingly important economic issue.[50] Piracy emerged as a global concern.[51] Prior to TRIPS, countries had a hard time dealing with piracy because there was "no universal application of traditional international conventions and agreements,"[52] and there were few incentives for countries to "accede to and develop traditional international conventions and agreements"[53] regarding IP protections.

Still, there was an international need to harmonize the IP systems of various countries and to combat piracy.[54] TRIPS was able to fulfill these needs. By linking "intellectual property rights to international free trade," TRIPS was able to obtain the signatures and ratification of both developed and developing nations.[55] As of this date, there are 164 contracting parties to TRIPS, including the U.S., Japan, and the E.U., which have very strong IP protection systems.[56]

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47 Paul Katzenberger & Annette Kur, *TRIPs and Intellectual Property*, *in* FROM GATT TO TRIPS—THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, 1, (Friedrich-Karl Beier & Gerhard Schricker, eds., 1996).

48 *Id.* at 2.

49 *Id.* at 8.

50 *See id.* at 9 ("Research and development investments made in industrialized states and technology exports to developing and threshold countries" contributed to a nation's economic welfare).

51 *See* Katzenberger & Kur, *supra* note 47, at 8 ("[T]rademark and product piracy not only in industrialized countries but also in developing . . . countries, including exportation of counterfeit goods caus[es] losses in billions to industrialized states.").

52 *Id.* at 10.

53 *Id.* at 11.

54 *See id.* at 3–5.

55 *Id.* at 14.

56 *See Other IP Treaties*, WORLD INTELLECTUAL PROPERTY ORGANIZATION, https://perma.cc/6VEV-4XUC (last visited Mar. 30, 2017).

TRIPS called for the contracting nations to enact minimum standards of IP protections in their own domestic laws.[57] What constitutes minimum standards is detailed within TRIPS. Of course, nations have the discretion to establish higher standards of protection through their domestic legislation. TRIPS deals with all areas of IP law including patents, copyright, trademarks, and geographical indications.[58] In combating AWBS, the standards regarding patent and geographical indications are applicable.

1. TRIPS provides the minimum standards for patents.

Articles 27 to 34 of TRIPS relate to patents.[59] Article 27 governs the standards for patentability, which originates from American IP law.[60] Products and processes are patentable if they are "new, involve an inventive step and are capable of industrial application."[61] What it means to be "new," "inventive," and "capable of industrial application" is left up to the discretion of individual nations.[62]

Under Article 27, nations could exempt certain items from patentability.[63] Such products include biological resources.[64] However, many nations including the U.S. hold that biological materials are patentable.[65]

Inventors who want to patent their products or processes in a country must submit an application to the patent offices of that country. In the application, the inventors must disclose the invention "in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art."[66] There are also two optional conditions for further disclosures.[67] First, parties to TRIPS have the discretion to require that the patent applicant "indicate the best mode for carrying

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57 *See Overview: The TRIPS Agreement*, WORLD TRADE ORGANIZATION, https://perma.cc/9EZ6-PSVH. (last visited Mar. 30, 2017).

58 *See generally* TRIPS, *supra* note 23.

59 Joseph Straus, *Implications of the TRIPs Agreement in the Field of Patent Law*, *in* FROM GATT TO TRIPS-THE AGREEMENT ON TRADE ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 160, 179 (Friedrich-Karl Beier & Gerhard Schricker eds., 1996).

60 *See id.* at 196.

61 *See* TRIPS, *supra* note 23, at art. 27.

62 *See* Straus, *supra* note 59, at 196.

63 *See id.* at 183.

64 *See* TRIPS, *supra* note 23, at art. 27.

65 *See* Diamond v. Chakrabarty, 447 U.S. 303 (1980); Dwyer, *supra* note 1, at 224; Council Directive 98/44/EC, of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213/13); Examination Handbook for Patent and Utility Model, Japan Patent Office, Chs. 2–3, https://perma.cc/DQN6-VWDP.

66 *See* TRIPS, *supra* note 23, at art. 29.

67 *See id.* at art. 27

out the invention known to the inventor."[68] Second, a nation could require that the applicant "provide information concerning the applicant's corresponding foreign applications and grants."[69]

Under TRIPS, patent-holders generally have the sole right to exclude others from creating and selling their inventions.[70] In some instances, these patent-holders may license their inventions to others.[71]

2. TRIPS provides the minimum standards for geographical indications.

The provisions of TRIPS governing geographical indications are covered in Articles 22 to 24.[72] Article 22(1) defines geographical indications as "indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin."[73] Article 22 applies to all goods.[74] These indications "confer to all producers from a given geographical area the exclusive right to use a distinctive sign to identify their products if they possess a given quality, reputation, or other characteristic attributable to their geographical origins."[75]

TRIPS does not define the legal principles surrounding the "necessary link between good and geographical origin."[76] This Comment addresses the meaning of this phrase more in depth in Section V.

Article 22(2) requires states to "protect against any use of designations or presentations of goods that misleads the public as to the geographical origin thereof."[77] There are additional levels of protections of geographical indications for wines and spirits.[78] However, in the eyes of one commentator, "[t]he weak

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68 *Id.*

69 *Id.*

70 *See* TRIPS, *supra* note 23, at art. 28.

71 *Id.*

72 *See* Roland Knaak, *The Protection of Geographical Indications According to the TRIPs Agreement*, *in* FROM GATT TO TRIPS – THE AGREEMENT ON TRADE ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 117, 127 (Friedrich-Karl Beier & Gerhard Schricker, eds., 1996)).

73 TRIPS, *supra* note 23, at art. 22.

74 *See* Knaak, *supra* note 72, at 128 ("These words . . . make clear that the provisions of the TRIPs Agreement cover geographical indications for all goods, including industrial products").

75 José Manuel Cortés Martín, *TRIPS Agreement: Towards a Better Protection for Geographical Indications?*, 30 BROOK. J. INT'L L. 117, 117 (2004).

76 Knaak, *supra* note 72, at 128.

77 TRIPS, *supra* note 23, at art. 22.

78 *See id.*

point of the protection of geographical indications under Art. 22(2) of the TRIPS Agreement is that this protection is subject to the principle of the country of protection."[79] "This means that . . . it is the courts or authorities of the protecting country that decide on the basis of conditions or opinions of the relevant public prevailing there whether the use of a geographical indication is likely to cause deception or confusion."[80]

B. The Nagoya Protocol of the Convention on Biological Diversity

The Convention on Biological Diversity (CBD)[81] was enacted in response to the rapid growth of modern medicine.[82] Entered into force in 1992,[83] the CBD is dedicated to ensuring that access and benefits-sharing (ABS) and prior informed consent are obtained between the user and provider of the biological resources.[84]

In fact, one of the goals of the CBD is to guarantee "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources."[85] Recognizing that states have ownership over their biological resources,[86] the CBD "envisages the establishment of a relationship between the State and the local or indigenous community whose traditional knowledge is utilized for the conservation and sustainable use of biodiversity."[87]

The CBD had many deficiencies that prevented countries from reaching compliance. For one, "[f]ew CBD Parties have had the legal capacity to translate the CBD provisions" into their domestic law.[88] Second, the provisions pertaining to ABS are worded too generally.[89] Countries with strong pharmaceutical

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79 Knaak, *supra* note 72, at 130.

80 *Id.* at 130–31.

81 *See* Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S 79; 31 I.L.M. 818 (1992) [hereinafter CBD].

82 *See* Elisa Morgera, Matthias Buck, & Elsa Tsioumani, *Introduction*, *in* THE 2010 NAGOYA PROTOCOL ON ACCESS AND BENEFIT-SHARING IN PERSPECTIVE 1, 3 (Elisa Morgera, Matthais Buck, Elsa Tsioumani, eds., 2013) (stating that modern medical science "ha[s] led to the rapid growth of scientific research on the genetic base of life [and] on the relevance of genes for the biological and chemical make up of cells and organisms").

83 *See id.* at 4.

84 *Id.*

85 *Id.*

86 *Id.*

87 *Id.*

88 *Id.*

89 *See id.*

industries did not want to share profits.[90] Currently, there are 196 nations that are parties to the CBD.[91] The U.S. has signed but not ratified the CBD.[92]

The Nagoya Protocol was entered into force in 2014 to address some of these deficiencies.[93] It "set[s] out rules and procedures on access, benefit-sharing, and compliance" in regards to the use of genetic resources.[94] The Nagoya Protocol defines genetic resources broadly to include biological resources[95] and "spells out the basic conditions for ABS, including key elements of national measures in provider and user countries related to access, benefit-sharing, institutional responsibilities, and compliance."[96] This international instrument also addresses the "need to ensure the protection of traditional knowledge and to support [indigenous] communities' customary laws and procedures."[97]

Reaffirming that states have sovereignty over their natural resources,[98] the Nagoya Protocol requires that the user of biological resources obtain "prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention."[99] In essence, the Nagoya Protocol recognizes that in many instances of AWBS, the country providing the natural resources is also the geographical origin of those resources.

Once a user receives consent from the provider country, the Nagoya Protocol mandates that the user party and the provider party initiate a fair and equitable benefits-sharing agreement: "benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually

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90 *See id.* at 4–5.

91 *See List of Parties*, CONVENTION ON BIOLOGICAL DIVERSITY, https://perma.cc/PF5P-46JU (last visited Mar. 31, 2017).

92 *See id.*

93 *See generally* Nagoya Protocol, *supra* note 27.

94 Morgera, Buck, & Tsioumani, *supra* note 82, at 7.

95 Evanson Chege Kamau, Bevis Fedder, & Gerd Winter, *The Nagoya Protocol on Access to Generic Resources and Benefit Sharing: What is New and What are the Implications for Provider and User Countries and the Scientific Community?*, 6 LAW, ENV'T & DEV. J. 246, 251 (2011) ("Utilisation of genetic resources is defined as 'research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.").

96 Morgera, Buck, & Tsioumani, *supra* note 82, at 7.

97 *Id.*

98 *See* Nagoya Protocol, *supra* note 27, at art. 6.

99 *Id.*

agreed terms."[100] Though the Nagoya Protocol never defines what is "fair and equitable,"[101] it lists certain types of compensation that could constitute a shared benefit.[102]

The Nagoya Protocol necessitates that party states establish "an Access and Benefit-Sharing Clearing-House."[103] This clearing-house is a "platform"[104] that will "serve as a means for sharing of information related to access and benefit-sharing" and "provide access to information made available by each Party relevant to the implementation of this Protocol."[105] Such information includes "[l]egislative, administrative and policy measures on access and benefit-sharing . . . [and] [i]nformation on the national focal point and competent national authority or authorities."[106]

To ensure compliance with the provisions of this treaty, the Nagoya Protocol mandates that states create checkpoints.[107] "[C]heckpoints . . . have to be effective and have functions relevant to the monitoring of the utilisation of genetic resources or the gathering of relevant information at any stage of research, development, innovation and pre-commercialisation."[108] The Nagoya Protocol does not define what types of institutions could serve as checkpoints.[109] Neither does it give any types of attributes or properties that checkpoints should have.[110] Rather, it is the decision of the provider and the user state to designate checkpoints.[111] "Such flexibility is provided so that the checkpoints most suited to national circumstances can be selected. Thus, parties have the flexibility to decide on whether to designate the patent office as a checkpoint."[112]

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100 *Id.* at art. 5.

101 *See generally id.*

102 *See id.* at annex.

103 *See id.* at art. 15.

104 *The ABS Clearing-House*, CONVENTION ON BIODIVERSITY, https://perma.cc/5GNB-Q4H6. (last visited Mar. 31, 2017).

105 Nagoya Protocol, *supra* note 27, at art. 14.

106 *Id.* at art. 14.

107 *Id.* at art. 17.

108 Abdul Haseeb Ansari & Lekha Laxman, *A Review of the International Framework for Access and Benefit Sharing of Genetic Resources with Special Reference to the Nagoya Protocol*, 16 ASIA PAC. J. ENVT'L L. 105, 131 (2013).

109 *See generally* Nagoya Protocol, *supra* note 27; *see also* Ansari & Laxman, *supra* note 108, at 131.

110 *See generally* Nagoya Protocol, *supra* note 27*; see also* Ansari & Laxman, *supra* note 108, at 131.

111 *See* Ansari & Laxman, *supra* note 108, at 131.

112 *Id.*

As of the date, there are eighty-six parties to the Protocol including countries with strong IP systems such as the E.U. and Japan.[113] The U.S. has neither ratified nor signed the Protocol.[114]

IV. DISCLOSURE IS IMPORTANT IN COMBATING AWBS

Many nations have recognized the importance of disclosure in the patent application process and in combating AWBS.[115] One of the reasons that disclosure is significant is that it creates transparency in the patent application process.[116] By doing so, an origin-of-resource disclosure can give notice to those who want to challenge the patentability of the invention. For instance, had Grace's researchers disclosed in their patent application for azadirachin that they used neem seeds from India, a challenge to Grace could have occurred immediately after the application filing.

In fact, origin-of-resource disclosures could stop a product from becoming patented in the first place. According to Bolivia, Brazil, Colombia, Cuba, India, and Pakistan, which submitted a joint document to the TRIPS Council, disclosure might "prevent the grant of bad patents and promote greater legal certainty."[117] Disclosure "would ensure that the patent system does not issue bad patents" and would lead to fewer instances of patent revocations, which could place a costly burden on a patent office.[118]

Disclosure could also help "build databases to aid in 'the prior art information available to patent examiners and the general public.'"[119] These databases could potentially link different biological materials with their geographical origins and add to the expanding knowledge of the natural world that patent examiners may need to evaluate an invention.

Moreover, requiring disclosure can serve as a way for patent offices to keep track of any benefit-sharing agreement enacted between the country providing the

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113 *See Parties to the Nagoya Protocol*, CONVENTION ON BIOLOGICAL DIVERSITY, https://perma.cc/DJ4M-C7WG (last visited Mar. 31, 2017).

114 *See id.*

115 *See* de Werra, *supra* note 31, at 145–49.

116 *See* Jonathan Carr, *Agreements that Divide: TRIPS vs. CBD and Proposals for Mandatory Disclosure of Source and Origin of Genetic Resources in Patent Applications*, 18 J. TRANSNAT'L L. & POL'Y 131, 140 (2008).

117 *Id.*

118 Council for Trade-Related Aspects of Intellectual Property Rights, The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge: Technical Observations on the United States Submission IP/C/W449 by Bolivia, Brazil, Colombia, Cuba, India, and Pakistan, IP/C/W/459 (Nov. 18, 2005) [hereinafter IP/C/W/459].

119 Carr, *supra* note 116, at 140 (citing IP/C/W/459, *supra* note 118).

biological resource and the entity that wants to access the resource.[120] If countries find a way to enforce the disclosure requirement by conditioning disclosure on patentability, they could also enforce the benefit-sharing requirement of the Nagoya Protocol as well.[121]

However, some critics have argued that disclosure requirements are not worthwhile because they do not actually lead to benefit-sharing. These commentators have further asserted that sanctions against patent applicants who fail to disclose are not effective in encouraging transparency in the application process.[122] Even the strongest sanctions, such as the denial of the patent, may not lead to benefit-sharing.[123]

Implicit in these contentions may be the fact that currently, different countries have different rules on origin-of-resource disclosure and varying levels of enforcement.[124] If one country has fewer rules of disclosure or is more lenient on the enforcement of disclosure than another country, then a patent applicant could choose to file an application in the second country.

Nevertheless, as we will see in this Comment, one could argue that TRIPS provides a minimum standard of disclosure for all countries that are parties to the treaty and if these countries have a system enforcing this minimum standard, disclosure could likely lead to more transparency in the patent application process and more benefit-sharing.

V. TRIPS LIKELY MANDATES DISCLOSURE OF BIOLOGICAL RESOURCES ON PATENT APPLICATIONS UNDER ARTICLES 22 AND 29

There are strong arguments that under TRIPS, two circumstances trigger mandatory origin-of-resource disclosure on patent applications. First, when "the sources of the biological resources [that form the basis of an invention] are unique," Article 29 of TRIPS likely requires disclosure.[125] Second, when "a quality, characteristic, or reputation" of a biological material that contributed to the development of an invention is "essentially attributed" to a geographic region, Article 22 of TRIPS likely requires that a patent applicant indicate the geographic source of the biological element.[126]

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120 *See* de Werra, *supra* note 31, at 154.

121 *See id.* at §§ VI and VII, *infra.*

122 *See id.* at 155–56.

123 *See id.* at 156–57.

124 *See* Henninger, *supra* note 32.

125 WT/CTE/M/16, *supra* note 30, at ¶ 90.

126 TRIPS, *supra* note 23, at art. 22.

A. Article 29 of TRIPS

Commentators have asserted that Article 29 of TRIPS requires disclosure when "the source of the biological resource [is] unique."[127] However, they have not explained the implications of this statement.[128] In this section, I will illustrate the meaning of the phrase "the source of the biological resource [is] unique" and demonstrate how the uniqueness of the "source" triggers disclosure under Article 29.[129]

1. There are two possible interpretations of the phrase, "source of the biological resource [is] unique."

One can reasonably interpret the phrase "the source of the biological resource [is] unique" in two ways.[130] On one hand, one can assert that the word "source" refers to the area or country where a biological material is found. When that location has rare physical and environmental characteristics, then the geographical "source" of the biological material is "unique."[131]

On the other hand, one can argue that the phrase "the source of the biological resource [is] unique" refers to the nature of the biological material itself.[132] If an inventor uses a biological material with exceptional features, then one can characterize that material as "unique."[133]

2. Article 29 requires disclosure when either the geographical location is unique or the biological resource is unique because such disclosure is necessary to describe an invention clearly.

Article 29 of TRIPS states that "[m]embers shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art."[134] If the biological materials that form the basis of an invention are unique, Article 29 mandates disclosure. Similarly, if the geographical homes of those materials are unique, Article 29 requires disclosure.

The rationales behind these assertions are as follows: when a biological material cannot be found anywhere except in one area of a country, failure to

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127 WT/CTE/M/16, *supra* note 30, at ¶ 90.

128 *See id.*; Carvalho, *supra* note 19, at 391.

129 Carvalho, *supra* note 19, at 391.

130 *Id.*

131 *Id.*

132 *Id.*

133 *Id.*

134 TRIPS, *supra* note 23, at art. 29.

disclose the source of that material would make it extremely difficult, if not impossible, for another inventor to find it to recreate the invention. This failure would mean that the invention is not described "sufficiently clearly and completely."[135]

An example can illustrate the rationales more fully. Let us assume that a plant found in a remote part of the world contains a biochemical that is not located anywhere else in the world. The plant and the biochemical are unique. The location where the plant is found may also be unique because nowhere else can one find that plant. An inventor creates an antiviral drug based on the chemical found in the plant. If the inventor files a patent application without disclosing the source of the chemical, then a "person skilled in the art" may not know where to obtain such a resource in order to recreate the final product.[136] This implication contravenes Article 29's need for a patent description to be "sufficiently clear and complete."[137] As a result, if the biological elements that constitute the building blocks of an invention are distinct or if the geographical origin of these building blocks are unique, then under TRIPS, it becomes necessary for the patent applicant to reveal the geographic origin of the resource.

3. This interpretation of Article 29 has support from U.S. patent law.

U.S. patent law provides further support that Article 29 of TRIPS mandates disclosure when the "source of the biological resource [is] unique."[138] Article 29, which states that patent applicants must "disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art,"[139] is analogous to Section 112 of the U.S. Patent Act, which holds that the patent application "shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."[140] The provision of the Patent Act requiring that the patent application contain sufficient information to "enable any person in the skilled in the art . . . to make and use" the invention is the enablement clause.[141]

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135 *Id.*

136 *Id.*

137 *Id.*

138 WT/CTE/M/16, *supra* note 30, at ¶ 90.

139 TRIPS, *supra* note 23, at art. 29.

140 35 U.S.C. § 112 (2012).

141 *Id.*

Because of the similarity between the wording in Article 29 and the wording in the enablement clause of Section 112, the enablement clause in U.S. patent law likely provides guidance to the proper interpretation of Article 29. In the U.S., "patents are written to enable those skilled in the art to practice the invention."[142] The Federal Circuit, in the seminal case *In Re Wands*, held that the information disclosed in a patent application must teach an ordinary person with the relevant scientific or engineering expertise to recreate the invention without undue experimentation.[143] If methods or products used in the creation of the invention are not well known, then the patent applicant must disclose them in his or her application.[144] Failure to reveal such information implies that recreation would cause "undue experimentation."[145]

U.S. patent law, therefore, suggests that that if a biological material is unique or is found in a unique area of the world, then the patent applicant needs to disclose its location. After all, when a resource is one-of-a-kind, its geographical home is unlikely to be well-known to an ordinary person, even if that person has the right scientific skills. In this situation, a patent applicant must tell the reader where to obtain the material. Hiding information about the resource's geographical location would contravene the "undue experimentation" principle of the U.S.'s enablement clause.[146] Since Article 29 of TRIPS is the international analogue to Section 112, Article 29 also requires disclosure when "the source of biological resource [is] unique."[147]

B. Article 22

In many instances of AWBS, inventors often utilize biological resources whose "qualit[ies], reputation, or other characteristic[s]" are connected to, or "essentially attributable to" the regions in which they are found.[148] Examples of such resources may include the neem tree of India, camu camu of Peru, and Ballia barley of India.[149] When the biological resources that constitute the building blocks of an invention are "essentially attributable" to their geographic origins, then a possible argument exists that under Article 22 of TRIPS, an inventor must

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142 In re Wands, 858 F.2d 731, 735 (Fed. Cir. 1988) (citing W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1556 (Fed. Cir. 1983)).

143 *See id.* at 737–40.

144 *See id.*

145 *Id.* at 737.

146 *Id.*

147 WT/CTE/M/16, *supra* note 30, at ¶ 90.

148 TRIPS, *supra* note 23, at art. 22

149 This Comment will explain these examples in depth in Section VII, *infra.*

disclose the origins of resources on a patent application. The inventor can do this by using appropriate geographical indications. However, there is a limitation of Article 22 in mandating disclosure: if the biological and/or chemical materials that form the basis for an invention are synthesized in a lab, then Article 22 does not require that the patent applicant disclose the origins of those materials.

1. What are geographical indications?

Article 22 defines geographical indications as words, signs, or symbols that "identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin."[150] In layman terms, geographical indications are "names of places, regions, localities, and other identifying characteristics of that type" that tie the good to the specific country or region within the country of its origin.[151] Most commonly, a geographical indication consists of the name of the place of origin of the good, such as "Jamaica Blue Mountain" or "Darjeeling."[152] "But non-geographical names, such as 'Vinho Verde,' 'Cava' or 'Argan Oil,' or symbols commonly associated with a country, can also constitute" a geographical indication.[153]

Because "[t]he TRIPS Agreement does not contain product-specific limits to the scope of application of the provisions on geographical indications, any product, even inventions specified on patent applications, qualify as 'goods' within the scope of Article 22."[154]

2. What does the phrase "essentially attributable" mean under Article 22?

In order for a geographical indication to be valid under Article 22, it must link the good to its country of origin where a characteristic or reputation of the good is "essentially attributed" to that location.[155] In TRIPS, "no test is offered to determine what it means to be 'essentially attributed.'"[156] By not incorporating a

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150 TRIPS, *supra* note 23, at art. 22

151 Andrea Zappalaglio, *The Protection of Geographic Indications: Ambitions and Concrete Limitations*, 2 EDINBURGH STUDENT L. REV. 89, 90 (2013).

152 Geographic Indications: An Introduction, World Intellectual Property Organization, Pub. No. 952, at 8 (2013), https://perma.cc/663C-6JAJ.

153 *Id.*

154 Knaak, *supra* note 72, at 128.

155 TRIPS, *supra* note 23, at art. 22.

156 Albrecht Conrad, *The Protection of Geographic Indications TRIPS Agreement*, 86 TRADEMARK REP. 11, 32 (1996).

specific test, TRIPS leaves it to the discretion of member states to determine what kinds of goods are protected.[157]

We may be able to determine an implicit definition based on common uses of the geographical indications, as, traditionally, geographical indications are attached to products where a quality or reputation of that product is closely tied to that region. Geographical indications "reward goodwill and reputation created or built up by a group of producers over many years and, in this sense, operate to maintain traditional knowledge and practices."[158] One example of a geographical indication is the word "Champagne," which is attached to the "prestigious sparkling wine" made from the French region of Champagne.[159] Another example is the words "Parmigiano Reggiano," which is connected to the "famous cheese from Parma in Italy."[160] These historical uses of geographical indications suggest that geographic indications attach to goods with distinctive qualities "that cannot be replicated elsewhere."[161] This statement implies that environment contributed to the production of the good and that the labors of the citizens of that country helped contribute to the distinctive qualities or the unique reputation of the product. Thus, in the eyes of one commentator, "essentially attributable" means that "the territory and the characteristics of the product have to be linked by a causal relationship."[162]

3. Article 22 likely requires origin-of-resource disclosures on patent applications in certain cases.

When an inventor creates a product from a biological resource that has "a given quality, reputation or other characteristic [that] is essentially attributable" to a nation or region, and the invention takes advantage of the distinctive quality of the resource for its efficacy, Article 22 likely mandates that the inventor reveal the geographical origin of the biological material on a patent application because failure to do so would "mislead[] the public as to the geographical origin of the good."[163] The inventor can satisfy this requirement by using the proper

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157 *See* Cortés Martín, *supra* note 75, at 137–38.

158 *Id.* at 118–19.

159 Zappalaglio, *supra* note 151, at 89.

160 *Id.* at 89.

161 Kal Raustiala & Stephen Munzer, *The Global Struggle over Geographic Indications*, 18 EUR. J. INT'L L. 337, 338 (2007).

162 Zappalaglio, *supra* note 151, at 91.

163 TRIPS, *supra* note 23, at art. 22 (stating that "[i]n respect of geographical indications, [m]embers shall provide the legal means for interested parties to prevent . . . the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good").

geographical indications in his or her patent application.[164] The inventor cannot remain silent as to the origin of the resource. The requirement to disclose may be evident through an examination of: (1) how geographical indications would attach to biological inventions, and (2) how the absence of geographical indications on patent applications would mislead the public as to the origins of the invention.

a) How do geographical indications attach to inventions based on biological resources?

Suppose that an invention such as a new drug is made with a biological resource that has a quality or reputation "essentially attributable to its geographical origin."[165] This biological resource is not synthesized in a lab; rather, it is taken from its country of origin. The invention utilizes a quality of the biological resource for its efficacy. Under Article 22, a geographic indication should attach to the invention, connecting the invention to the country or region where the biological resource was found.

The rationale behind this assertion is that the invention is inherently linked to its building block and to geographic origin of the resource. Because the biological resource forms the basis for the patent, the biological material is necessary to the invention. As the invention takes advantage of a distinctive characteristic of the resource for its efficacy, the invention is also essentially linked to region or country where the resource is found. After all, the atmosphere, soil, and other physical conditions provided by that region or country were necessary to produce the distinctive qualities of that biological material. If people in the area had to cultivate the growth of the biological resource (such as a plant), then their cultivation methods might have contributed to the distinctiveness of the material. The labor of those individuals as well as the physical environment might have also contributed to any reputation that the biological resources enjoy in a regional or world market. Therefore, though the invention may be created and manufactured in another country, the invention's actual origin and efficacy are essentially tied to the geographical home of its biological building block, and a geographic indication linking the invention to the member state should be attached to the invention.

An illustration would clarify these principles. Let us assume that recently, researchers have found that a specific species of tea plant grown in a country has higher antioxidant levels than many other tea plants. The plant's high antioxidant levels are due to the soil and climate of its home country as well as the work of the farmers who grew the plant. Tea from this country may have a reputation of preventing cancer due to the high antioxidant concentration. As a result, the quality and the reputation of the tea plant is "essentially attributable" to its geographic origin. An inventor from another country then takes the plant and

164 *Id.*

165 *Id.*

creates an antioxidant drug to fight cancer. Because the drug utilizes the distinctively high antioxidant qualities of the plant, the effectiveness of the drug is essentially tied to the plant and to the plant's native territory. Similarly, the existence of the drug itself is owed to the plant and to the plant's native territory. Thus, the geographic origin of the drug is the same as the geographic origin of the plant. A geographic indication is needed to link the drug to that country or a region within that country.

b) How does nondisclosure of the origins of the biological resources on a patent application mislead the public on the origin of the invention when the invention is "essentially attributable" to the geographical source of the biological resource?

Article 22 requires that "[i]n respect of geographical indications, [m]embers shall provide the legal means for interested parties to prevent . . . the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good."[166] For patent applicants that utilize biological resources for their inventions, there is a strong argument that they must disclose the geographic origins of their biological resources through geographical indications when the resource has a quality or reputation "essentially attributable to its geographic origin."[167] Silence may not be an option.

Patent applications are public documents, as they are submitted to patent offices (which are public agencies) and then released to the public within a certain period of time. In the U.S., patent applications are submitted to the United States Patent and Trademark Office (USPTO) and the application is released to the public within 18 months of filing.[168] Similarly, in the E.U., inventors file patent application with the European Patent Office and applications are released to the public within 18 months of filing.[169] Thus, if an inventor misrepresents information on a patent application, the inventor is misleading the public.

When an invention based on a biological material is "essentially attributable" to the geographical origin of that material,[170] failure to disclose the geographical source of a biological material on a patent application can likely mislead the public on the origins of the patented product.[171] Silence can constitute deception in many areas of law. For instance, in the U.S., the FTC prohibits omissions of disclosure

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166 *Id.* at art. 22.

167 *Id.*

168 *See* § 112, *supra* note 140.

169 *See How to Apply for a European Patent*, EUROPEAN PATENT OFFICE, https://perma.cc/MEP4-LTKF.

170 TRIPS, *supra* note 23, at art. 22.

171 *Id.*

when such omissions occur "in the context of a half truth or occur under circumstances where silence constitutes an implied misrepresentation."[172] Similarly, the U.S. International Trade Commission has found that omitting designation of the country of origin for imported caulking guns constitutes misrepresentation.[173]

Patent applicants who omit the sources of biological materials likely commit an act of misrepresentation for two reasons. First, if the applicant does not mention the geographical origins of biological materials that are "essentially attributable" to a foreign country, patent examiners, who represent the public, and other members of the public who read the application may believe that the invention was created domestically without raw resources from other countries. Because some inventors would reveal the sources of foreign materials in their patent applications,[174] readers are more likely to believe that those who do not disclose are not using such materials. Under consumer protection laws of many nations such as the U.S. and much of the Continental Europe, the fact that a reasonable or average person would be deceived from silence constitutes misrepresentation.[175] As such, anyone reading patent applications including patent examiners could become mistaken to the actual geographic origin of the invention.

Second, silence as to the actual origin of the invention and the biological resources can constitute a material deception. We can draw a similarity between the legal principles governing geographical indications and the legal principles governing consumer protection because both deal with the presentation of information about products to the public. In the consumer protection laws of countries like the U.S., facts are material if they can influence consumer choice.[176] Analogously, information pertaining to the origin is material not only because it may influence consumers who purchase the product (as some consumers may want to learn about the origins of products before buying), but also because it identifies to the patent office (which is representative of the public) another country or region that may have an interest in the invention. Omission of this pertinent information would mislead the patent office or members of the public into believing that only the applicant has a right to the invention. Because Article 22 prevents misleading acts, the failure to disclose the origin of the biological resource that constitutes the basis for an invention contravenes Article 22.

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172 *See* Ross D. Petty, *Advertising Law and Social Issues: The Global Perspective*, 17 SUFFOLK TRANSNAT'L L. REV. 309, 323 (1994).

173 *See* In Re Certain Caulking Guns, 223 U.S.P.Q. 388 (I.T.C. 1984).

174 *See* 37 C.F.R. § 1.56; ROBINSON, *supra* note 14, at 48.

175 *See* Petty, *supra* note 172, at 327–28.

176 *See id.* at 321.

Therefore, when the biological materials and the invention based on those materials are "essentially attributable" to a geographical location, one can contend that Article 22 likely requires the revelation of that location on a patent application.[177] The patent applicant can satisfy this disclosure requirement by attaching a geographical indication to the invention or to the biological resources that form the basis of his or her invention.

4. There are strong counterarguments that Article 22 is not intended to apply to information on patent applications.

Nevertheless, there are compelling counterarguments that Article 22 is not meant to require disclosure on patent applications. Article 22 focuses on acts that "mislead[] the public as to the geographical origin of a good."[178] As geographical indications are traditionally placed on the packaging of products for the viewing of consumers,[179] one can assert that the word "public" in Article 22 refers only to consumers and does not encompass representatives of the public such as patent examiners.[180] Because most consumers do not read patent applications for disclosures of new inventions, it is possible that the drafters of TRIPS only intended Article 22 to apply to labels on product packaging.

Second, one could contend that omissions of geographical indications do not warrant TRIPS protection because, generally, omissions are not deceptive. The fact that Article 23 of TRIPS gives heightened requirements for protections of geographical indications for wines and spirits might suggest that for non-alcoholic goods, omissions of geographical origins might not be deceptive enough for TRIPS to remedy, or that for these products TRIPS only protects against affirmative acts of deception.[181]

As convincing as these arguments are, they may not be entirely conclusive. For instance, had the drafters intended Article 22 to apply solely to consumers, the drafters would have likely substituted the word "public" for "consumers." Rather, by using the word "public" in Article 22, the drafters of TRIPS might have wanted to interpret this word in a more general sense.[182] Even if this was not their intention, the word "public" has a broader meaning and opens the door for a more expansive interpretation of Article 22. Since government agencies like patent offices are representatives of the public, misrepresentations to a patent office may

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177 TRIPS, *supra* note 23, at art. 22.

178 *Id.*

179 *See generally* Zappalaglio, *supra* note 151; Conrad, *supra* note 156.

180 TRIPS, *supra* note 23, at art. 22. *See also* Aaron C. Lang, *On the Need to Expand Article 23 of the TRIPS Agreement*, 16 DUKE J. COMP. & INT'L L. 487 (2006).

181 *See* TRIPS, *supra* note 23, at art. 23.

182 *Id.* at art. 22.

be tantamount to deception of the public. Therefore, there is a forceful contention that the scope of Article 22 is not limited to the mislabeling of products to consumers.

Along the same lines, Article 22 never explicitly states that omissions are not tantamount to deception or that it only prevents affirmative acts of fraud. Instead, it frames the prohibition of deception in broad terms.[183] As detailed in the previous section, omissions can constitute deception and for biological resources that are "essentially attributable" to a foreign nation, failure to mention their origins would likely lead the patent office or other readers of patent applications to assume that the resources originated domestically.[184] Thus, there are sound grounds for the assertion that Article 22 applies not only to package labels for products but also to information on patent applications.

In practice, the WTO's treatment of Article 22 of TRIPS seems inconsistent. On one hand, in a PowerPoint presentation by the WTO entitled *Geographical Indications Ongoing Negotiations/Discussions in the WTO* (Beijing Presentation),[185] the WTO seems to implicitly connect the word "public" in Article 22 to consumers, though it did not limit the application of the Article solely to goods sold on a market.[186] If this is the correct interpretation of "public," then Article 22 may be unhelpful for arguing for disclosure on patent applications. In that case, one may be able to argue that Article 22 mandates origin-of-resource disclosures in other ways, such as ensuring that the invention or good is labeled with the correct geographical indications in the marketplace. Because consumers would see information regarding geographical origins on products' packaging, such disclosure through geographical indications may still give adequate notice to those who want to challenge the patentability of these goods.

On the other hand, in a document to the TRIPS Council (IP/C/W/247/Rev.1), various countries state that, although Article 22 is applicable in the consumer context, the definition of what constitutes misleading the public is not fixed; nations have the discretion to dictate the tests for misleading.[187] If this statement is true, then it leaves room for an expansive

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183 *Id.*

184 *Id.*

185 *Geographical Indications Ongoing Negotiations/Discussions in the WTO*, WIPO-SAIC International Symposium on Geographical Indications, Beijing, 26-28 June 2007, https://perma.cc/DQ47-AT9P [hereinafter Beijing Presentation].

186 *See* Thu Lang Tran Wasescha*, Geographical Indications Ongoing Negotiations/Discussions in the WTO*, WIPO-SAIC INTERNATIONAL SYMPOSIUM ON GEOGRAPHICAL INDICATIONS (June 26–28, 2007), available at https://perma.cc/P4GD-DALZ (last visited May 1, 2017).

187 *See* Council for Trade-Related Aspects of Intellectual Property Rights, Proposal from Bulgaria, Cuba, the Czech Republic, Egypt, Iceland, India, Jamaica, Kenya, Liechtenstein, Mauritius, Nigeria, Pakistan, Slovenia, Sri Lanka, Switzerland, Turkey and Venezuela, IP/C/W/247/Rev.1, at ¶ 13 (May 17, 2001).

definition of the word "public" to include representatives of the public and for the interpretation of "misleading" statements to include omissions. Furthermore, like the Beijing Presentation, IP/C/W/247/Rev.1 did not expressly exclude the applicability of Article 22 to patent applications, which also leaves room for arguments that information on patent applications falls under the scope of Article 22 and that Article 22 requires origin-of-resource disclosures.

VI. THE IMPLEMENTATION OF A NATIONAL SYSTEM OF CHECKPOINTS USING TRIPS AND THE NAGOYA PROTOCOL AS AN ENFORCEMENT MECHANISM

This Comment has identified two potential instances where one could argue for mandatory origin-of-resource disclosures under TRIPS: (1) when "the source" of the material is "unique,"[188] and (2) when a "quality, reputation or other characteristic" of the biological resources that contributed to the development of an invention is "essentially attributable" to a geographic region.[189] Having these requirements is the first step in ensuring that countries providing biological resources receive benefits and recognition from inventions that utilize such materials.

Nevertheless, many countries have asserted that TRIPS does not go far enough. They contend the WTO should amend TRIPS to require disclosures on patent applications whenever biological resources are used.[190] Some countries have enacted domestic legislation, requiring more disclosure than mandated in TRIPS. India, South Africa, and the Andean Community have taken initiative to mandate that all inventors must reveal the source of any biological materials to patent offices before they could obtain patents on their inventions.[191] One commentator has proposed that the U.S. should require an origin-of-source disclosure "whenever the invention being patented resulted from research on a biological source, or the invention was in any way furthered by such research."[192]

Currently, a committee within the World Intellectual Property Organization (WIPO) has been investigating the proper way to disclose biological resources on patent application.[193] In 2013, the Intergovernmental Committee on Intellectual

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188 WT/CTE/M/16, *supra* note 30, at ¶ 90.

189 TRIPS, *supra* note 23, at art. 22

190 *See* de Werra, *supra* note 31, at 145–49.

191 *See* Henninger, *supra* note 32.

192 Laura Grebe, *Requiring Genetic Source Disclosure in the United States*, 44 CREIGHTON L. REV. 367, 391 (2011).

193 Intergovernmental Committee (IGC), World Intellectual Property Organization, https://perma.cc/HK28-849M (last visited May 1, 2017).

Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) created a draft document for a new treaty.[194] Some of the provisions of the treaty require the disclosure of the geographical origins of genetic materials whenever such resources are used in an invention.[195]

In late 2016, parties to the IGC and TRIPS submitted a counterproposal that is void of any disclosure requirements.[196] According to the new proposal, patent examiners should just examine an invention on the basis of novelty and inventiveness to determine patentability.[197] A database of genetic resources could help patent offices with the evaluation.[198] The WIPO has neither ratified the draft treaty nor the counterproposal.[199]

Thus, there seems to be two sides to the discussion on disclosure: (1) there should be a broad requirement for patent applicants to reveal the geographical origins of biological resources whenever such resources are used in their inventions; and (2) there should be no mandatory disclosure requirements because protection of an invention should be limited to novelty and inventiveness.[200]

These interpretations may not be ideal in solving the problem of AWBS. For one, limiting the protection of biological resources to "novelty" and "inventiveness" without requiring disclosure may not be helpful in preventing instances of AWBS. The absence of obligatory origin-of-resource disclosure may make it difficult for patent examiners to determine whether an invention is novel or merely a repackaging of something that is already known. On the other hand, even though mandating that patent applicants disclose the geographical origins of all foreign genetic materials may prevent many instances of AWBS, a sweeping disclosure requirement may become very costly in the rule's enforcement.

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194 *See generally* Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Consolidated Document Relating to Intellectual Property and Genetic Resources, WIPO/GRTKF/IC/28/4 (June 2, 2014).

195 *See id.*

196 *See* Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Identifying Examples of Traditional Knowledge to Stimulate a Discussion of What Should Be Protectable Subject Matter and What Is Not Intended to Be Protected, WIPO/GRTKF/IC/32/10 (Nov. 30, 2016).

197 *See id.*

198 *See* Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Joint Recommendation on the Use of Databases for the Defensive Protection of Genetic Resources and Traditional Knowledge Associated With Genetic Resources, WIPO/GRTKF/IC/32/7 (Nov. 7, 2016) [hereinafter WIPO/GRTKF/IC/32/7].

199 The IGC has met recently from February 27, 2017 to March 3, 2017. In this meeting, the IGC proposed a draft for a treaty on the protection of traditional knowledge that did not bear on the topic of the patenting genetic resources. The IGC plans to meet again in June 2017. For more information on the meetings of the IGC, see IGC, *supra* note 193.

200 *See id.*

The mandatory disclosure provisions of TRIPS that were analyzed in the previous Section may be sufficient to resolve many instances of AWBS that result from nondisclosure.[201] What may be necessary to complement TRIPS is a system to enforce these disclosure requirements without incurring huge costs.

The Nagoya Protocol is helpful for this task. Many countries with strong IP systems such as Japan and members of the E.U. have signed and ratified the Nagoya Protocol, which mandates a checkpoints system to ensure that "fair and equitable benefit-sharing agreement[s]" are enacted between users and providers of biological resources.[202] A national checkpoints system enforcing the minimum standards of TRIPS and the Nagoya Protocol might likely be effective in combating AWBS. Assuming that the WTO has not found that Article 22 applies solely to labels on product packaging, this Section of the Comment shows that a nation that is party to both TRIPS and the Nagoya Protocol can establish such a system by requiring that its patent offices serve as checkpoints for the likely mandatory disclosures under TRIPS and for identifying whether a benefit-sharing agreement has been made.

A. Key provisions of the Nagoya Protocol

The goals of the Nagoya Protocol are to ensure that users of biological resources obtain consent from providers and that fair and equitable benefit-sharing agreements occur between these two parties.[203] Recognizing that nations have sovereignty over their biological resources,[204] the Nagoya Protocol requires benefit-sharing between the user and the provider of biological materials (which is also the country of origin for these resources) through the negotiation of mutually-agreed-upon terms.[205] The shared benefits must be "fair and equitable."[206] An example of such a benefit is joint ownership of IP rights between a user and provider of a biological resource for an invention based on that resource.[207]

To guarantee that benefits-sharing agreements are enacted, the Nagoya Protocol mandates that the country supplying the biological resources and the user of these resources designate national "checkpoints"[208]: these checkpoints

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201 *See* Section VII, *infra*.

202 Nagoya Protocol, *supra* note 27, at art. 5.

203 *See generally id.*

204 *See id.* at art. 6.

205 *See id.* at art. 5.

206 *Id.* at art. 5.

207 *See id.* at annex.

208 *See* Ansari & Laxman, *supra* note 108, at 131.

"monitor . . . the utilization" of a state's resources to determine whether the goals of the Protocol are met.[209] To guarantee that those who want to take biological resources from their geographical origins comply with the provisions of the Protocol, checkpoints would be empowered to receive information about the sources of genetic resources, prior informed consent, and mutually-agreed-upon terms.[210] By designating checkpoints within its jurisdiction, nations that are parties to the Nagoya Protocol have the discretion to require users of biological resources to disclose geographical origins of these materials.

Though the Nagoya Protocol does not explicitly name the types of public institutions that could serve as checkpoints,[211] commentators have taken the initiative to list possible examples of checkpoints that are allowed under the Protocol. One commentator has identified that examples of such checkpoints include "[r]esearch institutions subject to public funding, entities, publishing research results relating to the utilisation of biological resources, intellectual property examination offices, and authorities providing regulatory or marking approval of products derived from biological resources" can all serve to fulfill duties of a checkpoint.[212] In fact, many commentators have agreed that parties can designate patent offices to serve as checkpoints.[213] Thus, it seems that the Nagoya Protocol implicitly permits the user party and the country providing the biological resources to agree to establish patent offices as checkpoints to guarantee that fair and equitable benefits sharing occurs.

B. A Proposal: Patent Offices as Checkpoints for Enforcement of the Mandatory TRIPS Disclosures

A country that only adheres to the disclosure-of-origins rules mandated in TRIPS could likely implement an effective checkpoints system based on the Nagoya Protocol. For one, a nation that is a party to both TRIPS and the Protocol can enact legislation, declaring its patent offices to be checkpoints and requiring that anyone who wants to patent an invention in that country consent to these checkpoints. This action seems to be permissible under the Nagoya Protocol. Article 15 expressly dictates that each State Party to the Protocol "shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have

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209 Nagoya Protocol, *supra* note 27, at art. 17(1).

210 *See id.* at art. 17(1)(a)(i).

211 *See generally id.* at art. 17.

212 Pavoni, *supra* note 29, at 203.

213 *See, for example*, Ansari & Laxman, *supra* note 108; Evanson Chege Kamau & Gerd Winter, *An Introduction to the International ABS Regime and a Comment on its Transposition by the EU*, 9 L. ENV'T & DEV. J. 108, 119 (2013); Pavoni, *supra* note 29.

been accessed in accordance with prior informed consent and that mutually agreed terms have been established."[214] Because the Nagoya Protocol implicitly allows patent offices to serve as checkpoints, a national mandate designating patent offices as checkpoints would be an example of a legislative policy measure for ensuring that benefits-sharing occurs.

At the same time, a checkpoints system under the Nagoya Protocol must work in harmony with the minimum standards of TRIPS. The Nagoya Protocol "recogniz[es] that international instruments related to access and benefit-sharing should be mutually supportive with a view to achieving the objectives of the Convention."[215] Article 4 of the Protocol states that the treaty "shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol."[216] Thus, the disclosure requirements must be interpreted in compliance with TRIPS.

Accordingly, in a country that only implements the origin-of-resource disclosures stated in TRIPS, Article 4 of the Nagoya Protocol suggests that if the two conditions for disclosure are absent, then a patent applicant is not obligated to reveal any specific information pertaining to "prior informed consent" and "mutually agreed terms" on his or her patent application.[217] After all, if such information is required to be disclosed to the patent office, it would likely reveal the identity of the nation that is the geographical source of the biological material. This action would contravene Article 4 of the Nagoya Protocol, as well as the principle of TRIPS, by leaving it to each country to enact standards of patentability that go beyond TRIPS. The fact that the nation chooses to only adopt the minimum standards of TRIPS means that it does not want broader origin-of-resource disclosures.

How would a country that is a party to both the Nagoya Protocol and TRIPS implement a national system of using patent offices as checkpoints while adhering solely to the mandatory disclosure requirements of TRIPS? To be compliant with the two treaties, a country could set the following rules for patent offices to serve as effective checkpoints for disclosure and benefits-sharing:

First, the patent office would filter applications for patents based on biological materials from other applications.

Second, the patent office would check the identity of the biological resources or materials that are revealed within the application to determine whether they fit within the two categories that likely trigger the mandate for disclosure. For

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214 Nagoya Protocol, *supra* note 27, at art. 15(1).

215 *Id.* at pmbl.

216 *Id.* at art. 4(3).

217 *Id.* at arts. 5–6.

instance, patent offices could consult experts to find if the biological materials that constitute the basis for the patent are unique to a specific location or have qualities or reputation that are inherently tied to the location for which they are found. The patent offices may also be able to consult databases on these materials.[218]

Third, if the patent office determines that one of the conditions for mandatory disclosure are met, the patent office would be required to check if the applicant has disclosed the geographical origin of his or her resource. If he or she failed to disclose, then the patent office must deny the application. It can then inform the applicant of the grounds for denial and offer an opportunity for the applicant to revise the application accordingly.

Fourth, pursuant to the power given by the Protocol, the patent office must check whether the applicant has disclosed the fact that he or she obtained prior informed consent from the national or local government of the country where the resource is found.[219] The patent office would also need to check whether the applicant has disclosed any "mutually agreed terms" of a "fair and equitable benefit-sharing agreement" between the applicant and the government of the nation where the resource is located.[220] Because the Nagoya Protocol does not expressly define what constitutes "fair and equitable,"[221] the patent office as a checkpoint may be within its discretion to devise its own standard. If there is an absence of any of these features within the patent application, the patent office must deny the application. It can then inform the applicant of the grounds for denial and offer an opportunity for the applicant to revise the application accordingly.

C. Policy Concerns Regarding Enforcement

Currently, many patent offices may be against enforcing origin-of-resource disclosures.[222] For instance, in some South American countries, where sweeping disclosure rules for biological resources exist, patent examiners "oppose—or lack the capacity to perform—processing and reviewing more requirements than those they already evaluate as part of regular patent procedures.[223] Enforcement may cause delays in the patent application process due to the fact that biotechnological

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218 For discussion on implementation of analogous databases for traditional knowledge, see Dwyer, *supra* note 1, at 246. *See also* WIPO/GRTKF/IC/32/7, *supra* note 198, at ¶¶ 5–8.

219 *See* Nagoya Protocol, *supra* note 27, at art. 17.

220 *Id.* at art. 5–6.

221 *See generally id.*

222 *See* Manuel Ruiz Muller, *Disclosure of Origin and Legal Provenance: The Experience and Implementation Process in South America, in* TRIGGERING THE SYNERGIES BETWEEN INTELLECTUAL PROPERTY RIGHTS AND BIODIVERSITY 263 (Alexander Werth and Susanne Reyes-Knoche eds., 2010).

223 *Id.*

products use many different building blocks that may have different geographical origins.[224] In the view of one commentator, an enforcement mechanism should not impose "unnecessary burdens" on patent offices, and there must be "limitations of disclosure of origins."[225]

The proposed checkpoints system in this Section addresses these concerns. By enforcing only the minimum standards of TRIPS, the proposed system limits the scope of origin-of-resource disclosures. Although investigations into the origins of the biological resources may delay the patent application process, it is unclear whether such delays would be significant because patent examiners will be limited in their inquiry. Additionally, patent offices in countries with strong IP systems that attract inventors may not have the problem of being incapable of performing investigations. Even if such a problem exists, the added obligations of patent offices under international and domestic law may justify petitioning their legislature for more funding and manpower.

By setting the proposed rules for the patent office as a checkpoint, a country that is a party to both TRIPS and the Nagoya Protocol would be able to facilitate both the mandatory disclosure requirements of TRIPS and the goals of the Nagoya Protocol. The effectiveness of this proposed checkpoints system is explored in the following section.

VII. THE EFFECTIVENESS OF USING PATENT OFFICES AS NATIONAL CHECKPOINTS TO ENSURE DISCLOSURE AND TO FACILITATE BENEFIT-SHARING

Nondisclosure may be a cause of AWBS, but the proposed checkpoints system detailed in the previous section could be effective in preventing AWBS. To show how a proposed checkpoints system would function as an enforcement mechanism, this Comment analyzes the neem tree controversy and two possible instances of AWBS concerning camu camu and Ballia barley. Each of these situations involved inventors who failed to reveal the origins of the biological resources on their patent applications; however, relevant secondary literature suggests that they might have taken such resources from foreign territories. Assuming that the secondary literature is true, had TRIPS and the Nagoya

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224 *See id.* at 264 ("In the case of biotechnological inventions, determining the geographical origin of a specific gene, group of genes, and invention in broad terms of a molecular structure or species where the gene originates is complicated. The patent may relate to an already complex and multiple claim innovation or be part of an equally complex process that takes place over a long period.").

225 *Id.* at 265–66.

Protocol been in effect, and had the countries involved been parties to both treaties, the proposed checkpoints system could have mandated disclosure.[226]

A. The Neem Tree Controversy

The neem tree is native to India and is inherently connected to the cultural heritage of the country.[227] Neem extracts have many practical uses and the people of India have taken advantage of the many curative properties of the plant. For example, "[o]rdinary Indians use neem tree bark to clean their teeth. Neem-leaf juice is used to prevent psoriasis and other skin disorders and to control parasitic infections. Neem extract is applied as an antidote to malaria."[228]

Extracts from the neem tree can also be used as pesticides. For Indian farmers, the traditional way of killing insects is to use neem tree extracts.[229] Researchers studying different uses of neem trees have corroborated that the people of India have traditionally utilized the neem tree for pesticide purposes.[230]

After "[t]he West was alerted to the tree's wonders in 1959,"[231] the U.S. Company W.R. Grace became interested in its pesticide qualities. Importing neem tree seeds from India,[232] Grace soon isolated azadirachtin as the active insect-fighting chemical within the neem tree.[233] In 1990, Grace filed application No. 5,124,349 in the USPTO to obtain a patent for a stabilized solution of azadirachtin.[234] The application failed to mention that its seeds originated from India.[235] The USPTO granted the patent in 1992.[236] Grace did not share the proceeds of its patent with the Indian government.[237] In 1995, a nonprofit

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226 For the purposes of demonstrating the efficacy of the proposed checkpoints system, this Comment assumes here that Article 22 is applicable to information on patent applications.

227 *See* Dwyer, *supra* note 1, at 226–27; Marden, *supra* note 1, at 283 ("The tree is tightly interwoven with the fabric of Indian culture: in some regions, the new year begins with eating the tender shoots of the neem tree while in other areas, the tree is worshipped as sacred.").

228 Marden, *supra* note 1, at 283.

229 *See id.* at 283.

230 *See generally* Wawan Sujarwo et al., *Ethnobotanical Uses of Neem (Azadirachtaindica A.Juss.; Meliaceae) Leaves in Bali (Indonesia) and the Indian Subcontinent in Relation with Historical Background and Phytochemical Properties*, 189 J. ETHNOPHARMACOLOGY 186 (2016).

231 Marden, *supra* note 1, at 283.

232 *See* Grace Issues Statement About Patent For Neem Pesticide, *supra* note 4.

233 *See* Marden, *supra* note 1, at 283.

234 *See* U.S. Patent No. 5,124,349, *supra* note 7.

235 *See id.*

236 *See id.*

237 *See* Marden, *supra* note 1, at 286.

organization backed by the support of Indian farmers mounted a challenge to Grace's patent.[238]

The neem tree incident is an example of AWBS. Had the TRIPS and the Nagoya Protocol been in effect at this time and the U.S. and India been parties to the treaties, the disclosure mandate and the checkpoints system would have prevented Grace from obtaining a patent from the USPTO without acknowledging on its application that it used seeds from India. Additionally, those who wanted to challenge the patent would have done so much earlier in time because they would have prompt notice of the geographical origins of the neem tree.

For instance, when Grace applied for its patent for azadirachtin, Article 22 of TRIPS could have required disclosure. There may be a strong argument that the reputation of the neem tree as a pesticide is "essentially attributable" to India.[239] Azadirachtin is found within the neem tree. India has a long tradition of using the neem tree as a means to kill insects and Indian farmers have traditional ways of mixing and storing neem extracts for pesticide usage.[240] Although neem trees can be grown elsewhere, using neem extracts as a pesticide seems to be a custom limited to the Indian sub-continent.[241] Thus, unlike neem trees in India, neem trees in other countries might not enjoy a reputation for being effective pesticides. As a checkpoint, the USPTO would have done research to determine whether this fact was true. It could have found that Article 22 was applicable here. Accordingly, the USPTO could have enforced the disclosure requirement of TRIPS by giving Grace a choice—either Grace reveal the neem seeds' geographical origin or the USPTO would deny its application. If Grace chose to continue with the application process, the revelation of the seeds' geographical origin would have given timely notice to the international coalition that wanted to challenge Grace's patent.

If the origin-of-resource disclosure is triggered, then under the proposed framework, the USPTO would have checked whether Grace had enacted a "fair and equitable benefit-sharing agreement" with India for the use of the neem tree seeds. Since no benefit-sharing agreement existed, the USPTO would have not approved the chemical patent. If Grace were to continue to pursue the application process, the USPTO would have mandated that Grace negotiate an agreement

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238 *See id.*

239 TRIPS, *supra* note 23, at art. 22.

240 *See* Dwyer, *supra* note 1, at 226–27; Marden, *supra* note 1, at 283 ("The tree is tightly interwoven with the fabric of Indian culture: in some regions, the new year begins with eating the tender shoots of the neem tree while in other areas, the tree is worshipped as sacred.").

241 There seems to be an absence of literature showing that other countries have traditionally used neem extracts as pesticides. *See, for example,* Sujarwo et al., *supra* note 230, at 186 (detailing some of the historical uses of neem extracts in India and Indonesia).

with the Indian government and disclose the details of the agreement on its application.

Therefore, had such a national system of checkpoints been enacted under the guidelines of TRIPS and the Nagoya Protocol, and had the U.S. been a party to these treaties, the USPTO could have prevented an instance of AWBS. Given that a "fair and equitable benefit-sharing agreement" would have been enacted between India and Grace (if they continued to pursue the patent approval process), the economic harms to Indian farmers might have also been avoided.

B. Possible AWBS Involving Camu Camu

Camu camu (*Myrciara dubia*) is an Amazonian fruit that has an unusually high concentration of vitamin C and a high level of antioxidant activity.[242] It grows in Peru, Brazil, and other Western Amazonian countries.[243] Some researchers have asserted that camu camu originated in Peru.[244] In fact, Peru contains the largest population of camu camu as well as the largest genetic varieties of the fruit.[245] Evidence suggests that camu camu is much enjoyed in Peru[246] and that it has a reputation for being an ingredient in Peruvian jam and juice.[247] Peru also cultivates camu camu as a cash crop for export. In fact, "camu camu has become a flagship species of the regional government of Ucayali, Peru where more than 1,300 families are involved in its cultivation."[248]

Since the mid-1990s, companies in Japan became interested in camu camu's high vitamin C content and they began patenting many products based on this fruit.[249] In January 2000, the Japanese cosmetics company Kose Corporation patented a skin lotion in the Japan Patent Office (JPO), and camu camu was an ingredient in the lotion.[250] Kose's patent application for the skin lotion

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242 *See* ROBINSON, *supra* note 14, at 53; Paula Moura, *Will Camu Camu Be The Next Amazonian 'It' Fruit?*, NPR (July 15, 2014), https://perma.cc/3F8U-BGTM.

243 *See* Meredith P. Martin, Charles M. Peters, & Mark S. Ashton, *Revisiting Camu-camu (*Myrciaria dubia*): Twenty-seven Years of Fruit Collection and Flooding at an Oxbow Lake in Peruvian Amazonia*, 68 ECONOMIC BOTANY 169, 170 (2014); Ricardo Elesbão Alves et. al, *Camu-Camu (Myrciaria dubia McVaugh): A Rich Natural Source of Vitamin C*, 46 PROC. INTERAMER. SOC. TROP. HORT. 11, 11 (2002).

244 *See* Alves, *supra* note 243, at 11; Analysis of Potential Cases of Biopiracy, WTO Doc. IP/C/W/458 (Nov. 7, 2005).

245 *See* Martin, Peters, and Ashton, *supra* note 243, at 170; Moura, *supra* note 242.

246 *See id.*

247 *See id.*

248 *Camu Camu Production in the Peruvian Amazon*, ENTREPRENEUR'S TOOLKIT FOR SOCIAL AND ENVIRONMENTAL ENTREPRENEURS, https://perma.cc/RK45-L2WL.

249 *See* ROBINSON, *supra* note 14, at 53–54.

250 *See* Japan Patent 2001031558A (filed Jan. 20, 2000), https://perma.cc/DTY5-CA2D.

JP2001031558A did not reveal the geographical origin of the camu camu. However, because Japan was importing the fruit from Peru around this time,[251] there is a high likelihood that Kose's camu camu originated from Peru.[252] In 2005, Peru announced to the WTO that it had been investigating this patent application for possible violations of patentability, but its preliminary analysis did not find a specific violation.[253] Still, due to the adverse action that Peru had taken toward the patent, it is unlikely that Kose had enacted a benefit-sharing agreement with the Peruvian government for the skin lotion.

Both Japan and Peru had been signatories to TRIPS since 1995.[254] Let us suppose that the Nagoya Protocol had also been in force during this time and that Peru and Japan were parties to this treaty. Had the JPO been a checkpoint under the Nagoya Protocol implementing the disclosure requirements of TRIPS, it would have likely mandated Kose to reveal the origin of the camu camu that it used for its lotion. This disclosure would have given earlier notice to those in Peru who wanted to challenge the patent; an immediate challenge could have uncovered information about the skin lotion and its patentability that Peru's later investigation did not. Additionally, the checkpoints system under the Nagoya Protocol might have led to a benefit-sharing agreement between Kose and the Peruvian government.

For one, the JPO could have enforced the disclosure provisions of Article 29 against Kose. This provision might have required Kose to reveal the geographical origin of the camu camu if the type of camu camu in the skin lotion is a one-of-a-kind genetic variant that is found in Peru. Given that Peru contains the largest genetic varieties of the fruit, it is possible that the type of camu camu used by Kose may be unique to Peru.

Similarly, Article 22 of TRIPS might have mandated disclosure. The people of Peru grow camu camu as a cash crop.[255] One could argue that the way that the Peruvian people grow the crop might have contributed to the distinctively high concentration of Vitamin C in the plant and that the quality and reputation of camu camu as having high Vitamin C concentration might be "essentially attributable" to Peru.[256] As there may be a lack of research comparing the concentration of Vitamin C or the level of antioxidant activity in Peruvian cultivated camu camu with the qualities of camu camu grown in other Amazonian

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251 *See* IP/C/W/458, *supra* note 244; *see also* Masami Ito, *Peru Cash Crop Quest Bears Fruit*, THE JAPAN TIMES (Nov. 9, 2004), https://perma.cc/AK4H-WD77.

252 *See* IP/C/W/458, *supra* note 244.

253 *See id.* at 9.

254 *See Parties to the Nagoya Protocol*, *supra* note 113.

255 *See Camu*, *supra* note 248.

256 TRIPS, *supra* note 23, at art. 22.

countries, the JPO as checkpoint would have commissioned a study on whether the camu camu used by Kose had a quality or reputation distinctive to Peru. If JPO had found that there was a "quality or reputation" of camu camu "attributable to" Peru, then it would have required Kose to indicate on its application that Peru was the geographical origin of the fruit.[257] This information would allow the Peruvian government to investigate the claims within the application and to potentially challenge the patent at an earlier time. Failure to disclose would have led to a denial of Kose's application.

Furthermore, as a checkpoint, the JPO would have likely confirmed whether Kose had a "fair and equitable benefit-sharing agreement" with Peru for the use of camu camu.[258] Since Article 29 or Article 22 might have likely compelled Kose to disclose the geographical origin of the camu camu, the JPO would have required Kose to reveal the existence of a benefit-sharing agreement. Because it is likely that Kose did not enact any benefit-sharing agreements with the Peruvian government at the time, JPO would have likely denied Kose's patent application. Kose would have needed to negotiate an agreement with the Peruvian government in order to proceed with the application process.

C. Possible AWBS Involving Ballia Barley

Ballia barley is a type of barley grown in "the city of Ballia in India's northern state of Uttar Pradesh."[259] What makes Ballia barley distinctive is that it contains a defective lipoxygenase gene (LOX-less) that does not code for the protein lipoxygenase.[260] "Barley lipoxygenase (LOX-1) is an enzyme that naturally occurs in most barley grain, but for brewers, it causes headaches. Lox-1 is one of the reasons why beer develops a stale taste and weaker head (less foam) when stored for long periods."[261] Because LOX-1 is not present in Ballia barley, beer made from this type of barley can be stored longer without losing flavor.[262] The city of Ballia is also part of "an area of traditional barley cultivation" in India and "part of the crop's secondary centre of diversity in the Himalayan region."[263]

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257 *Id.* at art. 22.

258 *See* Nagoya Protocol, *supra* note 27, at art. 5.

259 Edward Hammond, *Better Beer Biopiracy: Indian Farmers' Barley Patented by Japanese Brewer*, TWN Briefing Paper No. 76 (Jun. 2015), https://perma.cc/8HMB-SKMB.

260 *See id.* at 1.

261 *Id.* at 1.

262 *See Sapporo Breweries' new barley helps keep beer fresher longer*, NIKKEI ASIAN REVIEW, Nov. 24, 2016, https://perma.cc/769V-WADH.

263 Hammond, *supra* note 259, at 1–2.

In the early twentieth century, a storage program was developed to protect Indian barley.[264] "The program '*was confined to the development of improved varieties by selection from the indigenous material*.' In other words, it used local seeds from local farmers, and not barleys from elsewhere. The products of this program included high quality malting barleys, the type used in brewing."[265] Ballia barley seeds were selected for storage in the mid-Twentieth century.[266] One researcher Edward Hammond of the Third World Network, which is a nonprofit international organization, believed that these seeds made their way to Japan's Okayama University where they were stored and then used by Sapporo Brewers, Ltd, a brewing company in Japan.[267]

Hammond suggested that Sapporo began to experiment with Ballia barley and other Lox-less barley around the early 2000s.[268] In 2013, Sapporo filed a patent application in the USPTO, claiming an invention of the Lox-less plant, Lox-less malt, and a method of production of making the Lox-less malt by cross-fertilizing Japanese barley Taishomugi with a Lox-less barley SBOU2.[269] In its USPTO application, Sapporo neither disclosed the geographical origin of SBOU2 nor identified the name of SBOU2.[270] However, Hammond speculated that SBOU2 corresponded to the Ballia barley.[271] This claim might have been made stronger by the fact that in a recent news article, Sapporo acknowledged that the Lox-less barley used in its experiments originated from India and that Okayama University had stored the barley in a gene bank.[272] In March 19, 2015, Sapporo refiled another USPTO application with the serial number US 2015/0257354 A1, covering the same invention and containing the same information as its 2013 application.[273]

Sapporo pursued the same patent in the European Patent Office (EPO), filing its application on March 25, 2004.[274] The EPO granted the patent on October 22, 2008.[275] In this application, Sapporo also did not disclose the geographical origin of the SBOU2 used in its patent.[276]

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264 *See id.* at 2.

265 *Id.*

266 *See id.*

267 *See id.*

268 *See id.* at 2–3.

269 *See* U.S. Patent Application Pub. No. 2013/0196027 A1 (filed Mar. 13, 2013).

270 *See id.*

271 *See* Hammond, *supra* note 259, at 1.

272 *See Sapporo Breweries*, *supra* note 262.

273 *See* U.S. Patent No. 9,497,919 (issued Nov. 22, 2016).

274 *See* European Patent Register No. EP1609866B1 (issued Oct. 22, 2008).

275 *See id.*

276 *See id.*

There is no evidence that Sapporo or Okayama University had negotiated a benefit-sharing agreement with the Indian government in regards to Sapporo's patent.[277] Given that Hammond is claiming biopiracy in this instance, it is unlikely that a benefit-sharing arrangement has been made.[278]

For the purpose of demonstrating how the proposed checkpoints system would operate as an enforcement mechanism, this Comment assumes that SBOU2 in Sapporo's patent application refers to Ballia barley, and that for its invention, Sapporo used seeds that originated from the Ballia region of India.[279] Both U.S. and the E.U. have been parties to TRIPS since it entered into force in 1995.[280] Had the Nagoya Protocol also been in force during this time and had U.S. and the E.U. been parties to the Nagoya Protocol, there is a possibility that the USTPO and EPO, as checkpoints, would have enforced the disclosure requirements and the benefit-sharing requirement against Sapporo.

First, the USPTO and EPO could have found that Article 29 of TRIPS was applicable. For example, the fact that the researchers only cross-fertilized Ballia barley with the Japanese Taishomugi barely to make its malt may suggest that other types of Lox-less barley might not be compatible with cross-fertilization or that they were not as viable as the Ballia barley. As a result, Ballia barley might be a unique variant of Lox-less barley and under Article 29, such uniqueness may trigger the origin-of-resource disclosure.

The USPTO and EPO could have also found that Article 22 of TRIPS was applicable. The fact that Ballia barley is Lox-less and/or the fact that Ballia barley is capable of being cross-fertilized with Taishomugi might be due to the environment of the Ballia region of India or to the farming methods that the Ballia residents cultivated the grain. As checkpoints, the EPO and the USPTO would have conducted investigations to verify these facts. If these checkpoints had found that there was a "quality or reputation" of Ballia barley "essentially attributable to" the Ballia region, they would have required Sapporo to indicate on its application that India was the geographical origin of the grain.[281] Information about the geographical origin would have also allowed the government of India or international watchdog organizations like the Third World Network to promptly

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277 Hammond, *supra* note 259, at 4.

278 *See id.*

279 From the available documents, such as the patent and Hammond's article, *supra* note 259, I cannot say with certainty that SBOU2 refers to Ballia barley. But if SBOU2 actually refers to the Ballia barley, my argument here is that the proposed checkpoints system would have likely mandated disclosure.

280 *See Other IP Treaties*, *supra* note 56.

281 TRIPS, *supra* note 23, at art. 22.

investigate and challenge the claims within Sapporo's applications as soon as they are made public.

Moreover, if the conditions for disclosure had been present, the EPO and USPTO would have investigated Sapporo to find whether the company had negotiated a "fair and equitable benefit-sharing agreement" with the government of India.[282] As Article 29 or Article 22 might have likely mandated disclosure, the EPO and the UPSTO would have required Sapporo to reveal the existence of a benefit-sharing agreement with India on its patent application. Since Sapporo likely had not enacted any benefit-sharing agreements with the Peruvian government at the time, the patent offices would have likely denied Sapporo's applications. If Sapporo wanted to continue to pursue the application process with either the EPO or USPTO, it would have agreed to share the benefits of its patent with India.

VIII. CONCLUSION

In regards to access of biological resources, AWBS is an important issue for the international community to address. While producing some positive effects,[283] AWBS also results in significant negative externalities.[284] One of the reasons that AWBS has persisted is that in many cases, patent applicants fail to disclose the geographical origins of the biological resources that form the basis for their inventions. As such, requiring that patent applicants disclose the geographical sources of their biological materials is the first step for the international community to combat AWBS.

Under TRIPS, one can likely argue that international law mandates origin-of-resource disclosures on patent applications in two circumstance: (1) when "the source of the biological resource [is] unique"[285] and (2) when "a quality, characteristic, or reputation of the biological resources that contributed to the development of an invention is essentially attributed" to a geographic region.[286]

Regarding enforcement of these mandates, a country that is a party to both TRIPS and the Nagoya Protocol could prevent AWBS by using patent offices as checkpoints. As checkpoints under the Nagoya Protocol, patent offices could operate to prevent many future cases of AWBS by enforcing the disclosure requirements of TRIPS and the benefit-sharing requirement of the Nagoya Protocol.

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282 *See* Nagoya Protocol, *supra* note 27, at art. 5.

283 *See* Heald, *supra* note 35, at 519.

284 *See generally* ROBINSON, *supra* note 14.

285 WT/CTE/M/16, *supra* note 30, at ¶ 90.

286 TRIPS, *supra* note 23, at art. 22.

It may be in the self-interest of countries with strong IP systems to have their patent offices enforce the minimum origin-of-resource requirements of TRIPS even if those countries are not parties to the Nagoya Protocol. As we have seen in neem incident, residents of nations providing biological resources can have strong emotional attachment to their countries' natural resources.[287] Instances of AWBS may lead to international ill will, decrease provider countries' willingness to deal with foreign entities, and prevent potential scientific innovation. Enforcing the disclosure mandates under TRIPS, patent offices may not only be able to avert many cases of AWBS but also foster international good will.

[287] *See, for example*, Marden, *supra* note 1.